IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELTIS USA, INC., LABORATORIOS LEON FARMA, S.A., CHEMO IBERICA, S.A., and CHEMO RESEARCH, S.L.	:	
Plaintiffs,	:	C.A. No. _____
v.	:	**JURY TRIAL DEMANDED**
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

PLAINTIFFS EXELTIS USA, INC., LABORATORIOS LEON FARMA, S.A., CHEMO IBERICA, S.A., AND CHEMO RESEARCH, S.L.'S
COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Exeltis USA, Inc. ("Exeltis"), Laboratorios Leon Farma, S.A. ("Leon Farma"), Chemo Ibérica, S.A. ("Chemo Iberica"), and Chemo Research, S.L. ("Chemo Research") (collectively "Plaintiffs") bring this Complaint for patent infringement and declaratory judgment against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("LPI") (collectively "Lupin" 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 Lupin'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; and 11,123,299 (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-F.

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 Lupin Ltd. is a foreign corporation organized and existing under the laws of India, having its principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai, 400 055, India.

8. On information and belief, Defendant LPI is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. On information and belief, LPI is an indirect, wholly-owned subsidiary of Lupin Ltd.

9. On information and belief, Lupin, 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, Lupin, themselves and with their subsidiaries, affiliates, agents, and partners, prepared and filed ANDA No. 216936 (the "Lupin ANDA"), seeking approval to manufacture, import, market, and/or sell a generic copy of Plaintiffs' SLYND® (drospirenone) tablets, 4 mg (the "Lupin ANDA Product") in the United States, including in this District, if the FDA approves the Lupin 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 Lupin 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, Lupin Ltd. regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic copies of branded pharmaceutical products in the United States, including Delaware. On information and belief, Lupin Ltd. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

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

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

15. Alternatively, this Court may exercise personal jurisdiction over Lupin Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Lupin 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 Lupin Ltd. satisfies due process.

16. This Court has personal jurisdiction over LPI in that it is incorporated in Delaware 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, LPI regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic copies of branded pharmaceutical products in the United States, including Delaware. On information and belief, LPI derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

17. On information and belief, LPI is licensed to sell generic pharmaceutical products in Delaware, pursuant to 24 Del. C. § 2540.

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

19. This Court also has personal jurisdiction over Lupin Ltd. and LPI because Lupin Ltd. and LPI 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 it in this District. *See, e.g.*, *ViiV Healthcare Co. v. Lupin Limited*, No. 1:17-cv-01576, D.I. 17 (D. Del. Dec. 19, 2017); *Forest Labs*,

LLC, et al. v. Lupin Limited, No. 1:14-cv-01058, D.I. 15 (D. Del. Sept. 8, 2014); *Teijin Limited, et al. v. Lupin Limited*, No. 1:14-cv-00184, D.I. 20 (D. Del. April 1, 2014).

20. Venue is proper as to Lupin Ltd. in this District under 28 U.S.C. § 1391(c)(3) because Lupin 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 LPI in this District under 28 U.S.C. § 1400(b) because LPI is incorporated in and resides in Delaware.

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.

Acts Giving Rise to This Action

34. 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.

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

36. In conjunction with NDA No. 211367, Exeltis has listed with the FDA six patents for SLYND®: U.S. Patent Nos. 9,603,860; 10,179,140; 10,603,281; 10,849,857; 10,987,364; and 11,123,299. The FDA has published each of these six 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").

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

38. On information and belief, Lupin submitted to the FDA the Lupin 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 Lupin ANDA Product before the expiration of the '860, '140, '281, '857, '364, and '299 Patents.

39. On information and belief, Lupin sent a letter dated February 18, 2022 to Exeltis and Leon Farma (the "Paragraph IV Letter"), purporting to be a notice pursuant to 21 U.S.C. §

355(j)(2)(B). Lupin'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, and '299 Patents.

40. Exeltis received Lupin's Paragraph IV Letter on February 21, 2022.

41. Leon Farma received Lupin's Paragraph IV Letter on February 21, 2022.

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

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

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

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

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

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

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

49. Lupin's Paragraph IV Letter included an Offer for Confidential Access to Application ("OCA") in which Lupin purported to offer to provide confidential access to certain information from the Lupin 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." Lupin's OCA contained unreasonable restrictions, above and beyond those that would apply under a court-ordered protective order.

50. Since receiving Lupin's Paragraph IV Letter, Plaintiffs have been negotiating in good faith to reach a mutually-acceptable agreement under which Lupin would provide the Lupin ANDA to Plaintiffs. To date, Lupin has refused to offer Plaintiffs access to the Lupin 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 Lupin ANDA.

