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. _____
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Shire Development LLC, Shire LLC, and Shire US Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendant Impax Laboratories, Inc. ("Impax" or "Defendant"), 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 Impax is a corporation organized and existing under the laws of Delaware, and its principal place of business is located at 30831 Huntwood Avenue, Hayward, California 94544.

6. Upon information and belief, Impax 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) 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) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Impax because, upon information and belief, Impax is incorporated under the laws of the State of Delaware.

9. Impax 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. 211235 seeking approval to engage in the commercial manufacture, use, and/or sale of Amphetamine Mixed Salts Extended Release Oral Capsules 12.5 mg, 25 mg, 37.5 mg, and 50

mg ("Defendant's ANDA Product") before the expiration of the '768, '100, and '857 patents throughout the United States, including in this judicial district.

10. Upon information and belief, Impax's tortious acts of preparing and filing ANDA No. 211235 and directing notice of its ANDA submission to Plaintiffs 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 Defendant's 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, Impax purposefully directed its 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, Impax reasonably anticipates being sued in Delaware.

11. Therefore, this Court has personal jurisdiction over Impax because, *inter alia*: (a) Impax has purposefully directed its activities at residents and corporate entities within the State of Delaware; (b) the claims set forth herein as to Impax arise out of or relate to those activities; (c) Impax'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 Impax.

12. Upon information and belief, if ANDA No. 211235 is approved, Defendant's ANDA Product will be marketed and distributed by Defendant 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.

13. Venue is proper in this judicial district under 28 U.S.C. § 1400(b).

BACKGROUND FACTS

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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®.

20. Upon information and belief, Defendant prepared, submitted, and filed ANDA No. 211235 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 Defendant’s ANDA Product. Defendant included in ANDA No. 211235 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. 211235, Defendant will be involved in the manufacture, use, sale, offer for sale, and/or importation of Defendant's ANDA Product.

21. 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).

22. Plaintiffs received a letter dated March 5, 2018 that was purportedly sent pursuant to § 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B) regarding Defendant's ANDA Product and the '768, '100, and '857 patents (the "Notice Letter").

23. The Notice Letter states that it was sent "on behalf of Impax to provide notice . . . to (i) Shire Development LLC ("Shire") as holder of approved New Drug Application ("NDA") No. 022063 for Mydayis®, (Amphetamine Mixed Salts) Extended Release Oral Capsules, 12.5 mg, 25 mg, 37.5 mg, and 50 mg, according to the records of the U.S. Food and Drug Administration ("FDA"); and (ii) "Shire LLC ("Shire") as owner of U.S. Patent Nos. 6,913,768 ("the '768 patent"); 8,846,100 ("the '100 patent"); and 9,173,857 ("the '857 patent") according to the assignments records of the United States Patent and Trademark Office ("USPTO")."

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

25. The Notice Letter does not include a factual or legal basis for any invalidity contention with respect to any claim of the patents in suit.

26. The Notice Letter does not include a factual or legal basis for any unenforceability contention with respect to any claim of the patents in suit.

27. The Notice Letter included an Offer of Confidential Access ("OCA") purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Plaintiffs objected to certain provisions of the OCA as unduly restrictive, unnecessary, and inconsistent with 21 U.S.C. § 355(j)(5)(C)(i)(III). By letter dated March 23, 2018, Plaintiffs proposed OCA 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 April 11, 2018, Defendant stated that it "cannot agree" to Plaintiffs' proposed OCA revisions and that "Shire and Impax appear to be too far apart on their positions regarding the terms of the OCA to allow the parties to reach agreement."

FIRST CLAIM FOR RELIEF
(Defendant's Infringement of the '768 Patent)

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

29. Upon information and belief, Defendant has submitted ANDA No. 211235 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's 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.

30. Upon information and belief, Defendant included in ANDA No. 211235 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Product before the expiration of the '768 patent.

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

32. The submission of ANDA No. 211235 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Product before the expiration of the '768 patent was an act of infringement by Defendant of one or more claims of the '768 patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's 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).

34. Upon information and belief, the sale or offer for sale of Defendant's ANDA Product by Defendant 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).

35. Defendant knew of the existence of the '768 patent, as evidenced by Defendant's filing of ANDA No. 211235 with a paragraph IV certification specifically referencing the '768 patent.

36. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant 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, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its 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.

37. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to infringement of claims of the ’768 patent by third parties because: (i) Defendant’s ANDA Product constitutes a material part of the methods of treatment claimed in the ’768 patent; (ii) Defendant knows or should know that Defendant’s ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’768 patent; and (iii) Defendant’s ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

38. Defendant’s infringement of the ’768 patent will cause Plaintiffs to suffer irreparable harm. Defendant’s 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 Defendant from infringing the ’768 patent.

39. At least as of the date of the Notice Letter, Defendant was 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 it 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
(Defendant's Infringement of the '100 Patent)

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

41. Upon information and belief, Defendant has submitted ANDA No. 211235 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Product—a product claimed in the '100 patent—before the expiration of the '100 patent.

42. Upon information and belief, Defendant included in ANDA No. 211235 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Product before the expiration of the '100 patent.

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

44. The submission of ANDA No. 211235 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Product before the expiration of the '100 patent was an act of infringement by Defendant of one or more claims of the '100 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's 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).

46. Defendant knew of the existence of the '100 patent, as evidenced by Defendant's filing of ANDA No. 211235 with a paragraph IV certification specifically referencing the '100 patent.

47. Defendant's infringement of the '100 patent will cause Plaintiffs to suffer irreparable harm. Defendant's 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 Defendant from infringing the '100 patent.

48. At least as of the date of the Notice Letter, Defendant was 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 it 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
(Defendant's Infringement of the '857 Patent)

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

50. Upon information and belief, Defendant has submitted ANDA No. 211235 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's 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.

51. Upon information and belief, Defendant included in ANDA No. 211235 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Product before the expiration of the '857 patent.

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

53. The submission of ANDA No. 211235 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Product before the expiration of the '857 patent was an act of infringement by Defendant of one or more claims of the '857 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's 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).

55. Defendant knew of the existence of the '857 patent, as evidenced by Defendant's filing of ANDA No. 211235 with a paragraph IV certification specifically referencing the '857 patent.

56. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant 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, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its 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.

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

58. Defendant’s infringement of the ’857 patent will cause Plaintiffs to suffer irreparable harm. Defendant’s 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 Defendant from infringing the ’857 patent.

59. At least as of the date of the Notice Letter, Defendant was 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 it 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 request 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. 211235 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Defendant’s 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 Defendant;

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 Defendant’s 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 Defendant’s 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 Defendant from manufacturing, using, selling, offering to sell, or importing into the United States Defendant’s 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 Defendant from manufacturing, using, selling, offering to sell, or importing Defendant’s 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 Defendant commercially manufactures, uses, sells, offers for sale, and/or imports any product that is the subject of ANDA No. 211235 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Karen Jacobs (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

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

April 13, 2018