

**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.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Supernus Pharmaceuticals, Inc. (“Supernus” or “Plaintiff”), by its undersigned attorneys, for its Complaint against Defendants Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. (collectively, “Lupin” or “Defendants”), alleges as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 (“the ’576 patent”), 8,298,580 (“the ’580 patent”), 8,663,683 (“the ’683 patent”), 8,877,248 (“the ’248 patent”), 8,889,191 (“the ’191 patent”), 8,992,989 (“the ’989 patent”), 9,549,940 (“the ’940 patent”), 9,555,004 (“the ’004 patent”), 9,622,983 (“the ’983 patent”), and 10,314,790 (“the ’790 patent”) attached hereto as Exhibits A–J (collectively, “the patents in suit”).

**THE PARTIES**

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

3. Upon information and belief, Lupin Limited is a corporation operating and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 400 051, India, and its registered office at Kalpataru Inspire, 3rd Floor, Off Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

4. Upon information and belief, Lupin Atlantis Holdings S.A. is a corporation organized and existing under the laws of Switzerland, having a corporate headquarters at Landis + Gyr-Strasse 1, 6300 Zug, Switzerland.

5. Upon information and belief, Nanomi B.V. is a corporation organized and existing under the laws of The Netherlands, having a corporate headquarters at Zutphenstraat 51, 7575 EJ Oldenzaal, Overijssel, The Netherlands.

6. Upon information and belief, Lupin Inc. is a corporation organized and existing under the laws of Delaware with a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801, and has a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

7. Upon information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801, and has a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202.

8. Upon information and belief, Lupin filed an Abbreviated New Drug Application (“ANDA”) No. 215561 (“the Lupin ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsules, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate (“the Lupin ANDA Products”).

9. Upon information and belief, Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. are acting cooperatively with respect to the Lupin ANDA.

#### **JURISDICTION AND VENUE**

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and/or (ii) Fed. R. Civ. P. 4(k)(2).

12. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of Delaware by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of Delaware.

13. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Lupin is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

14. Upon information and belief, Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. collaborate to develop, manufacture,

import, market, distribute, and/or sell pharmaceutical products, including generic drug products (e.g., famotidine powder, for suspension (40 mg/5 mL), lisinopril tablets (2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg), levothyroxine sodium tablets (25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg), and albuterol sulfate aerosol, metered (90 mcg per actuation)), which are or will be manufactured and sold pursuant to an ANDA, throughout the United States, including throughout the State of Delaware.

15. Upon information and belief, Lupin will market the Lupin ANDA Products throughout the United States, including in Delaware, upon FDA approval of the Lupin ANDA.

16. This Court has personal jurisdiction over Lupin Limited at least because, upon information and belief: (i) Lupin Limited has purposefully directed its activities and the activities of Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. at residents and corporate entities within the State of Delaware; (ii) the claims set forth herein against Lupin Limited arise out of or relate to those activities; (iii) Lupin Limited's contacts with the State of Delaware (direct and indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Lupin Limited.

17. Upon information and belief, Lupin Limited, directly or indirectly, is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware, and importing generic pharmaceutical products into the United States, including throughout the State of Delaware; (ii) in concert with and/or through its various subsidiaries, including Defendants Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) in concert

with and/or through its various subsidiaries, including Defendants Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

18. Lupin states on its website that “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 Website, <https://www.lupin.com/US/about-us/> (accessed September 9, 2021). Lupin on its website further states that it “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.” Lupin Website, <https://www.lupin.com/US/about-us/> (accessed September 9, 2021).

19. Upon information and belief, Lupin derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredients used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

20. Lupin’s website states that it has “operations in 11 countries across six continents,” “[i]n 2017-2018, Lupin achieved a milestone when US revenues crossed \$1 billion,” it has “15 state-of-the-art manufacturing facilities [] spread across India, the United States, Brazil and Mexico,” “437 ANDA filings,” “289 ANDA approvals,” and “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 Website, <https://www.lupin.com/about-us/global-presence/> (accessed September 9, 2021); Lupin Website,

<https://www.lupin.com/about-us/global-manufacturing/> (accessed September 9, 2021); Lupin Website, <https://www.lupin.com/about-us/research-and-innovation/> (accessed September 9, 2021).

