UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC., Plaintiff, v. JANSSEN PHARMACEUTICALS, INC., Defendant.	Case No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Mylan Pharmaceuticals Inc. ("Mylan"), by its undersigned attorneys, for its complaint against Janssen Pharmaceuticals, Inc., hereby alleges as follows:

NATURE OF THE CASE

1. Mylan seeks a declaratory judgment that United States Patent No. 8,629,179 ("the '179 Patent") is invalid and/or not infringed by Mylan's proposed Methylphenidate Hydrochloride Extended-release Tablets USP, 18 mg, 27 mg, 36 mg and 54 mg product that is the subject of its Abbreviated New Drug Application ("ANDA") No. 20-6726 ("Mylan's ANDA Product").

PARTIES

2. Mylan is a corporation organized under the laws of the State of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

3. On information and belief, Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a corporation organized and existing under the laws of Pennsylvania with its corporate headquarters at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 184, Pub L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (the "Hatch-Waxman Act").

5. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Janssen is subject to personal jurisdiction in the Eastern District of Pennsylvania because, on information and belief, Janssen is incorporated within the Commonwealth of Pennsylvania.

7. On information and belief, Janssen has a regular and established place of business within the Eastern District of Pennsylvania located at 420 Delaware Drive, Fort Washington, Pennsylvania 19034.

8. On information and belief, Janssen also has offices located within the Eastern District of Pennsylvania in Philadelphia, Chambersburg and Horsham, Pennsylvania and has recently posted job openings for these locations. Further, on information and belief, Janssen markets, distributes, and/or sells pharmaceutical products, including CONCERTA®, within the Eastern District of Pennsylvania and throughout the United States.

9. Venue for these Counterclaims is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

FACTUAL BACKGROUND

10. On or about January 14, 2014, the United States Patent and Trademark Office ("USPTO") issued the '179 Patent, titled "Methods and Devices for Providing Prolonged Drug Therapy." Alza Corporation is indicated in the records of the USPTO as the owner or assignee of the '179 Patent. A copy of the '179 Patent is attached hereto as Exhibit A.

11. Janssen is indicated in the records of the United States Food and Drug Administration ("FDA") as the holder of New Drug Application ("NDA") No. 21-121 for methylphenidate hydrochloride extended-release tablets, 18 mg, 27 mg, 36 mg, and 54 mg, marketed by Janssen as CONCERTA®.

12. The '179 Patent currently is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in association with CONCERTA®.

13. With respect to NDA No. 21-121 for CONCERTA®, Janssen submitted to the FDA the '179 Patent, in addition to United States Patent Nos. 6,919,373, 6,930,129, and 8,163,798 ("the '798 Patent"), for listing in the Orange Book as patents that could reasonably be asserted against anyone marketing or seeking to market a generic version of the methylphenidate hydrochloride extended-release tablets that are indicated for the treatment of attention deficit/hyperactivity disorder that are the subject of the NDA.

14. In accordance with 21 U.S.C. § 355(j)(2)(B), Mylan notified Defendant in writing (the "Notice Letter") that it had filed ANDA No. 20-6726 with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, *inter alia*, the '179 Patent is invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6726.

15. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(ii), the Notice Letter included a detailed statement of the factual and legal basis for the certification that the '179 Patent is

invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6726.

16. In accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III), the Notice Letter included an Offer of Confidential Access to Mylan's ANDA. The Offer of Confidential Access contained certain restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as permitted under 21 U.S.C. § 355(j)(5)(C)(i)(III).

17. On information and belief, Defendant received a copy of the Notice Letter on April 2, 2014. Defendant did not bring an action for infringement of the '179 Patent within 45 days of receiving the Notice Letter. Defendant sued Mylan for infringement of U.S. Patent No. 8,163,798 (the "'798 patent") based on Mylan's ANDA No. 20-6726 in the action captioned *Alza Corporation and Janssen Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 1:14-cv-85 (Keeley) (N.D.W.V.). On information and belief, the first ANDA for a generic version of methylphenidate hydrochloride extended-release tablets, 18 mg, 27 mg, 36 mg, 54 mg, was filed on or before December 8, 2003. On information and belief, the first ANDA for a generic version of methylphenidate hydrochloride extended-release tablets, 18 mg, 27 mg, 36 mg, 54 mg containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") was submitted to the FDA on July 19, 2005.

