IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE-NPS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
PAR PHARMACEUTICAL COMPANIES, INC., PAR PHARMACEUTICAL, INC. and PAR STERILE PRODUCTS, LLC,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Shire-NPS Pharmaceuticals, Inc. ("Plaintiff"), by its undersigned attorneys, for its Complaint against defendants Par Pharmaceutical Companies, Inc., Par Pharmaceutical, Inc., and Par Sterile Products, LLC (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. 9,968,655 ("the '655 patent"), 9,968,656 ("the '656 patent"), 9,968,658 ("the '658 patent"), 9,974,835 ("the '835 patent"), 9,974,837 ("the '837 patent"), 9,981,014 ("the '014 patent"), 9,981,016 ("the '016 patent"), and 9,987,334 ("the '334 patent") (collectively "the Patents in Suit") attached hereto as Exhibits A-H, 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 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.

4. 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 wholly-owned subsidiaries, including defendants Par Pharmaceutical, Inc. and Par Sterile Products, LLC, 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, including throughout the State of Delaware; and (iii) alone, in concert with, and/or through its various wholly-owned subsidiaries, including defendants Par Pharmaceutical, Inc. and Par Sterile Products, LLC, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

5. 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.

6. 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) alone, in concert with, and/or through its various subsidiaries, including defendant Par Sterile Products, LLC, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) alone, in

concert with, and/or through its various subsidiaries, including defendant Par Sterile Products, LLC, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

7. 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* Endo International PLC's Form 10-K for the Year Ended December 31, 2017 at 16-17; *see also Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, C.A. No. 17-cv-00397 (RGA), D.I. 21 at ¶ 12.

8. Upon information and belief, Defendant Par Sterile Products, LLC is a limited liability company 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 Sterile Products, LLC 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, including throughout the State of Delaware; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

10. Upon information and belief, Par Sterile Products, LLC is an indirect, wholly-owned subsidiary of defendant Par Pharmaceutical, Inc. Upon information and belief, Par Sterile Products, LLC is wholly owned by defendant Par Pharmaceutical Companies, Inc. Upon information and belief, Par Sterile Products, LLC acts at the direction of, under the control of, and for the direct benefit of Par Pharmaceutical Companies, Inc. and/or Par Pharmaceutical, Inc., and is controlled and/or dominated by Par Pharmaceutical Companies, Inc. and/or Par Pharmaceutical, Inc.

11. Par Pharmaceutical, Inc.'s website indicates that Par is "among the top four leaders in the U.S. generics industry" and it "possesses a portfolio that includes sterile injectables, alternative dosage forms and many other differentiated products." *See* http://www.parpharm.com/generics.php. Par Pharmaceutical, Inc.'s website further indicates that Par markets an "extensive range of prescription and over-the-counter products" and that these products are "tablets, capsules, liquids, suspensions, creams, and ointments." *See* www.parpharm.com/products/product-catalog.php. Par offers "products in a wide variety of therapeutic categories, including antihypertensives, analgesics, antibiotics, cough/cold, antidepressants, antipsychotics, as well as others. Consumers can find [Par's] products at major retailers, as well as locally owned and operated pharmacies." *Id.*

12. 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.

13. Upon information and belief, Par Pharmaceutical Companies, Inc. manufactures generic pharmaceutical products for which Par Sterile Products, LLC is the named ANDA applicant, such products including Argatroban Injection (250 mg/2.5 mL (100 mg/mL)); Ethacrynate Sodium for Injection, USP (50 mg/vial); and Fluphenazine Decanoate Injection, USP (25 mg/mL). Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Sterile Products, LLC derive substantial revenue from the sale of such generic pharmaceutical products.

14. Upon information and belief, Par Pharmaceutical, Inc. directs the manufacture of and/or distributes generic pharmaceutical products for which Par Sterile Products, LLC is the named ANDA applicant, such products including Meropenem for Injection, USP (500 mg/vial and 1 g/vial); Mycophenolate Mofetil for Injection, USP (500 mg/vial); and Levothyroxine Sodium for Injection (200 mcg/vial). Upon information and belief, Par Pharmaceutical, Inc. and Par Sterile Products, LLC derive substantial revenue from the sale of such generic pharmaceutical products.

