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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **SUPERNUS PHARMACEUTICALS, INC.,**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**RICONPHARMA LLC and INGENUS PHARMACEUTICALS, LLC,**<br><br>**Defendants.** | **Civil Action No. _____**<br><br>**COMPLAINT FOR PATENT INFRINGEMENT**<br><br>**(Filed Electronically)** |

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants RiconPharma LLC ("Ricon") and Ingenus Pharmaceuticals, LLC ("Ingenus") (collectively, "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 No. 7,722,898 ("the '898 patent"), United States Patent No. 7,910,131 ("the '131 patent"), United States Patent No. 8,617,600 ("the '600 patent"), United States Patent No. 8,821,930 ("the '930 patent"), United States Patent No. 9,119,791 ("the '791 patent"), United States Patent No. 9,351,975 ("the '975

patent"), United States Patent No. 9,370,525 ("the '525 patent"), United States Patent No. 9,855,278 ("the '278 patent"), and United States Patent No. 10,220,042 ("the '042 patent"), attached hereto as Exhibits A–I (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, RiconPharma LLC ("Ricon") is a New Jersey limited liability company, having its principal place of business at 100 Ford Road, Suite 9, Denville, New Jersey 07834.

4. Upon information and belief, Ricon is in the business of, *inter alia*, developing, manufacturing, marketing, distributing, and directly and/or indirectly selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

5. Upon information and belief, Ricon either directly or through one or more of its affiliates and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic pharmaceutical products, including in the State of New Jersey.

6. On information and belief, Defendant Ingenus Pharmaceuticals, LLC ("Ingenus") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 4190 Millenia Road, Orlando, Florida 32839. On information and belief, Ingenus also has facilities at 140 New Dutch Lane, Fairfield, New Jersey 07004 and, like Ricon, at 100 Ford Road, Suite 9, Denville, New Jersey 07834.

7. Upon information and belief, Ricon and Ingenus work together for the direct benefit of each other.

8. Upon information and belief, Ingenus states on its webpage that it entered into a merger agreement with Ricon on August 8, 2014, and that the combined entity has filed multiple ANDAs. Ingenus website, https://www.ingenus.com/riconpharma%C2%ADingenus-merger-7/ (visited May 24, 2021).

9. Upon information and belief, Ingenus is in the business of, *inter alia*, developing, manufacturing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

10. Upon information and belief, Ingenus is registered as a wholesale drug distributor in the State of New Jersey under Registration No. 5004116. Upon information and belief, Ricon, with the assistance of Ingenus, prepared, and filed Abbreviated New Drug Application ("ANDA") No. 215796 ("the Ricon ANDA") with FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic oxcarbazepine extended-release tablets, containing 150 mg, 300 mg, and 600 mg of oxcarbazepine ("the Ricon Product").

## JURISDICTION AND VENUE

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

12. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1); and (ii) N.J. Ct. R. 4:4-4.

13. Upon information and belief, Defendants maintain a regular and established place of business in New Jersey and have purposefully availed themselves of the privilege of doing

business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, Ingenus states on its website that "Ingenus' New Jersey-based research & development facility specializes in the development of solid orals (IR, MR, SL, and Films), topicals (ointments, creams, lotions, gels, powders, foams, and sprays), transdermal patches (Hydrogel & Matrix), injectables (solutions, lyophilized, and suspensions), and nasal sprays" and that "Ingenus today is poised to file 25 ANDAs a year." Ingenus website, https://www.ingenus.com/manufacturing/ (visited May 9, 2021).

14. Upon information and belief, Defendants maintain a broad distributorship network within the State of New Jersey and enjoy substantial income from sales of their generic pharmaceutical products in the State of New Jersey.

15. Upon information and belief, Ingenus is registered as a wholesale drug distributor in the State of New Jersey under the Registration No. 5004116. Ingenus has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

16. On information and belief, Ricon and Ingenus have been, and continue to be, joint and primary actors in the drafting, submission, approval, and maintenance of the Ricon ANDA.

