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Boehringer Ingelheim Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (together, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Amneal Pharmaceuticals LLC ("Amneal"), hereby allege as follows:

THE PARTIES

1. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

3. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. Upon information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, New Jersey 08807-2663.

NATURE OF THE ACTION

5. This is a civil action concerning United States Patent No. 6,015,577 ("the '577 patent"). 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.

JURISDICTION AND VENUE

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

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

8. Upon information and belief, Amneal develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District, and has its principal place of business in New Jersey.

9. Upon information and belief, Amneal maintains research and development, manufacturing, and administrative facilities in New Jersey.

10. This Court has personal jurisdiction over Amneal at least by virtue of the fact that its principal place of business is in New Jersey. Additionally, Amneal routinely consents to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, Amneal Pharmaceuticals, LLC's and Amneal Pharmaceuticals of New York LLC's Answer, Defenses, and Counterclaims, *Novo Nordisk Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 13-4915 (MAS)(DEA) (D.N.J. September 24, 2013), ECF No. 9; Amneal Pharmaceuticals, LLC's Answer, Defenses, and Counterclaims, *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 13-391 (ES)(SCM) (D.N.J. April 15, 2013), ECF No. 9.

BACKGROUND

11. BIPI is the holder of New Drug Application ("NDA") No. 20-884, by which the United States Food and Drug Administration ("FDA") first granted approval for 200 mg extended-release dipyridamole / 25 mg acetylsalicylic acid ("aspirin") capsules. The dipyridamole/aspirin capsules described in BIPI's NDA are prescribed to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis. Boehringer sells these capsules in the United States under the tradename "AGGRENOX®."

12. BIPKG owns the '577 patent, which was duly and legally issued on January 18, 2000, and is titled "Pharmaceutical Compositions Containing Dipyridamole or

Mopidamol and Acetylsalicylic Acid or the Physiologically Acceptable Salts Thereof, Processes for Preparing Them and Their Use in Treating Clot Formation." BII has an exclusive license under the '577 patent in the United States from BIPKG. BIPI has an exclusive license under the '577 patent in the United States from BII. A copy of the '577 patent is attached as Exhibit A.

13. Amneal's Abbreviated New Drug Application ("ANDA") No. 206392 (the "Amneal ANDA") seeks approval to engage in the manufacture, use, sale, offer for sale, and/or importation of 200 mg extended-release dipyridamole / 25 mg aspirin capsules ("Amneal's ANDA product") prior to the expiration of the '577 patent.

14. BIPI received a letter dated June 16, 2014 ("Notice Letter") in which Amneal represented that it had filed an ANDA for Amneal's ANDA product, which allegedly includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") of invalidity and/or noninfringement concerning the '577 patent. The Notice Letter indicates that Amneal seeks approval of the Amneal ANDA prior to the expiration of the '577 patent.

15. Upon information and belief, Amneal did not send the Notice Letter to BIPKG.

16. BIPKG has not received the Notice Letter.

17. This action was commenced within 45 days of the date of Amneal's Notice Letter.

18. Upon information and belief, Amneal was aware, before June 16, 2014, of the lawsuits *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Barr Laboratories*, Civil Action No. 07-cv-432 (GMS) (D. Del.) ("Boehringer/Barr"), and *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Kremers Urban Pharmaceuticals Inc.*, Civil Action No. 13-cv-1580

(NLH)(KMW) ("Boehringer/Kremers"), the latter of which was pending in the United States District Court for the District of New Jersey as of the date of the Notice Letter.

19. Upon information and belief, Amneal was aware, at some time before June 16, 2014, that a generic challenge to the '577 patent was possible under FDA regulations on or after January 31, 2000.

20. Amneal first raised a challenge to the '577 patent more than fourteen years after a challenge was first possible under FDA regulations, more than five years after the conclusion of the Boehringer/Barr litigation, and more than one year after the commencement of the Boehringer/Kremers litigation.

21. Upon information and belief, Amneal's ANDA product is a pharmaceutical composition containing 25 mg aspirin and 200 mg dipyridamole.

22. Upon information and belief, Amneal's ANDA product is a capsule containing 25 mg aspirin as an immediate-release tablet and 200 mg dipyridamole as extended-release pellets.

23. Upon information and belief, the dipyridamole pellets in Amneal's ANDA product have a coating including lacqueurs which are insoluble in acid, but soluble in intestinal juices.

24. Upon information and belief, the dipyridamole pellets in Amneal's ANDA product have a coating made up of 50 to 100% of lacqueurs which are insoluble in acid, but soluble in intestinal juices.

25. Upon information and belief, the dipyridamole pellets in Amneal's ANDA product have a coating made up of 50 to 0% of lacqueurs which are insoluble in both gastric and intestinal juices.

26. Upon information and belief, Amneal's ANDA product contains either fumaric acid or tartaric acid.

27. Upon information and belief, Amneal's ANDA seeks FDA approval for the following indication: "to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis."

28. Upon information and belief, Amneal has applied for a use of Amneal's ANDA product that will inhibit the occurrence of strokes of the type caused by a blood clot when administered to a patient requiring inhibition of venous or arterial clot formation.

29. Amneal's Notice Letter does not deny infringement of claims 2, 4, 6, 8, 12-14, and 16-18 of the '577 patent separate and apart from a defense of patent invalidity.

30. The only patent invalidity defense asserted in Amneal's Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

31. Amneal's Notice Letter cites U.S. Patent No. 4,367,217 ("Gruber") and U.S. Patent No. 4,694,024 ("Weithmann"), both of which were of record in the United States Patent and Trademark Office ("PTO") during prosecution of the application for the '577 patent.

