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

EXELTIS USA, INC., LABORATORIOS LEON FARMA, S.A., CHEMO IBERICA, S.A., and CHEMO RESEARCH, S.L., Plaintiffs, v. GLENMARK PHARMACEUTICALS LIMITED, GLENMARK PHARMACEUTICALS INC., USA, Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL**

Plaintiffs Exeltis USA, Inc. ("Exeltis"), Laboratorios Leon Farma, S.A. ("Leon Farma"), Chemo Iberica, S.A. ("Chemo Iberica"), and Chemo Research, S.L. ("Chemo Research") (collectively, "Plaintiffs") bring this complaint for patent infringement and declaratory judgment against Defendants Glenmark Pharmaceuticals Limited ("Glenmark Ltd.") and Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") (collectively, "Glenmark" or "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, §§ 1, *et seq.*, including 35 U.S.C. § 271(e)(2); and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(a), (b), and (c); relating to patents that concern Plaintiffs' groundbreaking progestin-only birth control pill, SLYND®.

2. This action arises out of Glenmark's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiffs' successful product containing drospirenone, SLYND®, prior to the expiration of U.S. Patent Nos. 9,603,860; 10,179,140; 10,603,281; 10,849,857; 10,987,364; 11,123,299; 11,291,632; 11,291,633; 11,351,122; 11,413,249; 11,439,598; 11,452,695; 11,478,487; 11,491,113; 11,504,334; 11,951,213; 12,090,231; and 12,280,151 (collectively, the "Patents-in-Suit"), including any extensions and/or additional periods of exclusivity to which Plaintiffs are or will be entitled. Plaintiffs attach hereto true and accurate copies of each of the Patents-in-Suit as Exhibits A-R.

THE PARTIES

3. Plaintiff Exeltis is a corporation organized and existing under the laws of the state of New Jersey, having its principal place of business at 180 Park Avenue, Suite 101, Florham Park, New Jersey 07932. Exeltis is a leader in women's health care that discovers, develops, and brings to market innovative products to improve the quality of life for women. Exeltis meets the needs of women at different stages of their lives, by providing, *inter alia*, contraceptives, treatments and diagnostic tools for bacterial vaginosis, as well as prenatal vitamins and dietary supplements. Exeltis commercializes and distributes a novel estrogen-free oral contraceptive containing the

hormone drospirenone under the registered trademark SLYND® in this District and throughout the United States. Exeltis is the exclusive licensee in the United States for the Patents-in-Suit.

4. Plaintiff Chemo Research is a company organized and existing under the laws of Spain, having its principal place of business at Calle Manuel Pombo Angulo, 28, 3rd Floor, 28050 Madrid, Spain. Chemo Research is involved in the development of SLYND®. Chemo Research is the owner of, and holds certain rights in, the Patents-in-Suit.

5. Plaintiff Leon Farma is a company organized and existing under the laws of Spain, having its principal place of business at Calle La Vallina s/n, P.I. Navatejera – 24008 Leon, Spain. Leon Farma manufactures SLYND® for sale in this District and throughout the United States. Leon Farma is the original assignee of the Patents-in-Suit.

6. Plaintiff Chemo Iberica is a company organized and existing under the laws of Spain, having its principal place of business at Calle Dulcinea s/n, 28805 Alcalá de Henares, Madrid, Spain. Chemo Iberica is a global healthcare business, delivering specialized expertise and experience in sales and marketing of a wide range of active pharmaceutical ingredients, finished dosage forms, and branded pharmaceuticals, both for human and animal health. Chemo Iberica is involved in the commercialization and distribution of SLYND® in this District and throughout the United States. Chemo Iberica holds certain commercialization rights with respect to the Patents-in-Suit.

7. On information and belief, Defendant Glenmark Pharmaceuticals Limited is a foreign corporation organized and existing under the laws of India, having its principal place of business at Glenmark House, HDO-Corporate Building, Wing A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (E), Mumbai, 400 099, India.

8. On information and belief, Defendant Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. On information and belief Glenmark USA's new corporate headquarters and principal place of business will be at 619 River Drive, Suite 400-B, Elmwood Park, NJ 07407. On information and belief, Glenmark USA is a wholly owned subsidiary of Glenmark Ltd.

9. On information and belief, Glenmark, themselves and through their subsidiaries, affiliates, agents and partners, manufacture, distribute, and/or import generic copies of branded pharmaceutical products for sale and use throughout the United States, including in this District.

10. On information and belief, Glenmark, themselves and with their subsidiaries, affiliates, agents, and partners, prepared and filed ANDA No. 219233 (the "Glenmark ANDA"), seeking approval to manufacture, import, market, and/or sell a generic copy of Plaintiffs' SLYND® (drospirenone) tablets, 4 mg (the "Glenmark ANDA Product") in the United States, including in this District, if the FDA approves the Glenmark ANDA.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including §§ 271(e)(2); 271(a), (b), and (c); and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Glenmark Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Glenmark Ltd. regularly and continuously transacts business within New Jersey, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic copies of branded

pharmaceutical products in the United States, including New Jersey. On information and belief, Glenmark Ltd. 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.

13. On information and belief, Glenmark Ltd. markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates, including Glenmark USA.

14. This Court also has personal jurisdiction over Glenmark Ltd. because Glenmark Ltd. filed the Glenmark ANDA seeking approval from the FDA to market and sell the Glenmark ANDA Product throughout the United States, including in New Jersey. By filing the Glenmark ANDA, Glenmark Ltd. has made clear that it intends to use its distribution channels to direct sales of the Glenmark ANDA Product into, *inter alia*, New Jersey.

15. Alternatively, this Court may exercise personal jurisdiction over Glenmark Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Glenmark Ltd. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Glenmark Ltd. has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of personal jurisdiction over Glenmark Ltd. satisfies due process.

16. This Court has personal jurisdiction over Glenmark USA in that it has a principal place of business in New Jersey and by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Glenmark USA regularly and continuously transacts business within New Jersey, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic copies of branded pharmaceutical products in the United

States, including New Jersey. On information and belief, Glenmark USA 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.

17. On information and belief, Glenmark USA is registered to do business in the State of New Jersey under Business ID Number 0400025135, and Glenmark USA is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Number 5003119.

18. On information and belief, Glenmark Ltd. and Glenmark USA intend to commercially manufacture, use, and sell the Glenmark ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves the Glenmark ANDA, the Glenmark ANDA Product would, *inter alia*, be marketed, distributed, and sold in New Jersey, and/or prescribed by practicing physicians and dispensed by pharmacies located within New Jersey, all of which would have a substantial effect on New Jersey.