JURISDICTION AND VENUE

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

16. This Court has personal jurisdiction over Par Sterile Products, LLC because, *inter alia*, upon information and belief, Par Sterile Products, LLC is organized under the laws of the State of Delaware and has a registered agent for service of process in Delaware.

17. This Court has personal jurisdiction over Par Sterile Products, LLC because, *inter alia*, Par Sterile Products, LLC 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, on April 21, 2017, Par Sterile Products, LLC accepted ownership of ANDA No. 210023, and is currently the owner of ANDA No. 210023. *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 21 at ¶ 23. Par Sterile Products, LLC seeks approval of ANDA No. 210023 to engage in the commercial manufacture, use, and/or sale of Teduglutide for Injection, 5 mg/vial (the "ANDA Product") throughout the United States, including in this judicial district, before the expiration of the Patents in Suit. Upon information and belief, Par Sterile Products, LLC accepted ownership of ANDA No. 210023 from Ambio, Inc., a previously-named defendant in a related litigation filed in this judicial district (the Related Action"). *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 1 and D.I. 15. 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 the ANDA Product throughout the United States, including in this judicial district, before the expiration of, *inter alia*, patents in the same patent family as the Patents in Suit. *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 1 at ¶ 18 and D.I. 15 at ¶ 23. In its efforts related to obtaining approval of ANDA No. 210023, Ambio, Inc. partnered with Par Sterile Products, LLC and Par Pharmaceutical, Inc. After transfer of the ownership of ANDA No. 210023 from Ambio, Inc. to Par Sterile Products, LLC, Ambio, Inc. entered into a stipulation to, *inter alia*, "be bound by any judgment, order, or decision, including any injunction, rendered as to [Defendants]," and was dismissed from the Related Action (*see Shire-NPS Pharms., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 30).

18. This Court also has personal jurisdiction over Par Sterile Products, LLC because, *inter alia*, upon information and belief, Par Sterile Products, LLC 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 Sterile Products, LLC has continuous and systematic contacts with Delaware.

19. This Court also has personal jurisdiction over Par Sterile Products, LLC because Par Sterile Products, LLC holds an active pharmacy wholesale license for the State of Delaware under License No. A4-0002209 and an active distributor/manufacturer license for controlled substances for the State of Delaware under License No. DM-0010911.

20. This Court also has personal jurisdiction over Par Sterile Products, LLC, because, *inter alia*, Par Sterile Products, LLC has not disputed personal jurisdiction for the purposes of the Related Action involving ANDA No. 210023, the ANDA Product, and patents in the same patent family as the Patents In Suit. *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 21 at ¶¶ 26-30, 33, 36.

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 Sterile Products, LLC is the current owner of ANDA No. 210023, and Par Pharmaceutical Companies, Inc. works in concert with its wholly-owned subsidiaries Par Sterile Products, LLC and Par Pharmaceutical, Inc. to seek approval of ANDA No. 210023 to engage in the commercial manufacture, use, and/or sale of the ANDA Product throughout the United States, including in this judicial district, before the expiration of the Patents in Suit.

24. This Court also has personal jurisdiction over Par Pharmaceutical Companies, Inc. because, *inter alia*, Par Pharmaceutical Companies, Inc. has not disputed personal jurisdiction for the purposes of the Related Action involving ANDA No. 210023, the ANDA Product, and patents in the same patent family as the Patents In Suit. *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 21 at ¶¶ 26-30, 33, 36.

25. 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.

26. 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 for service of process in 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, 2017 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 July 24, 2018, 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." *See* http://www.parpharm.com/about/.

