Melissa A. Chuderewicz
PEPPER HAMILTON LLP
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543-5276
(609) 452-0808

Attorney for Plaintiff
Otsuka Pharmaceutical Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. AMNEAL PHARMACEUTICALS, LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC and AMNEAL PHARMACEUTICALS CO. INDIA PRIVATE LIMITED, Defendants.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Private Limited (collectively "Amneal"), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Amneal Pharmaceuticals, LLC is a corporation organized under the laws of the State of Delaware, its principal place of business is located at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey 08807, and it is a subsidiary of Amneal Pharmaceuticals of New York, LLC.

3. Upon information and belief, Amneal Pharmaceuticals of New York, LLC is a corporation organized under the laws of the State of Delaware, having its principal place of business located at 85 Adams Ave, Hauppauge, New York, 11788.

4. Upon information and belief, Amneal Pharmaceuticals Co. India Private Limited is an Indian corporation and a subsidiary of Amneal Pharmaceuticals, LLC, having a principal place of business at 882/1-871, Rajoda Village, Near Hotel Kankavati, Bavla Taluka, Ahmedabad-382220, Gujarat, India.

NATURE OF THE ACTION

5. This is an action for infringement of United States Patent Number 8,759,350 ("the '350 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Amneal's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j) seeking U.S. Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product ("Amneal's generic product").

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, this Court has jurisdiction over Amneal Pharmaceuticals, LLC because at a minimum it (1) is registered to do business in New Jersey, (2)

has its headquarters in New Jersey, (3) has branches of business in New Jersey, (4) conducts business within this judicial district, (5) directly, or indirectly, manufactures, markets, sells and distributes generic drugs throughout the United States and in this judicial district, (6) purposefully has conducted and continues to conduct business in this judicial district and (7) this judicial district is a likely destination of its generic products.

8. Upon information and belief, this Court has jurisdiction over Amneal Pharmaceuticals of New York, LLC because at a minimum it (1) is in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products, (2) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharmaceuticals, LLC, conducts business within this judicial district, and (3) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharmaceuticals, LLC, manufactures, markets, sells and distributes generic drugs throughout the United States and in this judicial district.

9. Upon information and belief, this Court has jurisdiction over Amneal Pharmaceuticals Co. India Private Limited because at a minimum it (1) has availed itself of the rights and benefits of the State of New Jersey, (2) has engaged in substantial and continuing contacts with the State, (3) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharmaceuticals, LLC, conducts business within this judicial district, and (4) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharmaceuticals, LLC, manufactures, markets, sells and distributes generic drugs throughout the United States and in this judicial district.

10. Upon information and belief, Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Private Limited hold

themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products.

11. Upon information and belief, Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Private Limited work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

12. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

13. The U.S. Patent and Trademark Office ("PTO") issued the '350 patent on June 24, 2014, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '350 patent is attached as Exhibit A.

14. Otsuka is the owner of the '350 patent by virtue of assignment.

15. The '350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

16. The '350 patent is directed to and claims, *inter alia,* pharmaceutical compositions and methods of treatment.

17. Otsuka is the holder of NDA No. 21-713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. The Orange Book lists the '350 patent for NDA No. 21-713.

18. Otsuka markets aripiprazole oral solution in the United States under the trademark Abilify®.

19. Upon information and belief, Amneal filed with the FDA ANDA No. 20-3906, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

20. Upon information and belief, Amneal's ANDA No. 20-3906 seeks FDA approval to sell Amneal's generic product in the United States.

21. Otsuka received a letter from Amneal dated August 27, 2014, purporting to include a Notice of Certification for ANDA No. 20-3906 ("Amneal's 20-3906 letter") under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and (iv)(I) and 21 C.F.R. § 314.95(c)(1).

22. Amneal's 20-3906 letter alleges that the active ingredient in Amneal's generic product for which it seeks approval is aripiprazole.

23. Amneal's 20-3906 letter alleges that Amneal's generic product, if approved, will be marketed for the currently approved indications for Abilify® Oral Solution, which include adjunctive treatment of major depressive disorder.

24. Upon information and belief, Amneal's generic product will, if approved and marketed, infringe at least one claim of the '350 patent.

25. Under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-3906 seeking approval for the commercial marketing of Amneal's generic product before the expiration date of the '350 patent.

26. Upon information and belief, Amneal's actions relating to Amneal's ANDA No. 20-3906 complained of herein were done with the cooperation, participation, and assistance, and for the benefit, of Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Private Limited.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against the Amneal Defendants on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed at least one claim of the '350 patent through Amneal's submission of ANDA No. 20-3906 to the FDA to obtain approval to commercially manufacture, use, import, offer to sell and/or sell Amneal's generic product in the United States before expiration of the '350 patent;

2) order that the effective date of any approval by the FDA of Amneal's generic product be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;

3) enjoin Amneal from the commercial manufacture, use, import, offer for sale and/or sale of Amneal's generic product until the expiration of the '350 patent, or such later date as the Court may determine;

4) enjoin Amneal and all persons acting in concert with Amneal, from seeking, obtaining or maintaining approval of Amneal's ANDA No. 20-3906 until expiration of the '350 patent;

5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and

6) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully Submitted,

By: s/ Melissa A. Chuderewicz
Melissa A. Chuderewicz
chuderem@pepperlaw.com
PEPPER HAMILTON LLP
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543
(609) 452-0808

Attorneys for Plaintiff
Otsuka Pharmaceutical Co., Ltd.

Of Counsel:

James B. Monroe
Paul W. Browning
Denise Main
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
(202) 408-4000

Robert L. Baechtold
John D. Murnane
FITZPATRICK, CELLA, HARPER &
SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

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