IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. LUPIN LIMITED, LUPIN ATLANTIS HOLDINGS S.A., NANOMI B.V., LUPIN INC. AND LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 21-cv-01293-MN
LUPIN LIMITED, Counterclaimant, v. SUPERNUS PHARMACEUTICALS, INC., Counterdefendant.	

DEFENDANTS LUPIN LIMITED, LUPIN ATLANTIS HOLDINGS S.A., NANOMI B.V., LUPIN INC. AND LUPIN PHARMACEUTICALS, INC.'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), through their undersigned counsel, hereby answer the Complaint of Plaintiff Supernus Pharmaceuticals, Inc. ("Plaintiff") as follows:

To the extent not specifically admitted herein, the allegations of the Complaint are denied.

NATURE OF THE ACTION[1]

1. Lupin admits that the Complaint filed by Plaintiff purports to state a civil action for patent infringement under the United States patent laws, Title 35, United States Code. Lupin admits that the Complaint purports to allege infringement of 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") (collectively, the "Patents-in-Suit"). Lupin admits that Exhibits A-J are attached to the Complaint and purport to be a copy of the Patents-in-Suit. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 1 of the Complaint.

THE PARTIES

2. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 2 of the Complaint and, therefore, denies each and every allegation in Paragraph 2.

3. Lupin admits that Lupin Limited ("Lupin Ltd.") is a corporation organized and existing under the laws of India, with a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 3 of the Complaint.

4. Lupin admits that Lupin Atlantis Holdings S.A. is a corporation organized and existing under the laws of Switzerland and having a principal place of business at Landis+Gyr-Strasse 1, 6300 Zug, Switzerland. Lupin denies that Lupin Atlantis Holdings S.A. is a proper party

[1] For the Court's convenience, Lupin has incorporated the section titles that appear in the Complaint. Lupin does not necessarily agree with the characterizations of such section titles and does not waive any right to object to those characterizations.

to this action. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 4 of the Complaint.

5. Lupin admits that Nanomi B.V. is a corporation organized and existing under the laws of The Netherlands, with a registered office at Zutphenstraat 51, 7575 EJ Oldenzaal, Overijssel, The Netherlands. Lupin denies that Nanomi B.V. is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 5 of the Complaint.

6. Lupin admits that Lupin Inc. is a corporation organized and existing under the laws of Delaware and has a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801 and has its principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Lupin denies that Lupin Inc. is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 6 of the Complaint.

7. Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware and has a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801 and has its principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 7 of the Complaint.

8. Lupin admits that Lupin Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 215561 with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j), seeking approval of a proposed drug product that is in the form of capsules,

extended release, for oral administration, each containing 25 mg, 50 mg, 100 mg, or 200 mg topiramate as the active ingredient ("Lupin Ltd.'s ANDA Products"). Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 8 of the Complaint.

9. Lupin denies each and every allegation contained in Paragraph 9 of the Complaint.

JURISDICTION AND VENUE

10. Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2) related to Lupin Ltd.'s ANDA No. 215561. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 10 of the Complaint.

11. Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 11 of the Complaint.

12. Paragraph 12 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper

parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 12 of the Complaint.

13. Paragraph 13 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 13 of the Complaint.

14. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 14 of the Complaint.

15. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 15 of the Complaint.

16. Paragraph 16 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 17 of the Complaint.

18. Lupin admits that https://www.lupin.com/US/about-us/ (accessed 10/19/2021) contains text that states: "Lupin's presence in the United States is comprised of a diverse workforce encompassing manufacturing, research and development, and commercial divisions for generics, complex generics, biosimilars and branded pharmaceuticals." Lupin admits that the same website (accessed 10/19/2021) further states: "Lupin has a strong and well-established generic presence in the United States, having entered the U.S. market in 2003 and maintaining a competitive edge in the list of top 5 generic pharmaceutical companies by prescriptions dispensed since 2010" and

contains a footnote in reference to this statement. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 18 of the Complaint.

19. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 19 of the Complaint.

20. Lupin admits that https://www.lupin.com/about-us/global-presence/ (accessed 10/19/2021) contains text that states: "Lupin's journey began in India, when Dr Desh Bandhu Gupta (fondly called DBG) established the company in 1968. From one facility in Aurangabad in 1979, the company now has 11 state-of-the-art manufacturing facilities across the country. Scientists and R&D personnel at the company's two research centres in Pune and Aurangabad leverage cutting-edge technology to provide unique solutions, including those in the field of high quality affordable biosimilars." Lupin admits that the same website (accessed 10/19/2021) further states: "In 2017-18, Lupin achieved a milestone when US revenues crossed $1 billion." Lupin admits that https://www.lupin.com/about-us/global-manufacturing/ (accessed 10/19/2021) contains text that states: "Our 15 state-of-the-art manufacturing facilities are spread across India, the United States, Brazil and Mexico." Lupin admits that https://www.lupin.com/about-us/research-and-innovation/ (accessed 10/19/2021) contains text that states: "Lupin's R&D effort is aligned with our enterprise goal — to bring affordable, quality medicines to market in order to address unmet patient needs. This vision drives our 1,500+ scientists and R&D personnel in seven research centres spread across five countries – India (Pune and Aurangabad), the US (New Jersey and Florida), Mexico, Brazil and the Netherlands." Lupin admits that the same website (accessed

10/19/2021) further contains text identifying "437 ANDA filings" and "289 ANDA approvals." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 20 of the Complaint.

21. Lupin admits that https://lupin.com/annual-report-2021/img/lupin-ir-2021.pdf (accessed October 21, 2021) contains text that states: "The US is largest market for Lupin and other generic peers driven by its scale, preference for reimbursement schemes that favor substitution towards generic pharmaceuticals. Lupin admits that the same website (accessed October 21, 2021) further states: "Lupin products touch 100 Million patient lives in the US each year." Lupin admits that the same website (accessed October 21, 2021) further states: "In FY21, US sales contributed INR 53,730 million to the company's revenue, accounting for 36% of the overall sales." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 21 of the Complaint.