27. 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.*, *Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA (D. Del. Apr. 10, 2017); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 1:15-cv-01050-RGA (D. Del. Dec. 4, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 1:15-cv-01049-LPS (D. Del. Dec. 7, 2015); *Actavis Labs. U.T., Inc. v. Par Pharmaceutical, Inc.*, 1:15-cv-00886-LPS (D. Del. Dec. 1, 2015); *Acorda Therapeutics, Inc. v. Par Pharmaceutical, Inc.*, 1:15-cv-00824-LPS (D. Del. Oct. 7, 2015); *Ferring Pharmaceuticals Inc.*

v. Par Pharmaceutical, Inc., 1:15-cv-00173-RGA (D. Del. Mar. 13, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 1:15-cv-00116-LPS (D. Del. Feb. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 1:15-cv-00078-RGA (D. Del. Jan. 30, 2015); *Tris Pharma, Inc. v. Par Pharmaceutical, Inc.*, 1:15-cv-00068-GMS (D. Del. Feb. 12, 2015); *Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc.*, 1:14-cv-01573-RGA (D. Del. Jan. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 1:14-cv-01494-RGA (D. Del. Jan. 16, 2015).

28. 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.*, *Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals, Inc.*, 1:18-cv-00823-VAC-CJB (D. Del. May 31, 2018); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 1:15-cv-01050-RGA (D. Del. Dec. 4, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 1:15-cv-01049-LPS (D. Del. Dec. 7, 2015); *Actavis Labs. U.T., Inc. v. Par Pharmaceutical, Inc.*, 1:15-cv-00886-LPS (D. Del. Dec. 1, 2015); *Acorda Therapeutics, Inc. v. Par Pharmaceutical, Inc.*, 1:15-cv-00824-LPS (D. Del. Oct. 7, 2015); *Ferring Pharmaceuticals Inc. v. Par Pharmaceutical, Inc.*, 1:15-cv-00173-RGA (D. Del. Mar. 13, 2015); *Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.*, 1:15-cv-00116-LPS (D. Del. Feb. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 1:15-cv-00078-RGA (D. Del. Jan. 30, 2015); *Tris Pharma, Inc. v. Par Pharmaceutical, Inc.*, 1:15-cv-00068-GMS (D. Del. Feb. 12, 2015); *Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc.*, 1:14-cv-01573-RGA (D. Del. Jan. 26, 2015); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, 1:14-cv-01494-RGA (D. Del. Jan. 16, 2015).

29. 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.'s wholly-owned subsidiary Par Sterile Products, LLC is the current owner of ANDA No. 210023, and Par Pharmaceutical, Inc. works in concert with its wholly-owned subsidiary Par Sterile Products, LLC to seek approval of ANDA No. 210023 to engage in the commercial manufacture, use, and/or sale of the ANDA Product throughout the United States, including in this judicial district, before the expiration of the Patents in Suit.

30. This Court also has personal jurisdiction over Par Pharmaceutical, Inc., because, *inter alia*, Par Pharmaceutical, Inc. has not disputed personal jurisdiction for the purposes of the Related Action involving ANDA No. 210023, the ANDA Product, and patents in the same patent family as the Patents In Suit. *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 21 at ¶¶ 26-30, 33, 36.

31. Upon information and belief, if ANDA No. 210023 is approved, the 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.

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

33. Venue is also proper in this judicial district over Defendants, because, *inter alia*, Endo International PLC's Form 10-K for the Year Ended December 31, 2017, Exhibit 21.1

identifies 19 entities incorporated in Delaware, six of which are Par entities. Notably, Par Pharmaceutical Companies, Inc. and Par Sterile Products, LLC are incorporated under the laws of the State of Delaware and therefore reside in the State of Delaware for the purposes of venue under 28 U.S.C. § 1400(b).

34. Venue is also proper in this judicial district over Defendants, because, *inter alia*, Defendants did not dispute venue in this Court for the purposes of the Related Action involving ANDA No. 210023, the ANDA Product, and patents in the same patent family as the Patents In Suit.. *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 21 at ¶ 39.

BACKGROUND FACTS

35. 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.