19. This Court also has personal jurisdiction over Glenmark Ltd. and Glenmark USA because Glenmark Ltd. and Glenmark USA have previously been sued in this District, have not challenged personal jurisdiction in prior lawsuits in this District, and have affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in lawsuits filed against them in this District. *See, e.g.*, *Symed Labs Limited, et al. v. Glenmark Pharmaceuticals Inc., USA*, No. 2:15-cv-08306, ECF No. 21 (D.N.J. Jan. 6, 2016); *Sanofi-Aventis U.S. LLC, et al. v. Glenmark Pharmaceuticals Inc., USA, et al.*, No. 3:15-cv-02523, ECF No. 15 (D.N.J. June 15, 2015); *AstraZeneca Pharmaceuticals LP, et al. v. Glenmark Pharmaceuticals Ltd., et al.*, No. 1:15-cv-00615, ECF Nos. 5, 7 (D.N.J. March 3, 2015).

20. Venue is proper as to Glenmark Ltd. in this District under 28 U.S.C. § 1391(b)(3) because Glenmark Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

21. Venue is proper as to Glenmark USA in this District under 28 U.S.C. §§ 1391(b)(1) and 1400(b) because Glenmark USA has its principal place of business in and resides in New Jersey, and is subject to personal jurisdiction in this District.

FACTUAL BACKGROUND

PATENTS-IN-SUIT

U.S. Patent No. 9,603,860

22. U.S. Patent No. 9,603,860 (the "'860 Patent"), titled "Pharmaceutical Compositions Comprising Active Drugs, Contraceptive Kits Comprising Active Drugs, and Methods of Administering the Same," was duly and legally issued by the U.S. Patent and Trademark Office on March 28, 2017. A true and correct copy of the '860 Patent is attached hereto as **Exhibit A**.

23. The claims of the '860 Patent are valid, enforceable, and not expired.

U.S. Patent No. 10,179,140

24. U.S. Patent No. 10,179,140 (the "'140 Patent"), titled "Pharmaceutical Compositions Comprising Active Drugs, Contraceptive Kits Comprising Active Drugs, and Methods of Administering the Same," was duly and legally issued by the U.S. Patent and Trademark Office on January 15, 2019. A true and correct copy of the '140 Patent is attached hereto as **Exhibit B**.

25. The claims of the '140 Patent are valid, enforceable, and not expired.

U.S. Patent No. 10,603,281

26. U.S. Patent No. 10,603,281 (the "'281 Patent"), titled "Pharmaceutical Compositions Comprising Active Drugs, Contraceptive Kits Comprising Active Drugs, and Methods of Administering the Same," was duly and legally issued by the U.S. Patent and Trademark Office on March 31, 2020. A true and correct copy of the '281 Patent is attached hereto as **Exhibit C**.

27. The claims of the '281 Patent are valid, enforceable, and not expired.

U.S. Patent No. 10,849,857

28. U.S. Patent No. 10,849,857 (the "'857 Patent"), titled "Pharmaceutical Compositions Comprising Active Drugs, Contraceptive Kits Comprising Active Drugs, and Methods of Administering the Same," was duly and legally issued by the U.S. Patent and Trademark Office on December 1, 2020. A true and correct copy of the '857 Patent is attached hereto as **Exhibit D**.

29. The claims of the '857 Patent are valid, enforceable, and not expired.

U.S. Patent No. 10,987,364

30. U.S. Patent No. 10,987,364 (the "'364 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on April 27, 2021. A true and correct copy of the '364 Patent is attached hereto as **Exhibit E**.

31. The claims of the '364 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,123,299

32. U.S. Patent No. 11,123,299 (the "'299 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S.

Patent and Trademark Office on September 21, 2021. A true and correct copy of the '299 Patent is attached hereto as **Exhibit F**.

33. The claims of the '299 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,291,632

34. U.S. Patent No. 11,291,632 (the "'632 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on April 5, 2022. A true and correct copy of the '632 Patent is attached hereto as **Exhibit G**.

35. The claims of the '632 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,291,633

36. U.S. Patent No. 11,291,633 (the "'633 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on April 5, 2022. A true and correct copy of the '633 Patent is attached hereto as **Exhibit H**.

37. The claims of the '633 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,351,122

38. U.S. Patent No. 11,351,122 (the "'122 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on June 7, 2022. A true and correct copy of the '122 Patent is attached hereto as **Exhibit I**.

39. The claims of the '122 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,413,249

40. U.S. Patent No. 11,413,249 (the "'249 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on August 16, 2022. A true and correct copy of the '249 Patent is attached hereto as **Exhibit J**.

41. The claims of the '249 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,439,598

42. U.S. Patent No. 11,439,598 (the "'598 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on September 13, 2022. A true and correct copy of the '598 Patent is attached hereto as **Exhibit K**.

43. The claims of the '598 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,452,695

44. U.S. Patent No. 11,452,695 (the "'695 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on September 27, 2022. A true and correct copy of the '695 Patent is attached hereto as **Exhibit L**.

45. The claims of the '695 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,478,487

46. U.S. Patent No. 11,478,487 (the "'487 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on October 25, 2022. A true and correct copy of the '487 Patent is attached hereto as **Exhibit M**.

47. The claims of the ’487 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,491,113

48. U.S. Patent No. 11,491,113 (the “’113 Patent”), titled “Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same,” was duly and legally issued by the U.S. Patent and Trademark Office on November 8, 2022. A true and correct copy of the ’113 Patent is attached hereto as **Exhibit N**.

49. The claims of the ’113 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,504,334

50. U.S. Patent No. 11,504,334 (the “’334 Patent”), titled “Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same,” was duly and legally issued by the U.S. Patent and Trademark Office on November 22, 2022. A true and correct copy of the ’334 Patent is attached hereto as **Exhibit O**.

51. The claims of the ’334 Patent are valid, enforceable, and not expired.

U.S. Patent No. 11,951,213

52. U.S. Patent No. 11,951,213 (the “’213 Patent”), titled “Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same,” was duly and legally issued by the U.S. Patent and Trademark Office on April 9, 2024. A true and correct copy of the ’213 Patent is attached hereto as **Exhibit P**.

53. The claims of the ’213 Patent are valid, enforceable, and not expired.

U.S. Patent No. 12,090,231

54. U.S. Patent No. 12,090,231 (the “’231 Patent”), titled “Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same,” was duly and legally issued by the U.S.

Patent and Trademark Office on September 17, 2024. A true and correct copy of the '231 Patent is attached hereto as **Exhibit Q**.

55. The claims of the '231 Patent are valid, enforceable, and not expired.

U.S. Patent No. 12,280,151

56. U.S. Patent No. 12,280,151 (the "'151 Patent"), titled "Synthetic Progestogens and Pharmaceutical Compositions Comprising the Same," was duly and legally issued by the U.S. Patent and Trademark Office on April 22, 2025. A true and correct copy of the '151 Patent is attached hereto as **Exhibit R**.

57. The claims of the '151 Patent are valid, enforceable, and not expired.

ACTS GIVING RISE TO THIS ACTION

58. Exeltis is the holder of approved New Drug Application ("NDA") No. 211367 drospirenone tablets, 4 mg, for use by females of reproductive potential to prevent pregnancy, as further described in the SLYND® label.