22. Lupin admits that https://lupin.com/annual-report-2021/img/lupin-ir-2021.pdf (accessed October 21, 2021) contains text under a heading titled "United States" that states: "53 products rank #1 in market share." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 22 of the Complaint.

23. Lupin admits that https://lupin.com/annual-report-2021/img/lupin-ir-2021.pdf (accessed October 21, 2021) contains text in reference to "FY21" that states: "During the year, we filed 15 ANDAs and 1 BLA and received 19 ANDA approvals." Lupin admits that the same website (accessed October 21, 2021) further states: "In FY21, we settled 11 pending US litigations and 1 pending UK litigation." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 23 of the Complaint.

24. Paragraph 24 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 24 of the Complaint.

25. Lupin admits that Lupin Atlantis Holdings S.A. is a wholly-owned subsidiary of Lupin Ltd. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 25 of the Complaint.

26. Paragraph 26 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 26 of the Complaint.

27. Lupin admits that https://www.lupin.com/wp-content/uploads/2021/05/lupin-atlantis-holdings-sa-switzerland-2019.pdf (accessed October 21, 2021) contains text that states: "Lupin Inc. was incorporated by the Company in June 2013 in the state of Maryland, USA. Now, Lupin Inc. is engaged in owning intellectual properties and in distribution of pharmaceutical products." Lupin admits that the same website (accessed October 21, 2021) refers to Lupin Atlantis Holdings SA as "the Company." Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 27 of the Complaint.

28. Lupin admits that https://www.lupin.com/wpcontent/uploads/2021/05/lupin-atlantis-holdings-sa-switzerland-2018.pdf (accessed October 21, 2021) contains text that states:

"LAHSA along with its US subsidiary Lupin Inc. acquired GAVIS Pharmaceuticals LLC and Novel Laboratories Inc. (GAVIS), USA. This acquisition enhances Lupin's scale in the US generic market and also broadens Lupin's pipeline in dermatology, controlled substances and other high-value and niche generics." Lupin admits that the same website (accessed October 21, 2021) further states: "[T]he company is developing with Celon Pharma SA a dry powder inhaler (DPI) for commercialization in the US market." Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 28 of the Complaint.

29. Paragraph 29 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 29 of the Complaint.

30. Lupin admits that Nanomi B.V. is a wholly-owned subsidiary of Lupin Ltd. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 30 of the Complaint.

31. Paragraph 31 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 31 of the Complaint.

32. Lupin admits that https://www.lupin.com/wp-content/uploads/2021/05/lupin-atlantis-holdings-sa-switzerland-2020.pdf (accessed October 21, 2021) lists "Nanomi BV" under

a heading that states "Loans to subsidiaries." Lupin admits that https://www.lupin.com/wp-content/uploads/2021/07/lupin-inc-console-unsigned-fy-2020-21.pdf (accessed October 21, 2021) contains text that states: "Lupin Inc., including its consolidated subsidiaries, (collectively, the Company) was incorporated in the United States of America (USA) under the Laws of the State of Maryland on June 27, 2013 as a Maryland Corporation and converted to a Delaware Corporation on March 8, 2016. The Company was a consolidated subsidiary of Lupin Atlantis Holdings, S.A. (LAHSA), who is wholly owned by Lupin Limited (LL), the Company's ultimate parent company. On March 31, 2020, LAHSA entered into a Stock Purchase Agreement with Nanomi B.V. (Nanomi), which is also a wholly owned subsidiary under LL, to sell 100% of its ownership interests in the Company to Nanomi. As a result, the Company became a wholly owned subsidiary of Nanomi, effective March 31, 2020." Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 32 of the Complaint.

33. Paragraph 33 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin admits that Lupin Inc. is a corporation organized and existing under the laws of Delaware. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. To the extent an answer is required, Lupin denies each and every allegation contained in Paragraph 33 of the Complaint.

34. Lupin admits that Lupin Inc. is a wholly-owned subsidiary of Nanomi B.V. Lupin admits that Lupin Atlantis Holdings S.A. is a wholly-owned subsidiary of Lupin Ltd. Lupin admits that Nanomi B.V. is a wholly-owned subsidiary of Lupin Ltd. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to

this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 34 of the Complaint.

35. Paragraph 35 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 35 of the Complaint.

36. Lupin admits that https://www.lupin.com/wp-content/uploads/2021/07/lupin-inc-console-unsigned-fy-2020-21.pdf (accessed October 21, 2021) contains text that states: "The Company's core business as a distributor is to trade in pharmaceutical products and to render marketing and ancillary services related thereto." Lupin admits that the same website (accessed October 21, 2021) refers to Lupin Inc. as "the Company." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 36 of the Complaint.

37. Lupin admits that https://www.lupin.com/wp-content/uploads/2021/07/lupin-inc-console-unsigned-fy-2020-21.pdf (accessed October 21, 2021) contains text that states: "The Company's intangible assets include both finite lived and indefinite lived assets. Finite lived intangible assets, consisting of Currently Marketing Products (CMPs), New Drug Applications (NDAs) and Approved Abbreviated New Drug Applications (ANDAs) are amortized on a straight-line basis over the estimated useful life of the assets. Indefinite-lived intangible assets consist of acquired in process research and development (IPR&D) product rights and filed ANDAs not yet approved by the Food and Drug Administration (FDA)." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 37 of the Complaint.

38. Paragraph 38 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 38 of the Complaint.

39. Lupin admits that Lupin Pharmaceuticals, Inc. is indirectly a wholly-owned subsidiary of Lupin Ltd. Lupin admits that Lupin Inc. owns more than a 10% interest in Lupin Pharmaceuticals, Inc. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 39 of the Complaint.

40. Paragraph 40 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 40 of the Complaint.

41. Paragraph 41 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic

pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 41 of the Complaint.