18. On information and belief, Defendant filed an Amended Complaint on March 14, 2014, in the consolidated action captioned *Alza Corp. et al. v. Osmotica Kereskedelmi Es Szolgaltato KFT*, Civil Action No. 1:13-cv-1104-RGA (D. Del.), asserting that Norwich Pharmaceuticals Inc., Osmotica Kereskedelmi es Szolgaltato Kft, and Osmotica Pharmaceutical Corp. (collectively, "Osmotica") infringe, *inter alia*, the '179 Patent. Defendant's Amended Complaint in that case alleges that Osmotica submitted a Paragraph IV Certification as to the

'179 Patent. The litigation against Osmotica was dismissed with prejudice on June 13, 2014, through a Consent Judgment and Dismissal signed by the Court finding, *inter alia*, that the '179 Patent is valid or would be infringed by the product that is the subject of Osmotica's ANDA No. 20-5327. The Consent Judgment and Dismissal references a settlement agreement.

19. On information and belief, Defendant filed an Amended Complaint on March 14, 2014, in the consolidated action captioned *Alza Corp. et al. v. Par Pharmaceutical Inc.*, Civil Action No. 1:13-cv-1104-RGA (D. Del.), asserting that Par Pharmaceutical, Inc. ("Par") infringes, *inter alia*, the '179 Patent. The Amended Complaint alleges that Par submitted a Paragraph IV Certification as to the '179 Patent. The litigation against Par was dismissed with prejudice on September 9, 2014, through a Consent Judgment signed by the Court finding, *inter alia*, that the '179 Patent is valid or would be infringed by the product that is the subject of Par's ANDA No. 20-4659.

20. On information and belief, Defendant filed a Complaint on June 13, 2014, in the action captioned *Alza Corp. et al. v. Sandoz Inc.*, Civil Action No. 1:14-cv-744-RGA (D. Del.), asserting that Sandoz Inc. ("Sandoz") infringes, *inter alia*, the '179 Patent. The Complaint alleges that Sandoz submitted a Paragraph IV Certification as to the '179 Patent. The litigation against Sandoz was dismissed with prejudice on December 17, 2014, through a Consent Judgment signed by the Court finding, *inter alia*, that the '179 Patent is valid or would be infringed by the product that is the subject of Sandoz's ANDA No. 20-5714.

21. In a separate but related lawsuit captioned *Alza Corporation et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 1:14-cv-00085 (IMK) (N.D.W.V.), Defendant sued Mylan for infringement of the '798 Patent. Defendant, to date, has not sued Mylan for infringement of the '179 Patent.

22. Under the applicable statutory scheme, Mylan cannot obtain final approval from the FDA for its ANDA Product until 180 days after either (1) the first applicant ("first-filer") to submit a Paragraph IV Certification for the '179 Patent begins commercial marketing of its generic methylphenidate extended-release tablets, 18 mg, 27 mg, 36 mg, 54 mg product, or (2) the decision of a court holding that the '179 Patent is invalid and/or not infringed.

23. On information and belief, the first-filer is one of the generic companies identified above that Defendant previously sued in relation to the submission of a Paragraph IV Certification as to the '179 Patent. Until 180 days after either the first-filer chooses to market its generic methylphenidate extended-release tablets, 18 mg, 27 mg, 36 mg, 54 mg, product, or a court decision holds that the '179 Patent is invalid or not infringed, Mylan cannot obtain approval from the FDA to market its ANDA product.

24. On information and belief, the first-filer has not launched any such generic methylphenidate extended-release tablets, 18 mg, 27 mg, 36 mg, 54 mg product to date. Further, on information and belief, there is no decision of a court holding that the '179 Patent is invalid or not infringed.