21. Lupin's Annual Report 2020-21 states that "the US is [sic] largest market for Lupin" and "Lupin products touch 100 million patient lives in the US each year," and in "FY21, US sales contributed INR 53,730 million to the company's revenue, accounting for 36% of the overall sales." Lupin Limited Integrated Report 2020-21 at 32-33, <https://lupin.com/annual-report-2021/img/lupin-ir-2021.pdf> (accessed September 9, 2021).

22. Lupin's Annual Report 2020-21 states that 53 of its products "rank #1 in market share" in the U.S. Lupin Limited Integrated Report 2020-21 at 33, <https://lupin.com/annual-report-2021/img/lupin-ir-2021.pdf> (accessed September 9, 2021).

23. Lupin's Annual Report further states that in FY21 Lupin "filed 15 ANDAs and 1 BLA and received 19 ANDA approvals," and Lupin also "settled 11 pending US litigations." Lupin Limited Integrated Report 2020-21 at 33, <https://lupin.com/annual-report-2021/img/lupin-ir-2021.pdf> (accessed September 9, 2021).

24. This Court has personal jurisdiction over Lupin Atlantis Holdings S.A. at least because, upon information and belief: (i) Lupin Atlantis Holdings S.A. has purposefully directed its activities and the activities of Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. at residents and corporate entities within the State of Delaware; (ii) the claims set forth herein against Lupin Atlantis Holdings S.A. arise out of or relate to those activities; (iii) Lupin Atlantis Holdings S.A.'s contacts with the State of Delaware (direct and indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Lupin Atlantis Holdings S.A.

25. Upon information and belief, Lupin Atlantis Holdings S.A. is a wholly-owned subsidiary, directly or indirectly, of Lupin Limited. Upon information and belief, Lupin Atlantis Holdings S.A. acts at the direction of, under the control of, and for the direct benefit of Lupin Limited and various subsidiaries and is controlled and/or dominated by Lupin Limited and various subsidiaries.

26. Upon information and belief, Lupin Atlantis Holdings S.A., directly or indirectly, is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware, and importing generic pharmaceutical products into the United States, including throughout the State of Delaware; (ii) in concert with and/or through its various subsidiaries, including Defendants Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) in concert with and/or through its various subsidiaries, including Defendants Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

27. Lupin's financial statements state that Lupin Atlantis Holdings S.A. incorporated Lupin Inc., and "[n]ow, Lupin Inc. is engaged in owning intellectual properties and in distribution of pharmaceutical products." Lupin Atlantis Holdings S.A. Financial Statements for Year Ended 31 March 2019 at 8, <https://www.lupin.com/wp-content/uploads/2021/05/lupin-atlantis-holdings-sa-switzerland-2019.pdf> (accessed September 9, 2021).

28. Upon information and belief, Lupin's financial statements indicate that it collaborates to develop products "for commercialization in the US market," and that, along with

its subsidiary Lupin Inc., acquires US companies for the purpose of “enhanc[ing] Lupin’s scale in the US generic market . . . .” See Lupin Atlantis Holdings S.A. Financial Statements for Year Ended 31 March 2019 at 9, <https://www.lupin.com/wp-content/uploads/2021/05/lupin-atlantis-holdings-sa-switzerland-2019.pdf> (accessed September 9, 2021); Lupin Atlantis Holdings S.A. Financial Statements for Year Ended 31 March 2018 at 10, <https://www.lupin.com/wp-content/uploads/2021/05/lupin-atlantis-holdings-sa-switzerland-2018.pdf> (accessed September 9, 2021).

29. This Court has personal jurisdiction over Nanomi B.V. at least because, upon information and belief: (i) Nanomi B.V. has purposefully directed its activities and the activities of Lupin Inc. and Lupin Pharmaceuticals, Inc. at residents and corporate entities within the State of Delaware; (ii) the claims set forth herein against Nanomi B.V. arise out of or relate to those activities; (iii) Nanomi B.V.’s contacts with the State of Delaware (direct and indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Nanomi B.V.

30. Upon information and belief, Nanomi B.V. is a wholly-owned subsidiary, directly or indirectly, of Lupin Limited and Lupin Atlantis Holdings S.A. Upon information and belief, Nanomi B.V. acts at the direction of, under the control of, and for the direct benefit of Lupin Limited, Lupin Atlantis Holdings S.A., and various subsidiaries and is controlled and/or dominated by Lupin Limited, Lupin Atlantis Holdings S.A., and various subsidiaries.

