IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE DEVELOPMENT LLC, SHIRE LLC, and SHIRE US INC.,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC., ACTAVIS LABORATORIES FL, INC., and TEVA PHARMACEUTICAL INDUSTRIES LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Shire Development LLC, Shire LLC, and Shire US Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants Teva Pharmaceuticals USA, Inc., Actavis Laboratories FL, Inc., and Teva Pharmaceutical Industries Limited (collectively, "Defendants"), herein allege 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. 6,913,768 ("the '768 patent"), 8,846,100 ("the '100 patent"), and 9,173,857 ("the '857 patent"), attached hereto as Exhibits A, B, and C, respectively (collectively, "the patents in suit").

THE PARTIES

2. Plaintiff Shire Development 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 300 Shire Way, Lexington, Massachusetts 02421.

3. Plaintiff Shire LLC is a limited liability company organized and existing under the laws of the State of Kentucky, and its principal place of business is located at 9200 Brookfield Ct., Suite 108, Florence, Kentucky 41042.

4. Plaintiff Shire US Inc. is a corporation organized and existing under the laws of the State of New Jersey, and its principal place of business is located at 300 Shire Way, Lexington, Massachusetts 02421.

5. Upon information and belief, defendant Teva Pharmaceutical Industries Limited ("Teva Ltd.") is a corporation organized and existing under the laws of Israel and its principal place of business is located at 5 Basel Street, P.O. Box 3190, Petach Tikva, 4951033, Israel.

6. Teva Ltd. is the largest generic drug maker in the world (in terms of annual revenue). Teva Ltd. operates through a global network of subsidiaries that it directly or indirectly owns and controls, including defendants Teva Pharmaceuticals USA, Inc. and Actavis Laboratories FL, Inc.

7. In its most recent SEC Form 20-F, Teva Ltd. stated that its "operations are conducted through a network of global subsidiaries . . . including commercial activities, pharmaceutical manufacturing sites, API [active pharmaceutical ingredient] sites and R&D centers." Teva Ltd.'s Form 20-F for the fiscal year ending December 31, 2016, at 46. Teva Ltd. lists Teva Pharmaceuticals USA, Inc. as one of its wholly-owned "principal operating subsidiaries" located in the United States. *Id*.

8. According to Teva Ltd., "key elements of [its] strategy" include "[d]riving continuous growth and improving profitability in [its] generics business" using its "wide-reaching commercial presence, as the market leader in the United States and a top-three leadership position in over 40 other countries." *Id*. at 23. As of December 31, 2016, Teva Ltd.'s

"generic pipeline" included "330 product applications awaiting FDA approval in the U.S.," where "70% of [these] pending applications include a paragraph IV patent challenge." *Id*.

9. In August 2016, Teva Ltd. completed an "acquisition of Allergan plc's worldwide generic pharmaceuticals business ('Actavis Generics')," *id*. at 24, that, upon information and belief, included the assumption by Teva Ltd., or one of its many subsidiaries/affiliates, of a controlling interest in Actavis Laboratories FL, Inc.

10. Upon information and belief, Teva Ltd. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the world, including throughout the United States and, more specifically, throughout the State of Delaware; (ii) in concert with and/or through its various subsidiaries, including defendants Teva Pharmaceuticals USA, Inc. and Actavis Laboratories FL, Inc., the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking U.S. Food and Drug Administration ("FDA") approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) in concert with and/or through its various subsidiaries, including defendants Teva Pharmaceuticals USA, Inc. and Actavis Laboratories FL, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

11. Upon information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

12. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd. Upon information and belief, Teva USA acts at the direction of, under the control of, and for the direct benefit of Teva Ltd., and is controlled and/or dominated by Teva Ltd. Upon

information and belief, Teva USA and Teva Ltd. have at least one officer and/or director in common.

