IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ENDO PHARMACEUTICALS INC., Plaintiff, v. LUPIN ATLANTIS HOLDINGS SA, Defendant.	CIVIL ACTION NO. 2:17-cv-558 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Endo Pharmaceuticals Inc. ("Endo"), for its Complaint against Defendant Lupin Atlantis Holdings SA ("Lupin Atlantis"), herein alleges as follows:

NATURE OF ACTION

1. This is a civil action for infringement of U.S. Patent No. 7,229,636 ("the '636 patent"), U.S. Patent No. 7,404,489 ("the '489 patent"), U.S. Patent No. 7,879,349 ("the '349 patent"), U.S. Patent No. 8,003,353 ("the '353 patent"), U.S. Patent No. 8,940,714 ("the '714 patent"), and U.S. Patent No. 9,415,007 ("the '007 patent") (collectively, the "Patents-in-Suit") pursuant to the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

PARTIES

2. Endo is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

3. On information and belief, Lupin Atlantis is a corporation organized and existing under the laws of the Switzerland, having a principal place of business at Landis + Gyr – Strasse 1, 6300 Zug, Switzerland.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Lupin Atlantis by virtue of actions Lupin Atlantis has taken for the purpose of engaging in injury-causing and wrongful marketing conduct in Texas and this District. *See Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

6. On information and belief, Lupin Atlantis submitted to the United States Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") for a generic copy of Nascobal® nasal spray ("Lupin ANDA"), and seeks FDA approval to market and sell a generic copy of Nascobal® nasal spray ("Lupin ANDA Product").

7. On information and belief, Lupin Atlantis through the submission of the Lupin ANDA, intends to commercially manufacture, use, import, market, offer for sale, and sell the Lupin ANDA Product throughout the United States, including in Texas and this District, in the event FDA approves the Lupin ANDA. On information and belief, Lupin Atlantis intends to derive benefit from the Lupin ANDA.

8. On information and belief, Lupin Atlantis is in the business of developing pharmaceutical drug products that are distributed in the United States, including in Texas and this District.

9. On information and belief, Lupin Atlantis, itself or through one of its wholly-owned subsidiaries and/or commonly-owned affiliates, has agreements with pharmaceutical retailers, wholesalers, or distributors, including, but not limited to Amerisource Bergen, Cardinal Health, H D Smith Wholesale Drug, and McKesson Drug Company, providing for the distribution of its products throughout the United States, including in Texas and this District.

10. On information and belief, Lupin Atlantis, itself or through one of its wholly-owned subsidiaries and/or commonly-owned affiliates, distributes pharmaceutical drug products such as Antara (micronized) (fenofibrate) tablets, Allernaze triamcinolone acetonide nasal sprays, and generic desoximetasone creams and ointments throughout the United States, including in Texas and this District. On information and belief, Antara is listed in the Texas Department of State Health Services (DSHS) / Department of Aging and Disability Services (DADS) Drug Formulary.

11. On information and belief, Lupin Atlantis products are sold in pharmacies, including, but not limited to CVS, Rite Aid, and Walgreens, throughout the United States, including in Texas and this District.

12. On information and belief, Lupin Atlantis derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in Texas and this District.

13. Alternatively, this Court has jurisdiction over Lupin Atlantis under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Endo's claims arise under federal law; (b) Lupin Atlantis is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Atlantis has sufficient contacts with the United States as a whole, not least

through its development of generic drugs for sale in the United States, such that this Court's exercise of jurisdiction over Lupin Atlantis satisfies due process.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b). On information and belief, Lupin Atlantis is a foreign corporation that may be sued in any judicial district in the United States, in which it is subject to the court's personal jurisdiction. As set forth *supra*, Lupin Atlantis is subject to the Court's personal jurisdiction in Texas and this District.

THE PATENTS-IN-SUIT

15. The '636 patent, titled "Cyanocobalamin Low Viscosity Aqueous Formulations for Intranasal Delivery," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 12, 2007. Endo owns and has exclusive rights to the '636 patent, including all rights to sue for infringement thereof.

16. A true and correct copy of the '636 patent is attached hereto as Exhibit A.

17. The '489 patent, titled "Cyanocobalamin Low Viscosity Aqueous Formulations for Intranasal Delivery," was duly and legally issued by the USPTO on July 29, 2008. Endo owns and has exclusive rights to the '489 patent, including all rights to sue for infringement thereof.

18. A true and correct copy of the '489 patent is attached hereto as Exhibit B.

19. The '349 patent, titled "Cyanocobalamin Low Viscosity Aqueous Formulations for Intranasal Delivery," was duly and legally issued by the USPTO on February 1, 2011. Endo owns and has exclusive rights to the '349 patent, including all rights to sue for infringement thereof.