31. Upon information and belief, Nanomi B.V., directly or indirectly, is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware, and importing generic pharmaceutical products into the United States, including throughout the State of



Delaware; (ii) in concert with and/or through its various subsidiaries, including Defendants Lupin Inc. and Lupin Pharmaceuticals, Inc., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) in concert with and/or through its various subsidiaries, including Defendants Lupin Inc. and Lupin Pharmaceuticals, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

32. Upon information and belief, Lupin's financial statements indicate that Nanomi B.V. is a subsidiary of Lupin Atlantis Holdings S.A. *See* Lupin Atlantis Holdings S.A. Financial Statement for the Year Ended March 31, 2020 at 6, <https://www.lupin.com/wp-content/uploads/2021/05/lupin-atlantis-holdings-sa-switzerland-2020.pdf> (accessed September 9, 2021). Upon information and belief, Lupin's financial statements indicate that "Lupin Inc. was a consolidated subsidiary of Lupin Atlantis Holdings, S.A. (LAHSA), who is wholly owned by Lupin Limited (LL), [Lupin Inc.'s] ultimate parent company," and that "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 [Lupin Inc.] to Nanomi," and "[a]s a result, [Lupin Inc.] became a wholly owned subsidiary of Nanomi, effective March 31, 2021." *See* Lupin Inc. Consolidated Financial Statements for Year Ended March 31, 2021 at 6, <https://www.lupin.com/wp-content/uploads/2021/07/lupin-inc-console-unsigned-fy-2020-21.pdf> (accessed September 9, 2021).

33. This Court has personal jurisdiction over Lupin Inc. at least because, upon information and belief: (i) Lupin Inc. is incorporated in Delaware; (ii) Lupin Inc. has purposefully directed its activities and the activities of Lupin Pharmaceuticals, Inc. at residents

and corporate entities within the State of Delaware; (iii) the claims set forth herein against Lupin Inc. arise out of or relate to those activities; (iv) Lupin Inc.'s contacts with the State of Delaware (direct and indirect) are continuous and systematic; and (v) it is reasonable and fair for this Court to exercise personal jurisdiction over Lupin Inc.

34. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary, directly or indirectly, of Lupin Limited, Lupin Atlantis Holdings S.A., and Nanomi B.V. Upon information and belief, Lupin Inc. acts at the direction of, under the control of, and for the direct benefit of Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., and various subsidiaries and is controlled and/or dominated by Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., and various subsidiaries.

35. Upon information and belief, Lupin Inc., directly or indirectly, is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware, and importing generic pharmaceutical products into the United States, including throughout the State of Delaware; (ii) in concert with and/or through its various subsidiaries, including Defendant Lupin Pharmaceuticals, Inc., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) in concert with and/or through its various subsidiaries, including Defendant Lupin Pharmaceuticals, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

36. Upon information and belief, according to Lupin Inc.'s financial statements, Lupin Inc.'s core business is "to trade in pharmaceutical products and to render marketing and ancillary services related thereto." Lupin Inc. Financial Statements for Year Ended March 31,

2021 at 6, <https://www.lupin.com/wp-content/uploads/2021/07/lupin-inc-console-unsigned-fy-2020-21.pdf> (accessed September 9, 2021).

37. Upon information and belief, Lupin's financial statements describe its intangible assets as including ANDAs and ANDAs not yet approved by the FDA. Lupin Inc. Financial Statements for Year Ended March 31, 2021 at 9, <https://www.lupin.com/wp-content/uploads/2021/07/lupin-inc-console-unsigned-fy-2020-21.pdf> (accessed September 9, 2021).

38. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. at least because, upon information and belief: (i) Lupin Pharmaceuticals, Inc. is incorporated in Delaware; (ii) Lupin Pharmaceuticals, Inc. is doing business in Delaware and maintains continuous and systematic contacts with this Judicial District; (iii) Lupin Pharmaceuticals, Inc., together with its parents Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., and Lupin Inc., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of Delaware; (iv) Lupin Pharmaceuticals, Inc., together with its parents Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., and Lupin Inc., has committed, induced, and/or contributed to acts of patent infringement in Delaware; and (v) Lupin Pharmaceuticals, Inc. and its parents have previously submitted to the jurisdiction of this Court, has availed itself of Delaware's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.

39. Upon information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary, directly or indirectly, of Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., and Lupin Inc. Upon information and belief, Lupin Pharmaceuticals, Inc. acts at the direction of, under the control of, and for the direct benefit of Lupin Limited, Lupin Atlantis Holdings S.A.,

Nanomi B.V., Lupin Inc., and various subsidiaries and is controlled and/or dominated by Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and various subsidiaries.