42. Paragraph 42 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the Patents-in-Suit. Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin admits that one or more of Lupin Inc., Lupin Pharmaceuticals, Inc., Lupin Atlantis Holdings S.A., and Lupin Ltd. were named as a defendant in each of the following actions: *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A., et al.*, No. 21-229-LPS (D. Del.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd., et al.*, No. 20-1296-LPS (D. Del.); *Ferring Pharm. Inc. v. Lupin Inc., et al.*, No. 19-913-RGA (D. Del.); *Lupin Atlantis Holdings, S.A. v. Invagen Pharm., Inc.*, No. 16-708-SLR-SRF (D. Del.); and *Sanofi v. Lupin Atlantis Holdings S.A., et al.*, No. 15-415-RGA (D. Del.). Lupin denies that one or more of Lupin Inc., Lupin Pharmaceuticals, Inc., Lupin Atlantis Holdings S.A., and Lupin Ltd. asserted counterclaims in *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A., et al.*, No. 21-229-LPS (D. Del.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd., et al.*, No. 20-1296-LPS (D. Del.); *Ferring Pharm. Inc. v. Lupin Inc., et al.*, No. 19-913-RGA (D. Del.); *Lupin Atlantis Holdings, S.A. v. Invagen Pharm., Inc.*, No. 16-708-SLR-SRF (D. Del.); and *Sanofi v. Lupin Atlantis Holdings S.A., et al.*, No. 15-415-RGA (D. Del.). Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as

expressly admitted, Lupin denies each and every allegation contained in Paragraph 42 of the Complaint.

43. Paragraph 43 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin admits that in *Sanofi v. Lupin Atlantis Holdings S.A.*, No. 15-415-RGA (D. Del.), D.I. 31 at 4, Lupin stated: "Lupin admits that LPI sells and distributes pharmaceutical products throughout the United States, including Delaware." Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 43 of the Complaint.

44. Paragraph 44 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA. Lupin admits that Lupin Pharmaceuticals, Inc. sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 44 of the Complaint.

45. Lupin admits that https://www.lupin.com/US/generics/ (accessed October 28, 2021) contains text that states under the heading, "Generics" the phrase "Rapid Growth Through Vertical Integration." Lupin admits that the same website (accessed October 28, 2021) contains text that states: "We are vertically integrated, from process development of the API to the

submission of dossiers for finished dosages." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 45 of the Complaint.

46. Paragraph 46 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest venue in this Court for the purposes of this civil action only. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 46 of the Complaint.

47. Paragraph 47 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies that Lupin Atlantis Holdings S.A. is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 47 of the Complaint.

48. Paragraph 48 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies that Nanomi B.V. is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 48 of the Complaint.

49. Paragraph 49 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Inc. is a corporation organized and existing under the laws of Delaware. Lupin denies that Lupin Inc. is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 49 of the Complaint.

50. Paragraph 50 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware. Lupin denies that Lupin

Pharmaceuticals, Inc. is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 50 of the Complaint.

51. Paragraph 51 of the Complaint contains legal conclusions to which no answer is required and is vague in its allegations. To the extent an answer is required, Lupin admits that one or more of Lupin Inc., Lupin Pharmaceuticals, Inc., Lupin Atlantis Holdings S.A., and Lupin Ltd. were named as a defendant in each of the following actions: *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A., et al.*, No. 21-229-LPS (D. Del.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd., et al.*, No. 20-1296-LPS (D. Del.); *Ferring Pharm. Inc. v. Lupin Inc., et al.*, No. 19-913-RGA (D. Del.); *Lupin Atlantis Holdings, S.A. v. Invagen Pharm., Inc.*, No. 16-708-SLR-SRF (D. Del.); and *Sanofi v. Lupin Atlantis Holdings S.A., et al.*, No. 15-415-RGA (D. Del.). Lupin denies that one or more of Lupin Inc., Lupin Pharmaceuticals, Inc., Lupin Atlantis Holdings S.A., and Lupin Ltd. consented to venue in *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A., et al.*, No. 21-229-LPS (D. Del.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd., et al.*, No. 20-1296-LPS (D. Del.); *Ferring Pharm. Inc. v. Lupin Inc., et al.*, No. 19-913-RGA (D. Del.); *Lupin Atlantis Holdings, S.A. v. Invagen Pharm., Inc.*, No. 16-708-SLR-SRF (D. Del.); and *Sanofi v. Lupin Atlantis Holdings S.A., et al.*, No. 15-415-RGA (D. Del.). Lupin denies that Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. are proper parties to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 51 of the Complaint.

FACTS AS TO ALL COUNTS

52. Lupin admits that the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies "SUPERNUS PHARMACEUTICALS INC" as holding New Drug Application ("NDA") No. 201635 for

"TROKENDI XR" brand topiramate extended-release capsules in 25, 50, 100, and 200 mg dosages. Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 52 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 52.

53. Lupin admits that, pursuant a recent version of the FDA-approved label for Trokendi XR® brand capsules, it is presently indicated for "Epilepsy: initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older (1.1); adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS) in patients 6 years of age and older (1.2)" and "Preventive treatment of migraine in patients 12 years of age and older (1.3)." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 53 of the Complaint.

54. Lupin admits that, pursuant a recent version of the FDA-approved label for Trokendi XR® brand capsules, "[t]he recommended dose for TROKENDI XR monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily." Lupin further admits that, pursuant to the FDA-approved label for TROKENDI XR brand capsules, "[d]osing in patients 6 to 9 years of age is based on weight." Lupin further admits that, pursuant a recent version of the FDA-approved label for Trokendi XR® brand capsules, "[t]he recommended total daily dose of TROKENDI XR ® as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily." Lupin further admits that, pursuant a recent version of the FDA-approved label for Trokendi XR® brand capsules, "[t]he recommended total daily dose of TROKENDI XR ® as adjunctive therapy for patients 6 to 16

years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily." Lupin further admits that, pursuant a recent version of the FDA-approved label for Trokendi XR® brand capsules, "[t]he recommended total daily dose of TROKENDI XR ® as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 54 of the Complaint.