36. GATTEX (teduglutide [rDNA origin]) for injection is a glucagon-like peptide-2 (GLP-2) analog. The approved label for GATTEX states that it is indicated for the treatment of adult patients with Short Bowel Syndrome who are dependent on parenteral support. One or more claims of the Patents in Suit cover the use of GATTEX to treat the indication in the approved label for GATTEX.

37. The approved label for GATTEX instructs and encourages subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists to use GATTEX according to one or more of the methods claimed in the Patents in Suit.

38. The ’655 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on May 15, 2018. Plaintiff owns the ’655 patent.

39. The ’656 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the USPTO on May 15, 2018. Plaintiff owns the ’656 patent.

40. The ’658 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the USPTO on May 15, 2018. Plaintiff owns the ’658 patent.

41. The ’835 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the USPTO on May 22, 2018. Plaintiff owns the ’835 patent.

42. The ’837 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the USPTO on May 22, 2018. Plaintiff owns the ’837 patent.

43. The ’014 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the USPTO on May 29, 2018. Plaintiff owns the ’014 patent.

44. The ’016 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the USPTO on May 29, 2018. Plaintiff owns the ’016 patent.

45. The ’334 patent, entitled “Treatment of Short Bowel Syndrome Patients with Colon-in-Continuity” was duly and legally issued by the USPTO on June 5, 2018. Plaintiff owns the ’334 patent.

46. Pursuant to 21 U.S.C. § 355(b)(1), the Patents in Suit are listed in the FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) as covering methods of using GATTEX.

47. Upon information and belief, Defendants have included in ANDA No. 210023 a “paragraph IV” certification seeking approval from the FDA to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Patents in Suit. 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 the ANDA Product.

48. Upon information and belief, Defendants’ proposed labeling for the ANDA Product copies the approved label for GATTEX. Upon information and belief, Defendants intend, conditioned upon FDA approval of ANDA No. 210023, to market the ANDA Product for the indication included in the approved label for GATTEX. Upon information and belief, Defendants also intend for medical practitioners and/or physicians to prescribe, and for patients to use, the ANDA Product in accordance with, and as directed by, Defendants’ proposed labeling for the ANDA Product.

49. 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).

50. Plaintiff received a letter dated June 27, 2018, that was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(ii) regarding the ANDA Product and the '655, '656, '658, '835, '837, '014, '016, and '334 patents (the "Notice Letter").

51. The Notice Letter is provided on letterhead branded with the logo "Par Pharmaceutical *an endo international company.*" The return address on the letterhead indicates that the letter is from "Par Pharmaceutical" located at One Ram Ridge Road, Chestnut Ridge, NY 10977. The website contact on the letterhead is www.parpharm.com, and a phone number on the letterhead of 845-573-5500 is the phone number identified on the www.parpharm.com/generics website for the USA Headquarters of Par Pharmaceutical and on the www.parsterileproducts.com website for the "Corporate" division of Par Sterile Products.

52. The Notice Letter states: "This is a notice of certification letter on behalf of abbreviated new drug application holder Par Sterile Products, LLC ('Par')." The Notice Letter and the accompanying Offer of Confidential Access were signed by William Mcintyre, identified as Senior Vice President, Global Regulatory Affairs, on behalf of Par Pharmaceutical.

53. The Notice Letter does not include any noninfringement contentions with respect to any claim of the '655, '656, '658, '835, '837, '014, '016, or '334 patents.

54. Plaintiff filed the Related Action on April 10, 2017, within 45 days of its receipt of a notice letter dated February 28, 2017, concerning *inter alia*, ANDA No. 210023, the ANDA Product, and patents in the same patent family as the Patents in Suit. *See Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, 1:17-cv-00397-RGA, D.I. 15 at ¶¶ 57-66. Plaintiff received a second notice letter dated April 3, 2017, concerning ANDA No. 210023, the ANDA Product, and patents in the same patent family as the Patents in Suit. *Id.* Plaintiff amended its complaint in the Related Action on May 15, 2017. *Id.* Both notice letters were signed on behalf of Par Pharmaceutical by William McIntyre, identified as Senior Vice President, Regulatory Affairs. *Id.* at ¶ 60.