17. This Court has personal jurisdiction over Defendants because, *inter alia*: (i) Ricon, together with Ingenus, has committed, induced, or contributed to acts of patent infringement in New Jersey, including, but not limited to, the preparation of materials related to the Ricon ANDA submission; (ii) Defendants are doing business in New Jersey and maintain continuous and systematic contacts with this Judicial District, including by having a regular and established place of business in New Jersey; (iii) Defendants directly or indirectly through agents regularly do or solicit business in New Jersey and/or derive substantial revenue from services or

things used or consumed in New Jersey; (iv) Defendants transact business, perform work, and contract to supply services or products in New Jersey; and (v) Ingenus is registered as a wholesale drug distributor in the State of New Jersey under Registration No. 5004116. For example, the FDA requires ANDA filers to prepare test batches of the proposed generic product. *See, e.g.*, https://www.fda.gov/media/107325/download. Upon information and belief, the only Ingenus manufacturing facility identified on Ingenus' website for non-oncology products and treatments—such as those claimed in the patents in suit—is located in New Jersey. Ingenus website, https://www.ingenus.com/manufacturing/ (visited May 9, 2021).

18. Ricon's tortious acts of (i) preparing and filing ANDA No. 215796 with a paragraph IV certification to the patents in suit for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the patents in suit; and (ii) directing notice of its ANDA submission to Plaintiff Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Ricon's ANDA Product before the expiration of the patents in suit throughout the United States, including in this Judicial District. On information and belief, Ingenus participated with Ricon in the above-mentioned tortious acts. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Ricon and Ingenus should reasonably anticipate being sued in New Jersey.

19. Upon information and belief, if ANDA No. 215796 is approved, Ricon's ANDA Product will be marketed and distributed by Defendants in the State of New Jersey, prescribed by

physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1391(c), and § 1400(b).

21. Venue is proper for Ricon under 28 U.S.C. §§ 1391 and/or 1400(b), because, *inter alia*, Ricon is incorporated in New Jersey, maintains a regular and established place of business in New Jersey, is subject to personal jurisdiction in this Judicial District, has committed acts of infringement and will commit further acts of infringement in this Judicial District, and/or continuously transacts business in this Judicial District. In addition, Ricon does business in this Judicial District through a permanent and continuous presence in the State of New Jersey. Upon information and belief, Ricon employs a salesforce that includes personnel who regularly and continuously work in this Judicial District and, if Ricon succeeds in obtaining FDA approval, Ricon will use its salesforce to sell the Ricon ANDA Product in the State of New Jersey.

22. Venue is proper for Ingenus under 28 U.S.C. §§ 1391 and/or 1400(b), because, *inter alia*, Ingenus maintains a regular and established place of business in New Jersey, is subject to personal jurisdiction in this Judicial District, and, based on information and belief, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth above, and/or continuously transacts business in this Judicial District, as set forth above. Upon information and belief, Ingenus employs a salesforce that includes personnel who regularly and continuously work in this Judicial District. In addition, Ingenus is registered to do business in New Jersey, designating an in-state agent to receive service of process in New Jersey and, in fact, does business in this Judicial District through a permanent and continuous presence in the State of New Jersey. For example, Ingenus is registered with the State of New

Jersey's Department of Health as a drug wholesaler under Registration No. 5004116 and continuously sells its products in this Judicial District.

**FACTS AS TO ALL COUNTS**

23. Supernus owns New Drug Application ("NDA") No. 202810, which was approved by FDA for the manufacture and sale of oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg, which Supernus markets under the name Oxtellar XR®.

24. Oxtellar XR® is an antiepileptic drug indicated for: (i) adjunctive therapy in the treatment of partial seizures in adults; and (ii) adjunctive therapy in the treatment of partial seizures in children 6 to 17 years of age.

25. The '898 patent, entitled, "Modified-Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on May 25, 2010, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '898 patent.

26. The '131 patent, entitled, "Method of Treating Seizures Using Modified Release Formulations of Oxcarbazepine" was duly and legally issued by the United States Patent and Trademark Office on March 22, 2011, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '131 patent.

27. The '600 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '600 patent.

28. The ’930 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on September 2, 2014, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’930 patent.

29. The ’791 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on September 1, 2015, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’791 patent.

30. The ’975 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on May 31, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’975 patent.

31. The ’525 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on June 21, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’525 patent.

