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ATTORNEYS FOR PLAINTIFFS PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, AND ENDO PAR INNOVATION COMPANY, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC Plaintiffs, v. AMNEAL EU, LTD., AMNEAL PHARMACEUTICALS COMPANY GMBH, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL BIOSCIENCES LLC, and AMNEAL PHARMACEUTICALS PVT. LTD, Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), for their complaint against Amneal EU, Ltd., Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, Amneal Biosciences LLC, and Amneal Pharmaceuticals Pvt. Ltd. (collectively "Amneal" or the "Amneal Defendants"), hereby allege as follows:

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

3. Plaintiff Endo Par Innovation Company ("EPIC") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Upon information and belief, Defendant Amneal EU, Limited ("Amneal EU") is a limited liability company organized and existing under the laws of Ireland, having its principal place of business at Cahir Road, Cashel, Co. Tipperary, E25 ZD51, Ireland. Upon information and belief, Amneal EU is a pharmaceutical company engaged in the research, development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

5. Upon information and belief, Defendant Amneal Pharmaceuticals Company GmbH ("Amneal GmbH") is a limited liability company organized and existing under the laws of Switzerland, having its principal place of business at Turmtrasse 30 6312, Steinhausen, Switzerland. Upon information and belief, Amneal GmbH is a pharmaceutical company

engaged in the research, development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

6. Upon information and belief, Defendant Amneal Pharmaceuticals of New York, LLC ("Amneal New York") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. Upon information and belief, Amneal New York is the U.S. Agent for Amneal EU and Amneal GmbH. Upon information and belief, Amneal New York is a pharmaceutical company engaged, among other things, along and/or in concert with other Amneal Defendants, in the development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

7. Upon information and belief, Defendant Amneal Biosciences LLC ("Amneal Biosciences") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 400 Crossing Boulevard, Floor 3, Bridgewater, New Jersey 08807. Upon information and belief, Amneal Biosciences is a pharmaceutical company engaged, among other things, in the distribution of pharmaceutical products throughout the United States, including in this judicial district.

8. Upon information and belief, Defendant Amneal Pharmaceuticals Pvt. Ltd. ("Amneal India") is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 15, PHARMEZ Special Economic Zone, Sarkhej-Bavia N.H., No. 8A, Vil.: Matoda, Tal.: Sanand Ahmedabad, Gujarat 382213, India. Upon information and belief, Amneal India is a pharmaceutical company engaged, among other things, in the manufacturing, packaging, testing, distribution, and sale of pharmaceutical products sold in and imported into the United States.

NATURE OF ACTION

9. This is an action for infringement of United States Patent No. 10,844,435 (the '435 Patent" or "the Patent in Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

10. Par seeks declaratory judgment 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 *et seq.*, that Amneal's marketing and sale of its Proposed ANDA Products (as detailed below), if approved, would induce infringement of the '435 Patent.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 (patent infringement).

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) because, *inter alia*, Amneal has a regular and established place of business in this judicial district and they have engaged in and will engage in infringing conduct in and from this judicial district. Moreover, Amneal EU, Amneal GmbH, and Amneal India are not resident in the United States, and pursuant to 28 U.S.C. § 1391(c)(3), venue as to those defendants is proper in any judicial district, including this judicial district.

13. This Court has personal jurisdiction over Defendants because, *inter alia*, they have committed and will commit acts of infringement in this judicial district, have purposely availed themselves of the benefits and protections of the laws of New Jersey, and have had continuous and systematic contacts with this judicial district, including conducting business in New Jersey, including by acting in partnership and agency with each other, and marketing,

selling, and distributing pharmaceutical products throughout the United States and in this judicial district. In addition, Amneal Biosciences has a principal place of business in this judicial district.

FACTUAL BACKGROUND

The Drug Approval Process

14. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("FDA"), typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

15. Alternatively, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "reference listed drug" or "branded drug").

16. In general, and with a few exceptions, the labeling for a proposed ANDA product must track the labeling for the FDA-approved branded drug. Accordingly, pursuant to 21 C.F.R. § 314.94(a)(8)(iv), an ANDA filer must include as part of the ANDA a side-by-side comparison of the applicant's proposed labeling for its ANDA product with the approved labeling for the branded drug, with all differences annotated and explained.

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