IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VELOXIS PHARMACEUTICALS, INC., *Plaintiff*, v. SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES INC., *Defendants*.	C.A. No. 1:24-cv-00726-MN

DEFENDANTS, SUN PHARMACEUTICAL INDUSTRIES LTD. AND SUN PHARMACEUTICAL INDUSTRIES, INC.'S
ANSWER TO AMENDED COMPLAINT

Defendants, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (collectively herein, "Sun"), by and through their undersigned counsel, respectfully submit their Answer to Plaintiff's Amended Complaint, stating as follows:

RESPONSES TO ALLEGATIONS
CONERNING THE NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 et seq., arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 215836 ("Defendants' ANDA") to the United States Food and Drug Administration ("FDA"). Defendants' ANDA seeks FDA approval to market and sell 0.75 mg, 1 mg, and 4 mg extended-release tablets of tacrolimus ("Defendants' ANDA Products") prior to the expiration of U.S. Patent Nos. 8,685,998 ("the '998 Patent"); 9,549,918 ("the '918 Patent"); 10,166,190 ("the '190 Patent"); 10,864,199 ("the '199 Patent"); 11,110,081 ("the '081 Patent"); 11,123,331 ("the '331 Patent"); 11,419,823 ("the '823 Patent"); and 12,083,103 ("the '103 Patent").

RESPONSE: Sun admits Plaintiff purports to bring a civil action to assert infringement under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.* Sun admits to filing ANDA No. 215836 with the FDA seeking regulatory approval for Sun's tacrolimus extended-release tablets, 0.75 mg,

1 mg, and 4 mg, prior to the expiration of the '998, '918, '190, '199, '081, '331, '823, and '103 patents. Sun denies all further allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

2. Veloxis owns the patents-in-suit and is the holder of FDA approved New Drug Application ("NDA") No. 206406 for the brand name drug ENVARSUS XR® (tacrolimus). The patents-in-suit generally cover oral dosage forms and methods of use and administration of tacrolimus, including ENVARSUS XR®. Defendants' ANDA Products are generic versions of ENVARSUS XR®.

RESPONSE: On information and belief, Sun admits Veloxis is the holder of FDA approved NDA No. 206406 for the drug product marketed as Envarsus XR. Sun is without knowledge or information sufficient to form a belief as to the truth of the ownership of the patents-in-suit and, therefore, denies all such allegations. Sun denies all further allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING THE PARTIES

3. Plaintiff Veloxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Regency Parkway, Suite 500, Cary, NC 27518.

RESPONSE: Sun is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Amended Complaint and, therefore, denies the same.

4. Upon information and belief, Defendant Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, Maharashtra, India. Upon information and belief, Sun Pharmaceutical Industries Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

RESPONSE: Sun admits that Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of India with a place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai 400063, India. Sun admits that Sun Pharmaceutical

Industries Ltd.'s business includes, among other things, developing, manufacturing, and selling regulatory-approved drug products, including in and for the United States. Sun denies all further allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

5. Upon information and belief, Defendant Sun Pharmaceutical Industries, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540. Upon information and belief, Sun Pharmaceutical Industries, Inc., is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

RESPONSE: Sun admits that Sun Pharmaceutical Industries Inc. is organized under the laws of Delaware with a place of business located at 2 Independence Way, Princeton, New Jersey 08540. Sun admits that Sun Pharmaceuticals Industries Inc.'s business includes, among other things, developing, manufacturing, and selling regulatory-approved drug products, including in and for the United States. Sun denies all further allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

6. Upon information and belief, Sun Pharmaceutical Industries, Inc., is a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd., and is controlled and/or dominated by Sun Pharmaceutical Industries Ltd. Upon information and belief, Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries Ltd., are agents of each other and/or operate in concert as integrated parts of the same business group.

