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Sun Pharmaceutical Industries Ltd. and Sun
Pharmaceutical Industries, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

THERAPEUTICSMD, INC. and MAYNE
PHARMA LLC,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES
LTD. and SUN PHARMACEUTICAL
INDUSTRIES, INC.,

Defendants.

C.A. No. 24-cv-07974-BRM-SDA

**SUN PHARMACEUTICAL INDUSTRIES LTD. AND SUN PHARMACEUTICAL
INDUSTRIES, INC.’S ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO
PLAINTIFFS’ COMPLAINT**

Defendants Sun Pharmaceutical Industries Ltd. (“Sun Pharma Ltd.”) and Sun
Pharmaceutical Industries, Inc. (“Sun Pharma Inc.”) (collectively, “Defendants” or “Sun”), for

their Answer in response to the Complaint of Plaintiffs TherapeuticsMD, Inc. and Mayne Pharma LLC's (together, "Plaintiffs") in the above-entitled action, state and allege 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 of the United States Code, involving U.S. Patent Nos. 9,180,091 ("the '091 patent") (attached as Exhibit A); 9,289,382 ("the '382 patent") (attached as Exhibit B); 10,258,630 ("the '630 patent") (attached as Exhibit C); 10,398,708 ("the '708 patent") (attached as Exhibit D); 10,471,072 ("the '072 patent") (attached as Exhibit E); 10,537,581 ("the '581 patent") (attached as Exhibit F); 10,568,891 ("the '891 patent") (attached as Exhibit G); 10,668,082 ("the '082 patent") (attached as Exhibit H); 10,806,697 ("the '697 patent") (attached as Exhibit I); 10,835,487 ("the '487 patent") (attached as Exhibit J); 10,888,516 ("the '516 patent") (attached as Exhibit K); 11,065,197 ("the '197 patent") (attached as Exhibit L); 11,116,717 ("the '717 patent") (attached as Exhibit M); 11,123,283 ("the '283 patent") (attached as Exhibit N); 11,241,445 ("the '445 patent") (attached as Exhibit O); 11,246,875 ("the '875 patent") (attached as Exhibit P); 11,266,661 ("the '661 patent") (attached as Exhibit Q); 11,304,959 ("the '959 patent") (attached as Exhibit R); 11,351,182 ("the '182 patent") (attached as Exhibit S); and 11,497,709 ("the '709 patent") (attached as Exhibit T) (collectively, the "Patents-in-Suit").

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that the Complaint purports to set forth claims for infringement of the '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the '516 patent, the '197 patent, the '717 patent, the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent (collectively, the "Patents-in-Suit") against

Sun. Sun further admits that the Complaint purports to set forth claims arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Sun is without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 1; therefore, denied.

THE PARTIES

2. TherapeuticsMD is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 2; therefore, denied.

3. Mayne is a limited liability company organized and existing under the laws of Delaware, having a place of business at 3301 Benson Drive, Suite 401, Raleigh, North Carolina 27609.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 3; therefore, denied.

4. In December 2022, TherapeuticsMD completed transactions with Mayne pursuant to which: (i) TherapeuticsMD granted Mayne an exclusive, sublicensable, perpetual, irrevocable license to the Patents-in-Suit; and (ii) transferred to Mayne ownership of New Drug Application (“NDA”) No. 208564, which was approved by the U.S. Food and Drug Administration (“FDA”) for the manufacture and sale of Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg.

ANSWER: Sun admits that the FDA’s Orange Book identifies Mayne Pharma as the applicant holder for NDA No. 208564 and that the trade name for the product approved under NDA No. 208564 is Imvexxy®. Sun is without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 4; therefore, denied.

5. TherapeuticsMD is the current owner and assignee of each of the twenty (20) patents listed in FDA's publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Invexxy®, of which all twenty (20) are the Patents-in-Suit.

ANSWER: Sun admits that the Patents-in-Suit on their respective faces, list TherapeuticsMD as the assignee. Sun is without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 5; therefore, denied.

6. Upon information and belief, defendant Sun Pharma 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 (East), Mumbai, Maharashtra, 400063, India.

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

7. Sun Pharma Ltd.'s website states: "Sun Pharmaceutical Industries Ltd. (Sun Pharma) is the fourth largest specialty generic pharmaceutical company in the world." <https://sunpharma.com/worldwide>.

ANSWER: Sun admits that <https://sunpharma.com/worldwide> states: "Sun Pharmaceutical Industries Ltd. (Sun Pharma) is the fourth largest specialty generic pharmaceutical company in the world." Otherwise, denied.

8. Sun Pharma Ltd.'s website states: "Our U.S. headquarters is in Princeton, New Jersey, with distribution, manufacturing and R&D teams at multiple locations across the country." <https://sunpharma.com/usa/>.

ANSWER: Sun admits that <https://sunpharma.com/usa> states “Our U.S. headquarters is in Princeton, New Jersey, with distribution, manufacturing and R&D teams at multiple locations across the country.” Otherwise, denied.

9. Upon information and belief, Sun Pharma Ltd. operates through a global network of subsidiaries—including defendant Sun Pharma Inc.—that it directly or indirectly owns and/or controls.

ANSWER: Sun admits that Sun Pharmaceutical Industries, Inc. is a subsidiary of Sun Pharmaceutical Industries Ltd. Otherwise, denied.

10. Sun Pharma Ltd.’s website states: “Supported by 43 manufacturing facilities, we provide high-quality, affordable medicines, trusted by healthcare professionals and patients, to more than 100 countries across the globe.” <https://sunpharma.com/about-us/>.

ANSWER: Sun admits that <https://sunpharma.com/about-us/> states: “Supported by 43 manufacturing facilities, we provide high-quality, affordable medicines, trusted by healthcare professionals and patients, to more than 100 countries across the globe.” Otherwise, denied.

11. Sun Pharma Ltd.’s website states: “Our U.S. business makes up 30% of our global revenue.” <https://sunpharma.com/usa/>.

ANSWER: Sun admits that <https://sunpharma.com/usa/> states “Our U.S. business makes up 30% of our global revenue.” Otherwise, denied.

12. Upon information and belief, defendant Sun Pharma Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 2 Independence Way, Princeton, New Jersey 08540 and another place of business at 1 Commerce Drive, Cranbury, New Jersey 08512.

ANSWER: Sun admits that Sun Pharma Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 2 Independence Way, Princeton, New Jersey 08540 and another place of business at 1 Commerce Drive, Cranbury, New Jersey 08512.

13. Upon information and belief, Sun Pharma Inc. is headquartered in Princeton, New Jersey. <https://sunpharma.com/usa/>.

ANSWER: Sun admits that Sun Pharma Inc. is headquartered in Princeton, New Jersey

14. Upon information and belief, Sun Pharma Ltd. is in the business of, among other things: (i) the development and manufacture of generic pharmaceutical products for sale throughout the world, including throughout the United States and, more specifically, throughout the State of New Jersey; (ii) in concert with and/or through its various subsidiaries, including defendant Sun Pharma Inc., the preparation, submission, and filing of Abbreviated New Drug Applications (“ANDAs”) seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) in concert with and/or through its various subsidiaries, including defendant Sun Pharma Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: Sun admits that Sun or certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical drug products, including, directly or indirectly, for the United States market. Sun admits that Sun or certain Sun entities prepare, submit, and file Abbreviated New Drug Applications (“ANDAs”) seeking FDA approval to market and distribute pharmaceutical drug products in the United States. Otherwise, denied. For purposes of this action only, Sun does not contest personal jurisdiction in this Court.

15. Upon information and belief, Sun Pharma Inc. is a wholly owned subsidiary and U.S. agent of Sun Pharma Ltd. Upon information and belief, Sun Pharma Inc. acts at the direction of, under the control of, and for the benefit of Sun Pharma Ltd., and is controlled and/or dominated by Sun Pharma Ltd. Upon information and belief, Sun Pharma Inc. and Sun Pharma Ltd. have at least one officer and/or director in common.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Pharma Inc. is a subsidiary of Sun Pharma Ltd. Otherwise, denied.

16. Upon information and belief, Sun Pharma Inc. is in the business of, among other things: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey; (ii) alone or in concert with and/or through its parent and various subsidiaries, including defendant Sun Pharma Ltd., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through its parent and various subsidiaries, including defendant Sun Pharma Ltd., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: Sun admits that Sun or certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical drug products, including, directly or indirectly, for the United States market. Sun admits that Sun or certain Sun entities prepare, submit, and file ANDAs seeking FDA approval to market and distribute pharmaceutical drug products in the United States. Otherwise, denied. For purposes of this action only, Sun does not contest personal jurisdiction in this Court.