FIRST CLAIM FOR RELIEF
(Infringement of the '655 Patent)

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

56. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '655 patent.

57. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

58. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '655 patent.

59. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile

Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '655 patent.

60. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

61. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s and/or Par Sterile Products, LLC's infringement of one or more claims of the '655 patent.

62. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '655 patent.

63. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

64. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '655 patent.

65. 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 the ANDA Product—the methods of use of which are claimed in the '655 patent—before the expiration of the '655 patent.

66. 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 the ANDA Product before the expiration of the '655 patent.

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

68. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '655 patent was an act of infringement by Defendants of one or more claims of the '655 patent under 35 U.S.C. § 271(e)(2)(A).

69. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '655 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

70. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '655 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

71. Defendants knew of the existence of the '655 patent, as evidenced by Defendants' including in ANDA No. 210023 a paragraph IV certification specifically referencing the '655 patent.

72. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 '655 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 '655 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

73. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the '655 patent.

74. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the '655 patent.

75. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and

otherwise induce infringement of the ’655 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

76. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’655 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’655 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’655 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

77. Defendants’ infringement of the ’655 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 ’655 patent.

78. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’655 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 ’655 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF
(Infringement of the ’656 Patent)

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

80. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’656 patent.

81. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

82. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.’s infringement of one or more claims of the ’656 patent.

83. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’656 patent.

84. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

85. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.’s and/or Par Sterile Products, LLC’s infringement of one or more claims of the ’656 patent.

86. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’656 patent.

87. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

88. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '656 patent.

89. 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 the ANDA Product—the methods of use of which are claimed in the '656 patent—before the expiration of the '656 patent.

90. 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 the ANDA Product before the expiration of the '656 patent.

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

92. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '656 patent was an act of infringement by Defendants of one or more claims of the '656 patent under 35 U.S.C. § 271(e)(2)(A).

93. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '656 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

94. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '656 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

95. Defendants knew of the existence of the '656 patent, as evidenced by Defendants' including in ANDA No. 210023 a paragraph IV certification specifically referencing the '656 patent.

96. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 '656 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 '656 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

97. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers,

medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the ’656 patent.

98. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the ’656 patent.

99. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and otherwise induce infringement of the ’656 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

100. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’656 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’656 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’656 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

101. Defendants’ infringement of the ’656 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 ’656 patent.

102. At least as of the date of the Notice Letter, Defendants were aware of the existence of the '656 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 '656 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF
(Infringement of the '658 Patent)

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

104. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '658 patent.

105. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

106. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '658 patent.

107. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '658 patent.

108. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

109. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s and/or Par Sterile Products, LLC's infringement of one or more claims of the '658 patent.

110. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '658 patent.

111. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

112. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '658 patent.

113. 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 the ANDA Product—the methods of use of which are claimed in the '658 patent—before the expiration of the '658 patent.

114. 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 the ANDA Product before the expiration of the '658 patent.

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

116. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '658 patent was an act of infringement by Defendants of one or more claims of the '658 patent under 35 U.S.C. § 271(e)(2)(A).

117. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '658 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

118. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '658 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

119. Defendants knew of the existence of the '658 patent, as evidenced by Defendants' including in ANDA No. 210023 a paragraph IV certification specifically referencing the '658 patent.

120. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 '658 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 '658 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

121. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the '658 patent.

122. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the '658 patent.

123. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and otherwise induce infringement of the '658 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

124. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the

corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’658 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’658 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’658 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

125. Defendants’ infringement of the ’658 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 ’658 patent.

126. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’658 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 ’658 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

FOURTH CLAIM FOR RELIEF
(Infringement of the ’835 Patent)

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

128. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’835 patent.

129. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

130. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '835 patent.

131. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '835 patent.

132. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

133. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s and/or Par Sterile Products, LLC's infringement of one or more claims of the '835 patent.

134. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '835 patent.

135. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

136. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '835 patent.

137. 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 the ANDA Product—the methods of use of which are claimed in the '835 patent—before the expiration of the '835 patent.

