IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HARMONY BIOSCIENCES, LLC, BIOPROJET SOCIÉTÉ CIVILE DE RECHERCHE and BIOPROJET PHARMA SAS,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., NOVUGEN PHARMA SDN. BHD., NOVUGEN PHARMA (USA) LLC and MAKRO TECHNOLOGIES INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Harmony Biosciences, LLC ("Harmony"), Bioprojet Société Civile de Recherche ("Bioprojet SCR"), and Bioprojet Pharma SAS ("Bioprojet Pharma") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"); and Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. (collectively, "Novugen"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq*., arises from Lupin's and Novugen's recent submission of Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA"), seeking approval to market generic versions of the pharmaceutical product WAKIX® (pitolisant hydrochloride) tablets prior to the expiration of U.S. Patent

Nos. 8,486,947 ("the '947 patent") and 8,207,197 ("the '197 patent") (collectively, "the patents-in-suit").

WAKIX® AND THE PATENTS-IN-SUIT

2. WAKIX® is a first-in-class drug indicated for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adult patients with narcolepsy.

3. Narcolepsy is a debilitating disease that can severely affect a patient's day-to-day functioning and can have a devastating impact on quality of life.

4. WAKIX®'s active ingredient, pitolisant hydrochloride, is an antagonist/inverse agonist of the histamine-3 (H3) receptor.

5. WAKIX® first received FDA approval on August 14, 2019. It is the first FDA-approved H3 receptor antagonist/inverse agonist and the first and only FDA-approved once-daily tablet for treatment of EDS and cataplexy in narcolepsy. It is the only FDA-approved treatment for EDS and cataplexy in narcolepsy that is not a scheduled controlled substance.

6. WAKIX® was granted orphan drug exclusivity for the treatment of excessive daytime sleepiness in adult patients with narcolepsy and for the treatment of cataplexy in adult patients with narcolepsy; fast track designation for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy; and breakthrough therapy designation for the treatment of cataplexy in people with narcolepsy.

7. WAKIX® is available in film-coated tablets containing 5 mg or 20 mg of pitolisant hydrochloride (equivalent to 4.45 mg or 17.8 mg of pitolisant free base, respectively).

8. The '947 patent is entitled "Treatment of Parkinson's Disease, Obstructive Sleep Apnea, Dementia with Lewy Bodies, Vascular Dementia with Non-Imidazole Alkylamines Histamine H_3-Receptor Ligands," and was duly and lawfully issued by the USPTO on July 16, 2013. The '947 patent is attached hereto as Exhibit A.

9. The '197 patent is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine," and was duly and lawfully issued by the USPTO on June 26, 2012. The '197 patent is attached hereto as Exhibit B.

10. The '947 and '197 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for WAKIX®.

THE PARTIES

11. Plaintiff Harmony Biosciences, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 630 W Germantown Pike, Suite 215, Plymouth Meeting, PA 19462, USA. Harmony is the exclusive licensee of the patents-in-suit and the holder of New Drug Application ("NDA") No. 211150 for WAKIX®. Harmony is engaged in the clinical development of WAKIX® and sells WAKIX® tablets in the United States.

12. Plaintiff Bioprojet SCR is an independent, privately owned company organized and existing under the laws of France, having a place of business at 7, rue Rameau, 75002, Paris, France. Bioprojet SCR is the assignee and owner of the patents-in-suit.

13. Plaintiff Bioprojet Pharma is a wholly owned subsidiary of Bioprojet SCR, existing under the laws of France, having a place of business at 9, rue Rameau, 75002, Paris, France. Bioprojet Pharma was involved in commercialization efforts.

14. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, having a principal place of business in Kalpataru Inspire, 3rd Floor, Off. Western Expressway, Santacruz (East), Mumbai 400 005, India.

15. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202.

16. On information and belief, Lupin Pharmaceuticals, Inc. acts at the direction, and for the benefit, of Lupin Limited, and is controlled and/or dominated by Lupin Limited.

17. Lupin Limited and Lupin Pharmaceuticals, Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

18. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. caused ANDA No. 218846 ("Lupin ANDA") to be submitted to FDA and seek approval of that application to permit them to market generic versions of WAKIX® tablets in the United States.

19. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. acted collaboratively in the preparation and submission of ANDA No. 218846 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218846 and seeking to market the proposed generic pitolisant hydrochloride tablets described in that application.

20. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. intend to commercially manufacture, market, offer for sale, and sell the products described in ANDA No. 218846 (the "Lupin ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves the Lupin ANDA.

21. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. rely on material assistance from each other to market, distribute, offer for sale, and/or sell generic drugs

in the U.S. market, including in the State of Delaware. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the Lupin ANDA Products, in the event FDA approves the Lupin ANDA.

22. On information and belief, Defendant Novugen Pharma Sdn. Bhd. is a corporation organized and existing under the laws of Malaysia, having a principal place of business at No. 3, Jalan Jururancang U1/21, Hicom-glenmarie Industrial Park, 40150 Shah Alam, Selangor, Malaysia.

23. On information and belief, Defendant Novugen Pharma (USA) LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 100 Overlook Center, 2nd Floor, Princeton, New Jersey 08540.

24. On information and belief, Novugen Pharma (USA) LLC acts at the direction, and for the benefit, of Novugen Pharma Sdn. Bhd., and is controlled and/or dominated by Novugen Pharma Sdn. Bhd.

25. On information and belief, Defendant Makro Technologies Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4 Independence Way, Suite 110, Princeton, New Jersey 08540.

26. On information and belief, Makro Technologies Inc. is the U.S. agent for Novugen Pharma Sdn. Bhd. and acts at the direction, and for the benefit, of Novugen Pharma Sdn. Bhd.

27. On information and belief, Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro

Technologies Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

28. On information and belief, Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. caused ANDA No. 218834 ("Novugen ANDA") to be submitted to FDA and seeks approval of that application to permit Novugen to market generic versions of WAKIX® tablets in the United States.

29. On information and belief, Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. acted collaboratively in the preparation and submission of ANDA No. 218834 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218834 and seeking to market the proposed generic pitolisant hydrochloride tablets described in that application.

30. On information and belief, Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. intend to commercially manufacture, market, offer for sale, and sell the products described in ANDA No. 218834 ("Novugen ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves the Novugen ANDA.

31. On information and belief, Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the Novugen ANDA Products, in the event FDA approves Novugen's ANDA.

JURISDICTION AND VENUE

32. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

33. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because it is a corporation organized and existing under the laws of Delaware.

34. Additionally, this Court has personal jurisdiction over Lupin because, on information and belief, Lupin, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell the Lupin ANDA Products in the State of Delaware upon approval of the Lupin ANDA.

35. On information and belief, Lupin is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, throughout the United States, including in this judicial district.

36. On information and belief, Lupin is licensed to sell pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

37. Lupin has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated September 27, 2023, sent by Lupin Limited to Harmony and Bioprojet pursuant to 21 U.S.C. § 355(j)(2)(B) ("Lupin's Notice Letter"), Lupin prepared and filed the Lupin ANDA with the

intention of seeking to market the Lupin ANDA Products nationwide, including within this judicial district.

38. On information and belief, Lupin plans to sell the Lupin ANDA Products in the State of Delaware, list the Lupin ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Lupin ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

39. On information and belief, Lupin knows and intends that the Lupin ANDA Products will be distributed and sold in the State of Delaware and will thereby displace sales of WAKIX®, causing injury to Plaintiffs. Lupin intends to take advantage of its established channels of distribution in Delaware for the sale of the Lupin ANDA Products.

40. Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. have engaged in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in this judicial district in such litigation. *See, e.g.*, *Amicus Therapeutics US, LLC et al. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 22-1461, D.I. 50 (D. Del. June 22, 2023); *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, No. 22-1061, D.I. 6 (D. Del. Sept. 9, 2022); *ZS Pharma, Inc. et al. v. Lupin Limited et al*., No. 22- 1055, D.I. 19 (D. Del. Oct. 7, 2022).

41. Alternatively, this Court has personal jurisdiction over Lupin Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Lupin Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Limited has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of

the Lupin ANDA, and/or manufacturing and/or selling pharmaceutical products throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Lupin Limited satisfies due process.

42. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia,* it is a corporation organized and existing under the laws of the State of Delaware.

43. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) because, *inter alia,* it is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district, and is subject to personal jurisdiction in this judicial district.

44. This Court has personal jurisdiction over Novugen Pharma (USA) LLC because it is a limited liability company organized and existing under the laws of Delaware.

45. This Court has personal jurisdiction over Makro Technologies Inc. because it is a corporation organized and existing under the laws of Delaware.

