

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

_____	)	
NOVARTIS PHARMACEUTICALS	)	
CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
TORRENT PHARMA INC., TORRENT	)	
PHARMACEUTICALS LTD.,	)	
	)	
Defendants.	)	
_____	)	

**COMPLAINT AGAINST  
TORRENT PHARMA INC. AND TORRENT PHARMACEUTICALS 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, Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808, and having a principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd.

4. On information and belief, Torrent Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Off. Ashram Road, Ahmedabad – 380 009, Gujarat, India.

5. On information and belief, Torrent Pharma 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, Torrent Pharmaceuticals 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 letter dated November 11, 2021 (“Torrent Notice Letter”), Torrent Pharma Inc. notified Novartis that (i) Torrent Pharma Inc., on behalf of Torrent Pharmaceuticals Ltd., had submitted to the FDA ANDA No. 213604 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg (“Torrent ANDA Products”), seeking FDA approval to engage in

the commercial manufacture, use, sale, offer for sale, and/or importation of the Torrent ANDA Products in or into the United States, including Delaware, prior to the expiration of the '667 patent, and that (ii) ANDA No. 213604 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '667 patent.

8. Torrent Pharma Inc. has committed an act of infringement in this judicial district by filing ANDA No. 213604 with the intent to make, use, sell, offer for sale, and/or import the Torrent 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, Torrent Pharmaceuticals Ltd. acted in concert with and directed Torrent Pharma Inc. in the preparation and submission of ANDA No. 213604, and, if the ANDA is approved, will direct and act in concert with Torrent Pharma Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Torrent ANDA Products in or into the United States, including Delaware, prior to the expiration of the '667 patent.

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

11. On information and belief, Torrent Pharmaceuticals 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

including Torrent Pharma Inc.; 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. Both Torrent Pharmaceuticals Ltd., the entity identified in the Torrent Notice Letter as having submitted ANDA No. 213604 through Torrent Pharma Inc., and Torrent Pharma Inc. have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213604 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction or venue in the District of Delaware.

13. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. have each availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Bial-Portela & Ca., et al. v. Torrent Pharms. Ltd., et al.*, 18-279 (D. Del.); *H. Lundbeck A/S, et al. v. Torrent Pharms. Ltd., et al.*, 18-672 (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, 21-1330 (D. Del.).

### **JURISDICTION AND VENUE**

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

15. This Court has personal jurisdiction over Torrent Pharma Inc. and Torrent Pharmaceuticals 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. 213604 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.

16. This Court also has personal jurisdiction over Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. because, on information and belief, each such Defendant, upon approval of ANDA No. 213604, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213604 that will be purposefully directed at Delaware, including the marketing of the Torrent ANDA Products in Delaware, prior to the expiration of the '667 patent.

17. This Court also has personal jurisdiction over Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. because, on information and belief, each such Defendant's affiliations with the State of Delaware, including Torrent Pharma Inc.'s incorporation in Delaware, and Torrent Pharmaceuticals Ltd.'s ownership of and actions in concert with Torrent Pharma Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

18. This Court also has personal jurisdiction over Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. because each has availed itself of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

19. Both Torrent Pharmaceuticals Ltd., the entity identified in the Torrent Notice Letter as having submitted ANDA No. 213604 in concert with Torrent Pharma Inc., and Torrent Pharma Inc. have agreed not to challenge personal jurisdiction and venue in the District of Delaware with respect to any patent actions concerning ANDA No. 213604. This is an action concerning ANDA No 213604.

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

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