

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

SHIRE LLC,

Plaintiff,

v.

NEOS THERAPEUTICS, INC.,

Defendant.

Civil Action No. 3:13-CV-1452

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Shire LLC (“Shire”), by its attorneys, for its Complaint, alleges as follows:

Nature of the Action

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Shire seeks injunctive relief precluding infringement, attorneys’ fees, and any other relief as the Court deems just and proper.

Parties

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

3. Upon information and belief, defendant Neos Therapeutics, Inc. (“Neos”) is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 2940 North Highway 360 #100, Grand Prairie, TX 75050.

Jurisdiction and Venue

4. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, for infringement of U.S. Reissued Patent Nos. RE 42,096 (“the ’096 Patent”) and RE 41,148 (“the ’148 Patent”). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1338 (action arising under any act of Congress relating to patents).

5. Neos is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, operating, conducting and transacting business in Texas and contracting to supply goods and services in Texas. For example, upon information and belief, Neos has its principal place of business at 2940 North Highway 360 #100, Grand Prairie, TX 75050, is registered to do business in Texas, and has appointed a registered agent in Texas. Upon further information and belief, Neos rents, owns, and operates facilities in Texas that are engaged in the manufacture, research and development of pharmaceuticals. Also, upon information and belief, Neos employs and recruits Texas residents to work at Neos’s principal place of business in Grand Prairie, TX.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Shire’s Patents and Approved ADDERALL XR[®] Drug

7. Shire, through a corporate affiliate, makes and sells ADDERALL XR[®], a widely used drug that helps to control symptoms of Attention Deficit Hyperactivity Disorder (“ADHD”). ADHD is a condition that makes it difficult for adults and children to focus their attention, control their actions, and remain still.

8. The asserted ’096 and ’148 Patents cover ADDERALL XR[®].

9. The ’096 Patent, entitled “Oral Pulsed Drug Delivery System,” is a reissue of U.S. Patent. No. 6,322,819 (“the ’819 Patent”), which issued on November 27, 2001. A true and

correct copy of the '096 Patent is attached as Exhibit A. The '096 Patent discloses and claims, *inter alia*, a pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts. Plaintiff Shire owns the '096 Patent.

10. The '148 Patent, entitled "Oral Pulsed Drug Delivery System," is a reissue of U.S. Patent No. 6,605,300 ("the '300 Patent"), which issued on August 12, 2003. A true and correct copy of the '148 Patent is attached as Exhibit B. The '148 Patent discloses and claims, *inter alia*, a pharmaceutical preparation for the delivery of mixed amphetamine salts. Plaintiff Shire owns the '148 Patent.

11. Shire Development Inc., an affiliate of Shire, holds New Drug Application ("NDA") No. 21-303, under which the United States Food and Drug Administration ("FDA") has given Shire approval to make and sell ADDERALL XR[®] for the treatment of ADHD. FDA has listed the '096, '148, '819, and '300 Patents in the Orange Book—a publication formally known as Approved Drug Products With Therapeutic Equivalence Evaluations—under the listing for NDA No. 21-303 because those patents cover ADDERALL XR[®].

The Neos NDA

12. Upon information and belief, Neos submitted or caused to be submitted, a new drug application, NDA No. 204326 ("Neos NDA"), under 21 U.S.C. § 355(b)(2) (section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act) seeking approval to engage in the commercial manufacture, use, or sale of the product(s) described therein.

13. Upon information and belief, on or about February 26, 2013, Neos sent Shire a "Notice of Certification under Section 505(b)(3) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. §314.52" ("the Notice Letter"). The Notice Letter represented that Neos had submitted to FDA the Neos NDA and a purported Paragraph IV Certification to obtain approval

to engage in the commercial manufacture, use, or sale of the product described in the Neos NDA before the expiration of the patents listed in the Orange Book for NDA No. 21-303. Hence, Neos's purpose in submitting the Neos NDA is to market its products described therein before the expiration of the '096 and '148 Patents.