55. Lupin admits that the electronic version of the Orange Book (accessed October 31, 2021) lists the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents under a section titled "Patent Data" for each of the 25, 50, 100, and 200 mg dosages of "TROKENDI XR." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 55 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 55.

56. Lupin admits that, according to the face of the '576 patent, the '576 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on October 30, 2012. Lupin further admits that, according to the face of the '576 patent, the assignee of the '576 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '576 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 56 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 56.

57. Lupin admits that, according to the face of the '580 patent, the '580 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on October 30,

2012. Lupin further admits that, according to the face of the '580 patent, the assignee of the '580 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '580 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 57 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 57.

58. Lupin admits that, according to the face of the '683 patent, the '683 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on March 4, 2014. Lupin further admits that, according to the face of the '683 patent, the assignee of the '683 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '683 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 58 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 58.

59. Lupin admits that, according to the face of the '248 patent, the '248 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on November 4, 2014. Lupin further admits that, according to the face of the '248 patent, the assignee of the '248 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '248 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 59 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 59.

60. Lupin admits that, according to the face of the '191 patent, the '191 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on November 18, 2014. Lupin further admits that, according to the face of the '191 patent, the assignee of the '191 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '191 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 60 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 60.

61. Lupin admits that, according to the face of the '989 patent, the '989 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on March 31, 2015. Lupin further admits that, according to the face of the '989 patent, the assignee of the '989 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '989 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 61 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 61.

62. Lupin admits that, according to the face of the '940 patent, the '940 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on January 24, 2017. Lupin further admits that, according to the face of the '940 patent, the assignee of the '940 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '940 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or

information to form a belief as to the truth or falsity of the allegations in Paragraph 62 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 62.

63. Lupin admits that, according to the face of the '004 patent, the '004 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on January 31, 2017. Lupin further admits that, according to the face of the '004 patent, the assignee of the '004 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '004 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 63 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 63.

64. Lupin admits that, according to the face of the '983 patent, the '983 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on April 18, 2017. Lupin further admits that, according to the face of the '983 patent, the assignee of the '983 patent is Supernus Pharmaceuticals, Inc. Lupin further admits that, according to the face of the '983 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 64 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 64.

65. Lupin admits that, according to the face of the '790 patent, the '790 patent is titled "SUSTAINED-RELEASE FORMULATIONS OF TOPIRAMATE" and issued on June 11, 2019. Lupin further admits that, according to the face of the '790 patent, the assignee of the '790 patent is "SUPERNUS PHARMACEUTICALS, INC." Lupin further admits that, according to the face of the '790 patent, Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed

under a section titled "Inventors." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 65 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 65.

66. Lupin admits that Lupin Ltd. sent a letter, dated July 29, 2021, to Supernus Pharmaceuticals, Inc. at 1550 East Gude Drive, Rockville, MD 20850 providing a "Notice of Paragraph IV Certification" for ANDA No. 215561 ("Lupin Ltd.'s Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. § 314.95 with respect to the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent. Lupin admits that Lupin Ltd.'s Notice Letter notified Supernus Pharmaceuticals, Inc. that Lupin Ltd. has submitted, and the FDA has received, ANDA No. 215561 under FDCA § 505(j)(2)(B)(ii) in order to obtain approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 66.

67. Lupin admits that Lupin Ltd.'s Notice Letter was signed by Joseph M. Reisman. Lupin further admits that Lupin Ltd.'s Notice Letter identified each of Joseph Reisman, Ph.D., Esq. and William R. Zimmerman, Esq. as "[t]he agent in the United States authorized to accept service of process for Lupin Limited, limited to commencement of a patent infringement suit based on this notification of certification." Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 67.

68. Lupin admits that Lupin Ltd.'s ANDA Products are in the form of capsules, extended release, for oral administration, each containing 25 mg, 50 mg, 100 mg, or 200 mg topiramate as the active ingredient. Lupin further admits that the established name for Lupin Ltd.'s ANDA Products is topiramate and the proprietary name of Lupin Ltd.'s ANDA Products is

Trokendi XR®. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 68.

69. Lupin admits that Lupin Ltd.'s ANDA Products are in the form of capsules, extended release, for oral administration, each containing 25 mg, 50 mg, 100 mg, or 200 mg topiramate as the active ingredient. Lupin further admits that Lupin Ltd.'s ANDA No. 215561 sometimes refers to Lupin Ltd.'s ANDA Products as topiramate extended-release capsules. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 69.

70. Lupin admits that the proposed prescribing information submitted to the FDA with Lupin Ltd.'s ANDA No. 215561 includes a header titled "Indications and Usage" and states: "Epilepsy: initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older (1.1); adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS) in patients 6 years of age and older (1.2)" and "Preventive treatment of migraine in patients 12 years of age and older (1.3)." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 70 of the Complaint.

71. Lupin admits that the proposed prescribing information submitted to the FDA with Lupin Ltd.'s ANDA No. 215561 includes a header titled "Dosage and Administration" and states: "The recommended dose for topiramate extended-release capsules monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily." Lupin further admits that the proposed prescribing information submitted to the FDA with Lupin Ltd.'s ANDA No. 215561 includes a header titled "Dosage and Administration" and states: "Dosing in patients 6 to 9 years of age is based on weight." Lupin further admits that the proposed prescribing information

submitted to the FDA with Lupin Ltd.'s ANDA No. 215561 includes a header titled "Dosage and Administration" and states: "The recommended total daily dose of topiramate extended-release capsules as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily." Lupin further admits that the proposed prescribing information submitted to the FDA with Lupin Ltd.'s ANDA No. 215561 includes a header titled "Dosage and Administration" and states: "The recommended total daily dose of topiramate extended-release capsules as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily." Lupin further admits that the proposed prescribing information submitted to the FDA with Lupin Ltd.'s ANDA No. 215561 includes a header titled "Dosage and Administration" and states: "The recommended total daily dose of topiramate extended-release capsules as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 71 of the Complaint.

