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, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

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 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 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 U.S. Patent No. 11,951,213 (the "'213 patent"), which concerns Plaintiffs' groundbreaking progestin-only birth control pill, SLYND®.

2. This action arises out of Lupin's filing of Abbreviated New Drug Application No. 216936 (the "Lupin ANDA") with the United States Food and Drug Administration ("FDA")

seeking approval to market a generic version of Plaintiffs' successful product containing drospirenone, SLYND® (drospirenone) tablets, 4 mg (the "Lupin ANDA Product") prior to the expiration of the '213 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or will be entitled. Plaintiffs attach hereto a true and accurate copy of the '213 patent as Exhibit A.

3. This action is the second patent infringement suit under the Hatch-Waxman Act filed by Plaintiffs against Lupin in this Court. Prior to the filing of the instant complaint, Plaintiffs filed an action for patent infringement under the Hatch-Waxman Act against Lupin alleging infringement 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; and 11,504,334 (collectively, the "First Action Patents"). *Exeltis USA, Inc. v. Lupin Ltd.*, No. 1:22-cv-00434-RGA-MPT (D. Del.) (the "First Action"). The First Action arose out of Lupin's filing of the Lupin ANDA prior to the expiration of the First Action Patents. The Court conducted a four-day bench trial from February 26–29, 2024, concerning infringement and invalidity of claim 14 of U.S. Patent No. 11,123,299, claims 12 and 20 of U.S. Patent No. 11,291,632, claim 29 of U.S. Patent No. 11,351,122, claim 7 of U.S. Patent No. 11,413,249, and claim 19 of U.S. Patent No. 11,478,487.

4. The First Action triggered a thirty-month stay of FDA approval of the Lupin ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), which will expire on August 21, 2024.

PARTIES

5. 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 '213 patent.

6. 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 '213 patent.

7. 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 '213 patent.

8. 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 '213 patent.

9. 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.

10. On information and belief, Defendant LPI is a corporation organized and existing under the laws of Delaware, having a principal place of business at 5801 Pelican Bay Blvd., Suite 500, Naples, FL 34108. On information and belief, LPI is an indirect, wholly-owned subsidiary of Lupin Ltd.

11. 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.

12. On information and belief, Lupin, themselves and with their subsidiaries, affiliates, agents, and partners, prepared and filed the Lupin ANDA, seeking approval to manufacture, import, market, and/or sell the Lupin ANDA Product in the United States, including in this District, if the FDA approves the Lupin ANDA.

JURISDICTION AND VENUE

13. 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).

14. 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.

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

16. 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.

17. 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.

18. 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.

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

20. 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.

21. 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.*, *Exeltis USA, Inc. v. Lupin Ltd.*, No. 1:22-cv-00434-RGA-MPT, D.I. 90 (D. Del. Jan. 23, 2023); *ViiV Healthcare Co. v. Lupin Limited*, No. 1:17-cv-01576, D.I. 17 (D. Del. Dec. 19, 2017).

22. 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.

23. Venue is proper as to LPI in this District under 28 U.S.C. §§ 1391 and 1400(b) because LPI is incorporated in and resides in Delaware, and is subject to personal jurisdiction in this District.

FACTUAL BACKGROUND

The Patent-in-Suit

24. 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 A.

25. The claims of the ’213 patent are valid, enforceable, and not expired.

26. Representative claim 1 of the ’213 patent is reproduced below:

> 1. A method for providing effective contraception in a female patient over a 28-day period, comprising administering 24 scheduled daily oral doses of a pharmaceutical composition comprising from 2 mg to 6 mg of 6β,7β:15β,16β-Dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone to the female patient within a 24-day period, followed by a 4-day period wherein the daily oral dose is not administered, wherein the pharmaceutical composition does not comprise estrogen, and wherein administration of up to two non-consecutive scheduled daily oral doses may be delayed up to 24 hours from the scheduled daily administration, and the effective contraception is maintained when the up to two non-consecutive scheduled daily oral doses are delayed.

Acts Giving Rise to This Action

27. 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.

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

29. In conjunction with NDA No. 211367, Exeltis has listed with the FDA fourteen patents for SLYND®, including the ’213 patent. The FDA has published each of these fourteen 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").

30. At least one claim of the '213 patent covers approved methods of using SLYND®. A true and accurate copy of the June 2019 SLYND® label (the "SLYND® Label") is attached hereto as Exhibit B.

31. SLYND® is an estrogen-free oral contraceptive containing 4 mg of drospirenone. The SLYND® Label states, for example:

> The active tablet is a 5 mm, round, unscored, film-coated, white tablet that contains 4mg of drospirenone as the active ingredient, and microcrystalline cellulose NF, anhydrous lactose NF, colloidal silicon dioxide NF, magnesium stearate NF, polyvinyl alcohol partially hydrolyzed NF, talc NF, titanium dioxide NF, and polyethylene glycol NF as the inactive ingredients. Each tablet is debossed with the letter "E" on one side and the letter "D" on the other sides.

June 2019 SLYND® Label at 9

32. SLYND® is indicated for use by females of reproductive potential to prevent pregnancy. The SLYND® Label states, for example:

> **1 INDICATIONS AND USAGE**
> SLYND™ is a progestin indicated for use by females of reproductive potential to prevent pregnancy.

