IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI INC. AND ANDRX LABS, L.L.C.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AMNEAL PHARMACEUTICALS, LLC,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Shionogi Inc. and Andrx Labs, L.L.C. (collectively, "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States. This action relates to Abbreviated New Drug Application ("ANDA") No. 212148 filed by Amneal Pharmaceuticals, LLC ("Amneal") with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of Metformin Hydrochloride Extended Release 500 mg and 1000 mg tablets, a generic version of Shionogi's FORTAMET® Tablets, prior to expiration of U.S. Patent Nos. 6,790,459 (the "'459 Patent") and 6,866,866 (the "'866 Patent") (collectively, the "Patents-in-Suit").

PARTIES

2. Shionogi Inc. ("Shionogi") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

3. Andrx Labs, L.L.C. ("Andrx") is a Delaware limited liability company having a place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx is an affiliate of Teva Pharmaceuticals USA, Inc. ("Teva"), which is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Upon information and belief, Amneal is a company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, Bridgewater, NJ 08807. Upon information and belief, Amneal is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Amneal develops, manufactures, and/or distributes generic drug products for marketing, sale and/or use throughout the United States, including in this judicial district.

5. Upon information and belief, following any FDA approval of ANDA No. 212148, Amneal will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 212148 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

7. This Court has personal jurisdiction over Amneal because, among other things, Amneal is a company organized and existing under the laws of Delaware. *Daimler AG v. Bauman*, 571 U.S. 117, 137 (2014) ("[T]he place of incorporation and principal place of business are 'paradig[m] ... bases for general jurisdiction.'" (citation omitted)).

8. This Court also has personal jurisdiction over Amneal because of, among other things, its marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products in this judicial district. On information and belief, Amneal has purposefully conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue. Upon information and belief, Amneal holds a current and valid Delaware "Wholesale" pharmacy drug registration under License Nos. A4-0001536 (expires September 30, 2018) and A4-0002253 (expires September 30, 2018). Upon information and belief, Amneal also holds a current and valid Delaware "Distributor/Manufacturer CSR" controlled substance registration under License No. DM0006588 (expires June 30, 2019). Upon information and belief, Amneal has filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the generic drug product described in ANDA No. 212148 in the United States, including in Delaware.

9. Venue is proper in this judicial district under 28 U.S.C. § 1400(b) because, upon information and belief, Amneal is a company organized and existing under the laws of Delaware and therefore resides in Delaware. *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1517 (2017). Venue is also appropriate in this judicial district because, as set forth above, Amneal has committed an act of infringement and/or will commit further acts of infringement in this judicial district, *see Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. 17-cv-379-LPS, 2017 WL 3980155, at *8 (D. Del. Sept. 11, 2017) (acts of infringement "include[] all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is launched into the market").

10. For these reasons, and for other reasons that will be presented to the Court if jurisdiction and/or venue is challenged, the Court has personal jurisdiction over Amneal, and venue in this judicial district is proper.

PATENTS-IN-SUIT

11. Andrx is the owner of United States Patent No. 6,790,459, which was duly and legally issued on September 14, 2004, and is titled "Methods for Treating Diabetes Via Administration of Controlled Release Metformin." Shionogi has an exclusive license under the '459 Patent in the United States. A copy of the '459 Patent is attached as Exhibit A.

12. Andrx is the owner of United States Patent No. 6,866,866, which was duly and legally issued on March 15, 2005, and is titled "Controlled Release Metformin Compositions." Shionogi has an exclusive license under the '866 Patent in the United States. A copy of the '866 Patent is attached as Exhibit B.

ACTS GIVING RISE TO THIS ACTION

13. Andrx is the holder of New Drug Application ("NDA") No. 21-574, by which the FDA granted approval for 500 mg and 1000 mg extended-release metformin hydrochloride tablets. The metformin hydrochloride tablets described in Andrx's NDA are indicated as an adjunct to diet and exercise to lower blood glucose to improve glycemic control in adults with Type 2 diabetes mellitus. Shionogi markets these tablets in the United States under the tradename "FORTAMET®."

14. FORTAMET® and the use of FORTAMET® in accordance with its label are covered by one or more claims of the Patents-in-Suit.

15. The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the Patents-in-Suit in connection with FORTAMET®.

16. By letter dated August 27, 2018 (the "Notice Letter"), Amneal notified Andrx and Teva that it had submitted to the FDA ANDA No. 212148, seeking approval for the commercial manufacture, use, and sale of Metformin Hydrochloride Extended Release 500 mg and 1000 mg Tablets (the "Amneal ANDA Products") in the United States prior to the expiration of the Patents-in-Suit. Andrx, Teva, and Shionogi received the Notice Letter on August 28, 2018.

17. In the Notice Letter, Amneal notified Andrx and Teva that, as a part of its ANDA, it had filed a certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-in-Suit, asserting that those patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the Amneal ANDA Products in the United States.