72. Lupin admits that the proposed prescribing information submitted to the FDA with Lupin Ltd.'s ANDA No. 215561 includes a header titled "Administration Instructions" and states: "Topiramate extended-release capsules can be taken without regard to meals" and "Swallow capsule whole and intact. Do not sprinkle on food, chew, or crush." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 72 of the Complaint.

73. Lupin denies each and every allegation contained in Paragraph 73 of the Complaint.

74. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 74 of the Complaint.

75. Paragraph 75 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd.'s Notice Letter was sent pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. Lupin further admits that Lupin Ltd.'s Notice Letter included "a detailed statement of the factual and legal bases for Lupin's Paragraph IV Certification that, in its opinion, the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, and the '790 Patent, are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, importation, use, offer for sale or sale of Lupin's topiramate ANDA product, provided pursuant to FDCA Section 505(j)(2)(B)(iv)." Lupin further admits that Lupin Ltd.'s Notice Letter stated: "By providing this detailed statement, Lupin does not disclaim or waive other factual or legal bases upon which it might establish that one or more of the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, or the '790 Patent, are invalid, unenforceable and/or establish that the Patentee has failed to prove that one or more of the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, or the '790 Patent, will be infringed." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 75 of the Complaint.

76. Lupin admits Lupin Ltd.'s Notice Letter was sent pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 76 of the Complaint.

77. Paragraph 77 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd.'s Notice Letter included "a detailed statement of the factual and legal bases for Lupin's Paragraph IV Certification that, in its opinion, the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, and the '790 Patent, are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, importation, use, offer for sale or sale of Lupin's topiramate ANDA product, provided pursuant to FDCA Section 505(j)(2)(B)(iv)." Lupin further admits that Lupin Ltd.'s Notice Letter stated: "By providing this detailed statement, Lupin does not disclaim or waive other factual or legal bases upon which it might establish that one or more of the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, or the '790 Patent, are invalid, unenforceable and/or establish that the Patentee has failed to prove that one or more of the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, or the '790 Patent, will be infringed." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 77 of the Complaint.

78. Paragraph 78 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd.'s Notice Letter included "a detailed statement of the factual and legal bases for Lupin's Paragraph IV Certification that, in its opinion, the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, and the '790 Patent, are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, importation, use, offer for sale or sale of Lupin's topiramate ANDA product, provided pursuant to

FDCA Section 505(j)(2)(B)(iv)." Lupin further admits that Lupin Ltd.'s Notice Letter stated: "By providing this detailed statement, Lupin does not disclaim or waive other factual or legal bases upon which it might establish that one or more of the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, or the '790 Patent, are invalid, unenforceable and/or establish that the Patentee has failed to prove that one or more of the claims of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '194 Patent, the '989 Patent, the '940 Patent, the '004 Patent, the '983 Patent, or the '790 Patent, will be infringed." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 78 of the Complaint.

79. Lupin admits that Lupin Ltd.'s Notice Letter included "an Offer of Confidential Access to Application, provided pursuant to FDCA Section 505 and 21 U.S.C. § 355(j)(5)(C)(i)(III)." Lupin further admits that Lupin Ltd.'s Notice Letter stated: "Lupin offers to provide confidential access to certain information from its ANDA No. 215561 for the sole and exclusive purpose of permitting the patentee (and/or its licensee with a right to enforce) to determine whether an infringement action referenced in 35 U.S.C. § 271(e)(2) can be brought." Lupin further admits that Supernus Pharmaceuticals, Inc. refused the terms of Lupin Ltd.'s "Offer of Confidential Access to Application." Lupin further admits that because Supernus Pharmaceuticals, Inc. refused the terms of Lupin Ltd.'s "Offer of Confidential Access to Application," Lupin did not produce Lupin Ltd.'s ANDA No. 215561 before Supernus Pharmaceuticals, Inc. filed the instant Complaint. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 79 of the Complaint.

FIRST COUNT
(Defendants' Infringement of the '576 Patent)

80. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

81. The allegations of Paragraph 81 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '576 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 81 of the Complaint.

82. The allegations of Paragraph 82 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 82 of the Complaint.

83. Lupin denies each and every allegation contained in Paragraph 83 of the Complaint.

84. Lupin denies each and every allegation contained in Paragraph 84 of the Complaint.

85. Lupin denies each and every allegation contained in Paragraph 85 of the Complaint.

86. Lupin denies each and every allegation contained in Paragraph 86 of the Complaint.

87. Lupin denies each and every allegation contained in Paragraph 87 of the Complaint.

SECOND COUNT
(Defendants' Infringement of the '580 Patent)

88. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

89. The allegations of Paragraph 89 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as

initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '580 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 89 of the Complaint.

90. The allegations of Paragraph 90 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 90 of the Complaint.

91. Lupin denies each and every allegation contained in Paragraph 91 of the Complaint.

92. Lupin denies each and every allegation contained in Paragraph 92 of the Complaint.

93. Lupin denies each and every allegation contained in Paragraph 93 of the Complaint.

94. Lupin denies each and every allegation contained in Paragraph 94 of the Complaint.

95. Lupin denies each and every allegation contained in Paragraph 95 of the Complaint.

THIRD COUNT
(Defendants' Infringement of the '683 Patent)

96. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

97. The allegations of Paragraph 97 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '683 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 97 of the Complaint.