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

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun or certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical drug products, including, directly or indirectly, for the United States market, including pharmaceutical products for which Sun Pharma Ltd. is the named ANDA applicant. Otherwise, denied.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that this court has subject matter jurisdiction for Plaintiffs' infringement claims under 28 U.S.C. §§ 1331 and 1338(a). Otherwise, denied.

19. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1); (ii) Fed. R. Civ. P. 4(k)(2); and (iii) N.J. Ct. R. 4:4-4.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

20. This Court has personal jurisdiction over Sun Pharma Inc. at least because, upon information and belief: (i) Sun Pharma Inc. maintains a principal place of business in New Jersey located at 2 Independence Way, Princeton, New Jersey 08540; (ii) Sun Pharma Inc. maintains an

additional place of business in New Jersey located at 1 Commerce Drive, Cranbury, New Jersey 08512; (iii) Sun Pharma Inc. is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iv) Sun Pharma Inc., together with its parent Sun Pharma Ltd., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (v) Sun Pharma Inc., together with its parent Sun Pharma Ltd., has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (vi) Sun Pharma Inc. has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in over a hundred prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.¹

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Pharma Inc. maintains a place of business in New Jersey at 2 Independence Way, Princeton, New Jersey 08540 and at 1 Commerce Drive, Cranbury, New Jersey 08512. Sun further admits that Sun or certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical drug products, including, directly or indirectly, for the United States market. Sun further admits that it did not contest personal jurisdiction in the litigations identified in Paragraph 20 of the Complaint and asserted

¹ This Court has personal jurisdiction over Sun Pharma Ltd. and Sun Pharma Inc. because Sun Pharma Ltd. and Sun Pharma Inc. have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. See, e.g., *Astellas Pharma Inc. v. Sun Pharm. Indus., Inc.*, et al., No. 2-22-cv-07357 (SRC)(JSA) (D.N.J.) (Sun Pharma Inc. and Sun Pharma Ltd. filed counterclaims and did not contest jurisdiction); *Orexo AB, et al. v. Sun Pharm. Indus. Ltd.*, et al., No. 3-21-cv-17941 (ZNQ)(DEA) (D.N.J.) (same); *Allergan Pharm. Int'l Ltd., et al. v. Sun Pharm. Indus. Ltd.*, et al., No. 2-20-cv-10176 (SDW)(LDW) (D.N.J.) (same); *Janssen Products, LP, et al. v. eVenus Pharm. Lab'ys Inc.*, et al., No. 1-20-cv-09369 (FLW)(ZNQ) (D.N.J.) (same); *Merck Sharp & Dohme BV, et al. v. Sun Pharm. Indus., Inc.*, et al., 2-20-cv-03007 (CCC)(MF) (D.N.J.) (same); *Eisai R&D Mgmt. Co., Ltd., et al. v. Sun Pharm. Indus. Ltd. (f/k/a Ranbaxy Lab'ys Ltd.)*, et al., No. 3-19-cv-21857 (FLW)(DEA) (D.N.J.) (same); *Sun Pharm. Indus. Ltd. (f/k/a Ranbaxy Lab'ys Ltd.)*, et al. v. *Novartis Pharm. Corp.*, et al., No. 2-19-cv-21733 (CCC)(MF) (D.N.J.) (Sun Pharma Ltd. and Sun Pharma Inc. filed a complaint for patent infringement); *Sun Pharm. Indus. Ltd. v. Pfizer Inc.*, et al., No. 2-19-cv-09330 (KM)(SCM) (D.N.J.) (Sun Pharma Ltd. filed a complaint for patent infringement); *Sun Pharm. Indus. Ltd., et al. v. VistaPharm, Inc.*, No. 2-19-cv-07536 (SRC)(CLW) (D.N.J.) (same).

counterclaims and/or claims in them. Otherwise, denied. Sun does not contest personal jurisdiction in this Court for purposes of this action only.

21. Upon information and belief, Sun Pharma Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Numbers 0100954087, 0100970132, and 0101055400. Upon information and belief, Sun Pharma Inc. is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer and wholesaler" with Registration Number 5003437.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Sun admits that it has a place of business in New Jersey. Sun denies any remaining allegations in paragraph 21.

22. Upon information and belief, pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), Defendants have prepared, submitted, and filed with FDA, and FDA has received, Abbreviated New Drug Application ("ANDA") No. 214303, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Estradiol Vaginal Insert 0.004 mg and 0.01 mg ("Defendants' ANDA Product") before the expiration of the Patents-in-Suit throughout the United States, including in this Judicial District.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Pharma Ltd. prepared and submitted ANDA No. 214303 to FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Estradiol Vaginal Insert 0.004 mg and 0.01 mg ("Sun's Proposed Product") prior to the expiration of the Patents-in-Suit. Otherwise, denied.

23. Upon information and belief, Sun Pharma Inc. is the United States agent for ANDA No. 214303.

ANSWER: Sun admits that Sun Pharma Inc. is the United States Agent for ANDA No. 214303.

24. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if ANDA No. 214303 receives final approval, Defendants' ANDA Product will be manufactured, sold, distributed, and/or used by Defendants in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

25. Upon information and belief, Sun Pharma Ltd.'s acts of preparing and filing ANDA No. 214303 and directing notice of its ANDA submission to Plaintiffs were performed at the direction of, with the authorization of, and with the cooperation, participation, assistance, and, at least in part, the benefit of Sun Pharma Inc. These are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Defendants' ANDA Product before the expiration of the Patents-in-Suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an essential and expected part of a generic ANDA filer's business, Defendants reasonably anticipate being sued in New Jersey.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

26. This Court has personal jurisdiction over Sun Pharma Ltd. because, among other things: (i) Sun Pharma Ltd. has purposefully directed its activities and the activities of Sun Pharma Inc., its wholly owned subsidiary and U.S. agent, at residents and corporate entities within the State of New Jersey; (ii) the claims set forth herein as to Sun Pharma Ltd. arise out of or relate to those activities; (iii) Sun Pharma Ltd.'s contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Sun Pharma Ltd.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

27. Upon information and belief, Defendants hold themselves out as a unitary corporate entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in general and for ANDA No. 214303 in particular, throughout the United States, including in this Judicial District.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

28. Defendants' ANDA filing regarding the Patents-in-Suit relates to this litigation and is substantially connected with this Judicial District because it reliably and non-speculatively predicts Defendants' intent to market and sell Defendants' ANDA Product in this Judicial District.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

29. Defendants have taken the significant step of applying to FDA for approval to engage in future activities—including the marketing of Defendants’ ANDA Product—which, upon information and belief, will be purposefully directed at this Judicial District.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

30. Upon information and belief, Defendants intend to direct sales of Defendants’ ANDA Product in this Judicial District once Defendants receive final FDA approval to market Defendants’ ANDA Product.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

31. Upon information and belief, Defendants will market Defendants’ ANDA Product in New Jersey upon receiving final FDA approval of ANDA No. 214303.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

32. Upon information and belief, Defendants have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 214303 and intend to benefit from ANDA No. 214303.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

33. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest venue in this Court for purposes of this action only. Otherwise, denied.

FACTS COMMON TO ALL COUNTS

34. Imvexxy® is sold and marketed under NDA No. 208564, which was approved by FDA on May 29, 2018.

ANSWER: Sun admits that FDA's Orange book identifies Imvexxy® in connection with NDA No. 208564. Sun admits that the FDA website indicates that approval by the FDA was granted on May 29, 2018. Otherwise, denied.

35. Because NDA No. 208564 contained reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, FDA granted Imvexxy® three years of regulatory, "new product," exclusivity.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent a response is required, Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

36. Imvexxy® is supplied as a vaginal insert with either 4 mcg or 10 mcg of estradiol. Estradiol, the active ingredient in Imvexxy®, is an estrogen that is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

ANSWER: Sun admits that the FDA-approved prescribing information for Imvexxy® states “IMVEXXY is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause,” and in the “Dosage Forms and Strengths” section states “Vaginal inserts: 4 mcg or 10 mcg estradiol.” Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

37. Imvexxy®’s recommended dosage is one vaginal insert daily for two weeks, followed by one insert twice weekly.

ANSWER: Sun admits that the FDA-approved prescribing information for Imvexxy® states “Administer IMVEXXY intravaginally: 1 vaginal insert daily for 2 weeks, followed by 1 insert twice weekly (for example, Monday and Thursday).” Otherwise, denied.

38. The Orange Book lists twenty (20) patents as covering Imvexxy®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), the twenty (20) listed patents were submitted to FDA with or after the approval of NDA No. 208564. The twenty (20) listed patents are listed in the Orange Book as covering Imvexxy®.

