IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD., Defendant.	)	C.A. No. _____

COMPLAINT AGAINST CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD.

Plaintiff Novartis Pharmaceuticals Corporation (hereinafter "Plaintiff" or "Novartis"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning an Abbreviated New Drug Application ("ANDA") submitted to the United States Food and Drug Administration ("FDA") by the above-named defendant seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sacubitril/valsartan tablets, generic versions of Plaintiff's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patent No. 11,135,192 (the "'192 patent").

PARTIES

2. Plaintiff Novartis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

3. On information and belief, Defendant Crystal Pharmaceutical (Suzhou) Co., Ltd. ("Crystal") is a corporation organized and existing under the laws of China, having a principal place of business at B4-301 Biobay, Suzhou Industrial Park, Suzhou, China, 215123.

4. On information and belief, Crystal develops, manufactures, distributes, sells, and/or imports drugs for the entire United States market and does business in every state including Delaware, either directly or indirectly.

5. By a letter dated November 10, 2021 ("Crystal Notice Letter"), Crystal notified Plaintiff that (i) the FDA deemed acceptable for filing Crystal's ANDA No. 213605 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Crystal ANDA Products"), through which it seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products in or into the United States, including Delaware, prior to the expiration of the '192 patent, (ii) ANDA No. 213605 contains the required bioavailability and/or bioequivalence data, and that (iii) ANDA No. 213605 contains a Paragraph IV Certification with respect to the '192 patent.

6. Crystal has committed an act of infringement in this judicial district by filing ANDA No. 213605 with the intent to make, use, sell, offer for sale, and/or import the Crystal ANDA Products in or into this judicial district, prior to the expiration of the '192 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Plaintiff Novartis, a Delaware corporation.

7. Crystal has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Crystal ANDA Products, that will be purposefully directed at Delaware and elsewhere.

8. On information and belief, Crystal has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

9. Crystal has agreed with Plaintiff to litigate any patent action(s) concerning ANDA No. 213605 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware. This is an action concerning ANDA No. 213605.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Crystal because Crystal has committed tortious acts of patent infringement in preparing and submitting ANDA No. 213605 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Plaintiff Novartis, a Delaware corporation.

12. This Court also has personal jurisdiction over Crystal because, on information and belief, Crystal, upon approval of ANDA No. 213605, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213605 that will be purposefully directed at Delaware, including the marketing of the Crystal ANDA Products in Delaware, prior to the expiration of the '192 patent.

13. This Court also has personal jurisdiction over Crystal because, on information and belief, Crystal's affiliations with the State of Delaware are sufficiently continuous and systematic as to render Crystal essentially at home in this forum.

14. Crystal has agreed with Plaintiff to litigate any patent action(s) concerning ANDA No. 213605 in Delaware and not to contest personal jurisdiction or venue in Delaware in such an action. This is an action concerning ANDA No. 213605.

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

16. Venue is proper in this Court because Crystal is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1391(c)(3).

THE PATENT-IN-SUIT AND ENTRESTO®

17. The '192 patent, titled "Inhibitors for Treating Diseases Characterized by Atrial Enlargement or Remodeling," was duly and legally issued on October 5, 2021. A true and correct copy of the '192 patent is attached hereto as Exhibit A.

18. Novartis owns the '192 patent.

19. The '192 patent claims, *inter alia*, methods for treating heart failure with preserved ejection fraction (HF-PEF) in a human patient in need of such treatment comprising administering to the patient 50 mg, 100 mg, or 200 mg of a combination of (i) N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; and (ii) valsartan or a pharmaceutically acceptable salt thereof, twice daily for at least 36 weeks, wherein N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically

acceptable salt thereof and valsartan or a pharmaceutically acceptable salt thereof are administered in a 1:1 molar ratio.

20. Novartis is the holder of New Drug Application ("NDA") No. 207620 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of ENTRESTO® (sacubitril and valsartan) tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg. ENTRESTO® currently is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

21. One or more claims of the '192 patent cover the use of ENTRESTO®.

22. The FDA's official publication of approved drugs (the "Orange Book") lists the '192 patent in connection with ENTRESTO®.

INFRINGEMENT BY CRYSTAL OF THE PATENT-IN-SUIT

23. Plaintiff incorporates paragraphs 1 – 22 as if fully set forth herein.

24. On information and belief, Crystal submitted to the FDA ANDA No. 213605 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products prior to the expiration of the '192 patent.

25. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products in or into the United States prior to the expiration of the '192 patent, Crystal has committed an act of infringement under 35 U.S.C. § 271(e)(2).

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