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. _____
RHODES PHARMACEUTICALS L.P.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Shire Development LLC, Shire LLC, and Shire US Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendant Rhodes Pharmaceuticals L.P. ("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. RE41,148 ("the '148 patent") and RE42,096 ("the '096 patent"), attached hereto as Exhibits A and B, 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 Rhodes Pharmaceuticals L.P. is a limited partnership organized and existing under the laws of the State of Delaware, having a principal place of business at 498 Washington Street, Coventry, Rhode Island 02816.

6. Upon information and belief, Defendant 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 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 Defendant because Defendant is a limited partnership organized and existing under the laws of the State of Delaware.

9. This Court also has personal jurisdiction over Defendant because Defendant 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. 210651 seeking approval

to engage in the commercial manufacture, use, and/or sale of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate extended-release capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg. ("Defendant's ANDA Product") before the expiration of the patents in suit throughout the United States, including in this judicial district.

10. This Court also has personal jurisdiction over Defendant because upon information and belief, Defendant, itself or through its various partnerships, 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 Defendant has continuous and systematic contacts with the State of Delaware.

11. This Court also has personal jurisdiction over Defendant because Defendant has previously availed itself of this Court by initiating a patent infringement lawsuit in this jurisdiction. *See, e.g.*, *Rhodes Pharm. L.P. v. Indivior Inc.*, No. 1:16cv1308-SLR.

12. Therefore, this Court has personal jurisdiction over Defendant because, *inter alia*: (a) Defendant is a limited partnership organized and existing under the laws of the State of Delaware; (b) Defendant has purposefully directed its activities at residents and corporate entities within the State of Delaware; (c) Defendant'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 Defendant.

13. Upon information and belief, if ANDA No. 210651 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.

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

BACKGROUND FACTS

15. Plaintiff Shire Development LLC owns New Drug Application No. 021303 for dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate extended-release capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg, which is marketed under the name ADDERALL XR®. The 10 mg, 20 mg, and 30 mg strengths of ADDERALL XR® were approved on October 11, 2001 and the 5 mg, 15 mg, and 25 mg strengths of ADDERALL XR® were approved on May 22, 2002. ADDERALL XR® is indicated for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD"). Plaintiff Shire US Inc. markets, distributes, and sells ADDERALL XR®.

16. The '148 patent, entitled "Oral Pulsed Dose Drug Delivery System," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 23, 2010. Plaintiff Shire LLC owns the '148 patent.

17. The '096 patent, entitled "Oral Pulsed Dose Drug Delivery System" was duly and legally issued by the USPTO on February 1, 2011. Plaintiff Shire LLC owns the '096 patent.

18. 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 ADDERALL XR®.

19. Upon information and belief, Defendant prepared, submitted, and filed ANDA No. 210651 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. 210651 a "paragraph IV" certification seeking such approval before the expiration of the patents in suit. Upon information and belief, if the FDA approves

ANDA No. 210651, Defendant will manufacture, use, sell, offer for sale, and/or import Defendant's ANDA Product.

20. 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).

21. Plaintiffs received a letter dated November 9, 2017 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 patents in suit (the "Notice Letter").

22. The Notice Letter was signed and sent on Defendant's behalf by John L. Abramic, a partner of the law firm Steptoe & Johnson LLP.

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

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

25. The Notice Letter included an Offer of Confidential Access ("OCA") purportedly made pursuant to 21 U.S.C. § 355(j)(5)(C). 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 December 5, 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. As of the date of this Complaint, the parties have not reached agreement on OCA terms.

FIRST CLAIM FOR RELIEF
(Defendant's Infringement of the '148 Patent)

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

27. Upon information and belief, Defendant prepared, submitted, and filed ANDA No. 210651 with a paragraph IV certification to the '148 patent.

28. Upon information and belief, Defendant has submitted ANDA No. 210651 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 '148 patent—before the expiration of the '148 patent.

29. Upon information and belief, Defendant included in ANDA No. 210651 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 '148 patent.

30. 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.

31. The submission of ANDA No. 210651 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 '148 patent was an act of infringement by Defendant of one or more claims of the '148 patent under 35 U.S.C. § 271(e)(2)(A).

32. 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, literally and/or under the doctrine of equivalents, directly and/or indirectly, one or more claims of the '148 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

33. 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 '148 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

34. Defendant knew of the existence of the '148 patent, as evidenced by Defendant's filing of ANDA No. 210651 with a paragraph IV certification specifically referencing the '148 patent.

35. 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 '148 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 '148 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists. Upon information and belief, Defendant knows or should know that Defendant's ANDA Product will be made for uses that directly infringe the claims of the '148 patent and that Defendant's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

36. Defendant's infringement of the '148 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 '148 patent.

37. At least as of the date of the Notice Letter, Defendant was aware of the existence of the '148 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 '148 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF
(Defendant's Infringement of the '096 Patent)

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

39. Upon information and belief, Defendant prepared, submitted, and filed ANDA No. 210651 with a paragraph IV certification to the '096 patent.

40. Upon information and belief, Defendant has submitted ANDA No. 210651 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 '096 patent—before the expiration of the '096 patent.

41. Upon information and belief, Defendant included in ANDA No. 210651 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 '096 patent.

42. 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.

43. The submission of ANDA No. 210651 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 '096 patent was an act of infringement by Defendant of one or more claims of the '096 patent under 35 U.S.C. § 271(e)(2)(A).

44. 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, literally and/or under the doctrine of equivalents, directly and/or indirectly, one or more claims of the '096 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

45. 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 '096 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

46. Defendant knew of the existence of the '096 patent, as evidenced by Defendant's filing of ANDA No. 210651 with a paragraph IV certification specifically referencing the '096 patent.

47. 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 '096 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 '096 patent by, *e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists. Upon information and belief, Defendant knows or should know that Defendant's ANDA Product will be made for uses that directly infringe the claims of the '096 patent and that Defendant's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

48. Defendant's infringement of the '096 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 '096 patent.

49. At least as of the date of the Notice Letter, Defendant was aware of the existence of the '096 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 '096 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. 210651 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 patents in suit constitutes an act of infringement of the patents in suit 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 patents in suit would directly and indirectly infringe the patents in suit;

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 patents in suit, 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 patents in suit, 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 patents in suit, 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. 210651 that infringes the patents in suit;

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.

RICHARDS, LAYTON & FINGER, PA

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