138. 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 the ANDA Product before the expiration of the '835 patent.

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

140. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '835 patent was an act of infringement by Defendants of one or more claims of the '835 patent under 35 U.S.C. § 271(e)(2)(A).

141. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '835 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

142. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '835 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

143. Defendants knew of the existence of the ’835 patent, as evidenced by Defendants’ including in ANDA No. 210023 a paragraph IV certification specifically referencing the ’835 patent.

144. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 ’835 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 ’835 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

145. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the ’835 patent.

146. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions

included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the ’835 patent.

147. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and otherwise induce infringement of the ’835 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

148. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’835 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’835 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’835 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

149. Defendants’ infringement of the ’835 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 ’835 patent.

150. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’835 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 '835 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

FIFTH CLAIM FOR RELIEF
(Infringement of the '837 Patent)

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

152. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '837 patent.

153. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

154. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '837 patent.

155. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '837 patent.

156. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

157. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s and/or Par Sterile Products, LLC's infringement of one or more claims of the '837 patent.

158. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '837 patent.

159. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

160. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '837 patent.

161. 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 the ANDA Product—the methods of use of which are claimed in the '837 patent—before the expiration of the '837 patent.

162. 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 the ANDA Product before the expiration of the '837 patent.

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

164. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial

manufacture, use, or sale of the ANDA Product before the expiration of the '837 patent was an act of infringement by Defendants of one or more claims of the '837 patent under 35 U.S.C. § 271(e)(2)(A).

165. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '837 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

166. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '837 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

167. Defendants knew of the existence of the '837 patent, as evidenced by Defendants' including in ANDA No. 210023 a paragraph IV certification specifically referencing the '837 patent.

168. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 '837 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 '837 patent by, *e.g.*,

wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

169. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the ’837 patent.

170. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the ’837 patent.

171. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and otherwise induce infringement of the ’837 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

172. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’837 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’837 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the

methods of treatment claimed in the ’837 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

173. Defendants’ infringement of the ’837 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 ’837 patent.

174. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’837 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 ’837 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

SIXTH CLAIM FOR RELIEF
(Infringement of the ’014 Patent)

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

176. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’014 patent.

177. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

178. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.’s infringement of one or more claims of the ’014 patent.

179. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '014 patent.

180. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

181. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s and/or Par Sterile Products, LLC's infringement of one or more claims of the '014 patent.

182. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '014 patent.

183. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

184. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '014 patent.

185. 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 the ANDA Product—the methods of use of which are claimed in the '014 patent—before the expiration of the '014 patent.

186. 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 the ANDA Product before the expiration of the '014 patent.

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

188. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '014 patent was an act of infringement by Defendants of one or more claims of the '014 patent under 35 U.S.C. § 271(e)(2)(A).

189. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '014 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

190. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '014 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

191. Defendants knew of the existence of the '014 patent, as evidenced by Defendants' including in ANDA No. 210023 a paragraph IV certification specifically referencing the '014 patent.

192. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 '014 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 '014 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

193. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the '014 patent.

194. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the '014 patent.

195. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and

otherwise induce infringement of the ’014 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

196. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’014 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’014 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’014 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

197. Defendants’ infringement of the ’014 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 ’014 patent.

198. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’014 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 ’014 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

SEVENTH CLAIM FOR RELIEF
(Infringement of the ’016 Patent)

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

200. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’016 patent.

201. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

202. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.’s infringement of one or more claims of the ’016 patent.

203. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’016 patent.

204. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

205. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.’s and/or Par Sterile Products, LLC’s infringement of one or more claims of the ’016 patent.

206. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the ’016 patent.

207. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

208. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '016 patent.

209. 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 the ANDA Product—the methods of use of which are claimed in the '016 patent—before the expiration of the '016 patent.

210. 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 the ANDA Product before the expiration of the '016 patent.

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

212. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '016 patent was an act of infringement by Defendants of one or more claims of the '016 patent under 35 U.S.C. § 271(e)(2)(A).

213. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '016 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

214. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the ’016 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

215. Defendants knew of the existence of the ’016 patent, as evidenced by Defendants’ including in ANDA No. 210023 a paragraph IV certification specifically referencing the ’016 patent.

216. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 ’016 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 ’016 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

217. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers,

medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the ’016 patent.

218. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the ’016 patent.

219. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and otherwise induce infringement of the ’016 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

220. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’016 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’016 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’016 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

221. Defendants’ infringement of the ’016 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 ’016 patent.

222. At least as of the date of the Notice Letter, Defendants were aware of the existence of the '016 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 '016 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

EIGHTH CLAIM FOR RELIEF
(Infringement of the '334 Patent)

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

224. Upon information and belief, Par Sterile Products, LLC, the current owner of ANDA No. 210023, actively worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '334 patent.

225. Upon information and belief, Par Sterile Products, LLC will actively work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

226. Upon information and belief, Par Sterile Products, LLC is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '334 patent.

227. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '334 patent.

228. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. and/or Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

229. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s and/or Par Sterile Products, LLC's infringement of one or more claims of the '334 patent.

230. Upon information and belief, Par Pharmaceutical, Inc. actively directed, controlled, and/or worked in concert with Par Sterile Products, LLC to prepare, submit, and file ANDA No. 210023, and to include in ANDA No. 210023 a paragraph IV certification to the '334 patent.

231. Upon information and belief, Par Pharmaceutical, Inc. will actively direct, control, and/or work in concert with Par Sterile Products, LLC to commercially manufacture, use, sell, offer for sale, and/or import the ANDA Product.

232. Upon information and belief, Par Pharmaceutical, Inc. is jointly and severally liable for Par Sterile Products, LLC's infringement of one or more claims of the '334 patent.

233. 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 the ANDA Product—the methods of use of which are claimed in the '334 patent—before the expiration of the '334 patent.

234. 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 the ANDA Product before the expiration of the '334 patent.

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

236. The submission of ANDA No. 210023 and including in ANDA No. 210023 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '334 patent was an act of infringement by Defendants of one or more claims of the '334 patent under 35 U.S.C. § 271(e)(2)(A).

237. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product would indirectly infringe one or more claims of the '334 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

238. Upon information and belief, the sale or offer for sale of the ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '334 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

239. Defendants knew of the existence of the '334 patent, as evidenced by Defendants' including in ANDA No. 210023 a paragraph IV certification specifically referencing the '334 patent.

240. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the 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 '334 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 ’334 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

241. Upon information and belief, Defendants will include within the packaging of the ANDA Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the ’334 patent.

242. Upon information and belief, the use of the ANDA Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the ’334 patent.

243. Upon information and belief, through the labeling, package insert, and/or medication guide for the ANDA Product, Defendants will market the ANDA Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and otherwise induce infringement of the ’334 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.

244. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the ANDA Product and/or distributing the

corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’334 patent by third parties because: (i) the ANDA Product constitutes a material part of the methods of treatment claimed in the ’334 patent; (ii) Defendants know or should know that the ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’334 patent; and (iii) the ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

245. Defendants’ infringement of the ’334 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 ’334 patent.

246. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’334 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 ’334 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 the ANDA Product before the expiration of the ’655, ’656, ’658, ’835, ’837, ’014, ’016, and ’334 patents constitutes an act of infringement of the ’655, ’656, ’658, ’835, ’837, ’014, ’016, and ’334 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 the ANDA Product before the expiration of the ’655, ’656, ’658, ’835, ’837, ’014, ’016, and ’334 patents would directly and indirectly infringe the ’655, ’656, ’658, ’835, ’837, ’014, ’016, and ’334 patents;

C. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the ANDA Product shall be no earlier than the latest date of expiry of the ’655, ’656, ’658, ’835, ’837, ’014, ’016, and ’334 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 the ANDA Product prior to the date on which the ’655, ’656, ’658, ’835, ’837, ’014, ’016, and ’334 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 ’655, ’656, ’658, ’835, ’837, ’014, ’016, and ’334 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

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