59. Exeltis markets the drug approved under NDA No. 211367 in the United States under the registered trademark SLYND®.

60. In conjunction with NDA No. 211367, Exeltis has listed with the FDA fifteen patents for SLYND®: U.S. Patent Nos. 9,603,860; 10,179,140; 10,603,281; 10,849,857; 10,987,364; 11,123,299; 11,291,632; 11,291,633; 11,351,122; 11,413,249; 11,478,487; 11,504,334; 11,951,213; 12,090,231; and 12,280,151. The FDA has published each of these fifteen patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), which identifies drug products approved by the FDA on the basis of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act ("FD&C Act").

61. At least one claim of each of the Patents-in-Suit covers SLYND®, or approved methods of using it.

62. On information and belief, Glenmark submitted to the FDA the Glenmark ANDA under Section 505(j) of the FD&C Act, seeking approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Glenmark ANDA Product before the expiration of the '860, '140, '281, '857, '364, '299, '632, '633, '122, '249,'487, '334, '213, '231, and '151 Patents.

63. On information and belief, Glenmark sent a letter dated September 22, 2025 to Exeltis and Leon Farma (the "Paragraph IV Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Glenmark's Paragraph IV Letter purports to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '860, '140, '281, '857, '364, '299, '632, '633, '122, '249,'487, '334, '213, '231, and '151 Patents.

64. Exeltis received Glenmark's Paragraph IV Letter on September 23, 2025.

65. Leon Farma received Glenmark's Paragraph IV Letter on September 26, 2025.

66. This action is being commenced before the expiration of 45 days from the date Exeltis and Leon Farma received Glenmark's Paragraph IV Letter, which triggers an automatic stay of FDA approval of the Glenmark ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

67. By filing the Glenmark ANDA, Glenmark has necessarily represented to the FDA that the Glenmark ANDA Product has the same active ingredient as SLYND®; has the same dosage form and strength as SLYND®; and is bioequivalent to SLYND®.

68. On information and belief, Glenmark is seeking approval to market the Glenmark ANDA Product for the same approved indication as SLYND®.

69. On information and belief, the Glenmark ANDA contains data from bioavailability or bioequivalence studies for the Glenmark ANDA Product.

70. On information and belief, Glenmark's proposed prescribing information for the Glenmark ANDA Product (the "Proposed Glenmark Label") will refer to the product as, *inter alia*, drospirenone oral tablets, 4 mg, for use in females of reproductive potential to prevent pregnancy.

71. On information and belief, the Proposed Glenmark Label will instruct physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential to, *inter alia*, prevent pregnancy.

72. On information and belief, if and when FDA approves the Glenmark ANDA, Glenmark will sell its approved generic version of Plaintiffs' SLYND® tablets, 4 mg, throughout the United States, including in New Jersey.

73. Glenmark's Paragraph IV Letter included an Offer of Confidential Access to ANDA No. 219233 ("OCA") in which Glenmark purported to offer to provide confidential access to certain information from the Glenmark ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in 21 U.S.C. § 355(j)(5)(B)(iii) can be brought, subject to certain terms and conditions set forth in the OCA. Under 35 U.S.C. § 355(j)(5)(C)(i)(III), the "document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." Glenmark's OCA contained unreasonable restrictions, above and beyond those that would apply under a court-ordered protective order.

74. Since receiving Glenmark's Paragraph IV Letter, Plaintiffs attempted to negotiate in good faith to reach a mutually acceptable agreement under which Glenmark would provide the

Glenmark ANDA to Plaintiffs. To date, Glenmark has refused to offer Plaintiffs access to the Glenmark ANDA under terms consistent with a protective order entered for the purpose of protecting trade secrets and other confidential business information. As a result, Plaintiffs have been unable to access the Glenmark ANDA.

75. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including an automatic stay of FDA approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate, pursuant to 21 U.S.C. § 355(c)(3)(C).

76. Plaintiffs are not aware of any other means of obtaining information regarding the Glenmark ANDA Product within the 45-day statutory period set forth in 21 U.S.C. § 355(c)(3)(C). In the absence of such information, Plaintiffs must resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its belief, and to present to the Court evidence, that the Glenmark ANDA Product has and will infringe one or more claims of the Patents-in-Suit.

77. Because Plaintiffs have been unable to obtain a copy of the Glenmark ANDA, Plaintiffs allege the causes herein based primarily on the representations contained in Glenmark's Paragraph IV Letter and the other facts alleged herein.

COUNT I: Infringement of the '860 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

78. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

79. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '860 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial

manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '860 Patent.

80. Glenmark has actual knowledge of the '860 Patent.

81. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '860 Patent will not be infringed, is invalid, and/or is unenforceable.

82. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '860 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '860 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

83. On information and belief, Glenmark became aware of the '860 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

84. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

85. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '860 Patent.

86. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

87. Unless and until Glenmark is enjoined from infringing the '860 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: Declaratory Judgment of Infringement of the '860 Patent Under 35 U.S.C. §§ 271(b)-(c) by the Glenmark ANDA Product

88. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

90. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

91. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '860 Patent.

92. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

93. Glenmark's actions indicate that it does not intend to change its course of conduct.

94. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '860 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by actively inducing and/or contributing to

infringement of the ’860 Patent by others, under 35 U.S.C. §§ 271(b)-(c), unless enjoined by the Court.

95. Glenmark has actual knowledge of the ’860 Patent.

96. On information and belief, Glenmark became aware of the ’860 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs’ SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

97. On information and belief, Glenmark’s efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the ’860 Patent and without a reasonable basis for believing that it would not be liable for actively inducing and/or contributing to the infringement of the ’860 Patent.

98. On information and belief, Glenmark’s ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

99. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will actively induce and/or contribute to the actual infringement of the ’860 Patent.

100. On information and belief, the Proposed Glenmark Label will include directions and instructions that instruct physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in accordance with the methods described and claimed in the ’860 Patent.

101. On information and belief, physicians and healthcare providers will administer the Glenmark ANDA Product in the United States according to the directions and instructions in the

Proposed Glenmark Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 1 of the ’860 Patent.

102. On information and belief, at least through the Proposed Glenmark Label, Glenmark will encourage physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in accordance with the methods described and claimed in the ’860 Patent, and Glenmark will know or should know that such conduct will occur.

103. On information and belief, Glenmark will actively induce, encourage, aid, and abet the conduct set forth above by physicians and healthcare providers with knowledge and specific intent that the conduct infringe at least one claim, including, for example, claim 1 of the ’860 Patent.

104. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’860 Patent.

105. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the ’860 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

106. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the ’860 Patent.

107. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the ’860 Patent.

108. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the ’860 Patent.

109. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '860 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

110. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will induce and/or contribute to infringement of the '860 Patent.

111. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '860 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

112. Unless and until Glenmark is enjoined from inducing and/or contributing to the infringement of the '860 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: Infringement of the '140 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

113. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

114. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '140 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '140 Patent.

115. Glenmark has actual knowledge of the '140 Patent.

116. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '140 Patent will not be infringed, is invalid, and/or is unenforceable.

117. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '140 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '140 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

118. On information and belief, Glenmark became aware of the '140 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

119. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

120. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '140 Patent.

121. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

122. Unless and until Glenmark is enjoined from infringing the '140 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV: Declaratory Judgment of Infringement of the '140 Patent Under 35 U.S.C. §§ 271(b)-(c) by the Glenmark ANDA Product

123. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

125. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

126. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '140 Patent.

127. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

128. Glenmark's actions indicate that it does not intend to change its course of conduct.

129. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '140 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by actively inducing and/or contributing to infringement of the '140 Patent by others, under 35 U.S.C. §§ 271(b)-(c), unless enjoined by the Court.

130. Glenmark has actual knowledge of the '140 Patent.

131. On information and belief, Glenmark became aware of the '140 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange

Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

132. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '140 Patent and without a reasonable basis for believing that it would not be liable for actively inducing and/or contributing to the infringement of the '140 Patent.

133. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

134. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will actively induce and/or contribute to the actual infringement of the '140 Patent.

135. On information and belief, the Proposed Glenmark Label will include directions and instructions that instruct physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in accordance with the methods described and claimed in the '140 Patent.

136. On information and belief, physicians and healthcare providers will administer the Glenmark ANDA Product in the United States according to the directions and instructions in the Proposed Glenmark Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 1 of the '140 Patent.

137. On information and belief, at least through the Proposed Glenmark Label, Glenmark will encourage physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in

accordance with the methods described and claimed in the '140 Patent, and Glenmark will know or should know that such conduct will occur.

138. On information and belief, Glenmark will actively induce, encourage, aid, and abet the conduct set forth above by physicians and healthcare providers with knowledge and specific intent that the conduct infringe at least one claim, including, for example, claim 1 of the '140 Patent.

139. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '140 Patent.

140. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '140 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

141. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '140 Patent.

142. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '140 Patent.

143. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the '140 Patent.

144. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '140 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

145. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will induce and/or contribute to infringement of the '140 Patent.

146. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '140 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

147. Unless and until Glenmark is enjoined from inducing and/or contributing to the infringement of the '140 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V: Infringement of the '281 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

148. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

149. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '281 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '281 Patent.

150. Glenmark has actual knowledge of the '281 Patent.

151. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '281 Patent will not be infringed, is invalid, and/or is unenforceable.

152. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '281 Patent, and its inducement of and/or

contribution to such conduct, would constitute infringement of at least one or more claims of the '281 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

153. On information and belief, Glenmark became aware of the '281 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

154. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

155. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '281 Patent.

156. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

157. Unless and until Glenmark is enjoined from infringing the '281 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI: Declaratory Judgment of Infringement of the '281 Patent Under 35 U.S.C. §§ 271(b)-(c) by the Glenmark ANDA Product

158. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

160. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

161. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '281 Patent.

162. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

163. Glenmark's actions indicate that it does not intend to change its course of conduct.

164. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '281 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by actively inducing and/or contributing to infringement of the '281 Patent by others, under 35 U.S.C. §§ 271(b)-(c), unless enjoined by the Court.

165. Glenmark has actual knowledge of the '281 Patent.

166. On information and belief, Glenmark became aware of the '281 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

167. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge

of the ’281 Patent and without a reasonable basis for believing that it would not be liable for actively inducing and/or contributing to the infringement of the ’281 Patent.

168. On information and belief, Glenmark’s ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

169. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will actively induce and/or contribute to the actual infringement of the ’281 Patent.

170. On information and belief, the Proposed Glenmark Label will include directions and instructions that instruct physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in accordance with the methods described and claimed in the ’281 Patent.

171. On information and belief, physicians and healthcare providers will administer the Glenmark ANDA Product in the United States according to the directions and instructions in the Proposed Glenmark Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 1 of the ’281 Patent.

172. On information and belief, at least through the Proposed Glenmark Label, Glenmark will encourage physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in accordance with the methods described and claimed in the ’281 Patent, and Glenmark will know or should know that such conduct will occur.

173. On information and belief, Glenmark will actively induce, encourage, aid, and abet the conduct set forth above by physicians and healthcare providers with knowledge and specific

intent that the conduct infringe at least one claim, including, for example, claim 1 of the ’281 Patent.

174. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’281 Patent.

175. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the ’281 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

176. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the ’281 Patent.

177. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the ’281 Patent.

178. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the ’281 Patent.

179. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the ’281 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

180. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will induce and/or contribute to infringement of the ’281 Patent.

181. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the

’281 Patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

182. Unless and until Glenmark is enjoined from the ’281 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII: Infringement of the ’857 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

183. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

184. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the ’857 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the ’857 Patent.

185. Glenmark has actual knowledge of the ’857 Patent.

186. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the ’857 Patent will not be infringed, is invalid, and/or is unenforceable.

187. Glenmark’s commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the ’857 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the ’857 Patent, including without limitation claims 1, 2, and 4, either literally or under the doctrine of equivalents.

188. On information and belief, Glenmark became aware of the ’857 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange

Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

189. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

190. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '857 Patent.

191. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

192. Unless and until Glenmark is enjoined from infringing the '857 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII: Declaratory Judgment of Infringement of the '857 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

193. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

195. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

196. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage

in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '857 Patent.

197. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

198. Glenmark's actions indicate that it does not intend to change its course of conduct.

199. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '857 Patent, including without limitation claims 1, 2, and 4, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '857 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

200. Glenmark has actual knowledge of the '857 Patent.

201. On information and belief, Glenmark became aware of the '857 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

202. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '857 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '857 Patent.

203. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

204. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '857 Patent.

205. On information and belief, Glenmark will encourage another's infringement of the '857 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '857 Patent.

206. On information and belief, the Proposed Glenmark Label will include directions and instructions that instruct physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in accordance with the methods described and claimed in the '857 Patent.

207. On information and belief, physicians and healthcare providers will administer the Glenmark ANDA Product in the United States according to the directions and instructions in the Proposed Glenmark Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 2 of the '857 Patent.

208. On information and belief, at least through the Proposed Glenmark Label, Glenmark will encourage physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, prevent pregnancy in accordance with the methods described and claimed in the '857 Patent, and Glenmark will know or should know that such conduct will occur.

209. On information and belief, Glenmark will actively induce, encourage, aid, and abet the conduct set forth above by physicians and healthcare providers with knowledge and specific intent that the conduct infringe at least one claim, including, for example claim 2 of the '857 Patent.

210. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 2 of the '857 Patent.

211. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '857 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

212. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '857 Patent.

213. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 2 of the '857 Patent.

214. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 2 of the '857 Patent.

215. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '857 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

216. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '857 Patent.

217. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '857 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

218. Unless and until Glenmark is enjoined from infringing the '857 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IX: Infringement of the '364 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

219. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

220. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '857 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '364 Patent.

221. Glenmark has actual knowledge of the '364 Patent.

222. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '364 Patent will not be infringed, is invalid, and/or is unenforceable.

223. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '364 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '364 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

224. On information and belief, Glenmark became aware of the '364 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for the approved SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

225. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

226. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '364 Patent.

227. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

228. Unless and until Glenmark is enjoined from infringing the '364 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT X: Declaratory Judgment of Infringement of the '364 Patent Under 35 U.S.C. § 271(a)-(c) by the Glenmark ANDA Product

229. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

231. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

232. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '364 Patent.

233. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

234. Glenmark's actions indicate that it does not intend to change its course of conduct.

235. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '364 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '364 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

236. Glenmark has actual knowledge of the '364 Patent.

237. On information and belief, Glenmark became aware of the '364 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

238. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '364 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '364 Patent.

239. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

240. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '364 Patent.

241. On information and belief, Glenmark will encourage another's infringement of the '364 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '364 Patent.

242. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '364 Patent.

243. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '364 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

244. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '364 Patent.

245. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '364 Patent.

246. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the '364 Patent.

247. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '364 Patent if and when the Glenmark ANDA is approved by

the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

248. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '364 Patent.

249. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will infringe the '364 Patent in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

250. Unless and until Glenmark is enjoined from infringing the '364 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XI: Infringement of the '299 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

251. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

252. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '299 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '299 Patent.

253. Glenmark has actual knowledge of the '299 Patent.

254. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '299 Patent will not be infringed, is invalid, and/or is unenforceable.

255. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '299 Patent, and its inducement of and/or

contribution to such conduct, would constitute infringement of at least one or more claims of the '299 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

256. On information and belief, Glenmark became aware of the '299 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for the approved SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

257. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

258. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '299 Patent.

259. The commercial manufacture, importation, use, sale, or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

260. Unless and until Glenmark is enjoined from infringing the '299 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XII: Declaratory Judgment of Infringement of the '299 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

261. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

263. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

264. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '299 Patent.

265. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

266. Glenmark's actions indicate that it does not intend to change its course of conduct.

267. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '299 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '299 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

268. Glenmark has actual knowledge of the '299 Patent.

269. On information and belief, Glenmark became aware of the '299 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

270. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '299 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '299 Patent.

271. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

272. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '299 Patent.

273. On information and belief, Glenmark will encourage another's infringement of the '299 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '299 Patent.

274. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '299 Patent.

275. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '299 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

276. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '299 Patent.

277. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '299 Patent.

278. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the '299 Patent.

279. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '299 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

280. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '299 Patent.

281. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will infringe the '299 Patent in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

282. Unless and until Glenmark is enjoined from infringing the '299 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIII: Infringement of the '632 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

283. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

284. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '632 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '632 Patent.

285. Glenmark has actual knowledge of the '632 Patent.

286. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '632 Patent will not be infringed, is invalid, and/or is unenforceable.

287. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '632 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '632 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

288. On information and belief, Glenmark became aware of the '632 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for the approved SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

289. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

290. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '632 Patent.

291. The commercial manufacture, importation, use, sale, or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

292. Unless and until Glenmark is enjoined from infringing the '632 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIV: Declaratory Judgment of Infringement of the '632 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

293. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

295. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

296. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '632 Patent.

297. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

298. Glenmark's actions indicate that it does not intend to change its course of conduct.

299. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '632 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '632 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

300. Glenmark has actual knowledge of the '632 Patent.

301. On information and belief, Glenmark became aware of the ’632 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs’ SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

302. On information and belief, Glenmark’s efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the ’632 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the ’632 Patent.

303. On information and belief, Glenmark’s ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

304. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the ’632 Patent.

305. On information and belief, Glenmark will encourage another’s infringement of the ’632 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the ’632 Patent.

306. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’632 Patent.

307. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the ’632 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

308. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '632 Patent.

309. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '632 Patent.

310. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the '632 Patent.

311. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '632 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

312. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '632 Patent.

313. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will infringe the '632 Patent in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

314. Unless and until Glenmark is enjoined from infringing the '632 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XV: Infringement of the '633 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

315. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

316. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '633 Patent by submitting the Glenmark ANDA to the

FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '633 Patent.

317. Glenmark has actual knowledge of the '633 Patent.

318. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '633 Patent will not be infringed, is invalid, and/or is unenforceable.

319. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '633 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '633 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

320. On information and belief, Glenmark became aware of the '633 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for the approved SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

321. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

322. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '633 Patent.

323. The commercial manufacture, importation, use, sale, or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

324. Unless and until Glenmark is enjoined from infringing the '633 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVI: Declaratory Judgment of Infringement of the '633 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

325. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

327. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

328. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '633 Patent.

329. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

330. Glenmark's actions indicate that it does not intend to change its course of conduct.

331. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '633 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the

Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '633 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

332. Glenmark has actual knowledge of the '633 Patent.

333. On information and belief, Glenmark became aware of the '633 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

334. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '633 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '633 Patent.

335. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

336. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '633 Patent.

337. On information and belief, Glenmark will encourage another's infringement of the '633 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '633 Patent.

338. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '633 Patent.

339. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '633 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

340. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '633 Patent.

341. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '633 Patent.

342. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the '633 Patent.

343. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '633 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

344. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '633 Patent.

345. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will infringe the '633 Patent in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

346. Unless and until Glenmark is enjoined from infringing the '633 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVII: Infringement of the '122 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

347. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

348. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '122 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '122 Patent.

349. Glenmark has actual knowledge of the '122 Patent.

350. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '122 Patent will not be infringed, is invalid, and/or is unenforceable.

351. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '122 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '122 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

352. On information and belief, Glenmark became aware of the '122 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for the approved SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

353. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

354. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '122 Patent.

355. The commercial manufacture, importation, use, sale, or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

356. Unless and until Glenmark is enjoined from infringing the '122 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVIII: Declaratory Judgment of Infringement of the '122 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

357. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

359. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

360. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '122 Patent.

361. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

362. Glenmark's actions indicate that it does not intend to change its course of conduct.

363. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '122 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '122 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

364. Glenmark has actual knowledge of the '122 Patent.

365. On information and belief, Glenmark became aware of the '122 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

366. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '122 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '122 Patent.

367. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

368. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '122 Patent.

369. On information and belief, Glenmark will encourage another's infringement of the '122 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '122 Patent.

370. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '122 Patent.

371. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '122 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

372. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '122 Patent.

373. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '122 Patent.

374. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the '122 Patent.

375. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '122 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

376. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '122 Patent.

377. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will infringe the '122 Patent in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

378. Unless and until Glenmark is enjoined from infringing the '122 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIX: Infringement of the '249 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

379. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

380. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '249 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '249 Patent.

381. Glenmark has actual knowledge of the '249 Patent.

382. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '249 Patent will not be infringed, is invalid, and/or is unenforceable.

383. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '249 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '249 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

384. On information and belief, Glenmark became aware of the '249 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange

Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

385. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

386. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '249 Patent.

387. The commercial manufacture, importation, use, sale, or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

388. Unless and until Glenmark is enjoined from infringing the '249 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XX: Declaratory Judgment of Infringement of the '249 Patent Under 35 U.S.C. §§ 271(b)-(c) by the Glenmark ANDA Product

389. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

391. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

392. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage

in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '249 Patent.

393. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

394. Glenmark's actions indicate that it does not intend to change its course of conduct.

395. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '249 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by actively inducing and/or contributing to infringement of the '249 Patent by others, under 35 U.S.C. §§ 271(b)-(c), unless enjoined by the Court.

396. Glenmark has actual knowledge of the '249 Patent.

397. On information and belief, Glenmark became aware of the '249 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

398. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '249 Patent and without a reasonable basis for believing that it would not be liable for actively inducing and/or contributing to the infringement of the '249 Patent.

399. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

400. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will actively induce and/or contribute to the actual infringement of the ’249 Patent.

401. On information and belief, the Proposed Glenmark Label will include directions and instructions that instruct physicians and healthcare providers to administer the Glenmark ANDA Product to female patients in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the ’249 Patent.

402. On information and belief, physicians and healthcare providers will administer the Glenmark ANDA Product in the United States according to the directions and instructions in the Proposed Glenmark Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 1 of the ’249 Patent.

403. On information and belief, through the Proposed Glenmark Label, Glenmark will encourage physicians and healthcare providers to administer the Glenmark ANDA Product to female patients in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the ’249 Patent, and Glenmark will know or should know that such conduct will occur.

404. On information and belief, Glenmark will actively induce, encourage, aid, and abet the conduct set forth above by physicians and healthcare providers with knowledge and specific intent that the conduct infringe at least one claim, including, for example, claim 1 of the ’249 Patent.

405. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’249 Patent.

406. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '249 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

407. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '249 Patent.

408. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '249 Patent.

409. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including, for example, claim 1 of the '249 Patent.

410. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '249 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

411. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will induce and/or contribute to infringement of the '249 Patent.

412. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will infringe the '249 Patent in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

413. Unless and until Glenmark is enjoined from inducing and/or contributing to the infringement of the '249 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXI: Infringement of the '598 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

414. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

415. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '598 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '598 Patent.

416. Glenmark has actual knowledge of the '598 Patent.

417. On information and belief, Glenmark became aware of the '598 Patent no later than the date on which it was issued by the Patent and Trademark Office, and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter, and/or the date of this complaint.

418. Plaintiffs asserted the '598 Patent in *Exeltis USA, Inc. v. Lupin Ltd. et al.*, 1:22-cv -00434 (D. Del.). On information and belief, Glenmark has knowledge of this prior litigation.

419. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '598 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '598 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

420. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's final approval of the Glenmark ANDA.

421. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '598 Patent.

422. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

423. Unless and until Glenmark is enjoined from infringing the '598 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXII: Declaratory Judgment of Infringement of the '598 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

424. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

426. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

427. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. As described in the foregoing paragraphs, on information and belief, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '598 Patent.

428. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

429. Glenmark's actions indicate that it does not intend to change its course of conduct.

430. On information and belief, upon final FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '598 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '598 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

431. Glenmark has actual knowledge of the '598 Patent.

432. On information and belief, Glenmark became aware of the '598 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter, and/or the date of this complaint.

433. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '598 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '598 Patent.

434. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

435. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '598 Patent.

436. On information and belief, Glenmark will encourage another's infringement of the '598 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '598 Patent.

437. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’598 Patent.

438. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the ’598 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

439. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the ’598 Patent.

440. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the ’598 Patent.

441. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the ’598 Patent.

442. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the ’598 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

443. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the ’598 Patent.

444. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the ’598 Patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

445. Unless and until Glenmark is enjoined from infringing the ’598 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXIII: Infringement of the ’695 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

446. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

447. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the ’695 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the ’695 Patent.

448. Glenmark has actual knowledge of the ’695 Patent.

449. On information and belief, Glenmark became aware of the ’695 Patent no later than the date on which it was issued by the Patent and Trademark Office, and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter, and/or the date of this complaint.

450. Plaintiffs asserted the ’695 Patent in *Exeltis USA, Inc. v. Lupin Ltd. et al.*, 1:22-cv-00434 (D. Del.). On information and belief, Glenmark has knowledge of this prior litigation.

451. Glenmark’s commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the ’695 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the ’695 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

452. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and

belief, Glenmark will engage in such activities upon the FDA's final approval of the Glenmark ANDA.

453. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '695 Patent.

454. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

455. Unless and until Glenmark is enjoined from infringing the '695 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXIV: Declaratory Judgment of Infringement of the '695 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

456. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

458. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

459. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. As described in the foregoing paragraphs, on information and belief, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '695 Patent.

460. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

461. Glenmark's actions indicate that it does not intend to change its course of conduct.

462. On information and belief, upon final FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '695 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '695 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

463. Glenmark has actual knowledge of the '695 Patent.

464. On information and belief, Glenmark became aware of the '695 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter, and/or the date of this complaint.

465. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '695 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '695 Patent.

466. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

467. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '695 Patent.

468. On information and belief, Glenmark will encourage another's infringement of the '695 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '695 Patent.

469. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '695 Patent.

470. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '695 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

471. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '695 Patent.

472. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '695 Patent.

473. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the '695 Patent.

474. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '695 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

475. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '695 Patent.

476. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '695 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

477. Unless and until Glenmark is enjoined from infringing the '695 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXV: Infringement of the '487 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

478. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

479. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '487 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '487 Patent.

480. Glenmark has actual knowledge of the '487 Patent.

481. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '487 Patent will not be infringed, is invalid, and/or is unenforceable.

482. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '487 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the

'487 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

483. On information and belief, Glenmark became aware of the '487 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

484. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's final approval of the Glenmark ANDA.

485. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '487 Patent.

486. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

487. Unless and until Glenmark is enjoined from infringing the '487 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXVI: Declaratory Judgment of Infringement of the '487 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

488. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

490. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

491. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '487 Patent.

492. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

493. Glenmark's actions indicate that it does not intend to change its course of conduct.

494. On information and belief, upon final FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '487 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '487 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

495. Glenmark has actual knowledge of the '487 Patent.

496. On information and belief, Glenmark became aware of the '487 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

497. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '487 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '487 Patent.

498. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

499. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '487 Patent.

500. On information and belief, Glenmark will encourage another's infringement of the '487 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '487 Patent.

501. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '487 Patent.

502. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '487 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

503. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '487 Patent.

504. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '487 Patent.

505. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the ’487 Patent.

506. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the ’487 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

507. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the ’487 Patent.

508. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the ’487 Patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

509. Unless and until Glenmark is enjoined from infringing the ’487 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXVII: Infringement of the ’113 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

510. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

511. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the ’113 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the ’113 Patent.

512. Glenmark has actual knowledge of the ’113 Patent.

513. On information and belief, Glenmark became aware of the '113 Patent no later than the date on which it was issued by the Patent and Trademark Office, and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter, and/or the date of this complaint.

514. Plaintiffs asserted the '113 Patent in *Exeltis USA, Inc. v. Lupin Ltd. et al.*, 1:22-cv -00434 (D. Del.). On information and belief, Glenmark has knowledge of this prior litigation.

515. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '113 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '113 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

516. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's final approval of the Glenmark ANDA.

517. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '113 Patent.

518. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

519. Unless and until Glenmark is enjoined from infringing the '113 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXVIII: Declaratory Judgment of Infringement of the '113 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

520. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

522. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

523. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. As described in the foregoing paragraphs, on information and belief, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '113 Patent.

524. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

525. Glenmark's actions indicate that it does not intend to change its course of conduct.

526. On information and belief, upon final FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '113 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '113 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

527. Glenmark has actual knowledge of the '113 Patent.

528. On information and belief, Glenmark became aware of the '113 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter, and/or the date of this complaint.

529. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '113 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '113 Patent.

530. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

531. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '113 Patent.

532. On information and belief, Glenmark will encourage another's infringement of the '113 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '113 Patent.

533. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '113 Patent.

534. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '113 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

535. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '113 Patent.

536. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '113 Patent.

537. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the '113 Patent.

538. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '113 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

539. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '113 Patent.

540. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '113 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

541. Unless and until Glenmark is enjoined from infringing the '113 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXIX: Infringement of the '334 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

542. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

543. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '334 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial

manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '334 Patent.

544. Glenmark has actual knowledge of the '334 Patent.

545. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '334 Patent will not be infringed, is invalid, and/or is unenforceable.

546. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '334 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '334 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

547. On information and belief, Glenmark became aware of the '334 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

548. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's final approval of the Glenmark ANDA.

549. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '334 Patent.

550. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

551. Unless and until Glenmark is enjoined from infringing the '334 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXX: Declaratory Judgment of Infringement of the '334 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

552. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

554. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

555. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '334 Patent.

556. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

557. Glenmark's actions indicate that it does not intend to change its course of conduct.

558. On information and belief, upon final FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '334 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or

selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the ’334 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

559. Glenmark has actual knowledge of the ’334 Patent.

560. On information and belief, Glenmark became aware of the ’334 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs’ SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

561. On information and belief, Glenmark’s efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the ’334 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the ’334 Patent.

562. On information and belief, Glenmark’s ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

563. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the ’334 Patent.

564. On information and belief, Glenmark will encourage another’s infringement of the ’334 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the ’334 Patent.

565. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’334 Patent.

566. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '334 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

567. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '334 Patent.

568. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '334 Patent.

569. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the '334 Patent.

570. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '334 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

571. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '334 Patent.

572. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '334 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

573. Unless and until Glenmark is enjoined from infringing the '334 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXXI: Infringement of the ’213 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

574. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

575. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the ’213 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the ’213 Patent.

576. Glenmark has actual knowledge of the ’213 Patent.

577. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the ’213 Patent will not be infringed, is invalid, and/or is unenforceable.

578. Glenmark’s commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the ’213 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the ’213 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

579. On information and belief, Glenmark became aware of the ’213 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

580. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA’s approval of the Glenmark ANDA.

581. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '213 Patent.

582. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

583. Unless and until Glenmark is enjoined from infringing the '213 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXXII: Declaratory Judgment of Infringement of the '213 Patent Under 35 U.S.C. §§ 271(b)-(c) by the Glenmark ANDA Product

584. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

586. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

587. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '213 Patent.

588. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

589. Glenmark's actions indicate that it does not intend to change its course of conduct.

590. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the ’213 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by actively inducing and/or contributing to infringement of the ’213 Patent by others, under 35 U.S.C. §§ 271(b)-(c), unless enjoined by the Court.

591. Glenmark has actual knowledge of the ’213 Patent.

592. On information and belief, Glenmark became aware of the ’213 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs’ SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

593. On information and belief, Glenmark’s efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the ’213 Patent and without a reasonable basis for believing that it would not be liable for actively inducing and/or contributing to the infringement of the ’213 Patent.

594. On information and belief, Glenmark’s ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

595. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will actively induce and/or contribute to the actual infringement of the ’213 Patent.

596. On information and belief, the Proposed Glenmark Label will include directions and instructions that instruct physicians and healthcare providers to administer the Glenmark

ANDA Product to females of reproductive potential in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the '213 Patent.

597. On information and belief, physicians and healthcare providers will administer the Glenmark ANDA Product in the United States according to the directions and instructions in the Proposed Glenmark Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 1 of the '213 Patent.

598. On information and belief, at least through the Proposed Glenmark Label, Glenmark will encourage physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the '213 Patent, and Glenmark will know or should know that such conduct will occur.

599. On information and belief, Glenmark will actively induce, encourage, aid, and abet the conduct set forth above by physicians and healthcare providers with knowledge and specific intent that the conduct infringe at least one claim, including, for example, claim 1 of the '213 Patent.

600. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '213 Patent.

601. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '213 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

602. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '213 Patent.

603. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the ’213 Patent.

604. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the ’213 Patent.

605. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the ’213 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

606. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will induce and/or contribute to infringement of the ’213 Patent.

607. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the ’213 Patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

608. Unless and until Glenmark is enjoined from inducing and/or contributing to the infringement of the ’213 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXXIII: Infringement of the ’231 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

609. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

610. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the ’231 Patent by submitting the Glenmark ANDA to the

FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '231 Patent.

611. Glenmark has actual knowledge of the '231 Patent.

612. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '231 Patent will not be infringed, is invalid, and/or is unenforceable.

613. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '231 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '231 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

614. On information and belief, Glenmark became aware of the '231 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

615. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

616. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '231 Patent.

617. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

618. Unless and until Glenmark is enjoined from infringing the '231 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXXIV: Declaratory Judgment of Infringement of the '231 Patent Under 35 U.S.C. §§ 271(b)-(c) by the Glenmark ANDA Product

619. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

621. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

622. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '231 Patent.

623. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

624. Glenmark's actions indicate that it does not intend to change its course of conduct.

625. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '231 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by actively inducing and/or contributing to

infringement of the ’231 Patent by others, under 35 U.S.C. §§ 271(b)-(c), unless enjoined by the Court.

626. Glenmark has actual knowledge of the ’231 Patent.

627. On information and belief, Glenmark became aware of the ’231 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs’ SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

628. On information and belief, Glenmark’s efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the ’231 Patent and without a reasonable basis for believing that it would not be liable for actively inducing and/or contributing to the infringement of the ’231 Patent.

629. On information and belief, Glenmark’s ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

630. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will actively induce and/or contribute to the actual infringement of the ’231 Patent.

631. On information and belief, the Proposed Glenmark Label will include directions and instructions that instruct physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the ’231 Patent.

632. On information and belief, physicians and healthcare providers will administer the Glenmark ANDA Product in the United States according to the directions and instructions in the

Proposed Glenmark Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 1 of the ’231 Patent.

633. On information and belief, at least through the Proposed Glenmark Label, Glenmark will encourage physicians and healthcare providers to administer the Glenmark ANDA Product to females of reproductive potential in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the ’231 Patent, and Glenmark will know or should know that such conduct will occur.