32. The PTO determined that the '577 patent claims were patentable notwithstanding the disclosures of Weithmann and Gruber.

33. No reference cited in Amneal's Notice Letter discloses a pharmaceutical composition for oral administration comprising:

> a first component selected from the group consisting of dipyridamole, and the pharmaceutically acceptable salts thereof; and
>
> a second component selected from the group consisting of acetylsalicylic acid and the pharmaceutically acceptable salts thereof;
>
> said first and second components being present in a weight ratio in the range between 8:1 and 100:1;
>
> a pharmaceutically acceptable acid excipient formulated together with said first component in the form of pellets provided with a coating made up of 50 to

100% of lacqueurs which are insoluble in acid but soluble in intestinal juices and 50 to 0% of lacqueurs which are insoluble in both gastric and intestinal juices, and said acid excipient being in a ratio of at least one equivalent of said acid excipient to 1 mol of said first component;

said second component being present in the form of a tablet; and all components being contained together within a capsule.

34. No reference cited in Amneal's Notice Letter discloses a pharmaceutical composition for oral administration wherein dipyridamole is present in an amount between 75 and 400 mg and aspirin is present in an amount of 5 to 80 mg.

35. No reference cited in Amneal's Notice Letter discloses a pharmaceutical composition for oral administration comprising:

a first component selected from dipyridamole and the pharmaceutically acceptable salts thereof; and

a second component selected from acetylsalicylic acid and the pharmaceutically acceptable salts thereof; and,

wherein the quantities of the first and second components are adjusted so that the weight ratio between them is between 8:1 and 100:1.

36. No reference cited in Amneal's Notice Letter discloses a pharmaceutical composition for oral administration comprising:

dipyridamole; and,

acetylsalicylic acid;

wherein the quantities of dipyridamole and acetylsalicylic acid are adjusted so that the final dosage form comprises 200 mg of dipyridamole and 25 mg of acetylsalicylic acid, and so that the weight ratio between them is 8:1.

37. No reference cited in Amneal's Notice Letter discloses a method for inhibiting the formation of venous and arterial blood clots, which comprises administering to a patient requiring inhibition of venous or arterial clot formation a first drug selected from the group consisting of dipyridamole and the pharmaceutically acceptable salts thereof and a second drug selected from the group consisting of acetylsalicylic acid and the pharmaceutically acceptable salts thereof, with said first and second drugs being administered in a weight ratio in the range between 8:1 and 100:1.

38. No reference cited in Amneal's Notice Letter discloses a method for inhibiting the occurrence of temporary ischemic episodes, which consists of administering to a patient requiring inhibition of venous or arterial clot formation a first drug selected from the group consisting of dipyridamole and the pharmaceutically acceptable salts thereof and a second drug selected from the group consisting of acetylsalicylic acid and the pharmaceutically acceptable salts thereof, with said first and second drugs being administered in a weight ratio in the range between 8:1 and 100:1.

39. No reference cited in Amneal's Notice Letter discloses a method for inhibiting the occurrence of strokes of the type caused by a blood clot, which consists of administering to a patient requiring inhibition of venous or arterial clot formation a first drug selected from the group consisting of dipyridamole and the pharmaceutically acceptable salts thereof and a second drug selected from the group consisting of acetylsalicylic acid and the pharmaceutically acceptable salts thereof, with said first and second drugs being administered in a weight ratio in the range between 8:1 and 100:1.

CLAIM FOR RELIEF

40. Plaintiffs reallege paragraphs 1-39 as if fully set forth herein.

41. Because Amneal seeks approval of the Amneal ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a drug claimed in the '577 patent, and/or whose approved use is also claimed in the '577 patent, before its expiration, Amneal has infringed the '577 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

42. Plaintiffs are entitled to a declaration that, if Amneal commercially manufactures, uses, sells, offers to sell, and/or imports any of Amneal's ANDA product, or induces or contributes to any such conduct, it would further infringe the '577 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

43. Upon information and belief, the commercial manufacture, use, sale, offer to sell, and/or importation of Amneal's ANDA product, if approved by the FDA prior to the expiration of the '577 patent for use in accordance with its proposed labeling, would infringe and/or induce and/or contribute to the infringement of the '577 patent. Boehringer is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Amneal's ANDA No. 206392 be a date that is not earlier than the expiration date of the '577 patent, or any later expiration of exclusivity for the '577 patent to which Boehringer is or may become entitled.

44. At least claims 2, 4, 6, 8, 12-14, and 16-18 of the '577 patent encompass within their scope Amneal's ANDA product. Amneal's ANDA product would therefore literally infringe at least those claims.

45. Upon information and belief, Amneal was aware of the existence of the '577 patent, and was aware that the filing of Amneal's ANDA and a Paragraph IV certification with respect to the '577 patent constituted an act of infringement of that patent.

46. Amneal's statements of the factual and legal bases for its opinion regarding the invalidity of the '577 patent are devoid of any objective good-faith basis in either the facts or the law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Amneal has infringed the '577 patent by submitting ANDA No. 206392;

B. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. § 285;

C. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Amneal, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '577 patent prior to its expiration, including any exclusivities or extensions.

D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Amneal's ANDA No. 206392 be a date that is not earlier than the expiration date of the '577 patent, or any later expiration of exclusivity for the '577 patent to which Plaintiffs are or may become entitled; and

E. Such other and further relief as the Court may deem just and proper.

Dated: July 30, 2014

Respectfully submitted,

By: s/ Charles M. Lizza

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