46. Additionally, this Court has personal jurisdiction over Novugen because, on information and belief, Novugen, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell the Novugen ANDA Products in the State of Delaware upon approval of the Novugen ANDA.

47. On information and belief, Novugen is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products,

either directly or through subsidiaries, agents, and/or alter egos, which Novugen manufactures, distributes, markets and/or sells throughout the United States and in this judicial district.

48. On information and belief, Novugen is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

49. Novugen has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated September 27, 2023, sent by Novugen Pharma Sdn. Bhd. to Harmony and Bioprojet pursuant to 21 U.S.C. § 355(j)(2)(B) ("Novugen's Notice Letter"), Novugen prepared and filed the Novugen ANDA with the intention of seeking to market the Novugen ANDA Products nationwide, including within this judicial district.

50. On information and belief, Novugen plans to sell the Novugen ANDA Products in the State of Delaware, list the Novugen ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Novugen ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

51. On information and belief, Novugen knows and intends that the Novugen ANDA Products will be distributed and sold in the State of Delaware and will thereby displace sales of WAKIX®, causing injury to Plaintiffs. Novugen intends to take advantage of its established channels of distribution in Delaware for the sale of the Novugen ANDA Products.

52. Defendant Novugen Pharma Sdn. Bhd. has engaged in patent litigation concerning FDA-approved drug products in this judicial district and has not contested personal jurisdiction or

venue in this judicial district in such litigation. *See, e.g.*, *Novartis Pharms. Corp. v. Dr. Reddy's Labs. Inc. et al.*, No. 19-2053, D.I. 36 (D. Del. Feb. 6, 2020).

53. Alternatively, this Court has personal jurisdiction over Novugen Pharma Sdn. Bhd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Novugen Pharma Sdn. Bhd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Novugen Pharma Sdn. Bhd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the Novugen ANDA, and/or manufacturing and/or selling pharmaceutical products throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Novugen Pharma Sdn. Bhd. satisfies due process.

54. Venue is proper in this district for Novugen Pharma (USA) LLC pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, it is a limited liability company organized and existing under the laws of the State of Delaware.

55. Venue is proper in this district for Makro Technologies Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia,* it is a corporation organized and existing under the laws of the State of Delaware.

56. Venue is proper in this district for Novugen Pharma Sdn. Bhd. pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) because, *inter alia,* Novugen Pharma Sdn. Bhd. is a corporation organized and existing under the laws of Malaysia and may be sued in any judicial district, and is subject to personal jurisdiction in this judicial district.

LUPIN'S ANDA NO. 218846

57. Lupin has submitted ANDA No. 218846 to FDA, or caused ANDA No. 218846 to be submitted to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the

commercial manufacture, use, or sale of pitolisant hydrochloride tablets as a purported generic version of WAKIX® prior to the expiration of the patents-in-suit.

58. Lupin sent a letter to Harmony and Bioprojet, dated September 27, 2023, identified as "Notice of Paragraph IV Certification Regarding NDA 211150 Pitolisant Hydrochloride Tablets (eq. 4.45 mg base; eq. 17.8 mg base) with respect to U.S. Patent Nos. 8,486,947 and 8,207,197." Lupin's Notice Letter represented that Lupin had submitted to FDA the Lupin ANDA and a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Lupin ANDA before the expiration of the '947 and '197 patents listed in the Orange Book for WAKIX®. Thus, Lupin's purpose in submitting the Lupin ANDA is to manufacture and market the Lupin ANDA Products before the expiration of the patents-in-suit.

59. Lupin's Notice Letter stated that the Paragraph IV certification in the Lupin ANDA alleges that the '947 patent and '197 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Lupin ANDA Products.

60. According to applicable regulations, Notice Letters such as Lupin's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

61. Lupin's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Lupin's Detailed Statement").

62. Lupin's Detailed Statement does not dispute infringement of Claims 1–5 or 10–14 of the '947 patent.

63. Lupin's Detailed Statement does not dispute infringement of any claim of the '197 patent.

64. On information and belief, Lupin is responsible for the submission of the Lupin ANDA, has participated in the preparation and submission of the Lupin ANDA, has provided material support to the preparation and submission of the Lupin ANDA, and intends to support the further prosecution of the Lupin ANDA.

65. If FDA approves the Lupin ANDA, Lupin will manufacture, offer for sale, or sell the Lupin ANDA Products within the United States, including within Delaware, or will import the Lupin ANDA Products into the United States, including Delaware.