ANSWER: Sun admits that, as of September 30, 2024, there are twenty (20) patents listed in the Orange Book for Imvexxy® Insert 0.004 mg and 0.01 mg. Otherwise, denied.

39. Defendants sent Plaintiffs a letter dated June 14, 2024 with the subject line: “Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)” (“Notice Letter”), purportedly “[p]ursuant to 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95.”

ANSWER: Sun admits that Sun Pharma Ltd. sent Plaintiffs a letter with the subject line: “Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)” (“Notice Letter”), “[p]ursuant to 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95.” Otherwise, denied.

40. 21 C.F.R. § 314.95 provides that “[f]or each patent that claims [Imvexxy®] or that claims a use for [Imvexxy®] for which [Sun] is seeking approval and for which [Sun] submits a paragraph IV certification, [Sun] must send notice of such certification by registered or certified mail, return receipt requested, or by a designated delivery service, as defined in paragraph (g) of this section” to “[e]ach owner of the patent that is the subject of the certification or the representative designated by the owner to receive the notice” and “[t]he holder of the approved NDA.” 21 C.F.R. § 314.95 permits “[a]n applicant [to] send notice by an alternative method [e.g., email] only if FDA has agreed in advance that the method will produce an acceptable form of documentation.”

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 C.F.R. § 314.95 states “For each patent that claims the listed drug or that claims a use for such listed drug for which the applicant is seeking approval and for which the applicant submits a paragraph IV certification, the applicant must send notice of such certification by registered or certified mail, return receipt requested, or by a designated delivery service, as defined in paragraph (g) of this section to each of the following persons.” Sun admits that 21 C.F.R. § 314.95 states that “An applicant may send notice by an alternative method only if FDA has agreed in advance that the method will produce an acceptable form of documentation.” Otherwise, denied.

41. Mayne received a copy of the Notice Letter via Federal Express on June 17, 2024.

ANSWER: Sun admits that Sun sent its Notice Letter to Mayne via Federal Express on June 14, 2024. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

42. The law firm Sterne, Kessler, Goldstein & Fox PLLC received a copy of the Notice Letter via Federal Express on June 18, 2024.

ANSWER: Sun admits that Sun sent its Notice Letter to the law firm of Sterne, Kessler, Goldstein & Fox via Federal Express on June 17, 2024. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

43. TherapeuticsMD received an incomplete copy of the Notice Letter through its registered corporate agent (Paracorp Incorporated) on June 17, 2024.

ANSWER: Sun admits that Sun sent its Notice Letter to TherapeuticsMD's registered agent, Paracorp Incorporated, via Federal Express on June 17, 2024. Sun further admits that Sun sent its Notice Letter to TherapeuticsMD via Federal Express on June 14, 2024, to 951 Yamato Road, Suite 220, Boca Raton, Florida 33431, which was returned to sender as undeliverable. Sun further admits that Sun sent an electronic copy of Sun's Notice Letter to TherapeuticsMD's counsel, Haug Partners LLP, on June 17, 2024. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

44. The Notice Letter states that ANDA No. 214303 has been submitted under § 505(j) of the FDCA, with paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Estradiol Vaginal Insert 0.004 mg and 0.01 mg, before the expiration of the '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the

'516 patent, the '197 patent, the '717 patent, the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent. The '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the '516 patent, the '197 patent, the '717 patent, the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent are the twenty (20) patents listed in FDA's Orange Book as covering Imvexxy®.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun's Notice Letter notified Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Products prior to the expiration of the Patents-in-Suit. Sun further admits that the '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the '516 patent, the '197 patent, the '717 patent, the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent. The '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the '516 patent, the '197 patent, the '717 patent, the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent are listed in FDA's Orange Book for Imvexxy®. Otherwise, denied.

45. Upon information and belief, ANDA No. 214303 was submitted under § 505(j)(2) of the FDCA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the '516 patent, the '197 patent, the '717 patent,

the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Defendants' ANDA Product.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun's Notice Letter notified Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Products prior to the expiration of the Patents-in-Suit. Otherwise, denied.

46. The Notice Letter included an Offer of Confidential Access to "certain [unspecified] information" from ANDA No. 214303, purportedly pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Defendants' Offer of Confidential Access contained numerous unreasonable and overly restrictive provisions. Plaintiffs proposed revisions that comport with restrictions that "would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." See 21 U.S.C. § 355. Plaintiffs and Defendants did not reach agreement on the terms of an Offer of Confidential Access and, to date, Defendants have not produced a copy of ANDA No. 214303 to Plaintiffs.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Plaintiffs and Defendants did not reach agreement on the terms of an Offer of Confidential Access. Otherwise, denied.

47. 21 U.S.C. § 355(j)(2)(A)(i) requires that an ANDA contain, "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7)." In addition, 21 U.S.C. § 355(j)(2)(A)(v) provides that an ANDA must contain "information to show that the

labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers.” The Notice Letter does not indicate that Defendants intend to market Defendants’ ANDA Product with labeling that differs from the Imvexxy® label in terms of conditions of use, including the indications, usage, dosage, administration, or composition of Defendants’ ANDA Product.

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(A)(i) states “An abbreviated application for a new drug shall contain...(i)information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a ‘listed drug’).” Sun admits that 21 U.S.C. § 355(j)(2)(A)(v) states “An abbreviated application for a new drug shall contain...information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers.” Otherwise, denied.

48. Upon information and belief, the proposed prescribing information for Defendants’ ANDA Product includes a header titled, “Indications and Usage,” and states that Defendants’ ANDA Product is for “Treatment of Moderate to Severe Dyspareunia, a Symptom of Vulvar and Vaginal Atrophy, Due to Menopause.”

ANSWER: Sun admits that the proposed draft labeling for Sun's Proposed Product includes a section with the header "Indications and Usage" which states "Estradiol vaginal inserts are an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause." Otherwise, denied.

49. Upon information and belief, the proposed prescribing information for Defendants' ANDA Product includes a header titled, "Dosage and Administration" that states:

Generally, start therapy with [Defendants' ANDA Product] 4 mcg dosage strength administered intravaginally; insert with the smaller end up for a depth of about two inches into the vaginal canal. Administer 1 insert daily at approximately the same time for 2 weeks, followed by 1 insert twice weekly, every three to four days (for example, Monday and Thursday). Make dosage adjustment based on the clinical response.

ANSWER: Sun states that Sun's proposed draft labeling speaks for itself. Otherwise, denied.

50. Upon information and belief, the proposed prescribing information for Defendants' ANDA Product includes a header titled, "Description," and states that Defendants' ANDA Product contains "the following inactive ingredients: ammonium hydroxide, ethanol, ethyl acetate, ethylene glycol palmitostearate, FD&C Red #40, gelatin, glycerin, isopropyl alcohol, lecithin, medium chain triglycerides, polyethylene glycol, polyethylene glycol stearates, polyvinyl acetate phthalate, propylene glycol, purified water, sorbitol-sorbitan solution, and titanium dioxide."

ANSWER: Denied.

51. Upon information and belief, Defendants' ANDA Product will be indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

ANSWER: Sun admits that the proposed draft labeling for Sun's Proposed Product includes a section with the header "Indications and Usage" which states "Estradiol vaginal inserts are an

estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.” Otherwise, denied.

52. The ’091 patent, titled, “Soluble Estradiol Capsule for Vaginal Insertion,” was duly and legally issued by the U.S. Patent and Trademark Office on November 10, 2015, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the United States Patent and Trademark Office (“PTO”), the PTO issued the ’091 patent on or about November 10, 2015. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the ’091 patent. Sun denies that the ’091 patent was duly and legally issued.

53. Pursuant to 21 U.S.C. § 355(b)(1), the ’091 patent was submitted to FDA with NDA No. 208564. The ’091 patent was subsequently listed in the Orange Book as covering Invexxy®. The Orange Book lists December 20, 2033 as the expiration date of the ’091 patent.

ANSWER: Sun admits that the Orange Book lists the ’091 patent in connection with Invexxy®, and that the Orange Book lists December 20, 2033 as the expiration date of the ’091 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

54. The ’382 patent, titled, “Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods,” was duly and legally issued by the U.S. Patent and Trademark Office on March 22, 2016, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued

the '382 patent on or about March 22, 2016. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '382 patent. Sun denies that the '382 patent was duly and legally issued.

55. Pursuant to 21 U.S.C. § 355(b)(1), the '382 patent was submitted to FDA with NDA No. 208564. The '382 patent was subsequently listed in the Orange Book as covering Invexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '382 patent.