RESPONSE: Sun admits Sun Pharmaceutical Industries Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. Sun denies all further allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING THE JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE: Sun admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

8. This Court has personal jurisdiction over Sun Pharmaceutical Industries Ltd., because Sun Pharmaceutical Industries Ltd., itself and/or through its subsidiaries, including, but not limited to Sun Pharmaceutical Industries, Inc., has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Sun Pharmaceutical Industries Ltd., directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Sun Pharmaceutical Industries Ltd., prepared and filed ANDA No. 215836 with the FDA. Upon information and belief, Sun Pharmaceutical Industries Ltd., on its own or acting in concert with Sun Pharmaceutical Industries, Inc., or other subsidiaries, will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including Delaware, upon approval of ANDA No. 215836, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

RESPONSE: Solely for the purpose of this litigation, Sun does not contest the Court's exercise of personal jurisdiction. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

9. This Court also has personal jurisdiction over Sun Pharmaceutical Industries Ltd., pursuant to Rule 4(k)(2), Fed. R. Civ. P. Sun Pharmaceutical Industries Ltd., is a foreign corporation who has directed actions toward Delaware and purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Sun Pharmaceutical Industries Ltd., regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Sun Pharmaceutical Industries Ltd., derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

RESPONSE: Solely for the purpose of this litigation, Sun does not contest the Court's exercise of personal jurisdiction. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

10. This Court also has personal jurisdiction over Sun Pharmaceutical Industries Ltd., by virtue of Sun Pharmaceutical Industries Ltd., previously consenting to personal jurisdiction in this Court and having taken advantage of the rights and protections provided by this Court,

including having asserted counterclaims in this jurisdiction (*see, e.g.*, Answer, Defenses, and Counterclaims, Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al., C.A. No. 23-1459 (D. Del. March 8, 2024), D.I. 9; Answer, Defenses, and Counterclaims, Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al., C.A. No. 22-296 (D. Del. May 9, 2022), D.I. 11; Answer, Affirmative Defenses and Counterclaims, Boehringer Ingelheim Pharmaceuticals, et al. v. Sun Pharmaceutical Industries Ltd., et al., C.A. No. 21-356 (D. Del. Apr. 5, 2021), D.I. 9; Answer, Affirmative Defenses, and Counterclaims, Allergan USA, Inc., et al. v. Sun Pharmaceutical Industries Ltd., C.A. No. 21-1065 (D. Del. Nov. 10, 2021), D.I. 266 in lead C.A. No. 19-1727).

RESPONSE: Solely for the purpose of this litigation, Sun does not contest the Court's exercise of personal jurisdiction. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

11. This Court has personal jurisdiction over Sun Pharmaceutical Industries, Inc., because Sun Pharmaceutical Industries, Inc., itself and/or through its parent Sun Pharmaceutical Industries Ltd., has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Sun Pharmaceutical Industries, Inc., directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Sun Pharmaceutical Industries, Inc., on its own or acting in concert with Sun Pharmaceutical Industries Ltd., prepared and submitted ANDA No. 215836 to the FDA. Upon information and belief, Sun Pharmaceutical Industries, Inc., on its own or acting in concert with Sun Pharmaceutical Industries Ltd., will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 215836, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

RESPONSE: Solely for the purpose of this litigation, Sun does not contest the Court's exercise of personal jurisdiction. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

12. This Court also has personal jurisdiction over Sun Pharmaceutical Industries Inc., by virtue of Sun Pharmaceutical Industries, Inc., previously consenting to personal jurisdiction in this Court and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, Answer, Defenses, and Counterclaims, Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al., C.A. No. 23-1459 (D. Del. March 8, 2024), D.I. 9; Answer, Defenses, and Counterclaims, Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al., C.A. No. 22-296 (D. Del. May 9, 2022), D.I. 11; Answer, Affirmative Defenses and Counterclaims, Boehringer Ingelheim Pharmaceuticals, et al. v. Sun Pharmaceutical Industries Ltd., et al., C.A. No. 21-356 (D. Del. Apr. 5, 2021), D.I. 9.;

Answer, Affirmative Defenses and Counterclaims, Pfizer, Inc. et al. v. Sun Pharmaceutical Industries Ltd. et al., C.A. No. 19-758 (D. Del. July 10, 2019), D.I. 11.