66. If FDA approves the Lupin ANDA, the manufacture, use, offer for sale, sale, or importation of the Lupin ANDA Products will directly infringe the patents-in-suit, and Lupin will actively induce or contribute to the manufacture, use, offer for sale, or sale of the Lupin ANDA Products within the United States, including within Delaware.

67. With the submission of the Lupin ANDA, Lupin seeks approval of a drug claimed in a patent or the use of which is claimed in a patent with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Lupin ANDA Products before the expiration of such patent (here, both patents-in-suit). Thus, Lupin has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). If Lupin engages in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin ANDA Products prior to the expiration of the patents-in-suit, it will infringe, contribute to the infringement of, and/or induce the infringement of the claims in the patents-in-suit under one or more of 35 U.S.C. § 271(a), (b), and/or (c).

68. This action is being filed within forty-five days of Plaintiffs' receipt of Lupin's Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Accordingly, Plaintiffs are entitled to a stay of FDA approval of the Lupin ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

NOVUGEN'S ANDA NO. 218834

69. Novugen has submitted ANDA No. 218834 to FDA, or caused ANDA No. 218834 to be submitted to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of pitolisant hydrochloride tablets as a purported generic version of WAKIX® prior to the expiration of the patents-in-suit.

70. Novugen sent a letter to Harmony and Bioprojet, dated September 27, 2023, identified as "Notice of Paragraph IV Certification Regarding U.S. Patent Nos. 8,207,197 and 8,486,947 Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 for ANDA No. 218834." Novugen's Notice Letter represented that Novugen had submitted to FDA the Novugen ANDA and a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Novugen ANDA before the expiration of the '947 and '197 patents listed in the Orange Book for WAKIX®. Thus, Novugen's purpose in submitting the Novugen ANDA is to manufacture and market the Novugen ANDA Products before the expiration of the patents-in-suit.

71. Novugen's Notice Letter stated that the Paragraph IV certification in the Novugen ANDA alleges that the '947 patent and '197 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Novugen ANDA Products.

72. According to applicable regulations, Notice Letters such as Novugen's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing

"for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); see also 21 C.F.R. § 314.52.

73. Novugen's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Novugen's Detailed Statement").

74. Novugen's Detailed Statement does not dispute indirect infringement of Claims 1–5 and 10–14 of the '947 patent.

75. Novugen's Detailed Statement does not assert that any claim of the '197 patent is invalid.

76. On information and belief, Novugen is responsible for the submission of the Novugen ANDA, has participated in the preparation and submission of the Novugen ANDA, has provided material support to the preparation and submission of the Novugen ANDA, and intends to support the further prosecution of the Novugen ANDA.

77. If FDA approves the Novugen ANDA, Novugen will manufacture, offer for sale, or sell the Novugen ANDA Products within the United States, including within Delaware, or will import the Novugen ANDA Products into the United States, including Delaware.

78. If FDA approves the Novugen ANDA, the manufacture, use, offer for sale, sale, or importation of the Novugen ANDA Products will directly infringe the patents-in-suit, and Novugen will actively induce or contribute to the manufacture, use, offer for sale, or sale of the Novugen ANDA Products within the United States, including within Delaware.

79. With the submission of the Novugen ANDA, Novugen seeks approval of a drug claimed in a patent or the use of which is claimed in a patent with the purpose of obtaining approval

to engage in the commercial manufacture, use, or sale of the Novugen ANDA Products before expiry of such patent (here, the patents-in-suit). Thus, Novugen has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). If Novugen engages in the commercial manufacture, use, offer to sell, sale, or importation of the Novugen ANDA Products prior to the expiration of the patents-in-suit, it will infringe, contribute to the infringement of and/or induce the infringement of the claims in the patents-in-suit under one or more of 35 U.S.C. § 271(a), (b), and/or (c).

80. This action is being filed within forty-five days of Plaintiffs' receipt of Novugen's Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Accordingly, Plaintiffs are entitled to a stay of FDA approval of the Novugen ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

COUNT I
INFRINGEMENT OF THE '947 PATENT BY LUPIN

81. Plaintiffs incorporate by reference paragraphs 1–80 as if fully set forth herein.

82. On information and belief, Lupin has submitted or caused the submission of the Lupin ANDA to FDA and continues to seek FDA approval of the Lupin ANDA.