13. Upon information and belief, Teva USA 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 or in concert with and/or through its parent and various subsidiaries, including defendants Teva Ltd. and Actavis Laboratories FL, Inc., 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 or in concert with and/or through its parent and various subsidiaries, including defendants Teva Ltd. and Actavis Laboratories FL, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

14. Upon information and belief, defendant Actavis Laboratories FL, Inc. ("Actavis FL") is a corporation organized and existing under the laws of the State of Florida, and its principal place of business is located at 4955 Orange Drive, Davie, Florida 33314.

15. Upon information and belief, Actavis FL is a wholly-owned subsidiary of Teva USA. Upon information and belief, Actavis FL acts at the direction of, under the control of, and for the direct benefit of Teva USA, and is controlled and/or dominated by Teva USA. Upon information and belief, Actavis FL and Teva USA have at least one officer and/or director in common. Upon information and belief, Actavis FL and Teva USA also share the use of common facilities.

16. Upon information and belief, Actavis FL 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 or in concert with and/or through

its parent and various affiliates, including defendants Teva Ltd. and Teva USA, 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 or in concert with and/or through its various affiliates, including defendants Teva Ltd. and Teva USA, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

17. Upon information and belief, Actavis FL specializes in the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products that are sold throughout the United States, including throughout the State of Delaware.

18. Upon information and belief, Defendants or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Teva USA is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sale of such generic pharmaceutical products.

JURISDICTION AND VENUE

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

20. This Court has personal jurisdiction over Teva USA because, upon information and belief, Teva USA is a Delaware corporation.

21. Teva USA 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. 210876 seeking approval to engage in the commercial manufacture, use, and/or sale of Mixed Salts of a Single-entity Amphetamine Extended-release Capsules, 12.5 mg, 25 mg, 37.5 mg, and 50 mg ("Defendants' ANDA Product") before the expiration of the '768, '100, and '857 patents throughout the United States, including in this judicial district.

22. Upon information and belief, Teva USA holds an active pharmacy wholesale license for the State of Delaware under License Nos. A4-0001468 and A4-0001447 and an active distributor/manufacturer license for controlled substances for the State of Delaware under License Nos. DM-0006546 and DM-0007115. Teva USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of Delaware's laws.

23. Upon information and belief, Teva Ltd., Teva USA, and Actavis FL are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of generic drug products throughout the United States, including throughout the State of Delaware.

24. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, upon information and belief, Teva Ltd., itself or in concert with and/or through its various subsidiaries, 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 Teva Ltd. has continuous and systematic contacts with the State of Delaware.

25. Upon information and belief, Teva USA's tortious acts of preparing and filing ANDA No. 210876 and directing notice of its ANDA submission to Plaintiffs were performed at the direction of, with the authorization of, and with the cooperation, participation, assistance and, at least in part, the benefit of Teva Ltd. These are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Defendants' ANDA Product before the expiration of the '768, '100, and '857 patents throughout the United States, including in this judicial district. Moreover, because Plaintiff Shire Development LLC is a Delaware limited liability company, these injuries

and consequences are suffered in Delaware. Therefore, Teva Ltd. and Teva USA together purposefully directed their activities towards the State of Delaware. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Teva Ltd. and Teva USA reasonably anticipated being sued in Delaware.

26. Therefore, this Court has personal jurisdiction over Teva Ltd. because, *inter alia*: (a) Teva Ltd. has purposefully directed its activities and the activities of Teva USA, its wholly-owned subsidiary and a Delaware corporation, at residents and corporate entities within the State of Delaware; (b) the claims set forth herein as to Teva Ltd. arise out of or relate to those activities; (c) Teva Ltd.'s contacts with the State of Delaware (direct and/or indirect) are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Teva Ltd.