ANSWER: Sun admits that the Orange Book lists the '382 patent in connection with Invexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '382 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

56. The '630 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on April 16, 2019, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '630 patent on or about April 16, 2019. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '630 patent. Sun denies that the '630 patent was duly and legally issued.

57. Pursuant to 21 U.S.C. § 355(c)(2), the '630 patent was submitted to FDA after the approval of NDA No. 208564. The '630 patent was subsequently listed in the Orange Book as covering Invexxy®. The Orange Book lists December 20, 2033 as the expiration date of the '630 patent.

ANSWER: Sun admits that the Orange Book lists the '630 patent in connection with Invexxy®, and that the Orange Book lists December 20, 2033 as the expiration date of the '630

patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

58. The '708 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on September 3, 2019, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '708 patent on or about September 3, 2019. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '708 patent. Sun denies that the '708 patent was duly and legally issued.

59. Pursuant to 21 U.S.C. § 355(c)(2), the '708 patent was submitted to FDA after the approval of NDA No. 208564. The '708 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists December 20, 2033 as the expiration date of the '708 patent.

ANSWER: Sun admits that the Orange Book lists the '708 patent in connection with Imvexxy®, and that the Orange Book lists December 20, 2033 as the expiration date of the '708 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

60. The '072 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on November 12, 2019, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued

the '072 patent on or about November 12, 2019. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '072 patent. Sun denies that the '072 patent was duly and legally issued.

61. Pursuant to 21 U.S.C. § 355(c)(2), the '072 patent was submitted to FDA after the approval of NDA No. 208564. The '072 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists June 18, 2033 as the expiration date of the '072 patent. **ANSWER:** Sun admits that the Orange Book lists the '072 patent in connection with Imvexxy®, and that the Orange Book lists June 18, 2033 as the expiration date of the '072 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

62. The '581 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on January 21, 2020, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '581 patent on or about January 21, 2020. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '581 patent. Sun denies that the '581 patent was duly and legally issued.

63. Pursuant to 21 U.S.C. § 355(c)(2), the '581 patent was submitted to FDA after the approval of NDA No. 208564. The '581 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '581 patent.

ANSWER: Sun admits that the Orange Book lists the '581 patent in connection with Invexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '581 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

64. The '891 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on February 25, 2020, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '891 patent on or about February 25, 2020. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '891 patent. Sun denies that the '891 patent was duly and legally issued.

65. Pursuant to 21 U.S.C. § 355(c)(2), the '891 patent was submitted to FDA after the approval of NDA No. 208564. The '891 patent was subsequently listed in the Orange Book as covering Invexxy®. The Orange Book lists June 18, 2033 as the expiration date of the '891 patent.

ANSWER: Sun admits that the Orange Book lists the '891 patent in connection with Invexxy®, and that the Orange Book lists June 18, 2033 as the expiration date of the '891 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

66. The '082 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on June 2, 2020, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '082 patent on or about June 2, 2020. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '082 patent. Sun denies that the '082 patent was duly and legally issued.

67. Pursuant to 21 U.S.C. § 355(c)(2), the '082 patent was submitted to FDA after the approval of NDA No. 208564. The '082 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists June 18, 2033 as the expiration date of the '082 patent.

ANSWER: Sun admits that the Orange Book lists the '082 patent in connection with Imvexxy®, and that the Orange Book lists June 18, 2033 as the expiration date of the '082 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

68. The '697 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on October 20, 2020, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 68 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '697 patent on or about October 20, 2020. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '697 patent. Sun denies that the '697 patent was duly and legally issued.

69. Pursuant to 21 U.S.C. § 355(c)(2), the '697 patent was submitted to FDA after the approval of NDA No. 208564. The '697 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '697 patent.

ANSWER: Sun admits that the Orange Book lists the '697 patent in connection with Imvexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '697 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

70. The '487 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on November 17, 2020, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '487 patent on or about November 17, 2020. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '487 patent. Sun denies that the '487 patent was duly and legally issued.

71. Pursuant to 21 U.S.C. § 355(c)(2), the '487 patent was submitted to FDA after the approval of NDA No. 208564. The '487 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '487 patent.

ANSWER: Sun admits that the Orange Book lists the '487 patent in connection with Imvexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '487 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

72. The '516 patent, titled, "Soluble Estradiol Capsule For Vaginal Insertion," was duly and legally issued by the U.S. Patent and Trademark Office on January 12, 2021, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 72 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '516 patent on or about January 12, 2021. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '516 patent. Sun denies that the '516 patent was duly and legally issued.

73. Pursuant to 21 U.S.C. § 355(c)(2), the '516 patent was submitted to FDA after the approval of NDA No. 208564. The '516 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists June 18, 2033 as the expiration date of the '516 patent.

ANSWER: Sun admits that the Orange Book lists the '516 patent in connection with Imvexxy®, and that the Orange Book lists June 18, 2033 as the expiration date of the '516 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

74. The '197 patent, titled, "Soluble Estradiol Capsule For Vaginal Insertion," was duly and legally issued by the U.S. Patent and Trademark Office on July 20, 2021, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '197 patent on or about July 20, 2021. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '197 patent. Sun denies that the '197 patent was duly and legally issued.

75. Pursuant to 21 U.S.C. § 355(c)(2), the '197 patent was submitted to FDA after the approval of NDA No. 208564. The '197 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists June 18, 2033 as the expiration date of the '197 patent.

ANSWER: Sun admits that the Orange Book lists the '197 patent in connection with Invexxy®, and that the Orange Book lists June 18, 2033 as the expiration date of the '197 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

76. The '717 patent, titled, "Soluble Estradiol Capsule For Vaginal Insertion," was duly and legally issued by the U.S. Patent and Trademark Office on September 14, 2021, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 76 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '717 patent on or about September 14, 2021. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '717 patent. Sun denies that the '717 patent was duly and legally issued.

77. Pursuant to 21 U.S.C. § 355(c)(2), the '717 patent was submitted to FDA after the approval of NDA No. 208564. The '717 patent was subsequently listed in the Orange Book as covering Invexxy®. The Orange Book lists June 18, 2033 as the expiration date of the '717 patent.

ANSWER: Sun admits that the Orange Book lists the '717 patent in connection with Invexxy®, and that the Orange Book lists June 18, 2033 as the expiration date of the '717 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

78. The '283 patent, titled, "Soluble Estradiol Capsule For Vaginal Insertion," was duly and legally issued by the U.S. Patent and Trademark Office on September 21, 2021, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 78 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '283 patent on or about September 21, 2021. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '283 patent. Sun denies that the '283 patent was duly and legally issued.

79. Pursuant to 21 U.S.C. § 355(c)(2), the '283 patent was submitted to FDA after the approval of NDA No. 208564. The '283 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists June 18, 2033 as the expiration date of the '283 patent.

ANSWER: Sun admits that the Orange Book lists the '283 patent in connection with Imvexxy®, and that the Orange Book lists June 18, 2033 as the expiration date of the '283 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

80. The '445 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on February 8, 2022, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 80 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '445 patent on or about February 8, 2022. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '445 patent. Sun denies that the '445 patent was duly and legally issued.

81. Pursuant to 21 U.S.C. § 355(c)(2), the '445 patent was submitted to FDA after the approval of NDA No. 208564. The '445 patent was subsequently listed in the Orange Book as

covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '445 patent.

ANSWER: Sun admits that the Orange Book lists the '445 patent in connection with Imvexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '445 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

82. The '875 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on February 15, 2022, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 82 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '875 patent on or about February 15, 2022. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '875 patent. Sun denies that the '875 patent was duly and legally issued.

83. Pursuant to 21 U.S.C. § 355(c)(2), the '875 patent was submitted to FDA after the approval of NDA No. 208564. The '875 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '875 patent.

ANSWER: Sun admits that the Orange Book lists the '875 patent in connection with Imvexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '875 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

84. The '661 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on March 8, 2022, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '661 patent on or about March 8, 2022. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '661 patent. Sun denies that the '661 patent was duly and legally issued.

85. Pursuant to 21 U.S.C. § 355(c)(2), the '661 patent was submitted to FDA after the approval of NDA No. 208564. The '661 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists February 2, 2034 as the expiration date of the '661 patent.

ANSWER: Sun admits that the Orange Book lists the '661 patent in connection with Imvexxy®, and that the Orange Book lists February 2, 2034 as the expiration date of the '661 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

86. The '959 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on April 19, 2022, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '959 patent on or about April 19, 2022. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '959 patent. Sun denies that the '959 patent was duly and legally issued.

87. Pursuant to 21 U.S.C. § 355(c)(2), the '959 patent was submitted to FDA after the approval of NDA No. 208564. The '959 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '959 patent.

