IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE-NPS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AMBIO, INC., AMBIOPHARM, INC., PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Shire-NPS Pharmaceuticals, Inc. ("Plaintiff"), by its undersigned attorneys, for its Complaint against defendants Ambio, Inc., AmbioPharm, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical, Inc. (collectively "Defendants"), herein alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 7,056,886 ("the '886 patent"), 7,847,061 ("the '061 patent"), and 9,060,992 ("the '992 patent"), attached hereto as Exhibits A, B, and C, respectively.

THE PARTIES

2. Plaintiff Shire-NPS Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at 300 Shire Way, Lexington, Massachusetts 02421. Shire-NPS Pharmaceuticals, Inc. was formerly known as NPS Pharmaceuticals, Inc.

3. Upon information and belief, Defendant Ambio, Inc. is a corporation organized and existing under the laws of the State of Nevada, and its principal place of business is located at 1024 Dittman Court, North Augusta, South Carolina 29842.

4. Upon information and belief, Ambio, Inc. is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including throughout the State of Delaware.

5. Upon information and belief, Defendant AmbioPharm, Inc. is a corporation organized and existing under the laws of the State of California, and its principal place of business is located at 1024 Dittman Court, North Augusta, South Carolina 29842.

6. Upon information and belief, AmbioPharm, Inc. is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of drugs throughout the United States, including throughout the State of Delaware. Upon information and belief, AmbioPharm, Inc. specializes in the development, manufacture, marketing, sale, and distribution of peptide-based active pharmaceutical ingredients used in new chemical entities and generic pharmaceutical products that are sold throughout the United States, including throughout the State of Delaware.

7. Upon information and belief, Ambio, Inc. and AmbioPharm, Inc. have at least one officer and/or director in common, including Chris (Juncai) Bai as Chief Executive Officer and President, Snow Wang as Secretary, and Eric Bednarski as a member of the Board of Directors of Ambio, Inc. and a director of AmbioPharm, Inc. Upon information and belief, Ambio, Inc. and AmbioPharm, Inc. share a common principal place of business, website, and telephone number. *See infra* ¶ 40.

8. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at One Ram Ridge Road, Chestnut Ridge, New York 10977.

9. Upon information and belief, Par Pharmaceutical Companies, Inc. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware; (ii) alone, in concert with, and/or through its various subsidiaries, including defendant Par Pharmaceutical, Inc., the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking U.S. Food and Drug Administration ("FDA") approval to market generic drugs throughout the United States; and (iii) alone, in concert with, and/or through its various subsidiaries, including defendant Par Pharmaceutical, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

10. Upon information and belief, Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of New York, and its principal place of business is located at One Ram Ridge Road, Chestnut Ridge, New York 10977.

11. Upon information and belief, Par Pharmaceutical, Inc. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware; (ii) the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

12. Upon information and belief, Par Pharmaceutical, Inc. is wholly owned by defendant Par Pharmaceutical Companies, Inc. Upon information and belief, Par Pharmaceutical, Inc. acts at the direction of, under the control of, and for the direct benefit of Par Pharmaceutical Companies, Inc., and is controlled and/or dominated by Par Pharmaceutical Companies, Inc. Upon information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. have at least one officer and/or director in common. *See* Par Pharmaceutical Companies, Inc.'s Form 10-K for the Year Ended December 31, 2014 ("Par Pharmaceutical Companies, Inc.'s Form 10-K") at 131-32.

13. Par Pharmaceutical Companies, Inc.'s Form 10-K states that "[t]he majority of [its] revenues are generated by [its] generic products division" and that "[a]s of the fourth quarter of 2014, [it] or [its] strategic partners had approximately 115 ANDAs pending with the FDA, which included 32 first-to-file opportunities and six potential first-to-market product opportunities." Par Pharmaceutical Companies, Inc.'s Form 10-K at 29, 81. Par Pharmaceutical Companies, Inc.'s Form 10-K further states that Par Pharmaceutical Companies, Inc. "sells [its] products primarily in the United States" and that it markets its "generic products principally to wholesalers, drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and the government." *Id.* at 13.