40. Upon information and belief, Lupin Pharmaceuticals, Inc. is in the business of, *inter alia*: (i) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of Delaware; (ii) in concert with and/or through its parents, including Defendants Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and various subsidiaries, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) alone or in concert with and/or through its parents, including Defendants Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and various subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

41. Lupin has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at Delaware and elsewhere throughout the United States. Upon information and belief, Lupin intends to direct sales of its generic drugs in this Judicial District, among other places, once Lupin receives the requested FDA approval to market its generic products. Upon information and belief, Lupin will engage in marketing its proposed Lupin ANDA Products in Delaware upon approval of the Lupin ANDA.

42. Lupin's tortious acts of (i) preparing and filing the Lupin ANDA with a paragraph IV certification to the patents in suit for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products before the expiration of the

patents in suit, and (ii) directing notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, offer to sell, and/or sale of the Lupin ANDA Products by Defendants before the expiration of the patents in suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Lupin should reasonably anticipate being sued in Delaware.<sup>1</sup>

43. This Court has personal jurisdiction over Lupin at least because, upon information and belief, if the Lupin ANDA is approved, the Lupin ANDA Products will be marketed and distributed by Lupin in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and used by patients in the State of Delaware. Upon information and belief, if Lupin succeeds in obtaining FDA approval, Lupin will sell the Lupin ANDA Products in the State of Delaware. Upon information and belief, Lupin has previously admitted to marketing and selling drug products in the State of Delaware and throughout the United States, or to seeking to do the same, directly and through its affiliates.<sup>2</sup>

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<sup>1</sup> This Court also has personal jurisdiction over Defendants because Lupin Pharmaceuticals, Inc., Lupin Inc., Lupin Atlantis Holdings S.A., and Lupin Limited have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A., et al.*, No. 21-229-LPS (D. Del.), D.I. 28; *Otsuka Pharm. Co., Ltd. v. Lupin Ltd., et al.*, No. 20-1296-LPS (D. Del.), D.I. 8; *Ferring Pharm. Inc. v. Lupin Inc., et al.*, No. 19-913-RGA (D. Del.), D.I. 18; *Lupin Atlantis Holdings, S.A. v. Invagen Pharm., Inc.*, No. 16-708-SLR-SRF (D. Del.), D.I. 1; *Sanofi v. Lupin Atlantis Holdings S.A., et al.*, No. 15-415-RGA (D. Del.), D.I. 31.

<sup>2</sup> *See, e.g., Sanofi v. Lupin Atlantis Holdings S.A.*, No. 15-415-RGA (D. Del.), D.I. 31 at 4, 5, 9 (showing that Lupin admitted to manufacturing drug products for the United States, including

44. Upon information and belief, Lupin intends to benefit directly if the Lupin ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the Lupin ANDA.

45. Upon information and belief, Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. act, operate, and/or hold themselves out to the public as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District. Upon information and belief, Lupin employs “[r]apid [g]rowth [t]hrough [v]ertical [i]ntegration” and Lupin is “vertically integrated, from process development of the API to the submission of dossiers for finished dosages.” Lupin Website, <https://www.lupin.com/US/generics/> (accessed September 9, 2021).

46. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Lupin Limited is a foreign corporation and it may be sued in any judicial district in the United States in which the Defendant is subject to the court’s personal jurisdiction.

47. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Lupin Atlantis Holdings S.A. is a foreign corporation and it may be sued in any judicial district in the United States in which the Defendant is subject to the court’s personal jurisdiction.

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the State of Delaware, and to marketing and selling drug products through the United States, including the State of Delaware).

48. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Nanomi B.V. is a foreign corporation and it may be sued in any judicial district in the United States in which the Defendant is subject to the court's personal jurisdiction.

49. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because Lupin Inc. is incorporated in the State of Delaware.

50. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because Lupin Pharmaceuticals, Inc. is incorporated in the State of Delaware.

51. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because Lupin has previously consented to venue in this Judicial District.<sup>3</sup>

#### **FACTS AS TO ALL COUNTS**

52. Supernus's Trokendi XR<sup>®</sup> is sold and marketed under New Drug Application ("NDA") No. 201635, which was approved by FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

53. Trokendi XR<sup>®</sup> is an antiepileptic drug indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of

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<sup>3</sup> See, e.g., *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A.*, No. 21-229-LPS (D. Del.), D.I. 28 (showing that Lupin Atlantis Holdings, S.A. did not contest venue); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd.*, No. 20-1296-LPS (D. Del.), D.I. 8 (showing that Lupin Limited and Lupin Pharmaceuticals, Inc. did not contest venue); *Ferring Pharm. Inc. v. Lupin Inc.*, No. 19-913-RGA (D. Del.), D.I. 18 (showing that Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited and Lupin Pharmaceuticals, Inc. did not contest venue); *Lupin Atlantis Holdings, S.A. v. Invagen Pharm., Inc.*, No. 16-708-SLR-SRF (D. Del.), D.I. 1 (showing that Lupin Atlantis Holdings, S.A. filed a complaint in the District of Delaware and admitted to jurisdiction and proper venue); *Sanofi v. Lupin Atlantis Holdings S.A.*, No. 15-415-RGA (D. Del.), D.I. 31 (showing that Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. did not contest venue).

age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

54. Trokendi XR<sup>®</sup>'s recommended dosage: (i) for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and in patients 6 to 9 years of age is based on weight; (ii) for 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, and for 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; and (iii) for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

55. FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") lists ten (10) patents, specifically the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, as covering Supernus's Trokendi XR<sup>®</sup>. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), these ten (10) patents were submitted to FDA with or after the approval of NDA No. 201635. These ten (10) patents are listed in the *Orange Book* as covering Trokendi XR<sup>®</sup>.

56. The '576 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.



57. The '580 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '580 patent.

58. The '683 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

59. The '248 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '248 patent.

60. The '191 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '191 patent.

61. The '989 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 31, 2015, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '989 patent.

62. The '940 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 24, 2017, to

Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '940 patent.

63. The '004 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 31, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '004 patent.

64. The '983 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on April 18, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '983 patent.

65. The '790 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on June 11, 2019, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '790 patent.

66. On or about July 29, 2021, Lupin sent a letter purportedly pursuant to subsection 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. § 314.95 regarding the Lupin ANDA Products and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "July 29 Notice Letter") to Supernus at 1550 East Gude Drive, Rockville, MD 20850.

67. The July 29 Notice Letter was signed by Joseph M. Reisman of Knobbe Martens on behalf of Lupin, and states that Mr. Reisman and William R. Zimmerman of Knobbe Martins are Lupin's authorized U.S. agents authorized to accept service of process for Lupin.

68. Upon information and belief, the Lupin ANDA is based upon Trokendi XR<sup>®</sup> (topiramate extended-release capsules), 25 mg, 50 mg, 100 mg, and 200 mg, as its reference listed drug.

69. Upon information and belief, the Lupin ANDA Products are topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

70. Upon information and belief, the proposed prescribing information for the Lupin ANDA Products includes a header titled “Indications and Usage” and states that Lupin ANDA Products are indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

71. Upon information and belief, the proposed prescribing information for the Lupin ANDA Products includes a header titled “Dosage and Administration” and states that: (i) the recommended dose for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and dosing in patients 6 to 9 years of age is based on weight; (ii) the recommended total daily dose 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, and the recommended total daily dose 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; and (iii) the recommended total daily dose

as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

72. Upon information and belief, the proposed prescribing information for the Lupin ANDA Products also states under the header “Dosage and Administration” that the Lupin ANDA Products can be taken without regard to meals, to swallow capsule whole and intact, and do not sprinkle on food, chew, or crush.

73. Upon information and belief, Lupin Limited, Lupin Atlantis Holdings S.A, Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. acted in concert to develop the Lupin ANDA Products and/or seek approval from the FDA to sell the Lupin ANDA Products throughout the United States, including within this Judicial District.

74. Upon information and belief, Lupin Limited, Lupin Atlantis Holdings S.A, Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. participated in the preparation and/or filing of the Lupin ANDA.

75. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement must include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)-(ii).

76. Upon information and belief, as of the date of the July 29 Notice Letter, Lupin was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

77. The July 29 Notice Letter does not include any noninfringement contentions unique to claims 2-3, 5-13, 15-18, 20-21, 23-25, and 27-30 of the '576 patent, claims 2-11, 13-16, and 18-31 of the '580 patent, claims 2, 4-21, 23, and 24 of the '683 patent, claims 2-12, 15-17, and 18-20 of the '248 patent, claims 2-24 of the '191 patent, claims 2-12, 16-17, and 19-20 of the '989 patent, claims 2-12, 16-17, and 19-20 of the '940 patent, claims 2-10 and 13-15 of the '004 patent, claims 2-11, 15-16, and 18-30 of the '983 patent, and claims 2-10 and 13-24 of the '790 patent.

