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# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC.,

Defendants.

Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent" or "Defendants"), alleges as follows:

### **NATURE OF THE ACTION**

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248



patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents in suit").

## THE PARTIES

- Plaintiff Supernus is a corporation organized and existing under the laws of
   Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland
   20850.
- 3. Upon information and belief, Defendant Torrent Pharmaceuticals Ltd. is a corporation operating and existing under the laws of India, with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad, Gujarat, 380009, India.
- 4. Upon information and belief, Torrent Pharmaceuticals Ltd. is in the business of, inter alia: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its various subsidiaries, including Defendant Torrent Pharma Inc., the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) in concert with and/or through its various subsidiaries, including Defendant Torrent Pharma Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.
- 5. According to Defendants' website, Torrent Pharmaceuticals Ltd. "is one of the leading pharma companies of the Country," "ranked amongst the leaders in therapeutic segment of cardiovascular (CV), central nervous system (CNS), gastro-intestinal (GI) and women healthcare (WHC)," "has significant presence in diabetology, pain management, gynaecology,



oncology and anti-infective segments," and has "a widespread global presence in over 40 countries." Torrent Website, https://torrentpharma.com/index.php/site/info/aboutUs (accessed July 28, 2021).

- 6. Torrent Pharmaceuticals Ltd.'s Annual Report 2020-2021 states that "[r]evenues from the US business were ₹1261 crores (sales US\$ 166 million) during 2020-21." Torrent Pharmaceuticals Ltd.'s Annual Report 2020-2021 at 114, https://torrentpharma.com/pdf/download/AR-2020-21.pdf (accessed July 28, 2021).
- 7. Torrent Pharmaceuticals Ltd.'s Annual Report 2020-2021 indicates that while new approvals for two of its facilities "were on hold pursuant to their negative classification by the USFDA," the company expected that "[n]ew approvals from said facilities shall commence, post its re-inspection by USFDA." Further, the company "has filled [sic] 12 ANDA's during 2020-21," "has 103 ANDA approvals (including 6 tentative approvals) and its pipeline consists of 54 pending approvals (not including tentative or partnered filings) and more than 40 products under development to be filed over the next 3 years." Torrent Pharmaceuticals Ltd.'s Annual Report 2020-2021 at 114, https://torrentpharma.com/pdf/download/AR-2020-21.pdf (accessed July 28, 2021).
- 8. Upon information and belief, Defendant Torrent Pharma Inc. is a Delaware limited liability company having its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, NJ 07920. Upon information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. Upon information and belief, Torrent Pharma Inc. acts at the direction of, under the control of, and for the direct benefit of Torrent Pharmaceuticals Ltd. and is controlled and/or dominated by Torrent Pharmaceuticals Ltd.



- 9. Upon information and belief, Torrent Pharma Inc. is in the business of, *inter alia*: (i) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its parent, including Defendant Torrent Pharmaceuticals Ltd. and various subsidiaries, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through its parent, including Defendant Torrent Pharmaceuticals Ltd. and various subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.
- 10. Upon information and belief, Torrent filed ANDA No. 215918 ("the Torrent ANDA") with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsules, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate ("the Torrent ANDA Products").
- 11. Upon information and belief, Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. are acting cooperatively with respect to the Torrent ANDA.
- 12. Upon information and belief, Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Losartan Potassium Tablets (25 mg, 50 mg, and 100 mg), Isosorbide Mononitrate Extended-Release Tablets (30 mg, 60 mg, and 120 mg), Felodipine Extended-Release Tablets (2.5 mg, 5 mg, and 10 mg), and Zolpidem Tartrate Tablets (5 mg and 10 mg)) that will be manufactured and sold pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.



- 13. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Torrent is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.
- 14. Upon information and belief, Torrent will market the Torrent ANDA Products throughout the United States, including in New Jersey, upon approval of the Torrent ANDA.

#### **JURISDICTION AND VENUE**

- 15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 16. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).
- 17. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, Torrent states on its website that, as "[t]he world's largest market for pharmaceuticals, USA has always been on Torrent Pharma's strategic radar. Torrent Pharma Inc., our subsidiary, serves the growing need of our products in the market and today we are ranked 10th amongst the US generic Indian Companies." Torrent Website, https://torrentpharma.com/index.php/site/info/business\_usa (accessed July 28, 2021). Regarding its U.S. business, Torrent Pharmaceuticals Ltd.'s Annual Report 2020-2021 further states that "Torrent continued to strengthen its pipeline and has filed 12 ANDAs (PY 12) during the year," and that "3 products were launched during the year." Torrent Pharmaceuticals Ltd.'s Annual Report 2020-2021 at 80,

https://torrentpharma.com/pdf/download/AR-2020-21.pdf (accessed July 28, 2021). In addition,



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