14. According to Par Pharmaceutical Companies, Inc.'s Form 10-K, Par Pharmaceutical Companies, Inc. "is a Delaware holding company that, principally through its wholly owned operating subsidiary, Par Pharmaceutical, Inc., specializes in developing, licensing, manufacturing, marketing and distributing generic drugs in the United States." *Id.* at 5. Par Pharmaceutical Companies, Inc. further identifies "Par Pharmaceutical" as its generic products division. *Id*. Par Pharmaceutical Companies, Inc.'s Form 10-K further states that Par

Pharmaceutical, Inc.'s "products are primarily sold through wholesalers, retailers and mail order pharmacies." *Id*. at 7, 81. Par Pharmaceutical Companies, Inc.'s Form 10-Q reports over $661 million in revenues for the Par Pharmaceutical business segment in the six months ended June 30, 2015. *See* Par Pharmaceutical Companies, Inc.'s Form 10-Q for the Quarterly Period Ended June 30, 2015 at 40.

15. Upon information and belief, Par Pharmaceutical Companies, Inc. manufactures and/or directs the manufacture of generic pharmaceutical products for which Par Pharmaceutical, Inc. is the named ANDA applicant, such products including Amlodipine and Valsartan Tablets (5 mg/160 mg, 10 mg/160 mg, 5 mg/320 mg, and 10 mg/320 mg); Glipizide Extended-Release Tablets (5 mg and 10 mg); and Dexamethasone Tablets (0.5 mg, 0.75 mg, 1.5 mg, 4 mg, and 6 mg). Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. derive substantial revenue from the sale of such generic pharmaceutical products.

JURISDICTION AND VENUE

16. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. This Court has personal jurisdiction over Ambio, Inc. because, *inter alia*, upon information and belief, Ambio, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Ambio, Inc. has continuous and systematic contacts with Delaware.

18. This Court also has personal jurisdiction over Ambio, Inc. because, *inter alia*, Ambio, Inc. has committed, encouraged, aided, abetted, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2)(A) that has led and/or will lead

to foreseeable harm and injury to Plaintiff, a Delaware corporation. Ambio, Inc. prepared, submitted, and filed with the FDA, pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), ANDA No. 210023 seeking approval to engage in the commercial manufacture, use, and/or sale of Teduglutide for Injection, 5 mg/vial ("Defendants' ANDA Product") before the expiration of the '886, '061, and '992 patents throughout the United States, including in this judicial district. In its efforts related to ANDA No. 210023, Ambio, Inc. partnered with Par Pharmaceutical, Inc. (*see infra* ¶ 43), which regularly conducts business in Delaware, is qualified to perform business under the laws of Delaware, has often submitted to jurisdiction in this Court, and has frequently availed itself of the rights, benefits, and privileges of this Court (*see infra* ¶¶ 26-29).

19. This Court has personal jurisdiction over AmbioPharm, Inc. because, *inter alia*, upon information and belief, AmbioPharm, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that AmbioPharm, Inc. has continuous and systematic contacts with Delaware. *See, e.g.*, Celldex Therapeutics, Inc. Form 10-K/A Amendment No. 1 for the Year Ended December 31, 2015 at 17, 44; VG Life Sciences Inc. Form 10-K for the Year Ended December 31, 2014 at 19, 34; Genspera, Inc. Form 10-Q for the Quarterly Period Ended March 31, 2012 at 24; Endocyte, Inc. Form 10-K for the Year Ended December 31, 2011 at 26.

20. This Court also has personal jurisdiction over AmbioPharm, Inc. because, *inter alia*, AmbioPharm, Inc. has committed, encouraged, aided, abetted, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2)(A) that has led and/or will lead to foreseeable harm and injury to Plaintiff, a Delaware corporation. Upon

information and belief, as of April 10, 2017, the FDA website identifies AmbioPharm, Inc. as the holder of Drug Master File ("DMF") No. 30583, Teduglutide Non-Sterile. Upon information and belief, AmbioPharm, Inc. worked in concert with Ambio, Inc. (Par Pharmaceutical, Inc.'s partner) to prepare, submit, and file with the FDA, pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)), ANDA No. 210023 seeking approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product (i.e., a generic teduglutide product) before the expiration of the '886, '061, and '992 patents throughout the United States, including in this judicial district.