ANSWER: Sun admits that the Orange Book lists the '959 patent in connection with Imvexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '959 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

88. The '182 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on June 7, 2022, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 88 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '182 patent on or about June 7, 2022. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '182 patent. Sun denies that the '182 patent was duly and legally issued.

89. Pursuant to 21 U.S.C. § 355(c)(2), the '182 patent was submitted to FDA after the approval of NDA No. 208564. The '182 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '182 patent.

ANSWER: Sun admits that the Orange Book lists the '182 patent in connection with Imvexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '182 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

90. The '709 patent, titled, "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was duly and legally issued by the U.S. Patent and Trademark Office on November 15, 2022, to TherapeuticsMD, Inc. on assignment from the named inventors.

ANSWER: Paragraph 90 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that, according to the records of the PTO, the PTO issued the '709 patent on or about November 15, 2022. Sun admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '709 patent. Sun denies that the '709 patent was duly and legally issued.

91. Pursuant to 21 U.S.C. § 355(c)(2), the '709 patent was submitted to FDA after the approval of NDA No. 208564. The '709 patent was subsequently listed in the Orange Book as covering Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '709 patent.

ANSWER: Sun admits that the Orange Book lists the '709 patent in connection with Imvexxy®, and that the Orange Book lists November 21, 2032 as the expiration date of the '709 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

92. Under 21 U.S.C. § 355(j)(2)(B), the filer of an Abbreviated New Drug Application containing a paragraph IV certification must provide notice of the filing to each patent owner and each New Drug Application holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each

claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 92 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states “A notice under this subparagraph shall...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.” Sun further admits that 21 C.F.R. § 314.95(c)(7) states: “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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

93. The Notice Letter does not include any specific invalidity contentions for any claim of the ’516 patent.

ANSWER: Paragraph 93 contains legal conclusions to which no answer is required. To the extent a response is required, Sun states that Sun’s Notice Letter speaks for itself. Otherwise, denied.

94. The Notice Letter does not include any specific noninfringement contentions for any claims of the ’197 patent, the ’717 patent, the ’283 patent, or the ’959 patent.

ANSWER: Paragraph 94 contains legal conclusions to which no answer is required. To the extent a response is required, Sun states that Sun’s Notice Letter speaks for itself. Otherwise, denied.

95. The Notice Letter does not include any unenforceability contentions with respect to any claims of the Patents-in-Suit.

ANSWER: Paragraph 95 contains legal conclusions to which no answer is required. To the extent a response is required, Sun states that Sun's Notice Letter speaks for itself. Otherwise, denied.

FIRST COUNT

(Defendants' Infringement of the '091 patent)

96. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

97. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

98. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 98 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

99. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

100. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

101. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '091 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '091 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product, prior to the expiration of the '091 patent. Otherwise, denied.

102. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim

of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 102 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states “A notice under this subparagraph shall...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.” Sun further admits that 21 C.F.R. § 314.95(c)(7) states: “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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 103 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 103.

104. Upon information and belief, Defendants admit infringement of claims 1-14 of the ’091 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for claims 1-14 of the ’091 patent.

ANSWER: Paragraph 104 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 104.

105. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '091 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '091 patent is an act of infringement of the '091 patent.

ANSWER: Denied.

106. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

107. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '091 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

108. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '091 patent under 35 U.S.C. § 271.

ANSWER: Denied.

109. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '091 patent.

ANSWER: Denied.

110. Defendants have knowledge of the '091 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '091 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

111. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '091 patent.

ANSWER: Denied.

112. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

113. Defendants have actual knowledge of the '091 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '091 patent. Otherwise, denied.

114. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

SECOND COUNT
(Defendants’ Infringement of the ’382 patent)

116. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

117. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s Proposed Product prior to the expiration of the Patents-in-Suit.

118. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 118 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

119. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

120. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

121. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '382 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '382 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '382 patent. Otherwise, denied.

122. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 122 contains statements of law that do not require an answer. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states "A notice under this subparagraph shall...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." Sun further admits that 21 C.F.R. § 314.95(c)(7) states: "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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Otherwise, denied.

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

ANSWER: Paragraph 123 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 123.

124. Upon information and belief, Defendants admit infringement of claims 4-15 and 18-21 of the '382 patent because—other than baseless invalidity allegations—the Notice Letter

does not disclose any specific noninfringement contentions for claims 4-15 and 18-21 of the '382 patent.

ANSWER: Paragraph 124 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 124.

125. Upon information and belief, Defendants admit that claims 1-3 and 16-17 of the '382 patent are valid and enforceable because the Notice Letter does not disclose any invalidity or unenforceability contentions for claims 1-3 and 16-17 of the '382 patent.

ANSWER: Paragraph 125 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 125.

126. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '382 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '382 patent is an act of infringement of the '382 patent.

ANSWER: Denied.

127. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

128. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '382 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

129. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '382 patent under 35 U.S.C. § 271.

ANSWER: Denied.

130. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '382 patent.

ANSWER: Denied.

131. Defendants have knowledge of the '382 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '382 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

132. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '382 patent.

ANSWER: Denied.

133. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

134. Defendants have actual knowledge of the '382 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '382 patent. Otherwise, denied.

135. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

THIRD COUNT
(Defendants' Infringement of the '630 patent)

137. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

138. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

139. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 139 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

140. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

141. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

142. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '630 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '630 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '630 patent. Otherwise, denied.

143. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '630 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '630 patent is an act of infringement of the '630 patent.

ANSWER: Denied.

144. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

145. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '630 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

146. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '630 patent under 35 U.S.C. § 271.

ANSWER: Denied.

147. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '630 patent.

ANSWER: Denied.

148. Defendants have knowledge of the '630 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '630 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

149. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '630 patent.

ANSWER: Denied.

150. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

151. Defendants have actual knowledge of the '630 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and

0.01 mg)” notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s proposed drug products prior to the expiration of the ’630 patent. Otherwise, denied.

152. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

FOURTH COUNT

(Defendants’ Infringement of the ’708 patent)

154. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

155. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s Proposed Product prior to the expiration of the Patents-in-Suit.

156. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 156 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

157. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

158. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

159. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '708 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '708 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '708 patent. Otherwise, denied.

160. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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.” 21 C.F.R. § 314.95(c)(7) requires that such notice 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: “For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 160 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states “A notice under this subparagraph shall...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.” Sun further admits that 21 C.F.R. § 314.95(c)(7) states: “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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 161 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 161.

162. Upon information and belief, Defendants admit that claim 2 of the '708 patent is valid and enforceable because the Notice Letter does not disclose any invalidity or unenforceability contentions for claim 2 of the '708 patent.

ANSWER: Paragraph 162 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 162.

163. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '708 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '708 patent is an act of infringement of the '708 patent.

ANSWER: Denied.

164. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

165. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '708 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

166. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '708 patent under 35 U.S.C. § 271.

ANSWER: Denied.

167. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '708 patent.

ANSWER: Denied.

168. Defendants have knowledge of the '708 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '708 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

169. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '708 patent.

ANSWER: Denied.

170. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

171. Defendants have actual knowledge of the '708 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv))

and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)” notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s proposed drug products prior to the expiration of the ’708 patent. Otherwise, denied.

172. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

FIFTH COUNT
(Defendants’ Infringement of the ’072 patent)

174. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

175. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use,

importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

176. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 176 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

177. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

178. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

179. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '072 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '072 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '072 patent. Otherwise, denied.

180. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '072 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '072 patent is an act of infringement of the '072 patent.

ANSWER: Denied.

181. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

182. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '072 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

183. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '072 patent under 35 U.S.C. § 271.

ANSWER: Denied.

184. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '072 patent.

ANSWER: Denied.

185. Defendants have knowledge of the '072 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '072 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

186. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '072 patent.

ANSWER: Denied.

187. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

188. Defendants have actual knowledge of the '072 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '072 patent. Otherwise, denied.

189. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

SIXTH COUNT
(Defendants’ Infringement of the ’581 patent)

191. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

192. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s Proposed Product prior to the expiration of the Patents-in-Suit.

193. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 193 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

194. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

195. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

196. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '581 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '581 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '581 patent. Otherwise, denied.

197. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 197 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states "A notice under this subparagraph shall...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." Sun further admits that 21 C.F.R. § 314.95(c)(7) states: "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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Otherwise, denied.

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

ANSWER: Paragraph 198 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 198.

199. Upon information and belief, Defendants admit infringement of claims 1-9 of the '581 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for claims 1-9 of the '581 patent.

ANSWER: Paragraph 199 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 199.

200. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '581 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '581 patent is an act of infringement of the '581 patent.