27. This Court also has personal jurisdiction over Teva Ltd. and Teva USA because Teva Ltd. and Teva USA have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, No. 17-0249 (GMS) (D. Del.) (Teva USA and Teva Ltd. filed complaint for patent infringement); *Teva Pharms. USA, Inc. v. Doctor Reddy's Labs., Ltd.*, No. 16-1267 (GMS) (D. Del.) (same); *Teva Pharms. USA, Inc. v. Biocon Ltd.*, No. 16-0278 (GMS) (D. Del.) (same); *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 15-0306 (GMS) (D. Del.) (same); *Teva Pharms. USA, Inc. v. Amneal Pharms. LLC.*, No. 15-0124 (GMS) (D. Del.) (same); *Teva Pharms. USA, Inc. v. Synthon Pharms., Inc.*, No. 14-1419 (GMS) (D. Del.) (same); *Orexo AB v. Actavis Elizabeth LLC*, No. 17-0758 (GMS) (D. Del.) (Teva USA and Teva Ltd. did not contest jurisdiction); *Momenta*

Pharms., Inc. v. Teva Pharms. USA, Inc., No. 17-0109 (GMS) (D. Del.) (same); *Amneal Pharms. LLC v. Teva Pharms. USA, Inc*., No. 17-0074 (GMS) (D. Del.) (same); *Onyx Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. 17-0449 (LPS) (D. Del) (Teva USA filed counterclaims and did not contest jurisdiction); *Bayer HealthCare, LLC v. Teva Pharms. USA, Inc.*, No. 16-1220 (D. Del.) (same).

28. Alternatively, this Court has personal jurisdiction over Teva Ltd. under Fed. R. Civ. P. 4(k)(2).

29. This Court has personal jurisdiction over Actavis FL because, *inter alia*, upon information and belief, Actavis FL, itself or in concert with and/or through its various subsidiaries, 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 Actavis FL has continuous and systematic contacts with Delaware.

30. Upon information and belief, Teva USA's tortious acts of preparing and filing ANDA No. 210876 and directing notice of its ANDA submission to Plaintiffs were performed at the direction of, with the authorization of, and with the cooperation, participation, assistance and, at least in part, the benefit of Actavis FL. These are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Defendants' ANDA Product before the expiration of the '768, '100, and '857 patents throughout the United States, including in this judicial district. Moreover, because Plaintiff Shire Development LLC is a Delaware limited liability company, these injuries and consequences are suffered in Delaware. Therefore, Actavis FL and Teva USA together purposefully directed their activities towards the State of Delaware. Because defending against

an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Actavis FL and Teva USA reasonably anticipated being sued in Delaware.

31. Actavis FL has previously submitted to the jurisdiction of this Court and has availed itself of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in civil actions initiated in this jurisdiction. *See*, *e.g.*, Watson Labs., Inc.'s Answer, Affirmative Defenses, and Counterclaims at 4, *Forest Labs., Inc., et al. v. Apotex Corp. & Watson Labs., Inc. – Florida, et al.*, No. 14-200 (LPS) (D. Del. Apr. 22, 2014) (D.I. 22) (consenting to jurisdiction and venue and asserting counterclaims) and Notice of Name Change, No. 14-200 (LPS) (D. Del. June 6, 2014) (D.I. 48) (stating that Watson Laboratories, Inc. – Florida changed its name to Actavis Laboratories FL, Inc. on April 21, 2014); Stipulation and Order Dismissing Without Prejudice Defendants Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc., and Amending Caption to Reflect Same, *Recro Gainesville LLC v. Actavis Labs. FL, Inc.*, No. 14-1118 (GMS) (D. Del. Sept. 23, 2014) (D.I. 11) (consenting to jurisdiction and venue) and Actavis Laboratories FL, Inc.'s Answer, Separate Defenses, and Counterclaims to Plaintiff's Complaint, No. 14-1118 (GMS) (D. Del. Oct. 24, 2014) (D.I. 14) (consenting to jurisdiction and venue and asserting counterclaims); Actavis Laboratories FL, Inc.'s Answer, Separate Defenses, and Counterclaims to Plaintiff's Complaint, *Recro Gainesville LLC v. Actavis Labs FL, Inc.*, No. 15-413 (GMS) (D. Del. June 16, 2015) (D.I. 6) (consenting to jurisdiction and venue and asserting counterclaims); Actavis Laboratories FL, Inc.'s Answer and Affirmative Defenses to Third Amended Complaint, *Pernix Ireland Pain Ltd. v. Actavis Labs. FL, Inc.*, No. 16-138 (GMS) (D. Del. Nov. 30, 2016) (D.I. 59) (consenting to jurisdiction and venue and asserting counterclaims); Actavis Laboratories FL, Inc.'s Answer, Affirmative Defenses, and Counterclaims, *Purdue Pharma L.P. v. Alvogen Pine Brook LLC & Actavis Laboratories FL,*

