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## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

AJANTA PHARMA LIMITED and AJANTA PHARMA USA 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 Ajanta Pharma Limited and Ajanta Pharma USA Inc. (collectively, "Ajanta" 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 Ajanta Pharma Limited ("Ajanta Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at Ajanta House, Charkop, Kandivli West, Mumbai-400 067, Maharashtra, India.
- 4. According to Defendants' website, "Ajanta Pharma is a specialty pharmaceutical company engaged in development, manufacture and marketing of quality finished dosages in domestic and international markets" with over 7,000 employees operating in more than 30 countries across 4 continents. Ajanta Website, http://www.ajantapharma.com/index.aspx (accessed March 26, 2021).
- 5. Ajanta Ltd.'s Annual Report 2019-2020 states that it experienced "robust growth of 82% in the market" for FY 2020 in the United States. Ajanta Ltd.'s Annual Report 2019-2020 at 3 and 9, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021). Ajanta Ltd.'s Annual Report 2019-2020 further states, "[t]his growth was achieved on the back of 7 new product launches and market share gained by [Ajanta Ltd.] existing products. US has played key role in the resilience [Ajanta Ltd.] displayed amidst adversity." Ajanta Ltd.'s Annual Report 2019-2020 at 9, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021). Additionally, Ajanta Ltd.'s Annual Report 2019-2020 indicates the company "[r]eceived approvals for 9 ANDAs which lead to a total of 40 approvals (including 1 tentative approval) . . .



.[and] 12 New ANDAs filled with USFDA." Ajanta Ltd.'s Annual Report 2019-2020 at 39, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021).

- 6. Upon information and belief, Ajanta 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 Ajanta Pharma USA 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 Ajanta Pharma USA Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.
- 7. Upon information and belief, Defendant Ajanta Pharma USA Inc. ("Ajanta USA") is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807. Upon information and belief, Ajanta USA is a wholly-owned subsidiary of Ajanta Ltd. Upon information and belief, Ajanta USA acts at the direction of, under the control of, and for the direct benefit of Ajanta Ltd. and is controlled and/or dominated by Ajanta Ltd.
- 8. Upon information and belief, Ajanta USA 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 Ajanta 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 Ajanta Ltd. and various subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

- 9. Upon information and belief, Ajanta Ltd. filed ANDA No. 215663 ("the Ajanta ANDA") with 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 capsule, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate ("the Ajanta Products").
- 10. Upon information and belief, Ajanta Ltd. and Ajanta USA collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Risperidone Tablet (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg); Clomipramine Hydrochloride Capsules (25 mg, 50 mg, and 75 mg), and Aripiprazole Tablet (2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg), and Tadalafil Tablet (2.5 mg, 5 mg, 10 mg, 20 mg)) that will be manufactured and sold pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.
- 11. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Ajanta Ltd. 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.



#### **JURISDICTION AND VENUE**

- 12. This Court has jurisdiction over the subject matter of this action pursuant to 28U.S.C. §§ 1331 and 1338(a).
- 13. 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).
- 14. 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, Defendants state on their website that they are "gradually building a meaningful presence in the US market with select product portfolio, which include complex technology products to get the competitive advantage in the market place. We expect US market to be our key growth driver in the coming years." Ajanta Website, http://www.ajantapharma.com/overview.html (accessed March 26, 2021). Defendants further state on their website "[o]ur products are already available on the shelf in US through our subsidiary, located in New Jersey, the hub of pharma industry in USA." Ajanta Website, http://www.ajantapharma.com/generics.html (accessed March 26, 2021). In addition, Defendants' website indicates that as of February 2021, Defendants had 42 products approved by FDA with 18 additional products submitted and under approval with FDA. Ajanta Website, http://www.ajantapharma.com/AdminData/InvesterPresentation/InvestorPresentation ofQ3FY2021.pdf (accessed March 26, 2021).
- 15. This Court has personal jurisdiction over Ajanta USA at least because, upon information and belief: (i) Ajanta USA maintains a principal place of business in New Jersey located at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807; (ii) Ajanta USA is doing business in New Jersey and maintains continuous and systematic



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