25. Accordingly, the FDA is prohibited from granting final approval of Mylan's ANDA Product. As a result, Mylan seeks entry of a declaratory judgment that the manufacture, use, or sale of its ANDA product does not infringe any valid claim of the '179 Patent and/or that the '179 Patent is invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '179 Patent)

26. Mylan restates and realleges each of paragraphs 1-25 as if fully set forth herein.

27. The claims of the '179 Patent are invalid and/or not infringed for at least the reasons set forth in the detailed statement Mylan included with its Notice Letter to Defendant.

28. Mylan alleges that the claims of the '179 Patent are invalid, at the very least, over the prior art pursuant to 35 U.S.C. §§ 102 and 103 and, therefore, cannot be infringed. Additionally, at least claims 1-16 and 18 of the '179 Patent are invalid for lack of enablement under 35 U.S.C. § 112, ¶ 1, because the specification of the '179 Patent "does not provide sufficient guidance for a person of ordinary skill in the art to make the non-osmotic dosage forms as claimed," in line with the Federal Circuit's opinion in *Alza Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 943 (Fed. Cir. 2010).

29. A definite and concrete, real and substantial, justiciable, and reasonable apprehension of suit exists regarding non-infringement and invalidity of the '179 Patent. Indeed, a case or controversy sufficient to support declaratory judgment jurisdiction exists here because Mylan suffers a judicially cognizable injury-in-fact, the injury is traceable to Defendant, and the injury is redressable by a judgment on the '179 Patent.

30. Mylan is entitled to a judicial declaration that one or more of the claims of the '179 Patent are invalid and thus also not infringed.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '179 Patent)

31. Mylan restates and realleges each of paragraphs 1-30 as if fully set forth herein.

32. The claims of the '179 Patent are invalid and/or not infringed for at least the reasons set forth in the detailed statement Mylan included with its Notice Letter to Defendant.

33. Mylan denies infringement of the '179 Patent and alleges that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Mylan's ANDA No. 20-6726 has not infringed, does not infringe, and would not, if manufactured, used, sold,

offered for sale, or imported, infringe, either directly, indirectly or contributorily, and would not induce infringement of, any valid or enforceable claim of the '179 Patent.

34. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists regarding non-infringement and the invalidity of the '179 Patent. Indeed, a case or controversy sufficient to support declaratory judgment jurisdiction exists here because Mylan suffers a judicially cognizable injury-in-fact, the injury is traceable to Defendant, and the injury is redressable by a judgment on the '179 Patent.

35. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Mylan's ANDA No. 20-6726 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly or contributorily, and would not induce infringement of, any valid or enforceable claim of the '179 Patent.

PRAYER FOR RELIEF

WHEREFORE, Mylan respectfully prays for judgment in its favor and against Defendant:

(a) Declaring that the claims of the '179 Patent are invalid;

(b) Declaring that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Mylan's ANDA No. 20-6726 has not infringed, does not infringe and would not infringe any valid or enforceable claim of the '179 Patent, either literally or under the doctrine of equivalents;

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Mylan's ANDA No. 20-6726 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the '179 Patent;

(d) Declaring that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Mylan's ANDA No. 20-6726 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the '179 Patent;

(e) Declaring this case exceptional and awarding Mylan its reasonable attorney's fees and costs of these Counterclaims pursuant to 35 U.S.C. § 285; and

(f) Awarding Mylan such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: May 28, 2015

Laura Lange LLL8094

Laura A. Lange (Pa. Id. No. 310733)
McGuireWoods LLP
625 Liberty Avenue, 23rd Floor
Pittsburgh, Pennsylvania 15222
(412) 667-6000
llange@mcguirewoods.com

Of Counsel:
Timothy H. Kratz
George J. Barry III
Micheal L. Binns
Meghan M. Rachford
McGuireWoods LLP
1230 Peachtree Street, Suite 2100
Atlanta, Georgia 30309
(404) 443-5500
tkratz@mcguirewoods.com
gbarry@mcguirewoods.com
mbinns@mcguirewoods.com
mrachford@mcguirewoods.com

Cedric C.Y. Tan
McGuireWoods LLP
2001 K Street, N.W., Suite 400
Washington, D.C. 20006
(202) 828-2812
ctan@mcguirewoods.com

Attorneys for Mylan Pharmaceuticals Inc.