Inc., No. 15-687 (GMS) (consolidated) (D. Del. Oct. 20, 2017) (D.I. 253, 254, 255) (consenting to jurisdiction and venue and asserting counterclaims to complaints filed in C.A. Nos. 17-677 (GMS), 17-1131 (GMS), and 17-1369 (GMS).

32. Therefore, this Court has personal jurisdiction over Actavis FL because, *inter alia*: (a) Actavis FL has purposefully directed its activities and the activities of Teva USA, its corporate parent and a Delaware corporation, at residents and corporate entities within the State of Delaware; (b) the claims set forth herein as to Actavis FL arise out of or relate to those activities; (c) Actavis FL's contacts with the State of Delaware (direct and/or indirect) are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Actavis FL.

33. Upon information and belief, if ANDA No. 210876 is approved, Defendants' ANDA Product will 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.

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

BACKGROUND FACTS

35. Plaintiff Shire Development LLC owns New Drug Application No. 022063 for mixed salts of a single-entity amphetamine product, extended-release capsules 12.5 mg, 25 mg, 37.5 mg, and 50 mg, which was approved on June 20, 2017 and is marketed under the name MYDAYIS®. MYDAYIS® is supplied as 12.5 mg, 25 mg, 37.5 mg, and 50 mg strength capsules for oral administration that contain three types of drug-releasing beads, an immediate release and two different types of delayed release beads.

36. MYDAYIS® (mixed salts of a single-entity amphetamine product) is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older.

37. The '768 patent, entitled "Sustained Release Delivery of Amphetamine Salts," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 5, 2005. Plaintiff Shire LLC owns the '768 patent.

38. The '100 patent, entitled "Controlled Dose Drug Delivery System" was duly and legally issued by the USPTO on September 30, 2014. Plaintiff Shire LLC owns the '100 patent.

39. The '857 patent, entitled "Controlled Dose Drug Delivery System" was duly and legally issued by the USPTO on November 3, 2015. Plaintiff Shire LLC owns the '857 patent.

40. Pursuant to 21 U.S.C. § 355(b)(1), the '768, '100, and '857 patents are listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering MYDAYIS®.

41. Upon information and belief, Defendants prepared, submitted, and filed ANDA No. 210876 under § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)), seeking approval from the FDA to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product. Defendants included in ANDA No. 210876 a "paragraph IV" certification seeking such approval before the expiration of the '768, '100, and '857 patents. Upon information and belief, upon approval of ANDA No. 210876, Defendants will be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product.

42. 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)(7) 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)(7)(i)-(ii).

43. Plaintiffs received a letter dated October 12, 2017 that was purportedly sent pursuant to § 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B) regarding Defendants' ANDA Product and the '768, '100, and '857 patents (the "Notice Letter").

44. The Notice Letter is provided on letterhead branded with the general logo "Actavis." The return address on the letterhead indicates that the letter is from Actavis FL located at 2945 W. Corporate Lakes Blvd., Building E, Suite B, Weston, Florida 33331. The website contact on the letterhead is www.actavis.com. The Notice Letter was signed by Janet Vaughn, identified as Senior Director, Regulatory Affairs, on behalf of Teva USA. Upon information and belief, Ms. Vaughn works at a facility located in Weston, Florida used jointly by Teva USA and Actavis FL personnel.

45. The Notice Letter states that it was sent by "Teva Pharmaceuticals USA, Inc. ("Teva USA") . . . to Shire Development LLC ("Shire") as the apparent holder of approved New Drug Application ("NDA") No. 022063 for Mydayis®, (mixed salts of a single-entity amphetamine product) extended release capsules," as well as "Shire LLC ("Shire"), as the record owner of U.S. Patent Nos. 6,913,768, 8,846,100, and 9,173,857."