20. A true and correct copy of the '349 patent is attached hereto as Exhibit C.

21. The ’353 patent, titled “Cyanocobalamin Low Viscosity Aqueous Formulations for Intranasal Delivery,” was duly and legally issued by the USPTO on August 23, 2011. Endo owns and has exclusive rights to the ’353 patent, including all rights to sue for infringement thereof.

22. A true and correct copy of the ’353 patent is attached hereto as Exhibit D.

23. The ’714 patent, titled “Cyanocobalamin Low Viscosity Aqueous Formulations for Intranasal Delivery,” was duly and legally issued by the USPTO on January 27, 2015. Endo owns and has exclusive rights to the ’714 patent, including all rights to sue for infringement thereof.

24. A true and correct copy of the ’714 patent is attached hereto as Exhibit E.

25. The ’007 patent, titled “Cyanocobalamin Low Viscosity Aqueous Formulations for Intranasal Delivery,” was duly and legally issued by the USPTO on August 16, 2016. Endo owns and has exclusive rights to the ’007 patent, including all rights to sue for infringement thereof.

26. A true and correct copy of the ’007 patent is attached hereto as Exhibit F.

ENDO’S NASCOBAL® NASAL SPRAY PRODUCT

27. Endo is the holder of approved New Drug Application (“NDA”) No. 021642 for Nascobal® brand cyanocobalamin, USP nasal spray 500 mcg/spray, 0.125 mL. Cyanocobalamin is a synthetic form of vitamin B_{12} with equivalent vitamin B_{12} activity. Nascobal® nasal spray is the only FDA-approved vitamin B_{12} nasal spray.

28. Nascobal® nasal spray is a solution of cyanocobalamin, USP for administration as a spray to the nasal mucosa. Each unit dose device of Nascobal® nasal spray contains 0.125 mL of a 500 mcg/0.1 mL solution of cyanocobalamin with sodium citrate, citric acid, glycerin and

benzalkonium chloride in purified water. The spray solution has a pH between 4.5 and 5.5. Each spray delivers an average of 500 mcg of cyanocobalamin.

29. Nascobal® nasal spray is a prescription medicine used to treat vitamin B_{12} deficiency. Nascobal® nasal spray is used for vitamin B_{12} deficiency after bariatric (weight loss) surgery, because persons who have undergone bariatric surgery may not absorb enough vitamin B_{12} from food. Nascobal® nasal spray may also be used for other causes of vitamin B_{12} deficiency. Nascobal® is a fine-mist nasal spray that is absorbed into the bloodstream through the nasal mucosa, bypassing the stomach and digestive tract.

30. Nascobal® nasal spray is indicated for the maintenance of normal hematologic status in pernicious anemia patients who are in remission following intramuscular vitamin B_{12} therapy and who have no nervous system involvement. Nascobal® nasal spray is also indicated as a supplement for other vitamin B_{12} deficiencies, including: (i) dietary deficiency of vitamin B_{12} occurring in strict vegetarians; (ii) malabsorption of vitamin B_{12} resulting from structural or functional damage to the stomach or the ileum; (iii) inadequate secretion of intrinsic factor, resulting from lesions that destroy the gastric mucosa, and a number of conditions associated with a variable degree of gastric atrophy; (iv) competition for vitamin B_{12} by intestinal parasites or bacteria; (v) inadequate utilization of vitamin B_{12}.

31. Prior to the availability of Nascobal® nasal spray, therapeutic amounts of cyanocobalamin were administered by intramuscular or deep subcutaneous injection of cyanocobalamin. Patients had to return to the physician's office periodically to receive additional injections to maintain their levels of vitamin B_{12}. The invention of the Patents-in-Suit — as embodied in the commercial Nascobal® nasal spray product — provides for an effective and convenient self-administration option that greatly improves patient compliance. Pursuant to

21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '636, '489, '349, '353, '714 and '007 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") with respect to Nascobal® nasal spray.

THE LUPIN ANDA

32. On information and belief, Lupin Atlantis submitted the Lupin ANDA to FDA, under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic copy of Nascobal® nasal spray, prior to the expiration of the Patents-in-Suit.

33. By letter dated June 16, 2017 (the "Notice Letter"), Lupin Atlantis asserted that it submitted the Lupin ANDA to FDA seeking approval to engage in the manufacture, use, importation, offer for sale, or sale of a generic copy of Nascobal® nasal spray prior to the expiration of the Patents-in-Suit.

34. The Notice Letter also asserted that the ANDA contains certifications by Lupin Atlantis pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") contending that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the Lupin ANDA Product.

35. On information and belief, Lupin Atlantis was aware of the Patents-in-Suit at the time it submitted the Paragraph IV Certifications to FDA.

