IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| AYTU BIOPHARMA, INC.,<br>NEOS THERAPEUTICS, INC.,<br>and NEOS THERAPEUTICS, LP,<br><br>Plaintiffs,<br><br>v.<br><br>GRANULES PHARMACEUTICALS INC.,<br><br>Defendant. | ) | C.A. No. _____ |

**COMPLAINT**

Plaintiffs Aytu BioPharma, Inc., Neos Therapeutics, Inc., and Neos Therapeutics, LP (collectively, "Plaintiffs"), for their Complaint against Defendant Granules Pharmaceuticals Inc. ("Granules" or "Defendant"), hereby allege as follows.

**THE PARTIES**

1. Plaintiff Aytu BioPharma, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 7900 East Union Avenue, Suite 920, Denver, Colorado 80237.

2. 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 7900 East Union Avenue, Suite 920, Denver, Colorado 80237. Plaintiff Neos Therapeutics, Inc. is a wholly owned subsidiary of Plaintiff Aytu BioPharma, Inc.

3. 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 7900 East Union Avenue, Suite 920, Denver, Colorado 80237. Plaintiff Neos Therapeutics, Inc. is the majority owner of Plaintiff Neos Therapeutics, LP.

4. Upon information and belief, Defendant Granules Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 3701 Concorde Parkway, Chantilly, Virginia 01801. Upon information and belief, Granules manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district ("District").

## NATURE OF THE ACTION

5. This is a civil action for infringement of the following U.S. patents by Granules: U.S. Patent Nos. 8,709,491 ("the '491 patent"), 8,840,924 ("the '924 patent"), 9,017,731 ("the '731 patent"), and 9,265,737 ("the '737 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

## JURISDICTION AND VENUE

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

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

8. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b).

## THE PATENTS

9. On April 29, 2014, the '491 patent, titled "Composition Comprising A Mixture Of Dextro- and Levo-Amphetamines Complexed With Ion-Exchange Resin Particles To Form Drug Resin Particles," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). Since the issuance of the '491 patent, Plaintiff Neos Therapeutics, LP has been, and continues to be, the sole owner of the '491 patent. A copy of the '491 patent is attached hereto as Exhibit A.

10. 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 USPTO. On June 6, 2017, the USPTO issued a Certificate Of Correction for the '924 patent, which corrected the length of the 35 U.S.C. § 154(b) adjustment. Since the issuance of the '924 patent, Plaintiff Neos Therapeutics, LP has been, and continues to be, the sole owner of the '924 patent. A copy of the '924 patent, as corrected, is attached hereto as Exhibit B.

11. On April 28, 2015, the '731 patent, titled "Composition Comprising A Mixture Of Dextro- and Levo-Amphetamines Complexed With Ion-Exchange Resin Particles To Form Drug Resin Particles," was duly and legally issued by the USPTO. Since the issuance of the '731 patent, Plaintiff Neos Therapeutics, LP has been, and continues to be, the sole owner of the '731 patent. A copy of the '731 patent is attached hereto as Exhibit C.

12. On February 23, 2016, the '737 patent, titled "Pharmaceutical Composition Comprising Amphetamines Complexed With Ion-Exchange Resin Particles," was duly and legally issued by the USPTO. Since the issuance of the '737 patent, Plaintiff Neos Therapeutics, LP has been, and continues to be, the sole owner of the '737 patent. A copy of the '737 patent is attached hereto as Exhibit D.

13. Plaintiff Neos Therapeutics, Inc. holds New Drug Application ("NDA") 204326 for ADZENYS XR-ODT® brand amphetamine extended-release orally disintegrating tablets.

14. ADZENYS XR-ODT® is the result of years of effort and innovation and is FDA approved for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD") in patients 6 years and older. Among other distinctions, ADZENYS XR-ODT® was the first FDA-approved extended-release orally disintegrating tablet for the treatment of ADHD. ADZENYS XR-ODT® was also the first FDA-approved drug product to employ ion-exchange resin particles in an

extended-release orally disintegrating tablet. ADZENYS XR-ODT® addressed a long-felt, unmet need for a safe and effective once-a-day tablet for treating ADHD that rapidly disintegrates in the mouth and can be administered without water.

15. The ’491 patent, ’924 patent, ’731 patent, and ’737 patent each contain one or more claims that cover Plaintiffs’ ADZENYS XR-ODT® products and are all listed in connection with the ADZENYS XR-ODT® products in the FDA publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (“the Orange Book”).

## ACTS GIVING RISE TO THIS ACTION

16. Upon information and belief, on or before October 31, 2024, Granules submitted Abbreviated New Drug Application (“ANDA”) No. 219800 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 219800 seeks FDA approval to commercially make, use, offer to sell, and sell amphetamine extended-release orally disintegrating tablets—containing 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, or 18.8 mg of amphetamine base as the active ingredient—as generic versions of Plaintiffs’ ADZENYS XR-ODT® products (“the Generic Products”). ANDA No. 219800 specifically seeks FDA approval to perform these commercial acts and market the Generic Products prior to the expiration of the ’491 patent, ’924 patent, ’731 patent, and ’737 patent.

17. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 219800 alleges that the claims of the ’491 patent, ’924 patent, ’731 patent, and ’737 patent are somehow invalid and/or will not be infringed by the commercial making, using, offering to sell, or selling of the Generic Products. Plaintiffs received written notification of ANDA No. 219800 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the ’491 patent, ’924 patent, ’731 patent, and ’737 patent no earlier than November 1, 2024.

