IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD., Defendants.	)	C.A. No. _____

COMPLAINT AGAINST
DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, 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 defendants 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. 11,058,667 (the "'667 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, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

4. On information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

5. On information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

6. On information and belief, Dr. Reddy's Laboratories, Ltd. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

7. By a letter dated March 24, 2022 ("Dr. Reddy's Notice Letter"), Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. notified Novartis that (i) Dr. Reddy's Laboratories, Inc., on behalf of Dr. Reddy's Laboratories, Ltd., had submitted to the FDA ANDA No. 213627 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Dr. Reddy's ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Dr. Reddy's ANDA Products in

or into the United States, including Delaware, prior to the expiration of the '667 patent, and that (ii) ANDA No. 213627 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '667 patent.

8. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have committed an act of infringement in this judicial district by filing ANDA No. 213627 with the intent to make, use, sell, offer for sale, and/or import the Dr. Reddy's ANDA Products in or into this judicial district, prior to the expiration of the '667 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

9. On information and belief, Dr. Reddy's Laboratories, Inc. acted in concert with and under the direction of Dr. Reddy's Laboratories, Ltd. in the preparation and submission of ANDA No. 213627, and, if the ANDA is approved, will act in concert with and under the direction of Dr. Reddy's Laboratories, Ltd. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Dr. Reddy's ANDA Products in or into the United States, including Delaware, prior to the expiration of the '667 patent.

10. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Dr. Reddy's ANDA Products, that will be purposefully directed at Delaware and elsewhere.

11. On information and belief, Dr. Reddy's Laboratories, Inc. 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, and has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

12. On information and belief, Dr. Reddy's Laboratories, Ltd. 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, and has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

13. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, consenting to jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 21-1330 (D. Del.); *Merck Sharp & Dohme Corp. v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 20-847 (D. Del.); *Novartis Pharms. Corp. v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 19-2053 (D. Del.); *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 19-2045 (D. Del.); *Boehringer Ingelheim Pharms. Inc. et al. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 19-1495 (D. Del.).

14. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., the entities identified in the Dr. Reddy's Notice Letter as having submitted ANDA No. 213627, have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213627 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to contest personal jurisdiction and venue in the District of Delaware.

JURISDICTION AND VENUE

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

16. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213627 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 Novartis, a Delaware corporation.

17. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because, on information and belief, each such Defendant, upon approval of ANDA No. 213627, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213627 that will be purposefully directed at Delaware, including the marketing of the Dr. Reddy's ANDA Products in Delaware, prior to the expiration of the '667 patent.

18. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because, on information and belief, each such Defendant's affiliations with the State of Delaware are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum. On information and belief, each such Defendant develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly and/or has engaged in systematic and continuous business contacts within the State of Delaware. Upon information and belief, each such Defendant regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, such generic pharmaceutical products are

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