51. 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).

52. Plaintiffs are not aware of any other means of obtaining information regarding the Lupin 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 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 Lupin ANDA Product has and will infringe one or more claims of the Patents-in-Suit.

53. Because Plaintiffs have been unable to obtain a copy of the Lupin ANDA, Plaintiffs allege the causes herein based primarily on the representations contained in Lupin'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 Lupin ANDA

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

55. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of one or more claims of the '860 Patent by submitting the Lupin 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 Lupin ANDA Product throughout the United States prior to the expiration of the '860 Patent.

56. Lupin has actual knowledge of the '860 Patent.

57. Lupin made and included in the Lupin 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.

58. Lupin's commercial manufacture, use, offer for sale, and/or importation of the Lupin 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.[1]

59. On information and belief, Lupin 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 February 18, 2022, when Lupin sent its Paragraph IV Letter.

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

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

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

63. Unless and until Lupin 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(a)-(c) by the Lupin ANDA Product

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

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

[1] Plaintiffs will identify all asserted claims of the '860 Patent in accordance with this Court's Local Rules and/or scheduling order.

66. 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.

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

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

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

70. On information and belief, upon FDA approval of the Lupin ANDA, Lupin will infringe one or more claims of the '860 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[2] by making, using, offering for sale, and/or selling the Lupin 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 '860 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

71. Lupin has actual knowledge of the '860 Patent.

72. On information and belief, Lupin 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

[2] Plaintiffs will identify all asserted claims of the '860 Patent in accordance with this Court's Local Rules and/or scheduling order.

Book for Plaintiffs' SLYND® product and/or by February 18, 2022, when Lupin sent its Paragraph IV Letter.

73. On information and belief, Lupin's efforts to make, use, sell, offer for sale, and/or import the Lupin 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 infringing and/or actively inducing and/or contributing to the infringement of the '860 Patent.

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

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

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

77. On information and belief, physicians and healthcare providers will administer the Lupin SLYND® ANDA Product in the United States according to the directions and instructions in the Proposed Lupin Label, and such administration will constitute direct infringement of at least one claim, including, for example, claim 1 of the '860 Patent.

78. On information and belief, at least through the Proposed Lupin Label, Lupin will encourage physicians and healthcare providers to administer the Lupin 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 Lupin will know or should know that such conduct will occur.

79. On information and belief, Lupin 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.

80. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claim, including, for example, claim 1 of the '860 Patent.

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

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

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

84. Through at least the foregoing actions, Lupin will contribute to the infringement of at least one claim, including for example, claim 1 of the '860 Patent.

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

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

87. The commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin 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.

88. Unless and until Lupin is enjoined from infringing 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 Lupin ANDA

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

90. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of one or more claims of the '140 Patent by submitting the Lupin 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 Lupin ANDA Product throughout the United States prior to the expiration of the '140 Patent.

91. Lupin has actual knowledge of the '140 Patent.

92. Lupin made and included in the Lupin 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.

93. Lupin's commercial manufacture, use, offer for sale, and/or importation of the Lupin 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.[3]

94. On information and belief, Lupin 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 February 18, 2022, when Lupin sent its Paragraph IV Letter.

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

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

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

98. Unless and until Lupin 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(a)-(c) by the Lupin ANDA Product

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

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

[3] Plaintiffs will identify all asserted claims of the '140 Patent in accordance with this Court's Local Rules and/or scheduling order.

101. 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.

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

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

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

105. On information and belief, upon FDA approval of the Lupin ANDA, Lupin will infringe one or more claims of the '140 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[4] by making, using, offering for sale, and/or selling the Lupin 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 '140 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

106. Lupin has actual knowledge of the '140 Patent.

107. On information and belief, Lupin 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

[4] Plaintiffs will identify all asserted claims of the '140 Patent in accordance with this Court's Local Rules and/or scheduling order.

Book for Plaintiffs' SLYND® product and/or by February 18, 2022, when Lupin sent its Paragraph IV Letter.

108. On information and belief, Lupin's efforts to make, use, sell, offer for sale, and/or import the Lupin 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 infringing and/or actively inducing and/or contributing to the infringement of the '140 Patent.

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

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

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

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

113. On information and belief, at least through the Proposed Lupin Label, Lupin will encourage physicians and healthcare providers to administer the Lupin 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 Lupin will know or should know that such conduct will occur.

114. On information and belief, Lupin 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.

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

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

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

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

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

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

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

122. The commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin 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.