ANSWER: Denied.

201. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

202. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '581 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

203. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '581 patent under 35 U.S.C. § 271.

ANSWER: Denied.

204. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '581 patent.

ANSWER: Denied.

205. Defendants have knowledge of the '581 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '581 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

206. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '581 patent.

ANSWER: Denied.

207. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

208. Defendants have actual knowledge of the '581 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and

0.01 mg)” notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s proposed drug products prior to the expiration of the ’581 patent. Otherwise, denied.

209. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

SEVENTH COUNT
(Defendants’ Infringement of the ’891 patent)

211. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

212. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s Proposed Product prior to the expiration of the Patents-in-Suit.

213. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 213 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

214. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

215. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

216. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '891 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '891 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '891 patent. Otherwise, denied.

217. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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.” 21 C.F.R. § 314.95(c)(7) requires that such notice 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: “For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 217 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states “A notice under this subparagraph shall...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.” Sun further admits that 21 C.F.R. § 314.95(c)(7) states: “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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 218 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 218.

219. Upon information and belief, Defendants admit that claims 13 and 16 of the '891 patent are valid and enforceable because the Notice Letter does not disclose any invalidity or unenforceability contentions for claims 13 and 16 of the '891 patent.

ANSWER: Paragraph 219 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 219.

220. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '891 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '891 patent is an act of infringement of the '891 patent.

ANSWER: Denied.

221. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

222. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '891 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

223. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '891 patent under 35 U.S.C. § 271.

ANSWER: Denied.

224. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '891 patent.

ANSWER: Denied.

225. Defendants have knowledge of the '891 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '891 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

226. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '891 patent.

ANSWER: Denied.

227. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

228. Defendants have actual knowledge of the '891 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv))

and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)” notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s proposed drug products prior to the expiration of the ’891 patent. Otherwise, denied.

229. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

EIGHTH COUNT
(Defendants’ Infringement of the ’082 patent)

231. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

232. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use,

importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

233. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 233 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

234. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

235. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

236. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '082 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '082 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '082 patent. Otherwise, denied.

237. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '082 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '082 patent is an act of infringement of the '082 patent.

ANSWER: Denied.

238. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

239. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '082 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

240. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '082 patent under 35 U.S.C. § 271.

ANSWER: Denied.

241. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '082 patent.

ANSWER: Denied.

242. Defendants have knowledge of the '082 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '082 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

243. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '082 patent.

ANSWER: Denied.

244. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

245. Defendants have actual knowledge of the '082 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '082 patent. Otherwise, denied.

246. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

NINTH COUNT
(Defendants’ Infringement of the ’697 patent)

248. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

249. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s Proposed Product prior to the expiration of the Patents-in-Suit.

250. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 250 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

251. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

252. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

253. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '697 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '697 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '697 patent. Otherwise, denied.

254. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 254 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states "A notice under this subparagraph shall...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." Sun further admits that 21 C.F.R. § 314.95(c)(7) states: "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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Otherwise, denied.

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

ANSWER: Paragraph 255 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 255.

256. Upon information and belief, Defendants admit infringement of claims 9-30 of the '697 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for claims 9-30 of the '697 patent.

ANSWER: Paragraph 256 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 256.

257. Upon information and belief, Defendants admit that claims 1-8 of the '697 patent are valid and enforceable because the Notice Letter does not disclose any invalidity or unenforceability contentions for claims 1-8 of the '697 patent.

ANSWER: Denied.

258. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '697 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '697 patent is an act of infringement of the '697 patent.

ANSWER: Denied.

259. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

260. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '697 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

261. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '697 patent under 35 U.S.C. § 271.

ANSWER: Denied.

262. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '697 patent.

ANSWER: Denied.

263. Defendants have knowledge of the '697 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '697 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

264. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '697 patent.

ANSWER: Denied.

265. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

266. Defendants have actual knowledge of the '697 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '697 patent. Otherwise, denied.

267. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

TENTH COUNT
(Defendants' Infringement of the '487 patent)

269. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

270. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

271. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 271 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

272. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

273. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

274. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '487 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '487 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '487 patent. Otherwise, denied.

275. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '487 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '487 patent is an act of infringement of the '487 patent.

ANSWER: Denied.

276. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

277. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '487 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

278. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '487 patent under 35 U.S.C. § 271.

ANSWER: Denied.

279. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '487 patent.

ANSWER: Denied.

280. Defendants have knowledge of the '487 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '487 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

281. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '487 patent.

ANSWER: Denied.

282. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

283. Defendants have actual knowledge of the '487 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and

0.01 mg)” notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s proposed drug products prior to the expiration of the ’487 patent. Otherwise, denied.

284. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

ELEVENTH COUNT
(Defendants’ Infringement of the ’516 patent)

286. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

287. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s Proposed Product prior to the expiration of the Patents-in-Suit.

288. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 288 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

289. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

290. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

291. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '516 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '516 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '516 patent. Otherwise, denied.

292. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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.” 21 C.F.R. § 314.95(c)(7) requires that such notice 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: “For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 292 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states “A notice under this subparagraph shall...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.” Sun further admits that 21 C.F.R. § 314.95(c)(7) states: “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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 293 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 293.

294. Upon information and belief, Defendants admit that the '516 patent is valid and enforceable because the Notice Letter does not disclose any invalidity or unenforceability contentions for the '516 patent.

ANSWER: Paragraph 294 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 294.

295. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '516 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '516 patent is an act of infringement of the '516 patent.

ANSWER: Denied.

296. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

297. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '516 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

298. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '516 patent under 35 U.S.C. § 271.

ANSWER: Denied.

299. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '516 patent.

ANSWER: Denied.

300. Defendants have knowledge of the '516 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '516 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

301. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '516 patent.

ANSWER: Denied.

302. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

303. Defendants have actual knowledge of the '516 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv))

and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)” notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun’s proposed drug products prior to the expiration of the ’516 patent. Otherwise, denied.

304. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

TWELFTH COUNT
(Defendants’ Infringement of the ’197 patent)

306. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

307. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants’ ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use,

importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

308. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 308 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

309. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

310. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

311. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '197 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '197 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '197 patent. Otherwise, denied.

312. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must “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.” 21 C.F.R. § 314.95(c)(7) requires that such notice 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: “For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 312 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states “A notice under this subparagraph shall...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.” Sun further admits that 21 C.F.R. § 314.95(c)(7) states: “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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 313 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 313.

314. Upon information and belief, Defendants admit infringement of the '197 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for the '197 patent.

ANSWER: Paragraph 314 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 314.

315. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '197 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '197 patent is an act of infringement of the '197 patent.

ANSWER: Denied.

316. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

317. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '197 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

318. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '197 patent under 35 U.S.C. § 271.

ANSWER: Denied.

319. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '197 patent.

ANSWER: Denied.

320. Defendants have knowledge of the '197 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '197 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

321. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '197 patent.

ANSWER: Denied.

322. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

323. Defendants have actual knowledge of the '197 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '197 patent. Otherwise, denied.

324. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

THIRTEENTH COUNT
(Defendants' Infringement of the '717 patent)

326. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

327. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

328. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 328 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

329. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

330. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

331. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '717 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '717 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '717 patent. Otherwise, denied.

332. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 332 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states "A notice under this subparagraph shall...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." Sun further admits that 21 C.F.R. § 314.95(c)(7) states: "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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of

a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 333 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 333.

334. Upon information and belief, Defendants admit infringement of the ’717 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for the ’717 patent.

ANSWER: Paragraph 334 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 334.

335. Under 35 U.S.C. § 271(e)(2)(A), Defendants’ submission of ANDA No. 214303 with a paragraph IV certification to the ’717 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants’ ANDA Product before the expiration of the ’717 patent is an act of infringement of the ’717 patent.

ANSWER: Denied.

336. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants’ ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

337. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '717 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

338. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '717 patent under 35 U.S.C. § 271.

ANSWER: Denied.

339. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '717 patent.

ANSWER: Denied.

340. Defendants have knowledge of the '717 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '717 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

341. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '717 patent.

ANSWER: Denied.

342. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

343. Defendants have actual knowledge of the '717 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '717 patent. Otherwise, denied.

344. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

FOURTEENTH COUNT
(Defendants' Infringement of the '283 patent)

346. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

347. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

348. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 348 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

349. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

350. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

351. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '283 patent for the purpose of obtaining FDA approval to engage

in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '283 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '283 patent. Otherwise, denied.

352. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 352 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states "A notice under this subparagraph shall...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." Sun further admits that 21 C.F.R. § 314.95(c)(7) states: "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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be

infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 353 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 353.