36. Endo commenced this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT ONE
Lupin Atlantis's Infringement of the '636 Patent

37. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

38. Lupin Atlantis's submission of the Lupin ANDA to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Lupin ANDA Product, prior to the expiration of the '636 patent, constitutes infringement of at least one claim, including at least claims 1, 24, 30, and/or 31 of the '636 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

39. On FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claim 1 of the '636 patent, by manufacturing, using, offering to sell, or selling the Lupin ANDA Product in the United States and/or importing the Lupin ANDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

40. On information and belief, the Lupin ANDA Product contains the same active ingredient and in the same concentration as Nascobal® brand cyanocobalamin, USP nasal spray 500 mcg/spray, 0.125 mL.

41. On information and belief, the Lupin ANDA Product infringes at least one claim, including at least claim 1 of the '636 patent, literally and/or by the doctrine of equivalents.

42. On information and belief, the Lupin ANDA Product is a stable pharmaceutical aqueous solution comprising cyanocobalamin, water, a preservative selected from the group consisting of benzyl alcohol, parabens thimerosal, chlorobutanol, benzethonium chloride, and benzalkonium chloride, and combinations thereof, a buffer selected from the group consisting of citric acid, sodium citrate, monopotassium phosphate, disodium phosphate, potassium biphthalate, sodium hydroxide, sodium acetate, acetic acid, and combinations thereof, and a humectant selected from the group consisting of sorbitol, propylene glycol, and glycerin, and combinations thereof, wherein said solution of cyanocobalamin is suitable for intranasal

administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin with the proviso that the solution contains no mercury or mercury compounds, as claimed in at least one claim, including at least claim 1 of the '636 patent, literally and/or by the doctrine of equivalents.

43. On FDA approval of the Lupin ANDA, Lupin Atlantis will induce infringement of at least one claim, including at least claims 24, 30, and/or 31 of the '636 patent, by promoting, encouraging, and/or recommending that persons perform methods of administering cyanocobalamin by infusing the nose with the claimed aqueous solution of cyanocobalamin, or administering intranasally a sufficient amount of the claimed solution of cyanocobalamin, and/or by contributing to the performance of said method, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

44. As part of the Lupin ANDA, Lupin Atlantis must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug," except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

45. The label for Nascobal® nasal spray states that Nascobal® nasal spray is administered in the nostril. *See* Exhibit G.

46. On information and belief, the proposed label for the Lupin ANDA Product is substantially identical to the approved label for Nascobal® nasal spray, and the Lupin ANDA Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Nascobal® nasal spray.

47. On information and belief, the proposed label for the Lupin ANDA Product also states that the Lupin ANDA Product is administered in the nostril. Therefore, the proposed label promotes or encourages persons to perform methods of administering cyanocobalamin by infusing the nose with the Lupin ANDA Product, or administering intranasally a sufficient amount of the Lupin ANDA Product.

48. On information and belief, Lupin Atlantis knowingly provides instruction in the proposed label for persons to administer the Lupin ANDA Product intranasally or by infusing the nose, and the proposed label reflects a specific intent to encourage persons to directly infringe at least one claim, including at least claims 24, 30, and/or 31 of the ’636 patent, literally and/or by the doctrine of equivalents.

49. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1, 24, 30, and/or 31 of the ’636 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States.

50. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1, 24, 30, and/or 31 of the ’636 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States. On information and belief, Lupin Atlantis will knowingly encourage direct infringement of the ’636 patent, and possess specific intent to encourage another’s direct infringement of the ’636 patent.

51. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1, 24, 30, and/or 31 of the ’636

patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States. On information and belief, the act of direct infringement of the ’636 patent is attributed to a single entity. On information and belief, the Lupin ANDA Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

52. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’636 patent. Endo does not have an adequate remedy at law.

53. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT TWO
Declaratory Judgment of Infringement of the ’636 Patent

54. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

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

56. There is an actual case or controversy such that the Court may resolve Endo’s request for declaratory relief consistent with Article III of the United States Constitution.

57. On information and belief, unless enjoined by this Court, Lupin Atlantis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product immediately following approval of the Lupin ANDA.

58. The commercial use of the Lupin ANDA Product will directly infringe the ’636 patent.

59. The commercial offer for sale and sale of the Lupin ANDA Product, in conjunction with the labeling and instructions for use thereof, will constitute an act of inducement of infringement of the ’636 patent.

60. On information and belief, Lupin Atlantis had knowledge of the ’636 patent since at least the time Lupin Atlantis submitted the Paragraph IV Certifications to FDA.

61. Because the Lupin ANDA Product is especially made or adapted for use in the claims of the ’636 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of the Lupin ANDA Product will constitute an act of contributory infringement of the ’636 patent.

62. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product before expiration of the ’636 patent by Lupin Atlantis or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the ’636 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

63. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’636 patent. Endo does not have an adequate remedy at law.

64. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT THREE
Lupin Atlantis's Infringement of the '489 Patent

65. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

66. Lupin Atlantis's submission of the Lupin ANDA to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Lupin ANDA Product, prior to the expiration of the '489 patent, constitutes infringement of at least one claim, including at least claim 1 of the '489 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

67. On FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claim 1 of the '489 patent, by manufacturing, using, offering to sell, or selling the Lupin ANDA Product in the United States and/or importing the Lupin ANDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

68. On information and belief, the Lupin ANDA Product contains the same active ingredient and in the same concentration as Nascobal® brand cyanocobalamin, USP nasal spray 500 mcg/spray, 0.125 mL.

69. On information and belief, the Lupin ANDA Product infringes at least one claim, including at least claim 1 of the '489 patent, literally and/or by the doctrine of equivalents.

70. By statute, a Notice of Paragraph IV Certification is required to provide a "detailed statement of the factual and legal basis of the opinion of the [ANDA] applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). The Notice Letter provided no statement that the Lupin ANDA product does not infringe the '489 patent, nor any basis for any opinion that the Lupin ANDA product does not infringe the '489 patent. By failing

to include such a statement and a basis for the statement, Lupin Atlantis admits that the Lupin ANDA Product meets all limitations of the ’489 patent claims and infringes those claims.

71. On information and belief, the Lupin ANDA Product is a kit for nasal drug delivery comprising an aqueous solution of cyanocobalamin and excipients in a container, and a droplet-generating actuator attached to said container and fluidly connected to the cyanocobalamin solution in the container; wherein said actuator produces a spray of the cyanocobalamin solution through a tip of the actuator when said actuator is engaged, wherein said spray of cyanocobalamin solution has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip, as claimed in at least one claim, including at least claim 1 of the ’489 patent.

72. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claim 1 of the ’489 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States.

73. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claim 1 of the ’489 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States. On information and belief, Lupin Atlantis will knowingly encourage direct infringement of the ’489 patent, and possess specific intent to encourage another’s direct infringement of the ’489 patent.

74. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claim 1 of the ’489 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to

sell, selling, and/or importing the Lupin ANDA Product into the United States. On information and belief, the act of direct infringement of the '489 patent is attributed to a single entity. On information and belief, the Lupin ANDA Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

75. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the '489 patent. Endo does not have an adequate remedy at law.

76. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT FOUR
Declaratory Judgment of Infringement of the '489 Patent

77. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

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

79. There is an actual case or controversy such that the Court may resolve Endo's request for declaratory relief consistent with Article III of the United States Constitution.

80. On information and belief, unless enjoined by this Court, Lupin Atlantis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product immediately following approval of the Lupin ANDA.

81. The commercial use of the Lupin ANDA Product will directly infringe the '489 patent.

82. The commercial offer for sale and sale of the Lupin ANDA Product, in conjunction with the labeling and instructions for use thereof, will constitute an act of inducement of infringement of the ’489 patent.

83. On information and belief, Lupin Atlantis had knowledge of the ’489 patent since at least the time Lupin Atlantis submitted the Paragraph IV Certifications to FDA.

84. Because the Lupin ANDA Product is especially made or adapted for use in the claims of the ’489 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of the Lupin ANDA Product will constitute an act of contributory infringement of the ’489 patent.

85. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product before expiration of the ’489 patent by Lupin Atlantis or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the ’489 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

86. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’489 patent. Endo does not have an adequate remedy at law.

87. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT FIVE
Lupin Atlantis's Infringement of the '349 Patent

88. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

89. Lupin Atlantis's submission of the Lupin ANDA to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Lupin ANDA Product, prior to the expiration of the '349 patent, constitutes infringement of at least one claim, including at least claims 1, 9, and/or 17 of the '349 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

90. On FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claim 1 of the '349 patent, by manufacturing, using, offering to sell, or selling the Lupin ANDA Product in the United States and/or importing the Lupin ANDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

91. On information and belief, the Lupin ANDA Product contains the same active ingredient and in the same concentration as Nascobal® brand cyanocobalamin, USP nasal spray 500 mcg/spray, 0.125 mL.

92. On information and belief, the Lupin ANDA Product infringes at least one claim, including at least claim 1 of the '349 patent, literally and/or by the doctrine of equivalents.

93. On information and belief, the Lupin ANDA Product is a stable pharmaceutical aqueous solution comprising cyanocobalamin and water, a preservative selected from the group consisting of benzyl alcohol, parabens, chlorobutanol, benzethonium chloride, and benzalkonium chloride, and combinations thereof, and a buffer selected from the group consisting of citric acid, sodium citrate, monopotassium phosphate, disodium phosphate, potassium biphthalate, sodium

hydroxide, sodium acetate, acetic acid, and combinations thereof, wherein said solution of cyanocobalamin is suitable for intranasal administration, and has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the solution contains no mercury or mercury compounds, as claimed in at least one claim, including at least claim 1 of the '349 patent, literally and/or by the doctrine of equivalents.