18. By filing ANDA No. 212148, Amneal has necessarily represented to the FDA that, upon approval, the Amneal ANDA Products will have the same active ingredient, method of administration, dosage form, and strength as FORTAMET®, and will be bioequivalent to FORTAMET®.

19. Amneal's Notice Letter contained an offer of confidential access, the terms of which the parties have begun negotiating in good faith in an effort to reach a mutually-acceptable agreement, and under which Amneal's ANDA would be provided to Plaintiffs. The parties have been unable to reach agreement. Plaintiffs require discovery from Amneal.

20. This Complaint is being filed before the expiration of forty-five days from the date Andrx and Shionogi received the Notice Letter on August 28, 2018.

COUNT ONE – INFRINGEMENT OF THE '459 PATENT

21. Plaintiffs reallege paragraphs 1-20 as if fully set forth herein.

22. Amneal's submission of ANDA No. 212148 to obtain approval to engage in the commercial import, manufacture, use, offer for sale and/or sale of the Amneal ANDA Products

in the United States, prior to the expiration of the '459 patent, constitutes infringement of the '459 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

23. Upon information and belief, Amneal's offering to sell, sale, making, and/or importation of the Amneal ANDA Products, once ANDA No. 212148 is approved by the FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '459 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

24. On information and belief, the Amneal ANDA Products, if approved by the FDA, will be imported by Amneal into the United States, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one claim of the '459 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the Amneal ANDA Products will occur with Amneal's specific intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '459 Patent.

25. Upon information and belief, Amneal's offering to sell, sale, making, and/or importation of the Amneal ANDA Products, once ANDA No. 212148 is approved by the FDA, would contribute to infringement of at least one of the claims of the '459 Patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Amneal knows that the Amneal ANDA Products are especially made or adapted for use in infringing the

'459 Patent, and that the Amneal ANDA Products are not suitable for substantial non-infringing use.

26. On information and belief, Amneal will induce infringement, under 35 U.S.C. § 271(b), or contribute to infringement, under 35 U.S.C. § 271(c) of at least independent claim 1 of the '459 Patent, either literally or under the doctrine of equivalents. The Amneal ANDA Products are "controlled release dosage form[s]" comprising "an effective dose of metformin," as required by claim 1. On information and belief, by the filing of ANDA No. 212148, Amneal has necessarily represented that the Amneal ANDA Products have the same indication, active ingredient, method of administration, dosage form, and strength as FORTAMET®, and will be bioequivalent to FORTAMET®.

27. Plaintiffs will be irreparably harmed if Amneal is permitted to make, use, sell, offer to sell, and/or import the Amneal ANDA Products in or into the United States, and is not enjoined from doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of the approval of Amneal's ANDA No. 212148 be a date that is not earlier than the expiration date of the '459 Patent, or any later expiration of exclusivity for the '459 Patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

COUNT TWO – INFRINGEMENT OF THE '866 PATENT

28. Plaintiffs reallege paragraphs 1-27 as if fully set forth herein.

29. Amneal's submission of ANDA No. 212148 to obtain approval to engage in the commercial import, manufacture, use, offer for sale and/or sale of the Amneal ANDA Products in the United States, prior to the expiration of the '866 Patent, constitutes infringement of the '866 Patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

30. On information and belief, the commercial manufacture, use, offer to sell, sale or import of the Amneal ANDA Products that are the subject of ANDA No. 212148 would infringe at least independent claim 1 of the '866 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. The Amneal ANDA Products are "controlled release oral dosage form[s]" comprising "an effective dose of metformin," as required by claim 1. On information and belief, by the filing of ANDA No. 212148, Amneal has necessarily represented that the Amneal ANDA Products have the same indication, active ingredient, method of administration, dosage form, and strength as FORTAMET®, and will be bioequivalent to FORTAMET®.

31. Plaintiffs will be irreparably harmed if Amneal is permitted to make, use, sell, offer to sell, and/or import the Amneal ANDA Products in or into the United States, and is not enjoined from doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of the approval of Amneal's ANDA No. 212148 be a date that is not earlier than the expiration date of the '866 Patent, or any later expiration of exclusivity for the '866 Patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

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

(a) A judgment that Amneal's submission of ANDA No. 212148 was an act of infringement of one or more claims of the Patents-in-Suit, and that Amneal's manufacture, use, offer to sell, sale, or importation of the Amneal ANDA Products in or into the United States prior to the expiration of the Patents-in-Suit, will infringe and/or actively induce or contribute to the infringement of one or more claims of the Patents-in-Suit;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Amneal's ANDA No. 212148, shall not be earlier than the latest

expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(c) An Order permanently enjoining Amneal, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, or importing in or into the United States the Amneal ANDA Products, or any product or compound that infringes the Patents-in-Suit, or inducing or contributing to the infringement of the Patents-in-Suit until after the latest expiration date of the Patents-in-Suit, including any extension and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(d) Damages or other monetary relief to Plaintiffs if Amneal engages in commercial manufacture, use, offers to sell, sale or importation in or into the United States of the Amneal ANDA Products prior to the expiration of the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled; and

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

Dated: October 11, 2018

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