123. Unless and until Lupin is enjoined from infringing 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 Lupin ANDA

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

125. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of one or more claims of the '281 Patent by submitting the Lupin 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 Lupin ANDA Product throughout the United States prior to the expiration of the '281 Patent.

126. Lupin has actual knowledge of the '281 Patent.

127. Lupin made and included in the Lupin 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.

128. Lupin's commercial manufacture, use, offer for sale, and/or importation of the Lupin 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.[5]

129. On information and belief, Lupin 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 February 18, 2022, when Lupin sent its Paragraph IV Letter.

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

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

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

133. Unless and until Lupin 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(a)-(c) by the Lupin ANDA Product

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

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

[5] Plaintiffs will identify all asserted claims of the '281 Patent in accordance with this Court's Local Rules and/or scheduling order.

136. 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.

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

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

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

140. On information and belief, upon FDA approval of the Lupin ANDA, Lupin will infringe one or more claims of the '281 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[6] by making, using, offering for sale, and/or selling the Lupin 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 '281 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

141. Lupin has actual knowledge of the '281 Patent.

142. On information and belief, Lupin 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

[6] Plaintiffs will identify all asserted claims of the '281 Patent in accordance with this Court's Local Rules and/or scheduling order.

Book for Plaintiffs' SLYND® product and/or by February 18, 2022, when Lupin sent its Paragraph IV Letter.

143. On information and belief, Lupin's efforts to make, use, sell, offer for sale, and/or import the Lupin 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 infringing and/or actively inducing and/or contributing to the infringement of the '281 Patent.

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

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

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

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

148. On information and belief, at least through the Proposed Lupin Label, Lupin will encourage physicians and healthcare providers to administer the Lupin 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 Lupin will know or should know that such conduct will occur.

149. On information and belief, Lupin 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.

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

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

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

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

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

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

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

157. The commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin 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.

158. Unless and until Lupin is enjoined from infringing 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 Lupin ANDA

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

160. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of one or more claims of the '857 Patent by submitting the Lupin 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 Lupin ANDA Product throughout the United States prior to the expiration of the '857 Patent.

161. Lupin has actual knowledge of the '857 Patent.

162. Lupin made and included in the Lupin 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.

163. Lupin's commercial manufacture, use, offer for sale, and/or importation of the Lupin 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.[7]

164. On information and belief, Lupin 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 February 18, 2022, when Lupin sent its Paragraph IV Letter.

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

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

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

168. Unless and until Lupin 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 Lupin ANDA Product

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

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

[7] Plaintiffs will identify all asserted claims of the '857 Patent in accordance with this Court's Local Rules and/or scheduling order.

171. 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.

172. Lupin has submitted the Lupin ANDA for a generic version of Plaintiffs' SLYND® product. According to Lupin's Paragraph IV Letter, Lupin intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Product in the United States before the expiration of the '857 Patent.

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

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

175. On information and belief, upon FDA approval of the Lupin ANDA, Lupin 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,[8] by making, using, offering for sale, and/or selling the Lupin 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.

176. Lupin has actual knowledge of the '857 Patent.

177. On information and belief, Lupin 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

[8] Plaintiffs will identify all asserted claims of the '857 Patent in accordance with this Court's Local Rules and/or scheduling order.

Book for Plaintiffs' SLYND® product and/or by February 18, 2022, when Lupin sent its Paragraph IV Letter.

178. On information and belief, Lupin's efforts to make, use, sell, offer for sale, and/or import the Lupin 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.

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

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

181. On information and belief, Lupin 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 Lupin ANDA Product, which is covered by the claims of the '857 Patent.

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

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

184. On information and belief, at least through the Proposed Lupin Label, Lupin will encourage physicians and healthcare providers to administer the Lupin 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 Lupin will know or should know that such conduct will occur.

185. On information and belief, Lupin 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.

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

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

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

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

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

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

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

193. The commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin 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.

194. Unless and until Lupin 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 Lupin ANDA

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

196. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of one or more claims of the '857 Patent by submitting the Lupin 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 Lupin ANDA Product throughout the United States prior to the expiration of the '364 Patent.

197. Lupin has actual knowledge of the '364 Patent.

198. Lupin made and included in the Lupin 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.

199. Lupin's commercial manufacture, use, offer for sale, and/or importation of the Lupin 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.[9]

200. On information and belief, Lupin 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 February 18, 2022, when Lupin sent its Paragraph IV Letter.

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

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

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

204. Unless and until Lupin 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 Lupin ANDA Product

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

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

[9] Plaintiffs will identify all asserted claims of the '364 Patent in accordance with this Court's Local Rules and/or scheduling order.