94. On FDA approval of the Lupin ANDA, Lupin Atlantis will induce infringement of at least one claim, including at least claims 9 and/or 17 of the '349 patent, by promoting, encouraging, and/or recommending that persons perform methods of administering cyanocobalamin by infusing the nose with the claimed aqueous solution of cyanocobalamin, or administering intranasally the claimed aqueous solution of cyanocobalamin, and/or by contributing to the performance of said method, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

95. As part of the Lupin ANDA, Lupin Atlantis must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug," except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

96. The label for Nascobal® nasal spray states that Nascobal® nasal spray is administered in the nostril. *See* Exhibit G.

97. On information and belief, the proposed label for the Lupin ANDA Product is substantially identical to the approved label for Nascobal® nasal spray, and the Lupin ANDA

Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Nascobal® nasal spray.

98. On information and belief, the proposed label for the Lupin ANDA Product also states that the Lupin ANDA Product is administered in the nostril. Therefore, the proposed label promotes or encourages persons to perform methods of administering cyanocobalamin by infusing the nose with the Lupin ANDA Product, or administering intranasally a sufficient amount of the Lupin ANDA Product.

99. On information and belief, Lupin Atlantis knowingly provides instruction in the proposed label for persons to administer the Lupin ANDA Product intranasally or by infusing the nose, and the proposed label reflects a specific intent to encourage persons to directly infringe at least one claim, including at least claim 9 and/or 17 of the ’349 patent, literally and/or by the doctrine of equivalents.

100. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1, 9, and/or 17 of the ’349 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States.

101. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1, 9, and/or 17 of the ’349 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States. On information and belief, Lupin Atalntis will knowingly encourage direct infringement of the ’349 patent, and possesses specific intent to encourage another’s direct infringement of the ’349 patent.

102. Unless enjoined by the Court, on FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1, 9, and/or 17 of the ’349 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the Lupin ANDA Product into the United States. On information and belief, the act of direct infringement of the ’349 patent is attributed to a single entity. On information and belief, the Lupin ANDA Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

103. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’349 patent. Endo does not have an adequate remedy at law.

104. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT SIX
Declaratory Judgment of Infringement of the ’349 Patent

105. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

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

107. There is an actual case or controversy such that the Court may resolve Endo’s request for declaratory relief consistent with Article III of the United States Constitution.

108. On information and belief, unless enjoined by this Court, Lupin Atlantis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product immediately following approval of the Lupin ANDA.

109. The commercial use of the Lupin ANDA Product will directly infringe the ’349 patent.

110. The commercial offer for sale and sale of the Lupin ANDA Product, in conjunction with the labeling and instructions for use thereof, will constitute an act of inducement of infringement of the ’349 patent.

111. On information and belief, Lupin Atlantis had knowledge of the ’349 patent since at least the time Lupin Atlantis submitted the Paragraph IV Certifications to FDA.

112. Because the Lupin ANDA Product is especially made or adapted for use in the claims of the ’349 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of the Lupin ANDA Product will constitute an act of contributory infringement of the ’349 patent.

113. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product before expiration of the ’349 patent by Lupin Atlantis or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the ’349 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

114. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’349 patent. Endo does not have an adequate remedy at law.

115. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT SEVEN
Lupin Atlantis's Infringement of the '353 Patent

116. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

117. Lupin Atlantis's submission of the Lupin ANDA to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Lupin ANDA Product, prior to the expiration of the '353 patent, constitutes infringement of at least one claim, including at least claim 1 of the '353 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

118. On FDA approval of the Lupin ANDA, Lupin Atlantis will induce infringement of at least one claim, including at least claim 1 of the '353 patent, by promoting, encouraging, and/or recommending that persons administer the claimed cyanocobalamin solution into a nose of an individual through an actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip, and/or by contributing to the performance of said method, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

119. As part of the Lupin ANDA, Lupin Atlantis must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug," except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

120. The label for Nascobal® nasal spray states that Nascobal® nasal spray is administered in the nostril. *See* Exhibit G.

121. On information and belief, the proposed label for the Lupin ANDA Product is substantially identical to the approved label for Nascobal® nasal spray, and the Lupin ANDA

Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Nascobal® nasal spray.

122. On information and belief, the proposed label for the Lupin ANDA Product also states that the Lupin ANDA Product is administered in the nostril. Therefore, the proposed label promotes or encourages persons to administer the Lupin ANDA Product into a nose of an individual.

123. On information and belief, Lupin Atlantis knowingly provides instruction in the proposed label for persons to administer the Lupin ANDA Product into a nose of an individual, and the proposed label reflects a specific intent to encourage persons to directly infringe at least one claim, including at least claim 1 of the ’353 patent, literally and/or by the doctrine of equivalents.

124. On information and belief, the administration of the Lupin ANDA Product into a nose of an individual infringes at least one claim, including at least claim 1 of the ’353 patent, literally and/or by the doctrine of equivalents.