46. Plaintiff Shire US Inc. markets, distributes, and sells MYDAYIS®.

47. The Notice Letter does not include any invalidity contentions with respect to any claim of the ’768 patent.

48. The Notice Letter does not include any unenforceability contentions with respect to any claim of the patents in suit.

49. The Notice Letter included an Offer of Confidential Access (“OCA”) purportedly pursuant to 21 U.S.C. § 355(j)(5)(C) and which Defendants proposed be “governed by the laws of the State of Florida.” Plaintiffs objected to certain provisions of the OCA as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III). By letter dated November 3, 2017, Plaintiffs proposed revisions that comport with provisions that “would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.” *See* 21 U.S.C. § 355. By letter dated November 6, 2017, Defendants stated that Plaintiffs’ proposed OCA revisions are “not acceptable” and that they “believe [the parties] are at an impasse.”

FIRST CLAIM FOR RELIEF
(Defendants’ Infringement of the ’768 Patent)

50. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

51. Upon information and belief, Teva Ltd. and Actavis FL actively worked in concert with Teva USA to prepare, submit, and file ANDA No. 210876 with a paragraph IV certification to the ’768 patent.

52. Upon information and belief, Teva Ltd. and Actavis FL will actively work in concert with Teva USA to commercially manufacture, use, sell, offer for sale, and/or import Defendants’ ANDA Product.

53. Upon information and belief, Teva Ltd. and Actavis FL are jointly and severally liable for Teva USA's infringement of one or more claims of the '768 patent.

54. Upon information and belief, Defendants have submitted ANDA No. 210876 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product—a product claimed and the methods of treatment of which are claimed in the '768 patent—before the expiration of the '768 patent.

55. Upon information and belief, Defendants included in ANDA No. 210876 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '768 patent.

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

57. The submission of ANDA No. 210876 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '768 patent was an act of infringement by Defendants of one or more claims of the '768 patent under 35 U.S.C. § 271(e)(2)(A).

58. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more claims of the '768 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

59. Upon information and belief, the sale or offer for sale of Defendants' ANDA Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '768 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

60. Defendants knew of the existence of the ’768 patent, as evidenced by Defendants’ filing of ANDA No. 210876 with a paragraph IV certification specifically referencing the ’768 patent.

61. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants’ ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (*e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the ’768 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 ’768 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

62. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants’ ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’768 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’768 patent; (ii) Defendants know or should know that Defendants’ ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’768 patent; and (iii) Defendants’

ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

63. Upon information and belief, by knowingly inducing, encouraging, aiding, abetting, contributing to, and/or participating in Teva USA's commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product, Teva Ltd. will induce and/or contribute to Teva USA's infringement of the '768 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

64. Upon information and belief, by knowingly inducing, encouraging, aiding, abetting, directing, controlling, contributing to, and/or participating in Teva USA's commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product, Actavis FL will induce and/or contribute to Teva USA's infringement of the '768 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

65. Defendants' infringement of the '768 patent will cause Plaintiffs to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Plaintiffs have no adequate remedy at law and, thus, preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '768 patent.

66. At least as of the date of the Notice Letter, Defendants were aware of the existence of the '768 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 '768 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF
(Defendants' Infringement of the '100 Patent)

67. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

68. Upon information and belief, Teva Ltd. and Actavis FL actively worked in concert with Teva USA to prepare, submit, and file ANDA No. 210876 with a paragraph IV certification to the '100 patent.

69. Upon information and belief, Teva Ltd. and Actavis FL will actively work in concert with Teva USA to commercially manufacture, use, sell, offer for sale, and/or import Defendants' ANDA Product.

70. Upon information and belief, Teva Ltd. and Actavis FL are jointly and severally liable for Teva USA's infringement of one or more claims of the '100 patent.

71. Upon information and belief, Defendants have submitted ANDA No. 210876 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product—a product claimed in the '100 patent—before the expiration of the '100 patent.

72. Upon information and belief, Defendants included in ANDA No. 210876 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '100 patent.