21. This Court has personal jurisdiction over Par Pharmaceutical Companies, Inc. because, *inter alia*, upon information and belief, Par Pharmaceutical Companies, Inc. is incorporated under the laws of the State of Delaware and has a registered agent for service of process in Delaware.

22. This Court also has personal jurisdiction over Par Pharmaceutical Companies, Inc. because, *inter alia*, upon information and belief, Par Pharmaceutical Companies, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Par Pharmaceutical Companies, Inc. has continuous and systematic contacts with Delaware.

23. This Court also has personal jurisdiction over Par Pharmaceutical Companies, Inc. because, *inter alia*, Par Pharmaceutical Companies, Inc. has committed, encouraged, aided, abetted, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2)(A) that has led and/or will lead to foreseeable harm and injury to Plaintiff, a Delaware corporation. Upon information and belief, Par Pharmaceutical Companies, Inc.

directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. (Ambio, Inc.'s partner) to prepare, submit, and file with the FDA, pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)), ANDA No. 210023 seeking approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product before the expiration of the '886, '061, and '992 patents throughout the United States, including in this judicial district.

24. This Court has personal jurisdiction over Par Pharmaceutical, Inc. because, *inter alia*, upon information and belief, Par Pharmaceutical, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Par Pharmaceutical, Inc. has continuous and systematic contacts with Delaware.

25. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, *inter alia*, Par Pharmaceutical, Inc. is qualified to do business under the laws of the State of Delaware under File No. 6125148 and has a registered agent in the State of Delaware. Upon information and belief, Par Pharmaceutical, Inc. is "doing business as Par Pharmaceutical." *See* Endo International plc's Form 10-K for the Year Ended December 31, 2016 at Exhibit 21.1. Par Pharmaceutical holds an active pharmacy wholesale license for the State of Delaware under License No. A4-0002347 and an active distributor/manufacturer license for controlled substances for the State of Delaware under License No. DM-0011836. As of April 10, 2017, Par Pharmaceutical's website states that its "sales place it among the leading generic pharmaceutical companies in the United States." Par Pharmaceutical "[c]onducts manufacturing in the United States and abroad and markets and/or license more than 200 prescriptions drug products families," and has "[s]trong distribution relationships in place at top U.S. retail chains,

wholesalers, distributors, managed care organizations, mail order pharmacies and group purchasing organizations."

26. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, *inter alia*, Par Pharmaceutical, Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protection of the State of Delaware, having consented to jurisdiction in this Court, *see, e.g., Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 15-1050-RGA (D. Del. Dec. 4, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 15-1049-LPS (D. Del. Dec. 7, 2015); *Actavis Labs. U.T., Inc. v. Par Pharmaceutical, Inc.*, 15-886-LPS (D. Del. Dec. 1, 2015); *Acorda Therapeutics, Inc. v. Par Pharmaceutical, Inc.*, 15-824-LPS (D. Del. Oct. 7, 2015); *Ferring Pharmaceuticals Inc. v. Par Pharmaceutical, Inc.*, 15-173-RGA (D. Del. Mar. 13, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 15-116-LPS (D. Del. Feb. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 15-078-RGA (D. Del. Jan. 30, 2015); *Tris Pharma, Inc. v. Par Pharmaceutical, Inc.*, 15-068-GSM (D. Del. Feb. 12, 2015); *Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc.*, 14-1573-RGA (D. Del. Jan. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 14-1494-RGA (D. Del. Jan. 16, 2015).

27. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, *inter alia*, Par Pharmaceutical, Inc. has previously availed itself of the rights, benefits, and privileges of this Court by asserting claims in prior Delaware actions, *see, e.g., Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 15-1050-RGA (D. Del. Dec. 4, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 15-1049-LPS (D. Del. Dec. 7, 2015); *Actavis Labs. U.T., Inc. v. Par Pharmaceutical, Inc.*, 15-886-LPS (D. Del. Dec. 1, 2015); *Acorda Therapeutics, Inc. v. Par Pharmaceutical, Inc.*, 15-824-LPS (D. Del. Oct. 7, 2015); *Ferring*

Pharmaceuticals Inc. v. Par Pharmaceutical, Inc., 15-173-RGA (D. Del. Mar. 13, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 15-116-LPS (D. Del. Feb. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 15-078-RGA (D. Del. Jan. 30, 2015); *Tris Pharma, Inc. v. Par Pharmaceutical, Inc.*, 15-068-GSM (D. Del. Feb. 12, 2015); *Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc.*, 14-1573-RGA (D. Del. Jan. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 14-1494-RGA (D. Del. Jan. 16, 2015).

28. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, *inter alia*, Par Pharmaceutical, Inc. has committed, encouraged, aided, abetted, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2)(A) that has led and/or will lead to foreseeable harm and injury to Plaintiff, a Delaware corporation. Par Pharmaceutical, Inc. together with its partner Ambio, Inc., prepared, submitted, and filed with the FDA, pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)), ANDA No. 210023 seeking approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product before the expiration of the '886, '061, and '992 patents throughout the United States, including in this judicial district.

29. Upon information and belief, if ANDA No. 210023 is approved, Defendants' ANDA Product will, *inter alia*, be marketed and distributed by Defendants in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

30. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND FACTS

31. Plaintiff owns New Drug Application No. 203441 for teduglutide [rDNA origin], which was approved on December 21, 2012 and is marketed under the name GATTEX®. GATTEX is supplied as a single-use glass vial containing 5 mg of teduglutide as a white, lyophilized powder for reconstitution with 0.5 mL Sterile Water for Injection provided in a prefilled syringe. GATTEX is sold in either a one-vial kit or a 30-vial kit.

32. GATTEX (teduglutide [rDNA origin]) for injection is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adult patients with Short Bowel Syndrome who are dependent on parenteral support.

33. The '886 patent, entitled "GLP-2 Formulations," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 6, 2006. Plaintiff owns the '886 patent.

34. The '061 patent, entitled "Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity" was duly and legally issued by the USPTO on December 7, 2010. Plaintiff owns the '061 patent.

35. The '992 patent, entitled "Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity" was duly and legally issued by the USPTO on June 23, 2015. Plaintiff owns the '992 patent.

36. Pursuant to 21 U.S.C. § 355(b)(1), the '886, '061, and '992 patents are listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering GATTEX.

37. Upon information and belief, Defendants prepared, submitted, and filed ANDA No. 210023 under § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)), seeking approval from the FDA to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product.

Defendants included in ANDA No. 210023 a "paragraph IV" certification seeking such approval before the expiration of the '886, '061, and '992 patents. And upon information and belief, upon approval of ANDA No. 210023, Defendants will be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product.

38. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)-(ii).

39. Plaintiff received a letter dated February 28, 2017 that was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(ii) regarding Defendants' ANDA Product and the '886, '061, and '992 patents (the "Notice Letter").

40. The Notice Letter is provided on letterhead branded with the general logo "Ambio." The return address on the letterhead indicates that the letter is from "Ambio, Inc." located at 1024 Dittman Court, North Augusta, South Carolina 29842. The website contact on the letterhead is www.ambiopharm.com, and a phone number on the letterhead of 803-442-7590 is the phone number identified on the www.ambiopharm.com website for the USA Headquarters

of AmbioPharm, Inc. The Notice Letter and the Offer of Confidential Access ("OCA") included in the Notice Letter were signed by Chris Bai, identified as CEO, on behalf of Ambio, Inc.

41. The Notice Letter states that it is "a notice of certification letter on behalf of abbreviated new drug application holder Ambio, Inc. and its partner Par Pharmaceutical, Inc. (collectively, 'Ambio')." The Notice Letter and the OCA were signed by William Mcintyre, identified as Senior Vice President, Regulatory Affairs, on behalf of Par Pharmaceutical. The Federal Express label on the Notice Letter indicates that the Notice Letter was sent from Par Pharmaceutical, One Ram Ridge Road, Chestnut Ridge, New York.

42. The Notice Letter does not include any invalidity contentions with respect to any claim of the '886 patent.

43. The Notice Letter does not include any noninfringement contentions with respect to any claim of the '061 or '992 patents.