125. On information and belief, the Lupin ANDA Product is an aqueous solution of cyanocobalamin comprising cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water, wherein said solution of cyanocobalamin is suitable for intranasal administration and has a viscosity less than about 1000 cPs, with the proviso that the solution of cyanocobalamin contains no mercury or mercury-containing compounds, as claimed in at least one claim, including at least claim 1 of the ’353 patent, literally and/or by the doctrine of equivalents.

126. On information and belief, the Lupin ANDA Product is administered into a nose of an individual through an actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip, as claimed in at least one claim, including at least claim 1 of the '353 patent, literally and/or by the doctrine of equivalents.

127. By statute, a Notice of Paragraph IV Certification is required to provide a "detailed statement of the factual and legal basis of the opinion of the [ANDA] applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). The Notice Letter provided no statement that the Lupin ANDA product does not infringe the '353 patent, nor any basis for any opinion that the Lupin ANDA product does not infringe the '353 patent. By failing to include such a statement and a basis for the statement, Lupin Atlantis admits that the Lupin ANDA Product meets all limitations of the '353 patent claims and infringes those claims.

128. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the '353 patent. Endo does not have an adequate remedy at law.

129. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT EIGHT
Declaratory Judgment of Infringement of the '353 Patent

130. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

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

132. There is an actual case or controversy such that the Court may resolve Endo's request for declaratory relief consistent with Article III of the United States Constitution.

133. On information and belief, unless enjoined by this Court, Lupin Atlantis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product immediately following approval of the Lupin ANDA.

134. The commercial use of the Lupin ANDA Product will directly infringe the '353 patent.

135. The commercial offer for sale and sale of the Lupin ANDA Product, in conjunction with the labeling and instructions for use thereof, will constitute an act of inducement of infringement of the '353 patent.

136. On information and belief, Lupin Atlantis had knowledge of the '353 patent since at least the time Lupin Atlantis submitted the Paragraph IV Certifications to FDA.

137. Because the Lupin ANDA Product is especially made or adapted for use in the claims of the '353 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of the Lupin ANDA Product will constitute an act of contributory infringement of the '353 patent.

138. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product before expiration of the '353 patent by Lupin Atlantis or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the '353 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

139. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’353 patent. Endo does not have an adequate remedy at law.

140. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT NINE
Lupin Atlantis’s Infringement of the ’714 Patent

141. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

142. Lupin Atlantis’s submission of the Lupin ANDA to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Lupin ANDA Product, prior to the expiration of the ’714 patent, constitutes infringement of at least one claim, including at least claims 1 and/or 10 of the ’714 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

143. On FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1 and/or 10 of the ’714 patent, by manufacturing, using, offering to sell, or selling the Lupin ANDA Product in the United States and/or importing the Lupin ANDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

144. As part of the Lupin ANDA, Lupin Atlantis must show that “the labeling proposed for the new drug is the same as the labeling approved for the listed drug,” except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

145. The label for Nascobal® nasal spray states that Nascobal® nasal spray is administered in the nostril to a subject in need thereof. *See* Exhibit G.

146. On information and belief, the proposed label for the Lupin ANDA Product is substantially identical to the approved label for Nascobal® nasal spray, and the Lupin ANDA Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Nascobal® nasal spray.

147. On information and belief, the proposed label for the Lupin ANDA Product also states that the Lupin ANDA Product is administered in the nostril to a subject in need thereof. Therefore, the proposed label promotes or encourages persons to administer the Lupin ANDA Product by infusing the nose of a subject in need thereof.

148. On information and belief, Lupin Atlantis knowingly provides instruction in the proposed label for persons to administer the Lupin ANDA Product by infusing the nose of a subject in need thereof, and the proposed label reflects a specific intent to encourage persons to directly infringe at least one claim, including at least claims 1 and/or 10 of the ’714 patent, literally and/or by the doctrine of equivalents.

149. On information and belief, the administration of the Lupin ANDA Product by infusing the nose of a subject in need thereof infringes at least one claim, including at least claims 1 and/or 10 of the ’714 patent, literally and/or by the doctrine of equivalents.

150. On information and belief, the Lupin ANDA Product comprises a pharmaceutically effective amount of cyanocobalamin at a concentration of about 0.5% of total weight of solution, wherein the solution has a viscosity of less than 1000 cPs, and wherein the solution has a bioavailability of about 7% or more relative to the bioavailability of an intramuscular injection containing cyanocobalamin at a concentration of 0.1% of the total weight

based on a same volume as the solution, as claimed in at least one claim, including at least claim 1 of the ’714 patent, literally and/or by the doctrine of equivalents.

151. On information and belief, the Lupin ANDA Product comprises a pharmaceutically effective amount of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid, sodium citrate, benzalkonium chloride, and glycerin, wherein the solution has a viscosity of less than 1000 cPs, and wherein the solution has a bioavailability of about 7% or more relative to the bioavailability of an intramuscular injection containing cyanocobalamin at a concentration of 0.1% of the total weight based on a same volume as the solution, as claimed in at least one claim, including at least claim 10 of the ’714 patent, literally and/or by the doctrine of equivalents.

152. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’714 patent. Endo does not have an adequate remedy at law.

153. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT TEN
Declaratory Judgment of Infringement of the ’714 Patent

154. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

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

156. There is an actual case or controversy such that the Court may resolve Endo’s request for declaratory relief consistent with Article III of the United States Constitution.

157. On information and belief, unless enjoined by this Court, Lupin Atlantis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product immediately following approval of the Lupin ANDA.

158. The commercial use of the Lupin ANDA Product will directly infringe the ’714 patent.

159. The commercial offer for sale and sale of the Lupin ANDA Product, in conjunction with the labeling and instructions for use thereof, will constitute an act of inducement of infringement of the ’714 patent.

160. On information and belief, Lupin Atlantis had knowledge of the ’714 patent since at least the time Lupin Atlantis submitted the Paragraph IV Certifications to FDA.

161. Because the Lupin ANDA Product is especially made or adapted for use in the claims of the ’714 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of the Lupin ANDA Product will constitute an act of contributory infringement of the ’714 patent.

162. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product before expiration of the ’714 patent by Lupin Atlantis or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the ’714 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

163. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’714 patent. Endo does not have an adequate remedy at law.

164. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT ELEVEN
Lupin Atlantis’s Infringement of the ’007 Patent

165. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

166. Lupin Atlantis’s submission of the Lupin ANDA to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Lupin ANDA Product, prior to the expiration of the ’007 patent, constitutes infringement of at least one claim, including at least claims 1 and/or 13 of the ’007 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

167. On FDA approval of the Lupin ANDA, Lupin Atlantis will infringe at least one claim, including at least claims 1 and/or 13 of the ’007 patent, by manufacturing, using, offering to sell, or selling the Lupin ANDA Product in the United States and/or importing the Lupin ANDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

168. As part of the Lupin ANDA, Lupin Atlantis must show that “the labeling proposed for the new drug is the same as the labeling approved for the listed drug,” except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

169. The label for Nascobal® nasal spray indicates that Nascobal® nasal spray may be administered to a subject having vitamin B12 deficiency associated with gastric surgery. *See* Exhibit G.

170. On information and belief, the proposed label for the Lupin ANDA Product is substantially identical to the approved label for Nascobal® nasal spray, and the Lupin ANDA Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Nascobal® nasal spray.

171. On information and belief, the proposed label for the Lupin ANDA Product also indicates that the Lupin ANDA Product may be administered to a subject having vitamin B12 deficiency associated with gastric surgery. Therefore, the proposed label promotes or encourages persons to administer the Lupin ANDA Product to a subject having vitamin B12 deficiency associated with gastric surgery.

172. On information and belief, Lupin Atlantis knowingly provides instruction in the proposed label to administer the Lupin ANDA Product to a subject having vitamin B12 deficiency associated with gastric surgery, and the proposed label reflects a specific intent to encourage persons to directly infringe at least one claim, including at least claims 1 and/or 13 of the ’007 patent, literally and/or by the doctrine of equivalents.

173. On information and belief, the administration of the Lupin ANDA Product to a subject having vitamin B12 deficiency associated with gastric surgery infringes at least one claim, including at least claims 1 and/or 13 of the ’007 patent, literally and/or by the doctrine of equivalents.

174. On information and belief, the Lupin ANDA Product comprises cyanocobalamin; water; a buffer selected from the group consisting of citric acid, sodium citrate, monopotassium

phosphate, disodium phosphate, potassium biphthalate, sodium hydroxide, sodium acetate, acetic acid, and combinations thereof; optionally, a humectant selected from the group consisting of sorbitol, propylene glycol, and glycerin, and combinations thereof; and optionally, a preservative selected from the group consisting of benzyl alcohol, parabens thimerosal, chlorobutanol, benzethonium chloride, and benzalkonium chloride, and combinations thereof; wherein the aqueous solution of cyanocobalamin is suitable for intranasal administration, has a viscosity of less than about 1000 cPs, and a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, as claimed in at least one claim, including at least claims 1 and/or 13 of the ’007 patent, literally and/or by the doctrine of equivalents.

175. On information and belief, the Lupin ANDA Product comprises an aqueous solution of cyanocobalamin in a container; and an actuator coupled to the container, the actuator comprising a tip for producing a spray of the aqueous solution of cyanocobalamin when the actuator is engaged, as claimed in at least one claim, including at least claim 13 of the ’007 patent, literally and/or by the doctrine of equivalents.

176. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the ’007 patent. Endo does not have an adequate remedy at law.

177. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT TWELVE
Declaratory Judgment of Infringement of the ’007 Patent

178. Endo realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

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

180. There is an actual case or controversy such that the Court may resolve Endo's request for declaratory relief consistent with Article III of the United States Constitution.