207. 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.

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

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

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

211. On information and belief, upon FDA approval of the Lupin ANDA, Lupin will infringe one or more claims of the '364 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[10] by making, using, offering for sale, and/or selling the Lupin 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.

212. Lupin has actual knowledge of the '364 Patent.

213. On information and belief, Lupin 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

[10] Plaintiffs will identify all asserted claims of the '364 Patent in accordance with this Court's Local Rules and/or scheduling order.

Book for Plaintiffs' SLYND® product and/or by February 18, 2022, when Lupin sent its Paragraph IV Letter.

214. On information and belief, Lupin's efforts to make, use, sell, offer for sale, and/or import the Lupin 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.

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

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

217. On information and belief, Lupin 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 Lupin ANDA Product, which is covered by the claims of the '364 Patent.

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

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

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

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

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

223. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the '364 Patent if and when the Lupin ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon final approval.

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

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

226. Unless and until Lupin 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 Lupin ANDA

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

228. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of one or more claims of the '299 Patent by submitting the Lupin 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 Lupin ANDA Product throughout the United States prior to the expiration of the '299 Patent.

229. Lupin has actual knowledge of the '299 Patent.

230. Lupin made and included in the Lupin 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.

231. Lupin's commercial manufacture, use, offer for sale, and/or importation of the Lupin 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.[11]

232. On information and belief, Lupin 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 February 18, 2022, when Lupin sent its Paragraph IV Letter.

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

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

[11] Plaintiffs will identify all asserted claims of the '299 Patent in accordance with this Court's Local Rules and/or scheduling order.

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

236. Unless and until Lupin 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 Lupin ANDA Product

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

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

239. 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.

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

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

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

243. On information and belief, upon FDA approval of the Lupin ANDA, Lupin will infringe one or more claims of the '299 Patent, including without limitation claim 1, either literally

or under the doctrine of equivalents,[12] by making, using, offering for sale, and/or selling the Lupin 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.

244. Lupin has actual knowledge of the '299 Patent.

245. On information and belief, Lupin 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 February 18, 2022, when Lupin sent its Paragraph IV Letter.

246. On information and belief, Lupin's efforts to make, use, sell, offer for sale, and/or import the Lupin 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.

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

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

[12] Plaintiffs will identify all asserted claims of the '299 Patent in accordance with this Court's Local Rules and/or scheduling order.

249. On information and belief, Lupin 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 Lupin ANDA Product, which is covered by the claims of the '299 Patent.

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

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

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

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

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

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

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

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

258. Unless and until Lupin is enjoined from infringing the '299 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 Lupin has infringed the '860 Patent, the '140 Patent, the '281 Patent, the '857 Patent, the '364 Patent, and/or the '299 Patent by submitting the Lupin 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 Lupin ANDA Product will constitute an infringement of the '860 Patent, the '140 Patent, the '281 Patent, the '857 Patent, the '364 Patent, and/or the '299 Patent;

B. A judgment declaring that the '860 Patent, the '140 Patent, the '281 Patent, the '857 Patent, the '364 Patent, and/or the '299 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 Lupin 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 Lupin, its affiliates, subsidiaries, and each of its officers, agents, servants and employees

and those acting in privity or concert with them, from making using, offer for sale, and/or selling in the United States, and/or importing into the United States the Lupin 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 Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin 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 Lupin or acting on Lupin'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 Lupin engages in commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the Lupin 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: April 1, 2022

FISH & RICHARDSON, P.C.

/s/ Martina Tyreus Hufnal

Martina Tyreus Hufnal (#4771)
Douglas E. McCann (#3852)
Gregory R. Booker (#4784)
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899
Telephone: (302) 652-5070
Email: tyreushufnal@fr.com;
dmccann@fr.com;
booker@fr.com

Brian Coggio
FISH & RICHARDSON P.C.
7 Times Square, 20th Floor
New York, NY 10036
Telephone: (212) 765-5070
Email: coggio@fr.com

Megan A. Chacon
Bernard Cryan
FISH & RICHARDSON P.C.
12860 El Camino Real, Ste. 400
San Diego, CA 92130
Telephone: (858) 678-5070
Email: chacon@fr.com;
cryan@fr.com

Philip K. Chen
FISH & RICHARDSON P.C.
One Marina Park Drive
Boston, MA 02210
Telephone: (617) 542-5070
Email: pchen@fr.com

Attorneys for Plaintiffs Exeltis USA, Inc., Laboratorios Leon Farma S.A., Chemo Iberica S.A., and Chemo Research S.L.