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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **TWI PHARMACEUTICALS, INC. and TWI INTERNATIONAL LLC (d/b/a TWI PHARMACEUTICALS USA),** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff") by its undersigned attorneys, for its Complaint against defendants TWi Pharmaceuticals, Inc. ("TWi") and TWi International LLC (d/b/a TWI Pharmaceuticals USA) (collectively, "Defendants") herein 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.

8,821,930 ("the '930 patent"), United States Patent No. 9,119,791 ("the '791 patent"), United States Patent No. 9,351,975 ("the '975 patent"), and United States Patent No. 9,370,525 ("the '525 patent"), attached hereto as Exhibits A–F (collectively, "the patents in suit").

THE PARTIES

1. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

2. Upon information and belief, TWi is a corporation organized under the laws of Taiwan and operating at its principal place of business at 3F, No. 41, Lane 221, Kang Chien Rd., Nei Hu Dist., Taipei 114 Taiwan.

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

4. Upon information and belief, TWi, 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.

5. In 2013, TWi filed ANDA No. 206576 ("the TWi ANDA") with the 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, and included a "paragraph IV" certification with respect to the '898, '131, '600, and '930 patents.

6. Upon information and belief, in 2017, TWi filed an amendment to ANDA No. 206576 with the FDA. In connection with that amendment, TWi submitted to the FDA a new "paragraph IV" certification with respect to the '898, '131, '600,[1] '930, '791, '975, and '525 patents, 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 TWi Product") before the expiration of the patents in suit.

7. Upon information and belief, TWi International LLC is an entity organized under the laws of Delaware and operating at its principal place of business at 115 West Century Road, Suite 180, Paramus, NJ 07652. Upon information and belief, TWi International LLC conducts business under the assumed/fictitious name TWi Pharmaceuticals USA. Upon information and belief, TWi International LLC is wholly-owned by defendant TWi. Upon information and belief, TWi International LLC acts at the direction of, under the control of, and for the direct benefit of TWi and is controlled and/or dominated by TWi.

8. Upon information and belief, TWi International LLC is in the business of marketing, selling, and distributing generic pharmaceutical products throughout the United States, including throughout the State of New Jersey.

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[1] "The '600 patent" refers to U.S. Patent No. 8,617,600.

9. Upon information and belief, TWi International LLC (d/b/a TWi Pharmaceuticals USA) is registered as a wholesale drug distributor in the State of New Jersey under the registration number 5004675.

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 N.J. Ct. R. 4:4-4; 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 New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, Defendants manufacture and ship to the United States divalproex sodium extended-release tablets 250 mg and 500 mg for sale within the State of New Jersey. Upon information and belief, Defendants also manufacture and ship to the United States cyclobenzaprine hydrochloride extended-release capsules 15 mg and 30 mg for sale within the State of New Jersey. Furthermore, upon information and belief, Defendants have entered into one or more pharmaceutical supply agreements with one or more companies based in New Jersey that distribute and sell pharmaceutical products within the State of New Jersey. For example, it appears from filings made with the Securities & Exchange Commission that Defendants regularly manufacture and ship pharmaceutical products to the United States for sale within the State of New Jersey under a

supply agreement with Par Pharmaceuticals, a company with headquarters in the State of New Jersey. *See* Par Pharmaceutical Companies, Inc., *Proxy Statement (Schedule 14A)*, at 24 (Sept. 11, 2012), *available at* http://www.sec.gov/Archives/edgar/data/878088/000119312512387426/d409435ddefa14a.htm.

13. This Court has personal jurisdiction over Defendants because, *inter alia*: (i) TWi, together with TWi International LLC, has committed, induced, or contributed to acts of patent infringement in New Jersey; (ii) Defendants are doing business in New Jersey and maintain continuous and systematic contacts with this Judicial District; (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; (v) TWi has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least two prior New Jersey actions (*Supernus Pharm., Inc. v. TWi Pharm., Inc.*, Civil Action No. 15-369 (RMB)(JS); *Purdue Pharm. Prods. L.P. et. al v. TWi Pharm., Inc.*, Civil Action No. 13-5003 (JLL)(JAD) (consolidated under 12-5311 (JLL)(JAD); (vi) TWi International LLC (d/b/a TWi Pharmaceuticals USA) is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under registration number 5004675; and (vii) TWi International LLC maintains a principal place of business at 115 West Century Road, Suite 180, Paramus, NJ 07652.

14. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

15. Supernus owns New Drug Application ("NDA") No. 202810, which was approved by the 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®.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. Pursuant to 21 U.S.C. § 355(b)(1), the '898 patent, the '131 patent, the '600 patent, the '930 patent, the '791 patent, the '975 patent, and the '525 patent are listed in the 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 ’898 patent, the ’131 patent, the ’600 patent, the ’930 patent, the ’791 patent, the ’975 patent, and the ’525 patent to the FDA to be listed in the Orange Book for NDA No. 202810.

24. Upon information and belief, Defendants worked in concert to prepare, submit, and file the TWi ANDA to the 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 TWi Product and included a “paragraph IV” certification seeking approval before the expiration of the ’898 patent, the ’131 patent, the ’600 patent, the ’930 patent, the ’791 patent, the ’975 patent, and the ’525 patent.

