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Supernus Pharmaceuticals, Inc.*

**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)

COMPLAINT

Plaintiff Supernus Pharmaceuticals, Inc. (“Supernus”) 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. 8,617,600 ("the '600 patent"), and United States Patent No. 8,821,930 ("the '930 patent"), attached hereto as Exhibits A–D (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 1550 East Gude Drive, Rockville, Maryland 20850.

3. Upon information and belief, TWi is a corporation organized under the laws of Taiwan having a place of business at No. 41, Lane 221, Kang Chien Rd., Nei Hu Dist., Tai Pei 114 Taiwan.

4. 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.

5. 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.

6. Upon information and belief, 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 ("the TWi Product").

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 8001 Irvine Center Drive,

Irvine, California 92618-2938. Upon information and belief, TWi International LLC conducts business under the assumed/fictitious name TWi Pharmaceuticals USA. Upon information and belief, defendant 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.

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, upon information and belief, Defendants regularly manufacture and ship pharmaceutical products to the United States for sale within the State of New Jersey under supply agreements with Par Pharmaceutical Companies, Inc., a company with corporate headquarters in the State of New Jersey. *See, e.g., 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 one prior New Jersey action (*Purdue Pharmaceutical Products L.P., et. al v. TWi Pharmaceuticals, Inc.*, Civil Action No. 13–5003 (JLL)(JAD) (consolidated under 12–5311 (JLL)(JAD))); and (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 the registration number 5004675.

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 ’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.

20. 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.

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

22. 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, and the '930 patent.

23. 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).

24. On or about December 8, 2014, 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, and the ’930 patent (the “December 8 Notice Letter”).

25. 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 December 8 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)(7).

26. The December 8 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, and claims 3 and 5–20 of the ’930 patents.

27. The December 8 Notice Letter does not include any detailed statement of the factual and legal basis for Defendants’ opinion that the patents in suit are invalid.

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

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

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

30. 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 TWi Product before the expiration of the '898 patent.

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.

32. The submission and filing of ANDA No. 206576 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 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).

33. 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).

34. 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.

35. As of the date of the December 8 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)

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

37. The submission and filing of ANDA No. 206576 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 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).

38. 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).

39. 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.

40. As of the date of the December 8 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 '600 Patent)

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

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

43. 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 '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).

44. 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.

45. As of the date of the December 8 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)

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

47. The submission and filing of ANDA No. 206576 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 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).

48. 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).

49. 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.

50. As of the date of the December 8 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- i. A Judgment declaring that the '898 patent is 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 patent by Defendants;
- iii. A Judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including under 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 patent, 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 patent 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. 206576 until the expiration of the '898 patent, 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 patent;
- vii. A Judgment declaring that infringement of the '898 patent 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 patent;
- viii. A Judgment declaring that the '131 patent is valid and enforceable;
- ix. 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 '131 patent by Defendants;

- x. A Judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including under 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 '131 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;
- xi. 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 '131 patent expires, including any regulatory extensions;
- xii. 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 '131 patent, including any regulatory extensions;
- xiii. 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 '131 patent;
- xiv. A Judgment declaring that infringement of the '131 patent 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 '131 patent;
- xv. A Judgment declaring that the '600 patent is valid and enforceable;

- xvi. 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 '600 patent by Defendants;
- xvii. A Judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including under 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 '600 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;
- xviii. 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 '600 patent expires, including any regulatory extensions;
- xix. 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 '600 patent, including any regulatory extensions;
- xx. 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 '600 patent;

- xxi. A Judgment declaring that infringement of the '600 patent 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 '600 patent;
- xxii. A Judgment declaring that the '930 patent is valid and enforceable;
- xxiii. 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 '930 patent by Defendants;
- xxiv. A Judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including under 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 '930 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;
- xxv. 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 '930 patent expires, including any regulatory extensions;
- xxvi. 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 '930 patent, including any regulatory extensions;

- xxvii. 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 '930 patent;
- xxviii. A Judgment declaring that infringement of the '930 patent 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 '930 patent;
- xxix. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Supernus its attorneys' fees and costs;
- xxx. Such other and further relief as this Court may deem just and proper.

Dated: January 16, 2015

Respectfully submitted,

By: s/ Charles M. Lizza

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