RESPONSE: Solely for the purpose of this litigation, Sun does not contest the Court's exercise of personal jurisdiction. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

13. This Court also has personal jurisdiction over Defendants because, inter alia, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and have sent notice of that infringement to Veloxis, a corporation organized and existing under the laws of the State of Delaware. On information and belief, Defendants intend a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will continue to lead to foreseeable harm and injury to Veloxis in Delaware.

RESPONSE: Solely for the purpose of this litigation, Sun does not contest the Court's exercise of personal jurisdiction. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

14. Defendant Sun Pharmaceutical Industries Ltd. is a foreign corporation not residing in the United States. Defendant Sun Pharmaceutical Industries, Inc., is incorporated in the State of Delaware and therefore resides in this Judicial District. Thus, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

RESPONSE: Solely for the purpose of this litigation, Sun does not contest venue in this Judicial District. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING THE PATENTS-IN-SUIT

15. On April 1, 2014, the '998 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Veloxis is the assignee of the '998 Patent. A true copy of the '998 Patent is attached hereto as Exhibit A.

RESPONSE: Sun admits Exhibit A appears to be a copy of the '998 patent, which is the best evidence of its contents. Sun admits Exhibit A identifies April 1, 2014, as the date the '998 patent issued. Sun admits the '998 patent is titled "Tacrolimus for Improved Treatment of Transplant

Patients." Sun denies the '998 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '998 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

16. On January 24, 2017, the '918 Patent, titled "Stabilized Tacrolimus Composition," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '918 Patent. A true copy of the '918 Patent is attached hereto as Exhibit B.

RESPONSE: Sun admits Exhibit B appears to be a copy of the '918 patent, which is the best evidence of its contents. Sun admits Exhibit B identifies January 24, 2017, as the date the '918 patent issued. Sun admits the '918 patent is titled "Stabilized Tacrolimus Composition." Sun denies the '918 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '918 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

17. On January 1, 2019, the '190 Patent, titled "Stabilized Tacrolimus Composition," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '190 Patent. A true copy of the '190 Patent is attached hereto as Exhibit C.

RESPONSE: Sun admits Exhibit C appears to be a copy of the '190 patent, which is the best evidence of its contents. Sun admits Exhibit C identifies January 1, 2019, as the date the '190 patent issued. Sun admits the '190 patent is titled "Stabilized Tacrolimus Composition." Sun denies the '190 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '190 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

18. On December 15, 2020, the '199 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '199 Patent. A true copy of the '199 Patent is attached hereto as Exhibit D.

RESPONSE: Sun admits Exhibit D appears to be a copy of the '199 patent, which is the best evidence of its contents. Sun admits Exhibit D identifies December 15, 2020, as the date the '199 patent issued. Sun admits the '199 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients." Sun denies the '199 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '199 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

19. On September 7, 2021, the '081 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '081 Patent. A true copy of the '081 Patent is attached hereto as Exhibit E.

RESPONSE: Sun admits Exhibit E appears to be a copy of the '081 patent, which is the best evidence of its contents. Sun admits Exhibit E identifies September 7, 2021, as the date the '081 patent issued. Sun admits the '081 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients." Sun denies the '081 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '081 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

20. On September 21, 2021, the '331 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '331 Patent. A true copy of the '331 Patent is attached hereto as Exhibit F.

RESPONSE: Sun admits Exhibit F appears to be a copy of the '331 patent, which is the best evidence of its contents. Sun admits Exhibit F identifies September 21, 2021, as the date the '331 patent issued. Sun admits the '331 patent is titled "Tacrolimus for Improved Treatment of

Transplant Patients." Sun denies the '331 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '331 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

21. On August 23, 2022, the '823 Patent, titled "Stabilized Tacrolimus Composition," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '823 Patent. A true copy of the '823 Patent is attached hereto as Exhibit G.