44. The Notice Letter included an OCA purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Plaintiff objected to certain provisions of the OCA as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III). By way of example only, the OCA contains a patent prosecution bar, even though no facts have been provided to show that there is good cause to impose such a bar.

FIRST CLAIM FOR RELIEF
(Direct and Indirect Infringement of the '886 Patent)

45. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

46. Upon information and belief, AmbioPharm, Inc. actively worked in concert with Ambio, Inc. to prepare, submit, and file ANDA No. 210023 with a paragraph IV certification to the '886 patent.

47. Upon information and belief, AmbioPharm, Inc. will actively work in concert with Ambio, Inc. to commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product.

48. Upon information and belief, AmbioPharm, Inc. is jointly and severally liable for Ambio, Inc.'s infringement of one or more claims of the '886 patent.

49. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023 with a paragraph IV certification to the '886 patent.

50. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product.

51. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '886 patent.

52. Upon information and belief, Defendants have submitted ANDA No. 210023 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product—a product claimed and the methods of making and use of which are claimed in the '886 patent—before the expiration of the '886 patent.

53. Upon information and belief, Defendants included in ANDA No. 210023 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '886 patent.

54. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product upon, or in anticipation of, FDA approval.

55. The submission of ANDA No. 210023 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '886 patent was an act of infringement by Defendants of one or more claims of the '886 patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more claims of the '886 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

57. Upon information and belief, the sale or offer for sale of Defendants' ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '886 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

58. Defendants knew of the existence of the '886 patent, as evidenced by Defendants' filing of ANDA No. 210023 with a paragraph IV certification specifically referencing the '886 patent.

59. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (*e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that

infringe the claims, or the making or use of which infringes the claims, of the ’886 patent. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the ’886 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

60. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants’ ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’886 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’886 patent; (ii) Defendants know or should know that Defendants’ ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’886 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

61. Upon information and belief, by knowingly inducing, encouraging, aiding, abetting, contributing to, and/or participating in Ambio, Inc.’s commercial manufacture, use, sale, offer for sale, and/or importation of Defendants’ ANDA Product, AmbioPharm, Inc. will induce and/or contribute to Ambio, Inc.’s infringement of the ’886 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

62. Upon information and belief, by knowingly inducing, encouraging, aiding, abetting, directing, controlling, contributing to, and/or participating in Par Pharmaceutical, Inc.’s

commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product, Par Pharmaceutical Companies, Inc. will induce and/or contribute to Par Pharmaceutical, Inc.'s infringement of the '886 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

63. Defendants' infringement of the '886 patent will cause Plaintiff to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Plaintiff has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '886 patent.

64. At least as of the date of the Notice Letter, Defendants were aware of the existence of the '886 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not infringe one or more valid claims of the '886 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF
(Indirect Infringement of the '061 Patent)

65. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

66. Upon information and belief, AmbioPharm, Inc. actively worked in concert with Ambio, Inc. to prepare, submit, and file ANDA No. 210023 with a paragraph IV certification to the '061 patent.

67. Upon information and belief, AmbioPharm, Inc. will actively work in concert with Ambio, Inc. to commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product.

68. Upon information and belief, AmbioPharm, Inc. is jointly and severally liable for Ambio, Inc.'s infringement of one or more claims of the '061 patent.

69. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023 with a paragraph IV certification to the '061 patent.

70. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product.

71. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '061 patent.

72. Upon information and belief, Defendants have submitted ANDA No. 210023 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product—the methods of use of which are claimed in the '061 patent—before the expiration of the '061 patent.

73. Upon information and belief, Defendants included in ANDA No. 210023 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '061 patent.

74. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product upon, or in anticipation of, FDA approval.

75. The submission of ANDA No. 210023 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of

Defendants' ANDA Product before the expiration of the '061 patent was an act of infringement by Defendants of one or more claims of the '061 patent under 35 U.S.C. § 271(e)(2)(A).

76. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' ANDA Product would indirectly infringe one or more claims of the '061 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

77. Upon information and belief, the sale or offer for sale of Defendants' ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '061 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

78. Defendants knew of the existence of the '061 patent, as evidenced by Defendants' filing of ANDA No. 210023 with a paragraph IV certification specifically referencing the '061 patent.

79. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (*e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to use products in a manner that infringes the claims of the '061 patent. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the '061

patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

80. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants' ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the '061 patent by third parties because: (i) Defendants' ANDA Product constitutes a material part of the methods of treatment claimed in the '061 patent; (ii) Defendants know or should know that Defendants' ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '061 patent; and (iii) Defendants' ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

81. Defendants' infringement of the '061 patent will cause Plaintiff to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Plaintiff has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '061 patent.

82. At least as of the date of the Notice Letter, Defendants were aware of the existence of the '061 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not infringe one or more valid claims of the '061 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF
(Indirect Infringement of the '992 Patent)

83. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

84. Upon information and belief, AmbioPharm, Inc. actively worked in concert with Ambio, Inc. to prepare, submit, and file ANDA No. 210023 with a paragraph IV certification to the ’992 patent.

85. Upon information and belief, AmbioPharm, Inc. will actively work in concert with Ambio, Inc. to commercially manufacture, use, sell, offer for sale, and/or import Defendants’ ANDA Product.

86. Upon information and belief, AmbioPharm, Inc. is jointly and severally liable for Ambio, Inc.’s infringement of one or more claims of the ’992 patent.

87. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023 with a paragraph IV certification to the ’992 patent.

88. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import Defendants’ ANDA Product.

89. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.’s infringement of one or more claims of the ’992 patent.

90. Upon information and belief, Defendants have submitted ANDA No. 210023 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants’ ANDA Product—the methods of use of which are claimed in the ’992 patent—before the expiration of the ’992 patent.

91. Upon information and belief, Defendants included in ANDA No. 210023 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '992 patent.

92. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product upon, or in anticipation of, FDA approval.

93. The submission of ANDA No. 210023 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '992 patent was an act of infringement by Defendants of one or more claims of the '992 patent under 35 U.S.C. § 271(e)(2)(A).

94. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' ANDA Product would indirectly infringe one or more claims of the '992 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

95. Upon information and belief, the sale or offer for sale of Defendants' ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '992 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

96. Defendants knew of the existence of the '992 patent, as evidenced by Defendants' filing of ANDA No. 210023 with a paragraph IV certification specifically referencing the '992 patent.

97. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly

encourage, advise, instruct, urge, aid, and otherwise induce third parties (*e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to use products in a manner that infringes the claims of the ’992 patent. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the ’992 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

98. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants’ ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’992 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’992 patent; (ii) Defendants know or should know that Defendants’ ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’992 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

99. Defendants’ infringement of the ’992 patent will cause Plaintiff to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court. Plaintiff has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’992 patent.

100. At least as of the date of the Notice Letter, Defendants were aware of the existence of the '992 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not infringe one or more valid claims of the '992 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 210023 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '886, '061, and '992 patents constitutes an act of infringement of the '886, '061, and '992 patents by Defendants;

B. A Judgment declaring that, pursuant to 35 U.S.C. §§ 271(a), (b), and (c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Defendants' ANDA Product before the expiration of the '886, '061, and '992 patents would directly and indirectly infringe the '886, '061, and '992 patents;

C. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA Product shall be no earlier than the latest date of expiry of the '886, '061, and '992 patents, including any regulatory extensions;

D. Injunctive relief pursuant to 35 U.S.C. § 271(e)(4)(B) precluding Defendants from manufacturing, using, selling, offering to sell, or importing Defendants' ANDA Product prior to the date on which the '886, '061, and '992 patents have expired, including any regulatory extensions;

E. A Judgment awarding Plaintiff damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer for sale, and/or import any product that is the subject of ANDA No. 210023 that infringes the '886, '061, and '992 patents;

F. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiff its attorneys' fees;

G. A Judgment awarding Plaintiff its costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

H. Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

Edgar H. Haug
Sandra Kuzmich, Ph.D.
HAUG PARTNERS LLP
745 Fifth Avenue
New York, NY 10151

April 10, 2017