**COUNT I**
**(Infringement of U.S. Patent No. 8,709,491)**

18. Plaintiffs hereby re-allege and incorporate by reference each and every allegation set forth in this Complaint.

19. Claim 1 of the '491 patent recites:

> 1. A pharmaceutical composition comprising a mixture of dextro- and levo-amphetamines complexed with ion-exchange resin particles to form drug resin particles, wherein said composition comprises 20 to 50% of a first plurality of drug-resin particles that are uncoated and 50 to 80% of a second plurality of drug-resin particles that are coated with a delayed release coating.

20. Granules' submission of ANDA No. 219800 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of one or more claims of the '491 patent, including at least Claim 1 of the '491 patent, under 35 U.S.C. § 271(e)(2)(A). Moreover, if Granules 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, it would further infringe one or more claims of the '491 patent under 35 U.S.C. § 271(a), (b), and/or (c).

21. Upon information and belief, Granules was aware of the '491 patent prior to filing ANDA No. 219800, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent.

22. Granules' actions render this an exceptional case under 35 U.S.C. § 285.

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

**COUNT II**
**(Infringement of U.S. Patent No. 8,840,924)**

24. Plaintiffs hereby re-allege and incorporate by reference each and every allegation set forth in this Complaint.

25. Claim 1 of the '924 patent recites:

> 1. A compressed, orally disintegrating, controlled release taste-masked pharmaceutical composition comprising:
>
> a coated drug-ion-exchange resin complex and a directly compressible, free-flowing pharmaceutical excipient,
>
> wherein the composition effectively masks an unpalatable taste associated with delivery of the drug,
>
> wherein the coated drug-ion-exchange resin complex is coated with a controlled release coating,
>
> and wherein the directly compressible, free-flowing pharmaceutical excipient aids in the liberation of the coated drug-resin complex in the mouth through disintegration.

26. Granules' submission of ANDA No. 219800 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of one or more claims of the '924 patent, including at least Claim 1 of the '924 patent, under 35 U.S.C. § 271(e)(2)(A). Moreover, if Granules 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, it would further infringe one or more claims of the '924 patent under 35 U.S.C. § 271(a), (b), and/or (c).

27. Upon information and belief, Granules was aware of the '924 patent prior to filing ANDA No. 219800, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent.

28. Granules' actions render this an exceptional case under 35 U.S.C. § 285.

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

**COUNT III**
**(Infringement of U.S. Patent No. 9,017,731)**

30. Plaintiffs hereby re-allege and incorporate by reference each and every allegation set forth in this Complaint.

31. Claim 1 of the '731 patent recites:

> 1. A pharmaceutical composition comprising a mixture of dextro- and levo-amphetamines complexed with ion-exchange resin particles to form drug resin particles, wherein 30 to 50% by weight of said amphetamines are present in a first plurality of drug-resin particles that are uncoated and 50 to 70% by weight of said amphetamines are present in a second plurality of drug-resin particles that are coated with a delayed release coating.

32. Granules' submission of ANDA No. 219800 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of one or more claims of the '731 patent, including at least Claim 1 of the '731 patent, under 35 U.S.C. § 271(e)(2)(A). Moreover, if Granules 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, it would further infringe one or more claims of the '731 patent under 35 U.S.C. § 271(a), (b), and/or (c).

33. Upon information and belief, Granules was aware of the '731 patent prior to filing ANDA No. 219800, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent.

34. Granules' actions render this an exceptional case under 35 U.S.C. § 285.

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

**COUNT IV**
**(Infringement of U.S. Patent No. 9,265,737)**

36. Plaintiffs hereby re-allege and incorporate by reference each and every allegation set forth in this Complaint.

37. Claim 1 of the '737 patent recites:

> 1. A pharmaceutical composition comprising amphetamines complexed with ion-exchange resin particles to form drug-resin particles, wherein 30 to 50% by weight of said amphetamines are present in a first plurality of immediate release drug-resin particles and 50 to 70% by weight of said amphetamines are present in a second plurality of drug-resin particles that are coated with a delayed release coating.

38. Granules' submission of ANDA No. 219800 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of one or more claims of the '737 patent, including at least Claim 1 of the '737 patent, under 35 U.S.C. § 271(e)(2)(A). Moreover, if Granules 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, it would further infringe one or more claims of the '737 patent under 35 U.S.C. § 271(a), (b), and/or (c).

39. Upon information and belief, Granules was aware of the '737 patent prior to filing ANDA No. 219800, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent.

40. Granules' actions render this an exceptional case under 35 U.S.C. § 285.

41. Plaintiffs will be irreparably harmed by Granules' 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 Granules has infringed the ’491 patent, ’924 patent, ’731 patent, and ’737 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of ANDA No. 219800 shall not be earlier than the expiration date of the last to expire of the ’491 patent, ’924 patent, ’731 patent, and ’737 patent, including any extensions or exclusivities;

C. That Granules, 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 ’491 patent, ’924 patent, ’731 patent, and/or ’737 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 Granules 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 ’491 patent, ’924 patent, ’731 patent, and/or ’737 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*

Jeremy A. Tigan (#5239)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jtigan@morrisnichols.com
mdellinger@morrisnichols.com

*Attorneys for Plaintiffs*

OF COUNSEL:

Peter J. Armenio
Colleen Tracy James
Andrew J. Cochran
Nick Lee
CAHILL GORDON & REINDEL LLP
32 Old Slip
New York, NY 10005
(212) 701-3000

December 11, 2024