14. Upon information and belief, Neos has assisted with, participated in, provided material support to the preparation and submission of, and intends to support the further prosecution of the Neos NDA.

15. Upon information and belief, if FDA approves the Neos NDA, Neos will manufacture, offer for sale, or sell the products described in the Neos NDA.

16. Upon information and belief, if FDA approves the Neos NDA, Neos will induce or contribute to the manufacture, offer for sale, or sale of the products described in the Neos NDA.

Count I: Patent Infringement of the '096 Patent

17. Shire restates, realleges, and incorporates by reference Paragraph 1–16 of this Complaint as if set forth here in their entirety.

18. Upon information and belief, Neos has submitted or caused to be submitted the Neos NDA and continues to seek approval of the Neos NDA from FDA.

19. Neos has infringed the '096 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting the Neos NDA with a Paragraph IV Certification and seeking FDA approval of the Neos NDA prior to the expiration of the '096 Patent.

20. Neos's commercial manufacture, use, sale, offer for sale, or importation into the United States of the purported drug product that is the subject of the Neos NDA would actively induce and contribute to infringement of the '096 Patent.

21. Neos had actual and constructive notice of the '096 Patent prior to filing the Neos NDA and filed the Neos NDA with a baseless Paragraph IV Certification without adequate justification for claiming the patent to be invalid and non-infringed by the product described in the Neos NDA. Neos's conduct in certifying invalidity and non-infringement with respect to the '096 Patent has been, and continues to be, willful.

22. Shire will be irreparably harmed if Neos is not enjoined from infringing or actively inducing or contributing to infringement of the '096 Patent. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Neos, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

Count II: Patent Infringement of the '148 Patent

23. Shire restates, realleges, and incorporates by reference Paragraphs 1–16 of this Complaint as if set forth here in their entirety.

24. Upon information and belief, Neos has submitted or caused to be submitted the Neos NDA and continues to seek approval of the Neos NDA from FDA.

25. Neos has infringed the '148 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting the Neos NDA with a Paragraph IV Certification and seeking FDA approval of the Neos NDA prior to the expiration of the '148 Patent.

26. Neos's commercial manufacture, use, sale, offer for sale, or importation into the United States of the purported drug product that is the subject of the Neos NDA would actively induce and contribute to infringement of the '148 Patent.

27. Neos had actual and constructive notice of the '148 Patent prior to filing the Neos NDA and filed the Neos NDA with a baseless Paragraph IV Certification without adequate justification for claiming the patent to be invalid and non-infringed by the product described in

the Neos NDA. Neos's conduct in certifying invalidity and non-infringement with respect to the '148 Patent has been, and continues to be, willful.

28. Shire will be irreparably harmed if Neos is not enjoined from infringing or actively inducing or contributing to infringement of the '148 Patent. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Neos, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

Prayer for Relief

WHEREFORE, Shire seeks the following relief:

- A. A judgment that Neos has infringed the '096 and '148 Patents under 35 U.S.C. § 271(e)(2)(A);
- B. A judgment providing that the effective date of any FDA approval of the Neos NDA be not earlier than the expiration date of the '096 and '148 Patents, including any extensions or regulatory exclusivities appended thereto;
- C. A judgment declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in the Neos NDA would constitute infringement of the '096 and '148 Patents, or inducing or contributing to such conduct, by Neos pursuant to 35 U.S.C. § 271(a), (b), (c) and (g);
- D. A judgment permanently enjoining Neos, and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using selling, or offering to sell in the United States, or importing into the United States, the products for which approval is sought in the Neos NDA, or any product that infringes or induces or contributes to the infringement of the '096 and '148 Patents, until

the expiration of those patents, including any extensions or regulatory exclusivities appended thereto;

- E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- F. Costs and expenses in this action; and
- G. Such further and other relief as this Court determines to be just and proper.

DATED: April 11, 2013

Respectfully submitted,

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