634. On information and belief, Glenmark will actively induce, encourage, aid, and abet the conduct set forth above by physicians and healthcare providers with knowledge and specific intent that the conduct infringe at least one claim, including, for example, claim 1 of the ’231 Patent.

635. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’231 Patent.

636. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the ’231 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

637. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the ’231 Patent.

638. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the ’231 Patent.

639. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the ’231 Patent.

640. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '231 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

641. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will induce and/or contribute to infringement of the '231 Patent.

642. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '231 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

643. Unless and until Glenmark is enjoined from inducing and/or contributing to the infringement of the '231 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXXV: Infringement of the '151 Patent
Under 35 U.S.C. § 271(e)(2) by the Glenmark ANDA

644. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

645. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark has committed an act of infringement of one or more claims of the '151 Patent by submitting the Glenmark ANDA to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product throughout the United States prior to the expiration of the '151 Patent.

646. Glenmark has actual knowledge of the '151 Patent.

647. Glenmark made and included in the Glenmark ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '151 Patent will not be infringed, is invalid, and/or is unenforceable.

648. Glenmark's commercial manufacture, use, offer for sale, and/or importation of the Glenmark ANDA Product prior to the expiration of the '151 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one or more claims of the '151 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

649. On information and belief, Glenmark became aware of the '151 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of SLYND® and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

650. On information and belief, Glenmark will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product. On information and belief, Glenmark will engage in such activities upon the FDA's approval of the Glenmark ANDA.

651. On information and belief, Glenmark knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '151 Patent.

652. The commercial manufacture, importation, use, sale, and/or offer for sale of the Glenmark ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

653. Unless and until Glenmark is enjoined from infringing the '151 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXXVI: Declaratory Judgment of Infringement of the '151 Patent Under 35 U.S.C. §§ 271(a)-(c) by the Glenmark ANDA Product

654. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

656. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

657. Glenmark has submitted the Glenmark ANDA for a generic version of Plaintiffs' SLYND® product. According to Glenmark's Paragraph IV Letter, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product in the United States before the expiration of the '151 Patent.

658. While the FDA has not yet approved the Glenmark ANDA, Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Glenmark ANDA Product.

659. Glenmark's actions indicate that it does not intend to change its course of conduct.

660. On information and belief, upon FDA approval of the Glenmark ANDA, Glenmark will infringe one or more claims of the '151 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents, by making, using, offering for sale, and/or selling the Glenmark ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '151 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

661. Glenmark has actual knowledge of the '151 Patent.

662. On information and belief, Glenmark became aware of the '151 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book for Plaintiffs' SLYND® product and/or by September 22, 2025, when Glenmark sent its Paragraph IV Letter.

663. On information and belief, Glenmark's efforts to make, use, sell, offer for sale, and/or import the Glenmark ANDA Product have been made and will be made with full knowledge of the '151 Patent and without a reasonable basis for believing that it would not be liable for infringing and/or actively inducing and/or contributing to the infringement of the '151 Patent.

664. On information and belief, Glenmark's ANDA Product, if approved by the FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Glenmark in the United States by Glenmark or on its behalf.

665. On information and belief, Glenmark knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '151 Patent.

666. On information and belief, Glenmark will encourage another's infringement of the '151 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product, which is covered by the claims of the '151 Patent.

667. Through at least the foregoing actions, Glenmark will actively induce the infringement of at least one claim, including, for example, claim 1 of the '151 Patent.

668. On information and belief, Glenmark knows or should know that the Glenmark ANDA Product will be especially made or adapted for use in infringing the '151 Patent and that the Glenmark ANDA Product is not suitable for substantial non-infringing use.

669. The commercial manufacture, use, sale, offer for sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of the '151 Patent.

670. On information and belief, Glenmark knows or should know that its offer for sale, sale, and/or importation of the Glenmark ANDA Product will contribute to the actual infringement of at least one claim, including, for example, claim 1 of the '151 Patent.

671. Through at least the foregoing actions, Glenmark will contribute to the infringement of at least one claim, including for example, claim 1 of the '151 Patent.

672. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '151 Patent if and when the Glenmark ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

673. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product by Glenmark will infringe and/or induce and/or contribute to infringement of the '151 Patent.

674. The commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product, which will actively induce and/or contribute to the infringement of the '151 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

675. Unless and until Glenmark is enjoined from infringing the '151 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues that are or may become triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Glenmark has infringed the '860 Patent, the '140 Patent, the '281 Patent, the '857 Patent, the '364 Patent, the '299 Patent, the '632 Patent, the '633 Patent, the '122 Patent, the '249 Patent, the '598 Patent, the '695 Patent, the '487 Patent, the '113 Patent, the '334 Patent, the '213 Patent, the '231 Patent, and/or the '151 Patent by submitting the Glenmark ANDA under Section 505(j) of the FD&C Act, and that the making, using, offering for sale, and/or selling within the United States, and/or importation into the United States of the Glenmark ANDA Product will constitute an infringement of the '860 Patent, the '140 Patent, the '281 Patent, the '857 Patent, the '364 Patent, the '299 Patent, the '632 Patent, the '633 Patent, the '122 Patent, the '249 Patent, the '598 Patent, the '695 Patent, the '487 Patent, the '113 Patent, the '334 Patent, the '213 Patent, the '231 Patent, and/or the '151 Patent;

B. A judgment declaring that the '860 Patent, the '140 Patent, the '281 Patent, the '857 Patent, the '364 Patent, the '299 Patent, the '632 Patent, the '633 Patent, the '122 Patent, the '249 Patent, the '598 Patent, the '695 Patent, the '487 Patent, the '113 Patent, the '334 Patent, the '213 Patent, the '231 Patent, and/or the '151 Patent have not been proven invalid or unenforceable;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Glenmark ANDA shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit as extended by any applicable periods of exclusivity to which Plaintiffs are or will be entitled;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Glenmark, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering for sale, and/or selling in the United States, and/or importing into the United States the Glenmark ANDA

Product until after the latest expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or will be entitled;

E. An order pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that Glenmark's commercial manufacture, use, offer for sale, sale, and/or importation of the Glenmark ANDA Product in or into the United States prior to the expiration of the Patents-in-Suit, including such actions by its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Glenmark or acting on Glenmark's behalf, will constitute infringement of the Patents-in-Suit under 35 U.S.C. §§ 271(a), (b), and/or (c) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

F. Damages or other monetary relief under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(c), and/or 35 U.S.C. § 284, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Glenmark engages in commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the Glenmark ANDA Product prior to the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or will be entitled;

G. An order that this case is exceptional under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

H. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

I. Such further and other relief as this Court deems proper and just.

Dated: November 6, 2025

Respectfully submitted,

By: */s/ Liza M. Walsh*

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending litigation in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action.

Dated: November 6, 2025

Respectfully submitted,

By: */s/ Liza M. Walsh*

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: November 6, 2025

Respectfully submitted,

By: */s/ Liza M. Walsh*

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