181. On information and belief, unless enjoined by this Court, Lupin Atlantis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product immediately following approval of the Lupin ANDA.

182. The commercial use of the Lupin ANDA Product will directly infringe the '007 patent.

183. The commercial offer for sale and sale of the Lupin ANDA Product, in conjunction with the labeling and instructions for use thereof, will constitute an act of inducement of infringement of the '007 patent.

184. On information and belief, Lupin Atlantis had knowledge of the '007 patent since at least the time Lupin Atlantis submitted the Paragraph IV Certifications to FDA.

185. Because the Lupin ANDA Product is especially made or adapted for use in the claims of the '007 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of the Lupin ANDA Product will constitute an act of contributory infringement of the '007 patent.

186. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Lupin ANDA Product before expiration of the '007 patent by Lupin Atlantis or its agents,

will constitute infringement, inducement of infringement, and/or contributory infringement of the '007 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

187. Endo will be irreparably harmed if Lupin Atlantis is not enjoined from infringing, inducing, or contributing to infringement of the '007 patent. Endo does not have an adequate remedy at law.

188. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Endo respectfully requests the following relief:

A. A judgment that Lupin Atlantis infringed, contributed to, or induced the infringement of one or more claims of the '636 patent, literally and/or by the doctrine of equivalents, by submitting the Lupin ANDA for a generic copy of Nascobal® nasal spray to FDA;

B. A judgment that Lupin Atlantis infringed, contributed to, or induced the infringement of one or more claims of the '489 patent, literally and/or by the doctrine of equivalents, by submitting the Lupin ANDA for a generic copy of Nascobal® nasal spray to FDA;

C. A judgment that Lupin Atlantis infringed, contributed to, or induced the infringement of one or more claims of the '349 patent, literally and/or by the doctrine of equivalents, by submitting the Lupin ANDA for a generic copy of Nascobal® nasal spray to FDA;

D. A judgment that Lupin Atlantis infringed, contributed to, or induced the infringement of one or more claims of the '353 patent, literally and/or by the doctrine of

equivalents, by submitting the Lupin ANDA for a generic copy of Nascobal® nasal spray to FDA;

E. A judgment that Lupin Atlantis infringed, contributed to, or induced the infringement of one or more claims of the ’714 patent, literally and/or by the doctrine of equivalents, by submitting the Lupin ANDA for a generic copy of Nascobal® nasal spray to FDA;

F. A judgment that Lupin Atlantis infringed, contributed to, or induced the infringement of one or more claims of the ’007 patent, literally and/or by the doctrine of equivalents, by submitting the Lupin ANDA for a generic copy of Nascobal® nasal spray to FDA;

G. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product within the United States, prior to expiration, infringes the ’636 patent;

H. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product within the United States, prior to expiration, infringes the ’489 patent;

I. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product within the United States, prior to expiration, infringes the ’349 patent;

J. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product within the United States, prior to expiration, infringes the ’353 patent;

K. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product within the United States, prior to expiration, infringes the ’714 patent;

L. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product within the United States, prior to expiration, infringes the ’007 patent;

M. A permanent injunction restraining and enjoining Lupin Atlantis, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Lupin ANDA Product, until the expiration of the ’636 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

N. A permanent injunction restraining and enjoining Lupin Atlantis, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Lupin ANDA Product, until the expiration of the ’489 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

O. A permanent injunction restraining and enjoining Lupin Atlantis, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Lupin ANDA Product, until the expiration of the ’349 patent,

including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

P. A permanent injunction restraining and enjoining Lupin Atlantis, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Lupin ANDA Product, until the expiration of the ’353 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

Q. A permanent injunction restraining and enjoining Lupin Atlantis, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Lupin ANDA Product, until the expiration of the ’714 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

R. A permanent injunction restraining and enjoining Lupin Atlantis, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Lupin ANDA Product, until the expiration of the ’007 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

S. An order that the effective date of any approval of the Lupin ANDA for a generic copy of Nascobal® nasal spray under 21 U.S.C. § 355(j) shall not be earlier than the expiration

date of the ’636 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

T. An order that the effective date of any approval of the Lupin ANDA for a generic copy of Nascobal® nasal spray under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the ’489 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

U. An order that the effective date of any approval of the Lupin ANDA for a generic copy of Nascobal® nasal spray under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the ’349 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

V. An order that the effective date of any approval of the Lupin ANDA for a generic copy of Nascobal® nasal spray under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the ’353 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

W. An order that the effective date of any approval of the Lupin ANDA for a generic copy of Nascobal® nasal spray under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the ’714 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

X. An order that the effective date of any approval of the Lupin ANDA for a generic copy of Nascobal® nasal spray under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the ’007 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

Y. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award to Endo of reasonable attorney fees, costs, and expenses in this action; and

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

Dated: July 28, 2017

Respectfully submitted

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