June 2019 SLYND® Label at 2

33. SLYND® is administered as 24 scheduled daily oral doses, followed by a 4-day period wherein the daily oral dose of SLYND® is not administered. The SLYND® Label states, for example:

> **2.2 How to Take SLYND™**
> SLYND™ (white active and green inert tablets) is swallowed whole once a day. Take one tablet daily for 28 consecutive days; one white active tablet daily during the first 24 days and one green inert tablet daily during the 4 following days. Tablets must be taken every day at about the same time of the day so that the interval between two tablets is always 24 hours.

June 2019 SLYND® Label at 2

34. Administration of up to two non-consecutive daily oral doses of SLYND® may be delayed up to 24 hours from the scheduled administration, and the effective contraception is maintained when the up to two non-consecutive scheduled daily oral doses are delayed. The SLYND® Label states, for example:

What should I do if I miss any SLYND™ pills?

If you miss 1 white pill (active pills):

- Take it as soon as you remember. Take the next pill at your regular time. This means you may take **2** pills in **1** day.
- Then continue taking **1** pill every day until you finish the pack.
- You do not need to use a back-up birth control method if you have sex.

June 2019 SLYND® Label at 2

35. 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 '213 patent.

36. On information and belief, Lupin sent a letter dated May 29, 2024 to Exeltis, Leon Farma, Chemo Iberica, and Chemo Research (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 '213 patent.

37. Exeltis received Lupin's Paragraph IV Letter on May 31, 2024.

38. Leon Farma received Lupin's Paragraph IV Letter on May 31, 2024.

39. Chemo Iberica received Lupin's Paragraph IV Letter on May 31, 2024.

40. Chemo Research received Lupin's Paragraph IV Letter on May 31, 2024.

41. 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®.

42. The FDA has determined 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® through its grant of tentative approval of the Lupin ANDA on November 3, 2022.

43. On information and belief, the Lupin ANDA identifies SLYND® as the reference listed drug ("RLD").

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, the Proposed Lupin Label will instruct physicians and healthcare providers to administer 24 scheduled daily oral doses of the Lupin ANDA Product, followed by a 4-day period wherein the daily oral dose of the Lupin ANDA Product is not administered.

49. On information and belief, the Proposed Lupin Label will instruct physicians and healthcare providers that administration of up to two non-consecutive daily oral doses of the Lupin ANDA Product may be delayed up to 24 hours from the scheduled administration.

50. On information and belief, the Proposed Lupin Label will instruct physicians and healthcare providers that effective contraception is maintained when up to two non-consecutive scheduled daily oral doses are delayed.

51. On information and belief, the Lupin ANDA Product will not contain estrogen.

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

COUNT I: Infringement of the '213 Patent
Under 35 U.S.C. § 271(e)(2) by the Lupin ANDA

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

54. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of one or more claims of the '213 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 '213 patent.

55. Lupin has actual knowledge of the '213 patent.

56. 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 '213 patent will not be infringed, is invalid, and/or is unenforceable.

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

58. On information and belief, Lupin became aware of the '213 patent no later than the date on which it was issued by the Patent and Trademark Office and/or by May 29, 2024, when Lupin sent its Paragraph IV Letter.

59. 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.

60. 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 '213 patent.

61. 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.

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

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

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

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

[1] Plaintiffs will identify all asserted claims of the '213 patent in accordance with this Court's Local Rules and/or scheduling order.

65. 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.

66. Lupin has submitted the Lupin ANDA for a generic version of Plaintiffs' SLYND® product. 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 '213 patent.

67. The FDA granted tentative approval of the Lupin ANDA on November 3, 2022. 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.

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

69. On information and belief, upon FDA approval of the Lupin ANDA, Lupin will infringe one or more claims of the '213 patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[2] 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.

70. Lupin has actual knowledge of the '213 patent.

71. On information and belief, Lupin became aware of the '213 patent no later than the date on which it was issued by the Patent and Trademark Office and/or by May 29, 2024, when Lupin sent its Paragraph IV Letter.

72. 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

[2] Plaintiffs will identify all asserted claims of the '213 patent in accordance with this Court's Local Rules and/or scheduling order.

'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.

73. On information and belief, Lupin's 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.

74. 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 actively induce and/or contribute to the actual infringement of the '213 patent.

75. 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 female patients in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the '213 patent.

76. On information and belief, physicians and healthcare providers will administer the Lupin 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 '213 patent.

77. On information and belief, through the Proposed Lupin Label, Lupin will encourage physicians and healthcare providers to administer the Lupin ANDA Product to female patients in order to, *inter alia*, provide effective contraception in accordance with the methods described and claimed in the '213 patent, and Lupin will know or should know that such conduct will occur.

78. 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 '213 patent.

79. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claim, including, for example, claim 1 of the ’213 patent.

80. 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 ’213 patent and that the Lupin ANDA Product is not suitable for substantial non-infringing use.

81. The commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Product will contribute to the actual infringement of the ’213 patent.

82. 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 ’213 patent.

83. Through at least the foregoing actions, Lupin will contribute to the infringement of at least one claim, including, for example, claim 1 of the ’213 patent.

84. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the ’213 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.

85. 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 induce and/or contribute to infringement of the ’213 patent.

86. The commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product, which will infringe the ’213 patent in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

87. Unless and until Lupin 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.

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 ’213 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 act of infringement of the ’213 patent;

B. A judgment declaring that the ’213 patent has 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 ’213 patent 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 preliminarily and/or 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 ’213 patent, 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 '213 patent, 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 '213 patent 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 '213 patent, 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: June 20, 2024

FISH & RICHARDSON P.C.

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