IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEOS THERAPEUTICS, INC. and NEOS THERAPEUTICS, LP,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Neos Therapeutics, Inc. and Neos Therapeutics, LP (collectively, "Plaintiffs"), for their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), hereby allege as follows.

PARTIES

1. Plaintiff Neos Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 2940 North Highway 360, Suite 400, Grand Prairie, Texas 75050.

2. Plaintiff Neos Therapeutics, LP is a limited partnership organized and existing under the laws of the State of Texas with a principal place of business at 2940 North Highway 360, Suite 400, Grand Prairie, Texas 75050.

3. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva develops, manufactures, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this District.

NATURE OF THE ACTION

4. This is a civil action for the infringement of the following U.S. patents by Teva: U.S. Patent Nos. 8,840,924 ("the '924 patent"); 9,072,680 ("the '680 patent"); and 9,089,496 ("the '496 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Teva for purposes of this civil action. This Court has personal jurisdiction over Defendant Teva by virtue of, *inter alia*, the fact that it is a Delaware corporation.

7. Venue is proper in this District as to Teva pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

8. On September 23, 2014, the '924 patent, titled "Compositions And Methods Of Making Rapidly Dissolving Ionically Masked Formulations," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). Since the issuance of the '924 patent, Plaintiff Neos Therapeutics, LP has been, and continues to be, the '924 patent's sole owner. A copy of the '924 patent is attached hereto as Exhibit A.

9. On July 7, 2015, the '680 patent, titled "Compositions Comprising Methylphenidate Complexed With Ion-Exchange Resin Particles," was duly and legally issued by the USPTO. Since the issuance of the '680 patent, Plaintiff Neos Therapeutics, LP has been,

and continues to be, the '680 patent's sole owner. A copy of the '680 patent is attached hereto as Exhibit B.

10. On July 28, 2015, the '496 patent, titled "Compositions Comprising Methylphenidate Complexed With Ion-Exchange Resin Particles," was duly and legally issued by the USPTO. Since the issuance of the '496 patent, Plaintiff Neos Therapeutics, LP has been, and continues to be, the '496 patent's sole owner. A copy of the '496 patent is attached hereto as Exhibit C.

11. Plaintiff Neos Therapeutics, Inc. holds New Drug Application ("NDA") 205489 for COTEMPLA XR-ODT™ brand methylphenidate extended-release orally disintegrating tablets.

12. COTEMPLA XR-ODT™ is the result of years of effort and innovation and is approved by the United States Food and Drug Administration ("FDA") for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD") in patients 6 to 17 years of age. Among other distinctions, COTEMPLA XR-ODT™ is the first and only FDA-approved methylphenidate extended-release orally disintegrating tablet for the treatment of ADHD.

13. The '924 patent, the '680 patent, and the '496 patent are all listed for COTEMPLA XR-ODT™ in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

ACTS GIVING RISE TO THIS ACTION

14. Upon information and belief, on or before October 30, 2017, Teva submitted ANDA No. 210924 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 210924 seeks FDA approval for the commercial manufacture, use, and sale of extended-release orally disintegrating tablets containing 8.6 mg, 17.3 mg, or 25.9 mg

of methylphenidate as the active ingredient ("the Generic Products"). ANDA No. 210924 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '924 patent, the '680 patent, and the '496 patent.

15. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 210924 alleges that the claims of the '924 patent, the '680 patent, and the '496 patent are invalid and/or will not be infringed by the manufacture, use, or sale of the Generic Products. Plaintiffs received written notification of ANDA No. 210924 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '924 patent, the '680 patent, and the '496 patent on or about October 31, 2017.

16. Teva's submission of ANDA No. 210924 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of at least Claims 1, 3-5, 7-12, 16-21, and 23-24 of the '924 patent, Claims 1-28 of the '680 patent, and Claims 1-22 of the '496 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Teva commercially makes, uses, offers to sell, or sells within the United States, or imports into the United States, the Generic Products, or induces or contributes to any such conduct, Teva will further infringe these claims of the '924 patent, the '680 patent, and the '496 patent under 35 U.S.C. § 271(a), (b), and/or (c).

17. Upon information and belief, Teva was aware of the '924 patent, the '680 patent, and the '496 patent prior to filing ANDA No. 210924, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

18. Upon information and belief, if the Generic Products are approved by the FDA, Teva will induce others to directly infringe the '924 patent, the '680 patent, and the '496 patent – including through Teva's prescribing information for the Generic Products – and Teva possesses the specific intent to encourage others to engage in such direct infringement.

19. Upon information and belief, if the Generic Products are approved by the FDA, the Generic Products will not be a staple article or commodity of commerce suitable for substantial non-infringing use, but rather will be especially made and/or adapted for use in the direct infringement of the '924 patent, the '680 patent, and the '496 patent, and Teva possesses the specific intent that the Generic Products will contribute to the direct infringement of those patents.

20. Teva's actions render this an exceptional case under 35 U.S.C. § 285.

21. Plaintiffs will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Teva has infringed the '924 patent, the '680 patent, and the '496 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of ANDA No. 210924 shall not be earlier than the expiration date of the last to expire of the '924 patent, the '680 patent, and the '496 patent, including any extensions or exclusivities;

C. That Teva, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially making, using, offering to sell, or selling in the United States, or importing into the United States, the Generic Products, and any other product that infringes or induces or contributes to the infringement of the '924 patent, the '680 patent, and/or the '496 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

D. That Plaintiffs be awarded monetary relief if Teva commercially makes, uses, offers to sell, or sells in the United States, or imports into the United States, the Generic

Products, or any other product that infringes or induces or contributes to the infringement of the '924 patent, the '680 patent, and/or the '496 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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