98. The allegations of Paragraph 98 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 98 of the Complaint.

99. Lupin denies each and every allegation contained in Paragraph 99 of the Complaint.

100. Lupin denies each and every allegation contained in Paragraph 100 of the Complaint.

101. Lupin denies each and every allegation contained in Paragraph 101 of the Complaint.

102. Lupin denies each and every allegation contained in Paragraph 102 of the Complaint.

103. Lupin denies each and every allegation contained in Paragraph 103 of the Complaint.

FOURTH COUNT
(Defendants' Infringement of the '248 Patent)

104. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

105. The allegations of Paragraph 105 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '248 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 105 of the Complaint.

106. The allegations of Paragraph 106 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 106 of the Complaint.

107. Lupin denies each and every allegation contained in Paragraph 107 of the Complaint.

108. Lupin denies each and every allegation contained in Paragraph 108 of the Complaint.

109. Lupin denies each and every allegation contained in Paragraph 109 of the Complaint.

110. Lupin denies each and every allegation contained in Paragraph 110 of the Complaint.

111. Lupin denies each and every allegation contained in Paragraph 111 of the Complaint.

FIFTH COUNT
(Defendants' Infringement of the '191 Patent)

112. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

113. The allegations of Paragraph 113 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '191 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 113 of the Complaint.

114. The allegations of Paragraph 114 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 114 of the Complaint.

115. Lupin denies each and every allegation contained in Paragraph 115 of the Complaint.

116. Lupin denies each and every allegation contained in Paragraph 116 of the Complaint.

117. Lupin denies each and every allegation contained in Paragraph 117 of the Complaint.

118. Lupin denies each and every allegation contained in Paragraph 118 of the Complaint.

119. Lupin denies each and every allegation contained in Paragraph 119 of the Complaint.

SIXTH COUNT
(Defendants' Infringement of the '989 Patent)

120. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

121. The allegations of Paragraph 121 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '989 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 121 of the Complaint.

122. The allegations of Paragraph 122 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 122 of the Complaint.

123. Lupin denies each and every allegation contained in Paragraph 123 of the Complaint.

124. Lupin denies each and every allegation contained in Paragraph 124 of the Complaint.

125. Lupin denies each and every allegation contained in Paragraph 125 of the Complaint.

126. Lupin denies each and every allegation contained in Paragraph 126 of the Complaint.

127. Lupin denies each and every allegation contained in Paragraph 127 of the Complaint.

SEVENTH COUNT
(Defendants' Infringement of the '940 Patent)

128. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

129. The allegations of Paragraph 129 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '940 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 129 of the Complaint.

130. The allegations of Paragraph 130 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 130 of the Complaint.

131. Lupin denies each and every allegation contained in Paragraph 131 of the Complaint.

132. Lupin denies each and every allegation contained in Paragraph 132 of the Complaint.

133. Lupin denies each and every allegation contained in Paragraph 133 of the Complaint.

134. Lupin denies each and every allegation contained in Paragraph 134 of the Complaint.

135. Lupin denies each and every allegation contained in Paragraph 135 of the Complaint.

EIGHTH COUNT
(Defendants' Infringement of the '004 Patent)

136. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

137. The allegations of Paragraph 137 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '004 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 137 of the Complaint.

138. The allegations of Paragraph 138 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 138 of the Complaint.

139. Lupin denies each and every allegation contained in Paragraph 139 of the Complaint.

140. Lupin denies each and every allegation contained in Paragraph 140 of the Complaint.

141. Lupin denies each and every allegation contained in Paragraph 141 of the Complaint.

142. Lupin denies each and every allegation contained in Paragraph 142 of the Complaint.

143. Lupin denies each and every allegation contained in Paragraph 143 of the Complaint.

NINTH COUNT
(Defendants' Infringement of the '983 Patent)

144. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

145. The allegations of Paragraph 145 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '983 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 145 of the Complaint.

146. The allegations of Paragraph 146 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 146 of the Complaint.

147. Lupin denies each and every allegation contained in Paragraph 147 of the Complaint.

148. Lupin denies each and every allegation contained in Paragraph 148 of the Complaint.

149. Lupin denies each and every allegation contained in Paragraph 149 of the Complaint.

150. Lupin denies each and every allegation contained in Paragraph 150 of the Complaint.

151. Lupin denies each and every allegation contained in Paragraph 151 of the Complaint.

TENTH COUNT
(Defendants' Infringement of the '790 Patent)

152. Lupin repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

153. The allegations of Paragraph 153 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA No. 215561, as initially submitted, included a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '790 patent. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 153 of the Complaint.

154. The allegations of Paragraph 154 are vague as to which "Lupin" entity is being referenced. Lupin admits that Lupin Ltd. submitted ANDA No. 215561 to the FDA, seeking

approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 154 of the Complaint.

155. Lupin denies each and every allegation contained in Paragraph 155 of the Complaint.

156. Lupin denies each and every allegation contained in Paragraph 156 of the Complaint.

157. Lupin denies each and every allegation contained in Paragraph 157 of the Complaint.

158. Lupin denies each and every allegation contained in Paragraph 158 of the Complaint.

159. Lupin denies each and every allegation contained in Paragraph 159 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

Lupin denies all allegations not specifically admitted herein, and further denies that Plaintiff is entitled to the judgment and relief requested in Paragraphs i-ix of the Complaint or to any other relief. Lupin respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Lupin; (c) award Lupin the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Lupin such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its responses to Paragraphs 1 through 159 of the Complaint and its Response to Prayer for Relief, and without undertaking any of the burdens imposed by law on the Plaintiff, Lupin avers and asserts the following separate defenses to the

Complaint. Lupin expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiff has failed to state a claim for which relief can be granted because, *inter alia*, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. have not committed an act of infringement as prescribed in 35 U.S.C. § 271(e)(2).

SECOND AFFIRMATIVE DEFENSE
(Lack of Subject Matter Jurisdiction)

This Court lacks subject matter jurisdiction over any and all claims asserted against Lupin under 35 U.S.C. § 271(a)-(c). This Court further lacks subject matter jurisdiction over any and all claims asserted against Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc.