RESPONSE: Sun admits Exhibit G appears to be a copy of the '823 patent, which is the best evidence of its contents. Sun admits Exhibit G identifies August 23, 2022, as the date the '823 patent issued. Sun admits the '823 patent is titled "Stabilized Tacrolimus Composition." Sun denies the '823 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '823 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

22. On September 10, 2024, the '103 Patent titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '103 Patent. A true copy of the '103 Patent is attached hereto as Exhibit H.

RESPONSE: Sun admits Exhibit H appears to be a copy of the '103 patent, which is the best evidence of its contents. Sun admits Exhibit H identifies September 10, 2024, as the date the '103 patent issued. Sun admits the '103 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients." Sun denies the '103 Patent was duly and lawfully issued. Sun is without knowledge or information sufficient to form a belief as to the truth of Veloxis's status as assignee of the '103 patent and, therefore, denies the same. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS
CONCERNING VELOXIS' ENVARSUS XR®

23. Veloxis holds approved NDA No. 206406 for extended-release tablets containing the active ingredient tacrolimus. Veloxis markets and sells tacrolimus extended-release tablets under the trade name ENVARSUS XR®.

RESPONSE: On information and belief, Admitted.

24. ENVARSUS XR® is a calcineurin-inhibitor immunosuppressant indicated for: (1) the prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants and (2) the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants. A copy of the complete prescribing information for ENVARSUS XR® is attached hereto as Exhibit I.

RESPONSE: Sun is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Amended Complaint and, therefore, denies the same.

25. Pursuant to 21 U.S.C. § 355(b)(1) and related FDA regulations, Veloxis listed the '998, '918, '190, '199, '081, '331, '823, and '103 patents in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ENVARSUS XR®. The prescribing information for ENVARSUS XR® instructs and encourages physicians, other healthcare workers and patients to administer ENVARSUS XR® tablets according to one or more of the methods claimed in the patents-in-suit.

RESPONSE: Sun admits the '998, '918, '190, '199, '081, '331, '823, and '103 patents are listed in the Orange Book in connection with the product marketed as Envarsus XR. Sun is without knowledge or information sufficient to form a belief as to the truth as to who caused the enumerated patents to be listed in the Orange Book. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
ACTS GIVING RISE TO THIS ACTION

26. By letter dated May 8, 2024 ("May 8 Notice Letter"), Sun notified Veloxis that Sun had submitted ANDA No. 215836 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Veloxis received the May 8 Notice Letter no earlier than May 9, 2024.

RESPONSE: Admitted.

27. The May 8 Notice Letter states that Sun seeks approval from the FDA to engage in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of Defendants' ANDA Products before expiration of the '998, '918, '190, '199, '081, '331, '823, and '103 patents. Upon information and belief, Defendants intend to, directly or indirectly, engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Products promptly upon receiving FDA approval.

RESPONSE: Sun admits the May 8 Notice Letter states that Sun seeks approval from the FDA to engage in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of Defendants' ANDA Products before expiration of the '998, '918, '190, '199, '331 and '823 patents. Sun denies the May 8 Notice Letter addressed either of the '103 or '081 patents. Sun denies all allegations in this paragraph of the Amended Complaint that are hypothetical in nature or concern uncertain future events. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

28. By filing ANDA No. 215836, Defendants have necessarily represented to the FDA that Defendants' ANDA Products have the same active ingredient, the same dosage form, the same route of administration, and the same strengths as ENVARSUS XR®. By submitting ANDA No. 215836, Defendants also have necessarily represented to the FDA that Defendants' ANDA Products are bioequivalent to ENVARSUS XR®. Upon information and belief, Defendants are seeking approval to market and sell their ANDA Products for the same approved indications as ENVARSUS XR®.

RESPONSE: Denied.

29. In the May 8 Notice Letter, Sun states that Defendants' ANDA contains a Paragraph IV Certification asserting that the claims of the '998 Patent are not infringed. The May 8 Notice Letter does not contest that the claims of the '998 Patent are valid and enforceable.