32. The ’278 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on January 2, 2018, to Supernus upon assignment from inventors

Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '278 patent.

33. The '042 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on March 5, 2019, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '042 patent.

34. Pursuant to 21 U.S.C. § 355(b)(1), the patents in suit are listed in FDA's publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") in connection with Oxtellar XR®. Supernus submitted the patents in suit to FDA to be listed in the Orange Book for NDA No. 202810.

35. Upon information and belief, Defendants prepared and filed the Ricon ANDA with FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product and included a "paragraph IV" certification seeking approval before the expiration of patents in suit.

36. 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).

37. On or about April 20, 2021, Ricon sent a letter purportedly pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. §§ 314.94, 314.95 regarding the Ricon Product and the '898 patent, the '131 patent, the '600 patent, the '930 patent, the '791 patent, the '975 patent, the '525 patent, the '278 patent, and the '042 patent (the "April 20 Notice Letter").

38. The April 20 Notice Letter contends that the Ricon Product does not infringe independent claim 1 of each of the patents in suit. The April 20 Notice Letter does not include any non-infringement contentions unique to claims 2-20 of the '898 patent, claims 2–24 of the '131 patent, claims 2–22 of the '600 patent, claims 2-20 of the '930 patent, claims 2-24 of the '791 patent, claims 2-20 of the '975 patent, claims 2-21 of the '525 patent, claims 2-21 of the '278 patent, and claims 2-27 of the '042 patent.

39. The April 20 Notice Letter does not include any detailed statement of the factual and legal basis for Defendants' opinion that the patents in suit are unenforceable.

40. The April 20 Notice Letter does not contend that the patents in suit are invalid as anticipated, obvious, or invalid for lack of enablement and/or written description. In fact, the April 20 Notice Letter does not include any prior-art based invalidity contentions based on 35 U.S.C. § 102 or 35 U.S.C. § 103.

41. The April 20 Notice Letter does not include any description of the composition, formulation, ingredients, development, manufacture, or testing of the Ricon Product beyond a vague and unsupported statement that the Ricon Product does not include a "'homogenous matrix' or any one of the polymers having pH dependent solubility" required by certain claims of

the patent in suit. Plaintiff and Defendants 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, Defendants have not produced the Ricon ANDA to Plaintiff.

**FIRST COUNT**
**(Defendants' Infringement of the '898 Patent)**

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

43. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Ricon Product.

44. Upon information and belief, Defendants included a paragraph IV certification to the '898 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '898 patent.

45. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Ricon Product upon, or in anticipation of, FDA approval.

46. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '898 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '898 patent is an act of infringement by Defendants of one or more claims of the '898 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. §271(e)(2)(A).

47. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will

infringe, directly and/or indirectly, one or more claims of the '898 patent under 35 U.S.C. § 271 *et seq.,* including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

48. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '898 patent under 35 U.S.C. § 271.

49. Defendants' infringement of the '898 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '898 patent.

50. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '898 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '898 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**SECOND COUNT**
**(Defendants' Infringement of the '131 Patent)**

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

52. Upon information and belief, Defendants included a paragraph IV certification to the '131 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '131 patent.

53. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '131 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon

Product before the expiration of the '131 patent is an act of infringement by Defendants of one or more claims of the '131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. §271(e)(2)(A).

54. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

55. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '131 patent under 35 U.S.C. § 271.

56. Defendants' infringement of the '131 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '131 patent.

57. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '131 patent—as well as the statutory provisions and regulations set forth in 21U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '131 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

## THIRD COUNT
**(Defendants' Infringement of the '600 Patent)**

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

59. Upon information and belief, Defendants included a paragraph IV certification to the '600 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '600 patent.

60. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '600 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '600 patent is an act of infringement by Defendants of one or more claims of the '600 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. §271(e)(2)(A).

61. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '600 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

62. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '600 patent under 35 U.S.C. § 271.

63. Defendants' infringement of the '600 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '600 patent.

64. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '600 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that

they would not be liable for infringement of the '600 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**FOURTH COUNT**
**(Defendants' Infringement of the '930 Patent)**

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

66. Upon information and belief, Defendants included a paragraph IV certification to the '930 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '930 patent.

67. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '930 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '930 patent is an act of infringement by Defendants of one or more claims of the '930 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

68. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '930 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

69. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '930 patent under 35 U.S.C. § 271.

70. Defendants' infringement of the '930 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '930 patent.

71. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '930 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '930 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**FIFTH COUNT**
**(Defendants' Infringement of the '791 Patent)**

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

73. Upon information and belief, Defendants included a paragraph IV certification to the '791 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '791 patent.

74. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '791 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '791 patent is an act of infringement by Defendants of one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

75. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

76. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '791 patent under 35 U.S.C. § 271.

77. Defendants' infringement of the '791 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '791 patent.

78. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '791 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '791 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**SIXTH COUNT**
**(Defendants' Infringement of the '975 Patent)**

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

80. Upon information and belief, Defendants included a paragraph IV certification to the '975 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '975 patent.

81. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '975 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '975 patent is an act of infringement by Defendants of one or

more claims of the '975 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

82. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '975 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

83. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '975 patent under 35 U.S.C. § 271.

84. Defendants' infringement of the '975 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '975 patent.

85. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '975 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '975 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

## SEVENTH COUNT
## (Defendants' Infringement of the '525 Patent)

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

87. Upon information and belief, Defendants included a paragraph IV certification to the '525 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '525 patent.

88. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '525 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '525 patent is an act of infringement by Defendants of one or more claims of the '525 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

89. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '525 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

90. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '525 patent under 35 U.S.C. § 271.

91. Defendants' infringement of the '525 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '525 patent.

92. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '525 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that

they would not be liable for infringement of the '525 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**EIGHTH COUNT**
**(Defendants' Infringement of the '278 Patent)**

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

94. Upon information and belief, Defendants included a paragraph IV certification to the '278 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '278 patent.

95. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '278 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '278 patent is an act of infringement by Defendants of one or more claims of the '278 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

96. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '278 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

97. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '278 patent under 35 U.S.C. § 271.

98. Defendants' infringement of the '278 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '278 patent.

99. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '278 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '278 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**NINTH COUNT**
**(Defendants' Infringement of the '042 Patent)**

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

101. Upon information and belief, Defendants included a paragraph IV certification to the '042 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ricon Product before the expiration of the '042 patent.

102. The submission and filing of ANDA No. 215796 with a paragraph IV certification to the '042 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product before the expiration of the '042 patent is an act of infringement by Defendants of one or more claims of the '042 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

103. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product that is the subject of ANDA No. 215796 will infringe, directly or indirectly, one or more claims of the '042 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

104. Upon information and belief, Defendants' offering for sale and/or sale of the Ricon Product will induce and/or contribute to third-party infringement of one or more claims of the '042 patent under 35 U.S.C. § 271.

105. Defendants' infringement of the '042 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '042 patent.

106. As of the date of the April 20 Notice Letter, Defendants were aware of the existence of the '042 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '042 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

i. A Judgment declaring that each of the patents in suit are valid and enforceable;

ii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to FDA and filing of ANDA No. 215796 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product was an act of infringement of the patents in suit by Defendants;

iii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ricon Product prior to the

expiration of the patents in suit, including any regulatory extensions, will constitute acts of infringement by Defendants;

iv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Ricon Product shall be no earlier than the latest date on which an infringed patent in suit expires, including any regulatory extensions;

v. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 215796 until the latest date on which an infringed patent in suit expires, including any regulatory extensions;

vi. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 215796 that infringes any of the patents in suit;

vii. A Judgment declaring that infringement of the patents in suit is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 215796 that infringes any of the patents in suit;

viii. A Judgment declaring that, pursuant to 35 U.S.C. § 285, 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: June 3, 2021

Respectfully submitted,

By: s/ William C. Baton

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1**

I hereby certify that the matter captioned *Supernus Pharmaceuticals, Inc. v. Apotex Inc., et al.*, Civil Action No. 20-7870 (FLW)(TJB) is related to the matter in controversy because the matter in controversy involves the same patents in suit, the same Plaintiff, and defendants seeking approval to market a generic version of the same drug product.

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: June 3, 2021

Respectfully submitted,

By: s/ William C. Baton

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