IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBOTT RESPIRATORY LLC,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS CO. INDIA PVT. LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs AbbVie Inc. and Abbott Respiratory LLC (collectively, "AbbVie"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent No. 6,080,428 ("the '428 patent") arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 204178 filed by Amneal Pharmaceuticals LLC with the U.S. Food and Drug Administration ("FDA") for approval to market 750 mg niacin extended release tablets, which are generic versions of the 750 mg forms of AbbVie's NIASPAN® drug product.

PARTIES

2. AbbVie Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1 N Waukegan Road, North Chicago IL, 60064.

3. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

4. Upon information and belief, Amneal Pharmaceuticals LLC ("Amneal Pharma") is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, New Jersey 08807.

5. Upon information and belief, Amneal Pharma is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market.

6. Upon information and belief, Amneal Pharma manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

7. Upon information and belief, Amneal Pharmaceuticals Co. India Pvt. Ltd. ("Amneal India") is a company organized and existing under the laws of India, having its principal place of business at 882/1-871, Near Hotel Kankavati, Village Rajoda, Taluka Bavla, District Ahmedabad-382220, India.

8. Upon information and belief, Amneal India is a wholly-owned subsidiary of Amneal Pharma and is controlled and/or dominated by Amneal Pharma.

9. Upon information and belief, Amneal India researches, develops, performs quality control/quality assurance on, manufactures, and distributes numerous generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Amneal Pharma.

10. Upon information and belief, Amneal Pharma and Amneal India hold themselves out as a unitary entity for purposes of developing and manufacturing generic products. For example, Amneal Pharma maintains a website, www.amneal.com, at which it represents that the "Research & Development Centre" operated by Amneal India "is one of two key drivers . . . behind [Amneal Pharma's] organic growth and achieving [Amneal Pharma's] goal of 30+ ANDA approvals per year."

11. Upon information and belief, based in part on representations on their website, Amneal Pharma and Amneal India worked collaboratively on the preparation and submission of ANDA No. 204178.

12. Upon information and belief, following any FDA approval of ANDA No. 204178, Amneal Pharma and Amneal India will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 204178 throughout the United States, and/or import such generic drug products into the United States.

13. Amneal Pharma and Amneal India are collectively referred to hereafter as "Amneal."

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

15. This Court has personal jurisdiction over Amneal because, *inter alia*, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious

act of patent infringement in filing ANDA No. 204178 that has led to foreseeable harm and injury to Delaware corporations AbbVie Inc. and Abbott Respiratory.

16. This Court also has personal jurisdiction over Amneal because, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within Delaware and therefore purposefully avails itself of the privilege of conducting activities within Delaware.

17. This Court also has personal jurisdiction over Amneal because it has availed itself of the legal protections of the State of Delaware by, *inter alia*, creating wholly-owned subsidiaries in Delaware (*e.g.*, Amneal Pharmaceuticals of New York LLC) and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware (*e.g.*, *Abbott Laboratories et al. v. Amneal Pharms. LLC et al.*, Civil Action No. 1:12-cv-00235-SLR (D. Del.); *Forest Labs., Inc. et al. v. Cobalt Labs., Inc. et al.*, Civil Action No 1:08-cv-00021-LPS (D. Del.); *Galderma Labs., Inc. et al v. Amneal Pharms. LLC et al.*, Civil Action No. 1:11-cv-01106-LPS (D. Del.).)

18. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Amneal.

PATENT IN SUIT

19. Abbott Respiratory is the owner by assignment of the ’428 patent, entitled “Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Thereof,” which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the ’428 patent is attached hereto as Exhibit A. The claims of the ’428 patent are valid and enforceable. AbbVie Inc. is an exclusive licensee of the ’428 patent with respect to

NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the ’428 patent.

20. AbbVie Inc. is the holder of New Drug Application (“NDA”) No. 20-0381 by which the FDA granted approval for the marketing and sale of 500 mg, 750 mg, and 1000 mg strength niacin extended-release tablets, which AbbVie markets in the United States under the trade name “NIASPAN®”. The formulation and dosing of NIASPAN® is covered by certain claims of the ’428 patent. The FDA’s official publication of approved drugs (the “Orange Book”) includes NIASPAN® together with the ’428 patent.

INFRINGEMENT BY AMNEAL

21. By letter dated July 16, 2012, (“the Notice Letter”), Amneal notified AbbVie that Amneal had submitted ANDA No. 204178 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of its 750 mg generic niacin extended-release tablets before the expiration of the ’428 patent. Upon information and belief, Amneal intends to engage in the commercial manufacture, use, and sale of its 750 mg generic niacin extended-release tablets promptly upon receiving FDA approval to do so.

22. By filing ANDA No. 204178, Amneal has necessarily represented to the FDA that its generic niacin extended-release tablets have the same active ingredient as NIASPAN®, have the same route of administration, dosage form, and strengths as NIASPAN®, and are bioequivalent to NIASPAN®.

23. This Complaint is being filed before the expiration of the forty-five days from the date AbbVie received the Notice Letter.

COUNT I
INFRINGEMENT OF THE '428 PATENT

24. Each of the preceding paragraphs 1 to 23 is incorporated as if fully set forth herein.

25. Amneal's submission of ANDA No. 204178 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 750 mg generic niacin extended-release tablets prior to the expiration of the '428 patent constitutes infringement of one or more of the claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon FDA approval of Amneal's ANDA No. 204178, Amneal will further infringe the '428 patent by making, using, offering to sell, and selling its 750 mg generic niacin extended-release tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

27. Upon information and belief, Amneal had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 204178 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

28. If Amneal's infringement of the '428 patent is not enjoined, AbbVie will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AbbVie prays that this Court grant the following relief:

1. A judgment that one or more claims of the '428 patent are infringed by Amneal's submission of ANDA No. 204178, and that Amneal's making, using, offering to sell, or selling in the United States, or importing into the United States Amneal's 750 mg generic niacin extended-release tablets will infringe the '428 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 204178 shall be a date which is not earlier than the latest expiration date of the ’428 patent, including any extensions and/or additional periods of exclusivity to which AbbVie is or becomes entitled.

3. An order permanently enjoining Amneal, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Amneal’s 750 mg generic niacin extended-release tablets until after the latest expiration date of the ’428 patent, including any extensions and/or additional periods of exclusivity to which AbbVie is or becomes entitled.

4. Damages or other monetary relief to AbbVie if Amneal engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Amneal’s 750 mg generic niacin extended-release tablets prior to the latest expiration date of the ’428 patent, including any extensions and/or additional periods of exclusivity to which AbbVie is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

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