RESPONSE: Sun admits the May 8 Notice Letter states that the claims of the '998 patent are not infringed by Sun's ANDA or ANDA product. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

30. In the May 8 Notice Letter, Sun states that Defendants' ANDA contains a Paragraph IV Certification asserting that the claims of the '918 Patent are not infringed. The May 8 Notice Letter does not contest that the claims of the '918 Patent are valid and enforceable.

RESPONSE: Sun admits the May 8 Notice Letter states that the claims of the '918 patent are not infringed by Sun's ANDA or ANDA product. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

31. In the May 8 Notice Letter, Sun states that Defendants' ANDA contains a Paragraph IV Certification asserting that the claims of the '190 Patent are not infringed. The May 8 Notice Letter does not contest that the claims of the '190 Patent are valid and enforceable.

RESPONSE: Sun admits the May 8 Notice Letter states that the claims of the '190 patent are not infringed by Sun's ANDA or ANDA product. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

32. In the May 8 Notice Letter, Sun states that Defendants' ANDA contains a Paragraph IV Certification asserting that the claims of the '199 Patent are not infringed. The May 8 Notice Letter does not contest that the claims of the '199 Patent are valid and enforceable.

RESPONSE: Sun admits the May 8 Notice Letter states that the claims of the '199 patent are not infringed by Sun's ANDA or ANDA product. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

33. In the May 8 Notice Letter, Sun does not address the '081 Patent, even though it is listed in the Orange Book. The May 8 Notice Letter does not contest that the claims of the '081 Patent are valid, enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Products.

RESPONSE: Sun admits the May 8 Notice Letter does not address the '081 Patent and, therefore, could not contest the validity, enforceability or potential infringement of the same, which Sun denies. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not admitted are denied.

34. In the May 8 Notice Letter, Sun states that its ANDA contains a Paragraph IV Certification asserting that the claims of the '331 Patent are not infringed and/or invalid under 35 U.S.C. §§ 103 and 112. The May 8 Notice Letter does not contest that the claims of the '331 Patent are enforceable. The May 8 Notice Letter also does not contest the validity of the claims of the '331 Patent under 35 U.S.C. § 102.

RESPONSE: Sun admits the May 8 Notice Letter states that the claims of the '331 patent are not infringed by Sun's ANDA or ANDA product and are invalid under 35 U.S.C. §§ 103 and 112. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

35. In the May 8 Notice Letter, Sun states that its ANDA contains a Paragraph IV Certification asserting that the claims of the '823 Patent are not infringed. The May 8 Notice Letter does not contest that the claims of the '823 Patent are valid and enforceable.

RESPONSE: Sun admits the May 8 Notice Letter states that the claims of the '823 patent are not infringed by Sun's ANDA or ANDA product. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT I ALLEGED INFRINGEMENT OF THE '998 PATENT

36. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs of the Amended Complaint as if fully set forth herein.

37. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '998 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

RESPONSE: Denied.

38. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '998 Patent.

RESPONSE: Denied.

39. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '998 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '998 patent. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

40. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '998 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

RESPONSE: Denied.

41. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '998 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '998 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '998 Patent.

RESPONSE: Denied.

42. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '998 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '998 Patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

RESPONSE: Denied.

43. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '998 Patent is not enjoined.

RESPONSE: Denied.

44. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

45. Upon information and belief, Defendants had knowledge of the '998 Patent prior to filing their ANDA with the FDA.

RESPONSE: Admitted.

46. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys' fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT II ALLEGED INFRINGEMENT OF THE '918 PATENT

47. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs of the Amended Complaint as if fully set forth herein.

48. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '918 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

RESPONSE: Denied.

49. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '918 Patent.

RESPONSE: Denied.

50. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '918 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '918 patent. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

51. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '918 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

RESPONSE: Denied.

52. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '918 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '918 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '918 Patent.

RESPONSE: Denied.

53. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '918 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '918 Patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

RESPONSE: Denied.

54. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '918 Patent is not enjoined.

RESPONSE: Denied.

55. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

56. Upon information and belief, Defendants had knowledge of the '918 Patent prior to filing their ANDA with the FDA.

RESPONSE: Admitted.

57. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys' fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT III ALLEGED INFRINGEMENT OF THE '190 PATENT

58. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs of the Amended Complaint as if fully set forth herein.

59. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '190 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

RESPONSE: Denied.

60. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '190 Patent.

RESPONSE: Denied.

61. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '190 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '190 patent. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

62. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '190 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

RESPONSE: Denied.

63. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '190 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of

the ’190 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the ’190 Patent.

RESPONSE: Denied.

64. Unless enjoined by this Court, upon FDA approval of Defendants’ ANDA Products, Defendants will contributorily infringe one or more claims of the ’190 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants’ ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants’ ANDA Products are especially adapted for a use that infringes one or more claims of the ’190 Patent and that there is no substantial non-infringing use for Defendants’ ANDA Products.

RESPONSE: Denied.

65. Veloxis will be substantially and irreparably damaged and harmed if Defendants’ infringement of the ’190 Patent is not enjoined.

RESPONSE: Denied.

66. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

67. Upon information and belief, Defendants had knowledge of the ’190 Patent prior to filing their ANDA with the FDA.

RESPONSE: Admitted.

68. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys’ fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT IV ALLEGED INFRINGEMENT OF THE ’199 PATENT

69. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs of the Amended Complaint as if fully set forth herein.

70. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '199 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 14.

RESPONSE: Denied.

71. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 14 of the '199 Patent.

RESPONSE: Denied.

72. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '199 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '199 patent. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

73. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '199 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '199 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '199 Patent.

RESPONSE: Denied.

74. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '199 patent under 35 U.S.C. § 271(e) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '199 Patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

RESPONSE: Denied.

75. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '199 Patent is not enjoined.

RESPONSE: Denied.

76. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

77. Upon information and belief, Defendants had knowledge of the '199 Patent prior to filing their ANDA with the FDA.

RESPONSE: Admitted.

78. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys' fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT V ALLEGED INFRINGEMENT OF THE '081 PATENT

79. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs of the Amended Complaint as if fully set forth herein.

80. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '081 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

RESPONSE: Denied.

81. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '081 Patent.

RESPONSE: Denied.

82. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '081 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '081 patent. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

83. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '081 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '081 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '081 Patent.

RESPONSE: Denied.

84. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '081 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '081 Patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

RESPONSE: Denied.

85. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '081 Patent is not enjoined.

RESPONSE: Denied.

86. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

87. Upon information and belief, Defendants had knowledge of the '081 Patent prior to filing their ANDA with the FDA.

RESPONSE: Admitted.

88. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys' fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT VI ALLEGED INFRINGEMENT OF THE '331 PATENT

89. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs of the Amended Complaint as if fully set forth herein.

90. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '331 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

RESPONSE: Denied.

91. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '331 Patent.

RESPONSE: Denied.

92. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '331 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '331 patent. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

93. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '331 Patent under 35 U.S.C. §271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '331 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '331 Patent.

RESPONSE: Denied.

94. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '331 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '331 Patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

RESPONSE: Denied.

95. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '331 Patent is not enjoined.

RESPONSE: Denied.

96. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

97. Upon information and belief, Defendants had knowledge of the '331 Patent prior to filing their ANDA with the FDA.

RESPONSE: Admitted.

98. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys' fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT VII ALLEGED INFRINGEMENT OF THE '823 PATENT

99. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs of the Amended Complaint as if fully set forth herein.

100. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '823 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

RESPONSE: Denied.

101. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '823 Patent.

RESPONSE: Denied.

102. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '823 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '823 patent. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

103. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '823 Patent is not enjoined.

RESPONSE: Denied.

104. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

105. The application that led to the '823 patent was published on September 19, 2019 as Patent Application Publication No. US 2019/0282504 A1 and claims priority to, inter alia, the '998, '918, and '190 patents. Upon information and belief, Defendants had knowledge of the application that led to the '823 Patent prior to filing their ANDA with the FDA.