78. The July 29 Notice Letter does not include any invalidity contentions to any claim of the '576, '580, '191, and '004 patents and to claims 20-30 of the '983 patent.

79. Supernus and Lupin did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, Lupin has not produced the Lupin ANDA to Supernus.

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

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

81. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '576 patent is an act of

infringement of the '576 patent by Lupin of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

82. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

83. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

84. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

85. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '576 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

86. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

87. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

89. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '580 patent is an act of infringement of the '580 patent by Lupin of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

90. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

91. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

92. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

93. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '580 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

94. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

95. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

97. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '683 patent is an act of infringement of the '683 patent by Lupin of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

98. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

99. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.



100. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

101. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '683 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

102. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '683 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

103. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

105. Upon information and belief, Lupin’s submission and filing of the Lupin ANDA with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '248 patent is an act of infringement of the '248 patent by Lupin of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

106. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of ANDA No. 215561.

107. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

108. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

109. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '248 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

110. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

111. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

113. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '191 patent is an act of infringement of the '191 patent by Lupin of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

114. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

115. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

116. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

117. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '191 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

118. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

119. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

121. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '989 patent is an act of infringement of the '989 patent by Lupin of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

122. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

123. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

124. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '989 patent under 35 U.S.C. § 271.

125. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '989 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

126. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '989 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

127. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

129. Upon information and belief, Lupin’s submission and filing of the Lupin ANDA with a paragraph IV certification to the '940 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '940 patent is an act of infringement of the '940 patent by Lupin of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

130. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

131. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '940 patent under 35 U.S.C. § 271.

132. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '940 patent under 35 U.S.C. § 271.

133. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '940 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

134. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '940 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

135. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

137. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United

States of the Lupin ANDA Products before the expiration of the '004 patent is an act of infringement of the '004 patent by Lupin of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

138. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

139. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

140. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '004 patent under 35 U.S.C. § 271.

141. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '004 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

142. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '004 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

143. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

145. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '983 patent is an act of infringement of the '983 patent by Lupin of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

146. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

147. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

148. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '983 patent under 35 U.S.C. § 271.

149. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '983 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).



150. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '983 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

151. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

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

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

153. Upon information and belief, Lupin's submission and filing of the Lupin ANDA with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products before the expiration of the '790 patent is an act of infringement of the '790 patent by Lupin of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

154. Upon information and belief, Lupin will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Lupin ANDA Products upon, or in anticipation of, FDA approval of the Lupin ANDA.

155. Upon information and belief, Lupin's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Lupin ANDA Products will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

156. Upon information and belief, the commercial offering for sale and/or sale of the Lupin ANDA Products by Lupin will induce and/or contribute to third-party infringement of one or more claims of the '790 patent under 35 U.S.C. § 271.

157. Upon information and belief, the factual and legal bases in the July 29 Notice Letter regarding the '790 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

158. Lupin acted without a reasonable basis for believing that it would not be liable for infringement of the '790 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

159. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Lupin is preliminarily and permanently enjoined by this Court.

**PRAYER FOR RELIEF**

WHEREFORE, Supernus respectfully requests the following relief:

- i. A Judgment declaring that the patents in suit are valid and enforceable;
- ii. A Judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that the submission to FDA and filing of ANDA No. 215561 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Lupin ANDA Products was an act of infringement of the patents in suit by Defendants;
- iii. A Judgment pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the Lupin ANDA Products

before the expiration of the patents in suit (including any regulatory extensions) would directly and/or indirectly infringe the patents in suit;

- iv. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, that the effective date of any approval of the Lupin ANDA Products shall be no earlier than the date on which the patents in suit expire (including any regulatory extensions);
- v. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and any person in active concert or participation or privity with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation in the United States of the Lupin ANDA Products until the expiration of the patents in suit (including any regulatory extensions);
- vi. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Supernus damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 215561 that infringes the patents in suit;
- vii. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, declaring that Defendants' infringement of the patents in suit is willful and awarding Supernus enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 215561 that infringes the patents in suit (including any regulatory extensions);
- viii. A Judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Supernus its attorneys' fees and costs; and
- ix. Such other and further relief as this Court may deem just and proper.

Dated: September 10, 2021

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