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

74. The submission of ANDA No. 210876 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of

Defendants' ANDA Product before the expiration of the '100 patent was an act of infringement by Defendants of one or more claims of the '100 patent under 35 U.S.C. § 271(e)(2)(A).

75. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' ANDA Product would infringe one or more claims of the '100 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

76. Defendants knew of the existence of the '100 patent, as evidenced by Defendants' filing of ANDA No. 210876 with a paragraph IV certification specifically referencing the '100 patent.

77. Upon information and belief, by knowingly inducing, encouraging, aiding, abetting, contributing to, and/or participating in Teva USA's commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product, Teva Ltd. will induce and/or contribute to Teva USA's infringement of the '100 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

78. Upon information and belief, by knowingly inducing, encouraging, aiding, abetting, directing, controlling, contributing to, and/or participating in Teva USA's commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product, Actavis FL will induce and/or contribute to Teva USA's infringement of the '100 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

79. Defendants' infringement of the '100 patent will cause Plaintiffs to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Plaintiffs have no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '100 patent.

80. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’100 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 ’100 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF
(Defendants’ Infringement of the ’857 Patent)

81. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

82. Upon information and belief, Teva Ltd. and Actavis FL actively worked in concert with Teva USA to prepare, submit, and file ANDA No. 210876 with a paragraph IV certification to the ’857 patent.

83. Upon information and belief, Teva Ltd. and Actavis FL will actively work in concert with Teva USA to commercially manufacture, use, sell, offer for sale, and/or import Defendants’ ANDA Product.

84. Upon information and belief, Teva Ltd. and Actavis FL are jointly and severally liable for Teva USA’s infringement of one or more claims of the ’857 patent.

85. Upon information and belief, Defendants have submitted ANDA No. 210876 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants’ ANDA Product—a product claimed and the methods of treatment of which are claimed in the ’857 patent—before the expiration of the ’857 patent.

86. Upon information and belief, Defendants included in ANDA No. 210876 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendants’ ANDA Product before the expiration of the ’857 patent.

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

88. The submission of ANDA No. 210876 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '857 patent was an act of infringement by Defendants of one or more claims of the '857 patent under 35 U.S.C. § 271(e)(2)(A).

89. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' ANDA Product would infringe directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '857 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

90. Defendants knew of the existence of the '857 patent, as evidenced by Defendants' filing of ANDA No. 210876 with a paragraph IV certification specifically referencing the '857 patent.

91. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (*e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '857 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 ’857 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

92. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants’ ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the ’857 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’857 patent; (ii) Defendants know or should know that Defendants’ ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’857 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

93. Defendants’ infringement of the ’857 patent will cause Plaintiffs to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court. Plaintiffs have no adequate remedy at law and, thus, preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’857 patent.

94. At least as of the date of the Notice Letter, Defendants were aware of the existence of the ’857 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 ’857 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs 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. 210876 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '768, '100, and '857 patents constitutes an act of infringement of the '768, '100, and '857 patents by Defendants;

B. A Judgment declaring that, pursuant to 35 U.S.C. §§ 271(a), (b), and (c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Defendants' ANDA Product before the expiration of the '768, '100, and '857 patents would directly and indirectly infringe the '768, '100, and '857 patents;

C. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA Product shall be no earlier than the expiration dates of the '768, '100, and '857 patents, including any regulatory extensions;

D. Injunctive relief pursuant to 35 U.S.C. § 283 precluding Defendants from manufacturing, using, selling, offering to sell, or importing into the United States Defendants' ANDA Product prior to the expiration dates of the '768, '100, and '857 patents, including any regulatory extensions;

E. Injunctive relief pursuant to 35 U.S.C. § 271(e)(4)(B) precluding Defendants from manufacturing, using, selling, offering to sell, or importing Defendants' ANDA Product prior to the expiration dates of the '768, '100, and '857 patents, including any regulatory extensions;

F. 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. 210876 that infringes the '768, '100, and '857 patents;

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

H. A Judgment awarding Plaintiffs their costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

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

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