RESPONSE: Admitted.

106. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys' fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS CONCERNING
COUNT VIII ALLEGED INFRINGEMENT OF THE '103 PATENT

107. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Sun repeats and restates its responses to the allegations of the preceding paragraphs as if fully set forth herein.

108. Defendant's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendant's ANDA Products, prior to the expiration of the '103 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

RESPONSE: Denied.

109. Upon information and belief, Defendant's ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '103 Patent.

RESPONSE: Denied.

110. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '103 Patent.

RESPONSE: Sun admits there is a justiciable controversy between the parties hereto as to the invalidity and alleged infringement of the '103 Patent. Sun denies all remaining allegations in this paragraph of the Amended Compliant. Allegations not expressly admitted are denied.

111. Unless enjoined by this Court, upon FDA approval of Defendant's ANDA Products, Defendant will induce infringement of one or more claims of the '103 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendant's ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendant's ANDA Products, Defendant will intentionally encourage acts of direct infringement with knowledge of the '103 Patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '103 Patent.

RESPONSE: Denied.

112. Unless enjoined by this Court, upon FDA approval of Defendant's ANDA Products, Defendant will contributorily infringe one or more claims of the '103 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendant's ANDA Products in the United States. Upon information and belief, Defendant has had and continues to have knowledge that Defendant's ANDA Products are especially adapted for a use that infringes one or more claims of the '103 Patent and that there is no substantial non-infringing use for Defendant's ANDA Products.

RESPONSE: Denied.

113. Veloxis will be substantially and irreparably damaged and harmed if Defendant's infringement of the '103 Patent is not enjoined.

RESPONSE: Denied.

114. Veloxis does not have an adequate remedy at law.

RESPONSE: Denied.

115. Upon information and belief, Defendant had knowledge of the '103 Patent prior to filing its ANDA with the FDA.

RESPONSE: Denied.

116. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 25 U.S.C. § 285.

RESPONSE: Sun admits this case is exceptional under 35 U.S.C. § 285 and avers Sun is entitled to an award of its reasonable attorneys' fees. Sun denies all remaining allegations in this paragraph of the Amended Complaint. Allegations not expressly admitted are denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFF'S REQUEST FOR RELIEF

All allegations in Plaintiff's Amended Complaint not expressly admitted by Sun are hereby denied. Having answered Plaintiff's Amended Complaint, Sun denies Plaintiff is entitled to any of the relief requested in the Amended Complaint or any relief whatsoever. With respect to Plaintiff's request for relief, Sun denies that Plaintiff is entitled to any relief for the allegations and claims made in the Amended Complaint, including the relief requested in paragraphs A-K of the Prayer for Relief set forth in the Amended Complaint.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Amended Complaint, and without admitting any allegations of the Amended Complaint not expressly admitted, Sun asserts the following separate defenses to the Amended Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiff.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the product(s) that is the subject of Sun's ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the Patents-in-Suit.

SECOND SEPARATE DEFENSE

Each of the claims of the Patents-in-Suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or Obviousness Type Double Patenting.

THIRD SEPARATE DEFENSE

Each of the claims of the Patents-in-Suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102 or 103, respectively, for example, for at least the reasons set forth in Sun's Notice Letters.

FOURTH SEPARATE DEFENSE

Each of the claims of the Patents-in-Suit is invalid, pursuant to 35 U.S.C. § 112, as, for example, indefinite, not enabled and/or failing to provide adequate written description.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the Patents-in-Suit, and specifically prosecution history estoppel, Plaintiff is estopped from maintaining that any valid or enforceable claim of the Asserted Patents is infringed by the product that is the subject of Sun's ANDA.

SIXTH SEPARATE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

RESERVATION OF ADDITIONAL DEFENSES

Sun reserves the right to assert additional separate defenses that may be developed through discovery, or otherwise, in this action, such as claims of inequitable conduct during the prosecution of the Patents-in-Suit.

Dated: June 9, 2025

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