83. Plaintiffs own all rights, title, and interest in and to the '947 patent.

84. Lupin did not dispute infringement of Claims 1–5 and 10–14 of the '947 patent in its Notice Letter. If Lupin had a factual or legal basis to contest infringement of Claims 1–5 or 10–14 of the '947 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

85. Lupin has infringed at least Claims 1–5 and 10–14 of the '947 patent.

86. According to Lupin's Notice Letter, the Lupin ANDA Products contain pitolisant hydrochloride.

87. According to Lupin's Notice Letter, the proposed package insert for the Lupin ANDA Products states that it will be indicated for the treatment of excessive daytime sleepiness ("EDS") in adult patients with narcolepsy.

88. Lupin has infringed at least the above claims of the '947 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA and seeking FDA approval of the Lupin ANDA prior to the expiration of the '947 patent.

89. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Lupin ANDA Products prior to the expiration of the '947 patent would infringe at least the above claims of the '947 patent under 35 U.S.C. § 271(a), and/or Lupin would induce the infringement of and/or contribute to the infringement of at least the above claims of the '947 patent under 35 U.S.C. § 271(b) and/or (c).

90. The importation, manufacture, sale, offer for sale, or use of the Lupin ANDA Products in the United States, including in the State of Delaware, would directly infringe the claims of the '947 patent.

91. Upon FDA approval of the Lupin ANDA, Lupin will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA Products, Lupin will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Lupin will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Lupin ANDA Products to directly infringe the claims of the '947 patent. In addition, on information and belief, Lupin will encourage acts of direct infringement with knowledge of the '947 patent and knowledge that they are

encouraging infringement. Lupin's conduct would intentionally actively induce and/or contribute to the infringement of the '947 patent.

92. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218846, Lupin will make, use, offer to sell, or sell the Lupin ANDA Products within the United States, or will import the Lupin ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the claims of the '947 patent.

93. Lupin had actual knowledge of the '947 patent prior to submitting the Lupin ANDA, was aware that the submission of the Lupin ANDA with the request for FDA approval prior to the expiration of the '947 patent would constitute an act of infringement of the '947 patent, and was aware that use of the Lupin ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '947 patent.

94. Lupin submitted the Lupin ANDA without a reasonable basis for asserting the '947 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Lupin ANDA Products. Lupin did not dispute infringement of Claims 1–5 or 10–14 of the '947 patent. Lupin's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '947 patent renders this case "exceptional" under 35 U.S.C. § 285.

95. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing the '947 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Lupin, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
INFRINGEMENT OF THE '197 PATENT BY LUPIN

96. Plaintiffs incorporate by reference paragraphs 1–95 as if fully set forth herein.

97. On information and belief, Lupin has submitted or caused the submission of the Lupin ANDA to FDA and continues to seek FDA approval of the Lupin ANDA.

98. Plaintiffs own all rights, title, and interest in and to the '197 patent.

99. Lupin did not dispute infringement of any claim of the '197 patent in its Notice Letter. If Lupin had a factual or legal basis to contest infringement of any claim of the '197 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

100. Lupin has infringed all claims of the '197 patent.

101. Lupin has infringed the claims of the '197 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA and seeking FDA approval of the Lupin ANDA prior to the expiration of the '197 patent.

102. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Lupin ANDA Products prior to the expiration of the '197 patent would infringe the claims of the '197 patent under 35 U.S.C. § 271(a), and/or Lupin would induce the infringement of and/or contribute to the infringement of the claims of the '197 patent under 35 U.S.C. § 271(b) and/or (c).

103. On information and belief, if the Lupin ANDA is approved, Lupin and its affiliates will make, offer for sale, sell, or otherwise distribute the Lupin ANDA Products in the United States, including in the State of Delaware, directly infringing the claims of the '197 patent.

104. On information and belief, upon FDA approval of the Lupin ANDA, Lupin will market and distribute the Lupin ANDA Products to resellers, pharmacies, health care professionals, and end users of the Lupin ANDA Products. Accompanying the Lupin ANDA

Products, Lupin will also knowingly and intentionally include a product label and insert containing instructions for administering the Lupin ANDA Products. Accordingly, Lupin will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Lupin ANDA Products to directly infringe the claims of the '197 patent. In addition, on information and belief, Lupin will encourage acts of direct infringement with knowledge of the '197 patent and knowledge that they are encouraging infringement. Lupin's conduct would intentionally actively induce and/or contribute to the infringement of the claims of the '197 patent.

105. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218846, Lupin will make, use, offer to sell, or sell the Lupin ANDA Products within the United States, or will import the Lupin ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the claims of the '197 patent.

106. Lupin had actual knowledge of the '197 patent prior to submitting the Lupin ANDA and was aware that the submission of the Lupin ANDA with the request for FDA approval prior to the expiration of the '197 patent would constitute an act of infringement of the '197 patent.

107. Lupin submitted the Lupin ANDA without a reasonable basis for asserting the '197 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Lupin ANDA Products. Lupin did not dispute infringement of any claim of the '197 patent. Lupin's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '197 patent renders this case "exceptional" under 35 U.S.C. § 285.

108. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing the '197 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Lupin, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III
INFRINGEMENT OF THE '947 PATENT BY NOVUGEN

109. Plaintiffs incorporate by reference paragraphs 1–108 as if fully set forth herein.

110. On information and belief, Novugen has submitted or caused the submission of the Novugen ANDA to FDA and continues to seek FDA approval of the Novugen ANDA.

111. Plaintiffs own all rights, title, and interest in and to the '947 patent.

112. Novugen did not dispute indirect infringement of Claims 1–5 and 10–14 of the '947 patent in its Notice Letter. If Novugen had a factual or legal basis to contest infringement of Claims 1–5 or 10–14 of the '947 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

113. Novugen has infringed at least Claims 1–5 and 10–14 of the '947 patent.

114. According to Novugen's Notice Letter, the Novugen ANDA Products contain pitolisant hydrochloride.

115. Novugen has infringed at least the above claims of the '947 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Novugen ANDA and seeking FDA approval of the Novugen ANDA prior to the expiration of the '947 patent.

116. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novugen ANDA Products prior to the expiration of the '947 patent would infringe at least the above claims of the '947 patent under 35 U.S.C. § 271(a), and/or Novugen would induce the infringement of and/or contribute to the infringement of at least the above claims of the '947 patent under 35 U.S.C. § 271(b) and/or (c).

117. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novugen ANDA Products in the United States, including in the State of Delaware, would directly infringe the claims of the '947 patent.

118. On information and belief, upon FDA approval of the Novugen ANDA, Novugen will market and distribute the Novugen ANDA Products to resellers, pharmacies, health care professionals, and end users of the Novugen ANDA Products. Accompanying the Novugen ANDA Products, Novugen will also knowingly and intentionally include a product label and insert containing instructions for administering the Novugen ANDA Products. Accordingly, Novugen will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Novugen ANDA Products to directly infringe the claims of the '947 patent. In addition, on information and belief, Novugen will encourage acts of direct infringement with knowledge of the '947 patent and knowledge that they are encouraging infringement. Novugen's conduct would intentionally actively induce and/or contribute to the infringement of the '947 patent.

119. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218834, Novugen will make, use, offer to sell, or sell the Novugen ANDA Products within the United States, or will import the Novugen ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the claims of the '947 patent.

120. Novugen had actual knowledge of the '947 patent prior to submitting the Novugen ANDA, was aware that the submission of the Novugen ANDA with the request for FDA approval prior to the expiration of the '947 patent would constitute an act of infringement of the '947 patent, and was aware that use of the Novugen ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '947 patent.

121. Novugen submitted the Novugen ANDA without a reasonable basis for asserting the '947 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Novugen ANDA Products. Novugen's conduct in certifying

invalidity, unenforceability, and/or non-infringement with respect to the '947 patent renders this case "exceptional" under 35 U.S.C. § 285.

122. Plaintiffs will be irreparably harmed if Novugen is not enjoined from infringing the '947 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Novugen, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
INFRINGEMENT OF THE '197 PATENT BY NOVUGEN

123. Plaintiffs incorporate by reference paragraphs 1–122 as if fully set forth herein.

124. On information and belief, Novugen has submitted or caused the submission of the Novugen ANDA to FDA and continues to seek FDA approval of the Novugen ANDA.

125. Plaintiffs own all rights, title, and interest in and to the '197 patent.

126. On information and belief, Novugen has infringed one or more claims of the '197 patent, including at least Claim 1 of the '197 patent.

127. On information and belief, Novugen has infringed one or more claims of the '197 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Novugen ANDA and seeking FDA approval of the Novugen ANDA prior to the expiration of the '197 patent.

128. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novugen ANDA Products prior to the expiration of the '197 patent would infringe one or more claims of the '197 patent under 35 U.S.C. § 271(a), and/or Novugen would induce the infringement of and/or contribute to the infringement of one or more claims of the '197 patent under 35 U.S.C. § 271(b) and/or (c).

129. On information and belief, if the Novugen ANDA is approved, Novugen and its affiliates will make, offer for sale, sell, or otherwise distribute the Novugen ANDA Products in

the United States, including in the State of Delaware, directly infringing one or more claims of the '197 patent.

130. On information and belief, upon FDA approval of the Novugen ANDA, Novugen will market and distribute the Novugen ANDA Products to resellers, pharmacies, health care professionals, and end users of the Novugen ANDA Products. Accompanying the Novugen ANDA Products, Novugen will also knowingly and intentionally include a product label and insert containing instructions for administering the Novugen ANDA Products. Accordingly, Novugen will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Novugen ANDA Products to directly infringe one or more claims of the '197 patent. In addition, on information and belief, Novugen will encourage acts of direct infringement with knowledge of the '197 patent and knowledge that they are encouraging infringement. Novugen's conduct would intentionally actively induce and/or contribute to the infringement of the '197 patent.

131. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218834, Novugen will make, use, offer to sell, or sell the Novugen ANDA Products within the United States, or will import the Novugen ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '197 patent.

132. Novugen had actual knowledge of the '197 patent prior to submitting the Novugen ANDA and was aware that the submission of the Novugen ANDA with the request for FDA approval prior to the expiration of the '197 patent would constitute an act of infringement of the '197 patent.

133. Novugen submitted the Novugen ANDA without a reasonable basis for asserting the '197 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Novugen ANDA Products. Novugen's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '197 patent renders this case "exceptional" under 35 U.S.C. § 285.

134. Plaintiffs will be irreparably harmed if Novugen is not enjoined from infringing the '197 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Novugen, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Lupin has infringed the claims of the '947 and '197 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Novugen has infringed one or more claims of the '947 and '197 patents under 35 U.S.C. § 271(e)(2)(A);

C. A judgment that, under one or more of 35 U.S.C. § 271(a), (b), and/or (c), Lupin's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '947 and '197 patents;

D. A judgment that, under one or more of 35 U.S.C. § 271(a), (b), and/or (c), Novugen's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Novugen ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '947 and '197 patents;

E. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Lupin's ANDA No. 218846 shall be no earlier than the expiration date of the '947 and '197 patents, or any later expiration of exclusivity for the '947 and '197 patents, including any extensions or regulatory exclusivities;

F. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Novugen's ANDA No. 218834 shall be no earlier than the expiration date of the '947 and '197 patents, or any later expiration of exclusivity for the '947 and '197 patents, including any extensions or regulatory exclusivities;

G. A permanent injunction restraining and enjoining Lupin, its affiliates and subsidiaries, and all persons and entities acting in concert with Lupin, from commercially manufacturing, using, offering for sale, or selling or importing into the United States the Lupin ANDA Products, until the day after expiration of the '947 and '197 patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '947 and '197 patents.

H. A permanent injunction restraining and enjoining Novugen, its affiliates and subsidiaries, and all persons and entities acting in concert with Novugen, from commercially manufacturing, using, offering for sale, or selling or importing into the United States the Novugen ANDA Products, until the day after expiration of the '947 and '197 patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '947 and '197 patents.

I. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Lupin engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Products, or any product that infringes the '947 and '197 patents, or induces or contributes

to such conduct, prior to the expiration of the ’947 and ’197 patents, or any later expiration of exclusivity for the ’947 and ’197 patents, including any extensions or regulatory exclusivities;

J. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Novugen engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Novugen ANDA Products, or any product that infringes the ’947 and ’197 patents, or induces or contributes to such conduct, prior to the expiration of the ’947 and ’197 patents, or any later expiration of exclusivity for the ’947 and ’197 patents, including any extensions or regulatory exclusivities;

K. The entry of a judgment declaring that Lupin’s acts render this case an exceptional case and awarding Plaintiffs their attorneys’ fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

L. The entry of a judgment declaring that Novugen’s acts render this case an exceptional case and awarding Plaintiffs their attorneys’ fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

M. An award to Plaintiffs of their costs and expenses in this action; and

N. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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November 9, 2023