25. 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)(6) 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)(6)(i)-(ii).

26. On or about February 16, 2017, TWi sent a letter purportedly pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. § 314.95 regarding the TWi Product and the ’898 patent, the ’131 patent, the ’600 patent, the ’930 patent, the ’791 patent, the ’975 patent, and the ’525 patent (the “February 16, 2017 Notice Letter”). The February 16, 2017 Notice Letter

expressly stated that "TWi has also recertified and reaffirmed its prior certification with respect to [the '898, '131, '600, and '930 patents]."

27. 21 C.F.R. § 314.95(c)(7) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification shall include, "[i]f the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant." The February 16, 2017 Notice Letter identified "Katherine E. Rohlf c/o Husch Blackwell LLP, 120 S. Riverside Plaza, Suite 2200, Chicago, Illinois 60606" as "an agent authorized to accept service of process" under 21 C.F.R. § 314.95(c)(9).

28. The February 16, 2017 Notice Letter does not include any non-infringement contentions unique to claims 3, 7–11, 13–14, 16, and 19 of the '898 patent, claims 2–24 of the '131 patent, claims 6–22 of the '600 patent, claims 3 and 5–20 of the '930 patent, claims 2–24 of the '791 patent, claims 2–20 of the '975 patent, or claims 5, 12, 14, 19, or 20 of the '525 patent.

29. The February 16, 2017 Notice Letter does not include any detailed statement of the factual and legal basis for Defendants' opinion that the patents in suit are invalid. More particularly, with respect to the '791, '975, and '525 patents, TWi states that these patents are invalid, without any detailed statement of the factual and legal basis for that conclusion.

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

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

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

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

33. Upon information and belief, Defendants filed with the FDA a new 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 TWi Product before the expiration of the '898 patent.

34. The submission and filing of ANDA No. 206576 with a new 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 TWi 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).

35. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the TWi Product that is the subject of ANDA No. 206576 will infringe 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).

36. 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.

37. As of the date of the February 16, 2017 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)

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

39. Upon information and belief, Defendants filed with the FDA a new 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 TWi Product before the expiration of the '131 patent.

40. The submission and filing of ANDA No. 206576 with a new 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 TWi 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).

41. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the TWi Product that is the subject of ANDA No. 206576 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) 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).

42. 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.

43. As of the date of the February 16, 2017 Notice Letter, Defendants were aware of the existence of the '131 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 '131 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD COUNT
(Defendants' Infringement of the '930 Patent)

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

45. Upon information and belief, Defendants filed with the FDA a new 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 TWi Product before the expiration of the '930 patent.

46. The submission and filing of ANDA No. 206576 with a new 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 TWi 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).

47. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the TWi Product that is the subject of ANDA No. 206576 will infringe 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).

48. 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.

49. As of the date of the February 16, 2017 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.

FOURTH COUNT
(Defendants' Infringement of the '791 Patent)

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

51. Upon information and belief, Defendants filed with the FDA 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 TWi Product before the expiration of the '791 patent.

52. The submission and filing of ANDA No. 206576 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 TWi 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).

53. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the TWi Product that is the subject of ANDA No. 206576 will infringe 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).

54. 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.

55. As of the date of the February 16, 2017 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.

FIFTH COUNT
(Defendants' Infringement of the '975 Patent)

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

57. Upon information and belief, Defendants filed with the FDA 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 TWi Product before the expiration of the '975 patent.

58. The submission and filing of ANDA No. 206576 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 TWi 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).

59. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the TWi Product that is the subject of ANDA No. 206576 will infringe 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).

60. 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.

61. As of the date of the February 16, 2017 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.

SIXTH COUNT
(Defendants' Infringement of the '525 Patent)

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

63. Upon information and belief, Defendants filed with the FDA 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 TWi Product before the expiration of the '525 patent.

64. The submission and filing of ANDA No. 206576 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 TWi 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).

65. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the TWi Product that is the subject of ANDA No. 206576 will infringe 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).

66. 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.

67. As of the date of the February 16, 2017 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

i. A Judgment declaring that the '898, '131, '930, '791, '975, and '525 patents are valid and enforceable;

ii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 206576 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 TWi Product was an act of infringement of the ’898, ’131, ’930, ’791, ’975, and ’525 patents 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 TWi Product prior to the expiration of the ’898, ’131, ’930, ’791, ’975, and ’525 patents, including any regulatory extensions, will constitute an act 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 TWi Product shall be no earlier than the date on which the ’898, ’131, ’930, ’791, ’975, and ’525 patents expire, 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. 206576 until the expiration of the ’898, ’131, ’930, ’791, ’975, and ’525 patents, 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. 206576 that infringes the ’898, ’131, ’930, ’791, ’975, and ’525 patents;

vii. A Judgment declaring that infringement of the '898, '131, '930, '791, '975, and '525 patents is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 206576 that infringes the '898, '131, '930, '791, '975, and '525 patents;

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: March 31, 2017

Respectfully submitted,

By: s/ William C. Baton

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is related to the matter captioned *Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc., et al.*, Civil Action No. 15-369 (RMB)(JS) because it involves the same parties, the same proposed generic drug product, and three of the same patents.

I further certify that 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: March 31, 2017

Respectfully submitted,

By: s/ William C. Baton

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