THIRD AFFIRMATIVE DEFENSE
(Non-Infringement)

Lupin does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent, or the ’790 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity)

One or more claims of the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent, or the ’790 patent are invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or

the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

FIFTH AFFIRMATIVE DEFENSE
(Failure to State a Claim for Exceptional Case)

To the extent the Complaint purports to seek an "exceptional case" determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Lupin's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE
(Improper Party)

Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. are not proper parties to this action.

SEVENTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Lupin reserves the right to present any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaimant Lupin Limited ("Lupin Ltd.") brings the following Counterclaims against Plaintiff/Counterdefendant Supernus Pharmaceuticals, Inc. ("Supernus") for a declaratory judgment that U.S. 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") are invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of the topiramate extended-

release capsules that are the subject of Lupin Ltd.'s Abbreviated New Drug Application ("ANDA") No. 215561 ("Lupin Ltd.'s ANDA Products").

PARTIES

1. Lupin Ltd. is a corporation organized and existing under the laws of India, with a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

2. On information and belief, and based on Counterdefendant's allegations, 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.

JURISDICTION AND VENUE

3. Lupin Ltd. seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

4. The Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271(e)(2).

5. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendant's choice of forum.

6. This is an action based upon an actual controversy between the parties concerning the invalidity and/or non-infringement of the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent and Lupin Ltd.'s right to continue to seek approval of Lupin Ltd.'s ANDA No. 215561 for Lupin Ltd.'s ANDA Products.

7. Lupin Ltd. has been and presently is engaged in the submission of documents to the Food & Drug Administration ("FDA") in connection with ANDA No. 215561, and those documents seek approval to engage in the commercially manufacture, import, use, offer to sale

and/or sale of Lupin Ltd.'s ANDA Products. Counterdefendant has alleged that the submission of Lupin Ltd.'s ANDA No. 215561 infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent.

8. Counterdefendant has filed in this Court an infringement action to enforce the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent against Lupin Ltd.

9. On information and belief, and according to Counterdefendant's allegations, Supernus is the assignee of the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent.

10. On information and belief, and according to Counterdefendant's allegations, Supernus is the holder of New Drug Application ("NDA") No. 201635 for Trokendi XR® (topiramate) extended release capsules.

11. Lupin Ltd. has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and/or enforceable claim of the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent.

12. Lupin Ltd. has further asserted that one or more claims of the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent is invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or the doctrine of obviousness-type double patenting and/or

any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

13. The ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent are listed in the electronic version of the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) with respect to Trokendi XR®.

14. Lupin Ltd.’s ANDA No. 215561 includes a certification pursuant to the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent, indicating that in the opinion of Lupin Ltd. and to the best of its knowledge, no valid, enforceable claim of any of the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent will be infringed by the manufacture, use, importation, offer for sale, or sale of Lupin Ltd.’s ANDA Products. On July 29, 2021, Lupin Ltd., pursuant to Section 505(j)(2)(B) of the FDCA, provided via FedEx® delivery written notifications to Counterdefendant that Lupin Ltd. filed ANDA No. 215561 with the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent are invalid and/or will not be infringed by Lupin Ltd.’s ANDA Products (“Lupin Ltd.’s Notice Letter”). On information and believe, and according to Counterdefendant’s allegations, Counterdefendant received Lupin Ltd.’s Notice Letter.

15. In view of the foregoing, a conflict of asserted rights has arisen between Lupin Ltd. and Counterdefendant with respect to the non-infringement and invalidity of the relevant claims

of the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent, and as to Lupin Ltd.’s right to obtain FDA approval of Lupin Ltd.’s ANDA Products. An actual controversy therefore exists between Counterdefendant and Lupin Ltd.

FIRST COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 8,298,576)

16. Lupin Ltd. realleges Paragraphs 1–15 as though fully set forth herein.

17. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’576 patent.

18. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’576 patent.

19. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.’s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the ’576 patent.

SECOND COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 8,298,576)

20. Lupin Ltd. realleges Paragraphs 1–19 as though fully set forth herein.

21. The claims of the ’576 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or

any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '576 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as additional examples, each of the claims of the '576 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description support and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, dissolution and/or pharmacokinetic parameters such as C_{max} and/or AUC values.

22. Lupin Ltd. is entitled to a judicial determination that the claims of the '576 patent are invalid.

THIRD COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 8,298,580)

23. Lupin Ltd. realleges Paragraphs 1–22 as though fully set forth herein.

24. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '580 patent.

25. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '580 patent.

26. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '580 patent.

FOURTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 8,298,580)

27. Lupin Ltd. realleges Paragraphs 1–26 as though fully set forth herein.

28. The claims of the '580 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '580 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as additional examples, each of the claims of the '580 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description support and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, dissolution and/or pharmacokinetic parameters such as C_{max}, AUC, and/or T_{max} values.

29. Lupin Ltd. is entitled to a judicial determination that the claims of the '580 patent are invalid.

FIFTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 8,663,683)

30. Lupin Ltd. realleges Paragraphs 1–29 as though fully set forth herein.

31. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '683 patent.

32. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents),

directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '683 patent.

33. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '683 patent.

SIXTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 8,663,683)

34. Lupin Ltd. realleges Paragraphs 1–33 as though fully set forth herein.

35. The claims of the '683 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '683 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as additional examples, each of the claims of the '683 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description support and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, the limitations "wherein greater than or equal to 80% of the topiramate contained therein is released in vitro in less than or equal to about 4 hours" or "wherein 80% of the topiramate contained therein is released in vitro in not more than 1 hour."

36. Lupin Ltd. is entitled to a judicial determination that the claims of the '683 patent are invalid.

SEVENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 8,877,248)

37. Lupin Ltd. realleges Paragraphs 1–36 as though fully set forth herein.

38. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '248 patent.

39. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '248 patent.

40. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '248 patent.

EIGHTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 8,877,248)

41. Lupin Ltd. realleges Paragraphs 1–40 as though fully set forth herein.

42. The claims of the '248 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '248 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as an additional example, each

of the claims of the '248 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, the limitations "wherein the XR component releases topiramate in a continuous manner and such that greater than or equal to about 80% of the topiramate is released in vitro in less than or equal to about 4 hours" or "wherein the XR component releases topiramate in a continuous manner and such that greater than or equal to about 80% of the topiramate is released in vitro in less than or equal to about 12 hours" and/or pharmacokinetic parameters such as C_{max} and/or AUC.

43. Lupin Ltd. is entitled to a judicial determination that the claims of the '248 patent are invalid.

NINTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 8,889,191)

44. Lupin Ltd. realleges Paragraphs 1–43 as though fully set forth herein.

45. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '191 patent.

46. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '191 patent.

47. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '191 patent.

TENTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 8,889,191)

48. Lupin Ltd. realleges Paragraphs 1–47 as though fully set forth herein.

49. The claims of the '191 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '191 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as additional examples, each of the claims of the '191 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description support and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, dissolution and/or pharmacokinetic parameters such as C_{max} and/or AUC values.

50. Lupin Ltd. is entitled to a judicial determination that the claims of the '191 patent are invalid.

ELEVENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 8,992,989)

51. Lupin Ltd. realleges Paragraphs 1–50 as though fully set forth herein.

52. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '989 patent.

53. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents),

directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '989 patent.

54. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '989 patent.

TWELFTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 8,992,989)

55. Lupin Ltd. realleges Paragraphs 1–54 as though fully set forth herein.

56. The claims of the '989 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '989 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as an additional example, each of the claims of the '989 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, dissolution and/or pharmacokinetic parameters such as C_{max}, AUC, and/or T_{max} values.

57. Lupin Ltd. is entitled to a judicial determination that the claims of the '989 patent are invalid.

THIRTEENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 9,549,940)

58. Lupin Ltd. realleges Paragraphs 1–57 as though fully set forth herein.

59. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '940 patent.

60. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '940 patent.

61. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '940 patent.

FOURTEENTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 9,549,940)

62. Lupin Ltd. realleges Paragraphs 1–61 as though fully set forth herein.

63. The claims of the '940 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '940 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as an additional example, each of the claims of the '940 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, dissolution and/or pharmacokinetic parameters such as C_{max}, AUC, and/or T_{max} values.

64. Lupin Ltd. is entitled to a judicial determination that the claims of the ’940 patent are invalid.

FIFTEENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 9,555,004)

65. Lupin Ltd. realleges Paragraphs 1–64 as though fully set forth herein.

66. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’004 patent.

67. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’004 patent.

68. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.’s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the ’004 patent.

SIXTEENTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 9,555,004)

69. Lupin Ltd. realleges Paragraphs 1–68 as though fully set forth herein.

70. The claims of the ’004 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the ’004

patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as additional examples, each of the claims of the '004 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description support and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, pharmacokinetic parameters such as C_{max}, AUC, and/or T_{ma} values.

71. Lupin Ltd. is entitled to a judicial determination that the claims of the '004 patent are invalid.

SEVENTEENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 9,622,983)

72. Lupin Ltd. realleges Paragraphs 1–71 as though fully set forth herein.

73. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '983 patent.

74. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '983 patent.

75. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '983 patent.

EIGHTEENTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 9,622,983)

76. Lupin Ltd. realleges Paragraphs 1–75 as though fully set forth herein.

77. The claims of the ’983 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the ’983 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as an additional example, each of the claims of the ’983 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, dissolution and/or pharmacokinetic parameters such as C_{max}, AUC, and/or T_{max} values.

78. Lupin Ltd. is entitled to a judicial determination that the claims of the ’983 patent are invalid.

NINTEENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 10,314,790)

79. Lupin Ltd. realleges Paragraphs 1–78 as though fully set forth herein.

80. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’790 patent.

81. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’790 patent.

82. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the '790 patent.

TWENTIETH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. 10,314,790)

83. Lupin Ltd. realleges Paragraphs 1–82 as though fully set forth herein.

84. The claims of the '790 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, each of the claims of the '790 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Cutler, Jenkins, Shargel, Thakur, and/or Nangia. Moreover, and as additional examples, each of the claims of the '790 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description and/or under 35 U.S.C. § 112, second paragraph, as indefinite for reciting, *inter alia*, pharmacokinetic parameters such as C_{max}, AUC, and/or T_{ma} values.

85. Lupin Ltd. is entitled to a judicial determination that the claims of the '790 patent are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Lupin Ltd. prays for the following relief:

A. That the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Lupin Ltd.;

B. That a judgment be entered declaring that Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent;

C. That a judgment be entered declaring that the manufacture, import, use, sale, and/or offer to sell Lupin Ltd.’s ANDA Products, has not infringed, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid and/or enforceable claim of the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent;

D. That a judgment be entered declaring the claims of the ’576 patent, the ’580 patent, the ’683 patent, the ’248 patent, the ’191 patent, the ’989 patent, the ’940 patent, the ’004 patent, the ’983 patent and the ’790 patent invalid;

E. That the Court declare that Lupin Ltd. has the lawful right to manufacture, import, use, sell, and/or offer to sell Lupin Ltd.’s ANDA Products in the United States once the product is approved by the FDA;

F. That Counterdefendant and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Lupin Ltd. or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Lupin Ltd., or charging any of them either orally or in writing with

infringement of the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent and the '790 patent;

G. That a judgment be entered, declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Lupin Ltd. is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

H. That Lupin Ltd. be awarded costs, attorney's fees, and other relief, both legal and equitable, to which it may be justly entitled; and

I. That Lupin Ltd. be awarded such other and further relief as is just and proper.

Dated: December 20, 2021

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