354. Upon information and belief, Defendants admit infringement of the ’283 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for the ’283 patent.

ANSWER: Paragraph 354 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 354.

355. Under 35 U.S.C. § 271(e)(2)(A), Defendants’ submission of ANDA No. 214303 with a paragraph IV certification to the ’283 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants’ ANDA Product before the expiration of the ’283 patent is an act of infringement of the ’283 patent.

ANSWER: Denied.

356. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants’ ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

357. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '283 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

358. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '283 patent under 35 U.S.C. § 271.

ANSWER: Denied.

359. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '283 patent.

ANSWER: Denied.

360. Defendants have knowledge of the '283 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '283 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

361. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '283 patent.

ANSWER: Denied.

362. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

363. Defendants have actual knowledge of the '283 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '283 patent. Otherwise, denied.

364. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

FIFTEENTH COUNT
(Defendants' Infringement of the '445 patent)

366. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

367. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

368. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 368 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

369. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

370. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

371. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '445 patent for the purpose of obtaining FDA approval to engage

in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '445 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '445 patent. Otherwise, denied.

372. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '445 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '445 patent is an act of infringement of the '445 patent.

ANSWER: Denied.

373. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

374. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '445 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

375. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '445 patent under 35 U.S.C. § 271.

ANSWER: Denied.

376. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '445 patent.

ANSWER: Denied.

377. Defendants have knowledge of the '445 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '445 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

378. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '445 patent.

ANSWER: Denied.

379. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

380. Defendants have actual knowledge of the '445 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '445 patent. Otherwise, denied.

381. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

SIXTEENTH COUNT
(Defendants' Infringement of the '875 patent)

383. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

384. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

385. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 385 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

386. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

387. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

388. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '875 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '875 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '875 patent. Otherwise, denied.

389. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 389 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states "A notice under this subparagraph shall...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." Sun further admits that 21 C.F.R. § 314.95(c)(7) states: "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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of

a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 390 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 390.

391. Upon information and belief, Defendants admit that claims 7-9 and 22 of the ’875 patent are valid and enforceable because the Notice Letter does not disclose any invalidity or unenforceability contentions for claims 7-9 and 22 of the ’875 patent.

ANSWER: Paragraph 391 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 391.

392. Under 35 U.S.C. § 271(e)(2)(A), Defendants’ submission of ANDA No. 214303 with a paragraph IV certification to the ’875 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants’ ANDA Product before the expiration of the ’875 patent is an act of infringement of the ’875 patent.

ANSWER: Denied.

393. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants’ ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

394. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '875 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

395. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '875 patent under 35 U.S.C. § 271.

ANSWER: Denied.

396. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '875 patent.

ANSWER: Denied.

397. Defendants have knowledge of the '875 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '875 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

398. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '875 patent.

ANSWER: Denied.

399. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

400. Defendants have actual knowledge of the '875 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '875 patent. Otherwise, denied.

401. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

SEVENTEENTH COUNT
(Defendants' Infringement of the '661 patent)

403. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

404. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

405. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 405 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

406. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

407. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

408. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '661 patent for the purpose of obtaining FDA approval to engage

in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '661 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '661 patent. Otherwise, denied.

409. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 409 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states "A notice under this subparagraph shall...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." Sun further admits that 21 C.F.R. § 314.95(c)(7) states: "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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be

infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 410 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 410.

411. Upon information and belief, Defendants admit infringement of claims 6-9 of the ’661 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for claims 6-9 of the ’661 patent.

ANSWER: Paragraph 411 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 411.

412. Upon information and belief, Defendants admit that claims 5 and 10 of the ’661 patent are valid and enforceable because the Notice Letter does not disclose any invalidity or unenforceability contentions for claims 5 and 10 of the ’661 patent.

ANSWER: Paragraph 412 contains legal conclusions for which no answer is required. To the extent an answer is required, Sun denies the allegations of Paragraph 412.

413. Under 35 U.S.C. § 271(e)(2)(A), Defendants’ submission of ANDA No. 214303 with a paragraph IV certification to the ’661 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants’ ANDA Product before the expiration of the ’661 patent is an act of infringement of the ’661 patent.

ANSWER: Denied.

414. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

415. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '661 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

416. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '661 patent under 35 U.S.C. § 271.

ANSWER: Denied.

417. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '661 patent.

ANSWER: Denied.

418. Defendants have knowledge of the '661 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '661 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

419. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '661 patent.

ANSWER: Denied.

420. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

421. Defendants have actual knowledge of the '661 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '661 patent. Otherwise, denied.

422. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

EIGHTEENTH COUNT
(Defendants' Infringement of the '959 patent)

424. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

425. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

426. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 426 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

427. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

428. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

429. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '959 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '959 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '959 patent. Otherwise, denied.

430. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "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." 21 C.F.R. § 314.95(c)(7) requires that such notice 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: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

ANSWER: Paragraph 430 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) states “A notice under this subparagraph shall...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.” Sun further admits that 21 C.F.R. § 314.95(c)(7) states: “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 applicant must include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” Otherwise, denied.

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

ANSWER: Paragraph 431 contains legal conclusions to which no answer is required and therefore denies the allegations of Paragraph 431.

432. Upon information and belief, Defendants admit infringement of the ’959 patent because—other than baseless invalidity allegations—the Notice Letter does not disclose any specific noninfringement contentions for the ’959 patent.

ANSWER: Paragraph 432 contains legal conclusions for which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 432.

433. Under 35 U.S.C. § 271(e)(2)(A), Defendants’ submission of ANDA No. 214303 with a paragraph IV certification to the ’959 patent for the purpose of obtaining approval to engage

in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '959 patent is an act of infringement of the '959 patent.

ANSWER: Denied.

434. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

435. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '959 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

436. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '959 patent under 35 U.S.C. § 271.

ANSWER: Denied.

437. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '959 patent.

ANSWER: Denied.

438. Defendants have knowledge of the '959 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct

infringement of at least one claim of the '959 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

439. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '959 patent.

ANSWER: Denied.

440. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

441. Defendants have actual knowledge of the '959 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '959 patent. Otherwise, denied.

442. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

NINETEENTH COUNT
(Defendants' Infringement of the '182 patent)

444. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

445. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

446. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 446 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

447. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

448. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

449. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '182 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '182 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '182 patent. Otherwise, denied.

450. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '182 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '182 patent is an act of infringement of the '182 patent.

ANSWER: Denied.

451. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

452. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '182 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

453. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '182 patent under 35 U.S.C. § 271.

ANSWER: Denied.

454. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '182 patent.

ANSWER: Denied.

455. Defendants have knowledge of the '182 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '182 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

456. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use

Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '182 patent.

ANSWER: Denied.

457. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

458. Defendants have actual knowledge of the '182 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '182 patent. Otherwise, denied.

459. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

TWENTIETH COUNT
(Defendants' Infringement of the '709 patent)

461. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

462. Upon information and belief, Defendants submitted ANDA No. 214303 to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Sun admits that it submitted ANDA No. 214303 to the FDA under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed Product prior to the expiration of the Patents-in-Suit.

463. Upon information and belief, ANDA No. 214303 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Paragraph 463 contains legal conclusions for which no answer is required. To the extent a response is required, Sun states that Sun provided Plaintiffs Sun's Notice Letter. Sun's Paragraph IV certification and Notice Letter speak for themselves. Otherwise, denied.

464. Upon information and belief, the established name of Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Sun admits that Sun's Proposed Product is referred to as Estradiol Vaginal Inserts and would be available in dosage strengths of 4 mcg and 10 mcg estradiol. Otherwise, denied.

465. Upon information and belief, Defendants have represented to FDA in ANDA No. 214303 that Defendants' ANDA Product is bioequivalent to Imvexxy®.

ANSWER: Sun states that Sun's ANDA speaks for itself. Otherwise, denied.

466. Upon information and belief, Defendants submitted ANDA No. 214303 with a paragraph IV certification to the '709 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '709 patent.

ANSWER: Sun admits that it prepared and submitted ANDA No. 214303 to the FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's ANDA Product, prior to the expiration of the '709 patent. Otherwise, denied.

467. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 214303 with a paragraph IV certification to the '709 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the '709 patent is an act of infringement of the '709 patent.

ANSWER: Denied.

468. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, Defendants' ANDA Product if ANDA No. 214303 receives final FDA approval.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

469. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product would infringe, directly and/or indirectly, one or more of the '709 patent's claims under 35 U.S.C. § 271.

ANSWER: Denied.

470. Upon information and belief, Defendants' commercial offering for sale and/or sale of Defendants' ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '709 patent under 35 U.S.C. § 271.

ANSWER: Denied.

471. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use Defendants' ANDA Product, and therefore will infringe at least one claim of the '709 patent.

ANSWER: Denied.

472. Defendants have knowledge of the '709 patent and, upon information and belief, know or should know that the proposed labeling for Defendants' ANDA Product will induce direct infringement of at least one claim of the '709 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

473. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for Defendants' ANDA Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use Defendants' ANDA Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '709 patent.

ANSWER: Denied.

474. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214303 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

475. Defendants have actual knowledge of the '709 patent, as evidenced by the Notice Letter.

ANSWER: Sun admits that it sent Plaintiffs a Notice Letter with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214303 (estradiol vaginal insert, 0.004 mg and 0.01 mg)" notifying Plaintiffs that Sun had filed ANDA No. 214303 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed drug products prior to the expiration of the '709 patent. Otherwise, denied.

476. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

ANSWER: Denied.

ANSWER TO PLAINTIFFS' REQUEST FOR RELIEF

Sun denies that Plaintiffs are entitled to the relief sought against Sun in Paragraphs A-J of the Complaint or any relief at all for the allegations relating to Sun made in the Complaint.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, on information and belief, Sun

asserts the following Separate Defenses to Plaintiffs' Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '091 patent.

SECOND SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '382 patent.

THIRD SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '630 patent.

FOURTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303

does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '708 patent.

FIFTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '072 patent.

SIXTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '581 patent.

SEVENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '891 patent.

EIGHTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '082 patent.

NINTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '697 patent.

TENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '487 patent.

ELEVENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to

the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '516 patent.

TWELFTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '197 patent.

THIRTEENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '717 patent.

FOURTEENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '283 patent.

FIFTEENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303

does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '445 patent.

SIXTEENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '875 patent.

SEVENTEENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '661 patent.

EIGHTEENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '959 patent.

NINETEENTH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '182 patent.

TWENTIETH SEPARATE DEFENSE

The submission of ANDA No. 214303 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed product that is subject to ANDA No. 214303 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '709 patent.

TWENTY-FIRST SEPARATE DEFENSE

Based on information and belief, each of the claims of the '091 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-SECOND SEPARATE DEFENSE

Based on information and belief, each of the claims of the '382 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity

or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-THIRD SEPARATE DEFENSE

Based on information and belief, each of the claims of the '630 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-FOURTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '708 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-FIFTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '072 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-SIXTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '581 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code,

including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-SEVENTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '891 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-EIGHTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '082 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

TWENTY-NINTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '697 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTIETH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '487 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-FIRST SEPARATE DEFENSE

Based on information and belief, each of the claims of the '516 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-SECOND SEPARATE DEFENSE

Based on information and belief, each of the claims of the '197 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-THIRD SEPARATE DEFENSE

Based on information and belief, each of the claims of the '717 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity

or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-FOURTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '283 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-FIFTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '445 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-SIXTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '875 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-SEVENTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '661 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code,

including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-EIGHTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '959 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

THIRTY-NINTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '182 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

FORTIETH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '709 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated June 14, 2024.

FORTY-FIRST SEPARATE DEFENSE

Plaintiffs have failed to state a proper claim for exceptional case under 35 U.S.C. § 285.

FORTY-SECOND SEPARATE DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. §§ 271(a)-(c) against Sun because Plaintiffs have not pleaded with particularity facts regarding any post-ANDA-approval activities.

FORTY-THIRD SEPARATE DEFENSE

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. §§ 271(a)-(c).

FORTY-FOURTH SEPARATE DEFENSE

Plaintiffs fail to state a claim upon which relief can be granted.

FORTY-FIFTH SEPARATE DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this lawsuit.

RESERVATION OF ADDITIONAL SEPARATE AND/OR AFFIRMATIVE DEFENSES

Sun reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, under 35 U.S.C. §§ 116 and/or 120, inequitable conduct, unclean hands, laches, estoppel, patent misuse or any other defense of unenforceability.

COUNTERCLAIMS

Defendants/Counterclaimants Sun Pharmaceutical Industries Ltd. (“Sun Ltd.”) and Sun Pharmaceutical Industries, Inc. (“Sun, Inc.”) (collectively “Sun” or “Defendants”), by and through their undersigned attorneys, counterclaim against TherapeuticsMD, Inc. (“TherapeuticsMD”) and Mayne Pharma LLC (“Mayne”) (collectively, “Counter Defendants”) for declaratory judgment that no valid and enforceable claim of U.S. Patent Nos. 9,180,091 (“the ’091 patent”); 9,289,382 (“the ’382 patent”); 10,258,630 (“the ’630 patent”); 10,398,708 (“the ’708 patent”); 10,471,072

(“the ’072 patent”); 10,537,581 (“the ’581 patent”); 10,568,891 (“the ’891 patent”); 10,668,082 (“the ’082 patent”); 10,806,697 (“the ’697 patent”); 10,835,487 (“the ’487 patent”); 10,888,516 (“the ’516 patent”); 11,065,197 (“the ’197 patent”); 11,116,717 (“the ’717 patent”); 11,123,283 (“the ’283 patent”); 11,241,445 (“the ’445 patent”); 11,246,875 (“the ’875 patent”); 11,266,661 (“the ’661 patent”); 11,304,959 (“the ’959 patent”); 11,351,182 (“the ’182 patent”); and 11,497,709 (“the ’709 patent”) (collectively, the “Patents-in-Suit”) is infringed or will be infringed under 35 U.S.C. § 271 by the submission of ANDA No. 214303 (“Sun’s ANDA”) or by the making, using, selling, offering for sale or importing of the drug product subject to Sun’s ANDA.

PARTIES

1. Counterclaimant Sun Pharmaceutical Industries, Ltd. (“Sun Ltd.”) is a company organized and existing under the laws of the Republic of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India.

2. Counterclaimant Sun Pharmaceutical Industries, Inc. (“Sun Inc.”) is a company 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.

3. On information and belief, and based on Counter Defendants’ allegations, Counter Defendant TherapeuticsMD is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431.

4. On information and belief, and based on Counter Defendants’ allegations, Counter Defendant Mayne is a limited liability company organized and existing under the laws of Delaware, having a place of business at 3301 Benson Drive, Suite 401, Raleigh, North Carolina 27609.

NATURE OF THE ACTION

5. Defendants/Counterclaimants seek declaratory judgment that no valid and enforceable claim of the '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the '516 patent, the '197 patent, the '717 patent, the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent is infringed by the product described in Sun's ANDA.

JURISDICTION AND VENUE

6. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

7. As a consequence of Counter Defendants' Complaint against Sun, there is now an actual controversy between the parties concerning the infringement of the '091 patent, the '382 patent, the '630 patent, the '708 patent, the '072 patent, the '581 patent, the '891 patent, the '082 patent, the '697 patent, the '487 patent, the '516 patent, the '197 patent, the '717 patent, the '283 patent, the '445 patent, the '875 patent, the '661 patent, the '959 patent, the '182 patent, and the '709 patent.

8. This action arises under and the Court has jurisdiction over these counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), 2201(b) and 35 U.S.C. § 271 based on an actual controversy between Sun and Counter Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

9. This Court may declare the rights and legal relation of the parties pursuant to §§ 2201 and 2202 of Title 28 of the United States Code and § 271(e)(5) of Title 35 of the United States Code because the Counterclaims present an actual controversy within the Court's

jurisdiction concerning the alleged infringement of the patent asserted by Counter Defendants against Sun.

10. This Court has personal jurisdiction over the Counter Defendants based, inter alia, on the filing by Counter Defendants of this lawsuit in this jurisdiction.

11. Venue is proper in this judicial district based on 28 U.S.C. §§ 1391 and 1400(b), and by Counter Defendants' choice of forum.

COUNT I
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,180,091)

12. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 11 of the Counterclaims as though fully set forth herein.

13. Counter Defendants have asserted the '091 patent against Sun.

14. Counter Defendants allege, and Sun denies, that the '091 patent is valid.

15. The '091 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

16. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '091 patent.

17. Sun is entitled to a judicial declaration that the '091 patent is invalid.

COUNT II

(Declaratory Judgment of Invalidity of U.S. Patent No. 9,289,382)

18. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 17 of the Counterclaims as though fully set forth herein.

19. Counter Defendants have asserted the '382 patent against Sun.

20. Counter Defendants allege, and Sun denies, that the '382 patent is valid.

21. The '382 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

22. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '382 patent.

23. Sun is entitled to a judicial declaration that the '382 patent is invalid.

COUNT III

(Declaratory Judgment of Invalidity of U.S. Patent No. 10,258,630)

24. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 23 of the Counterclaims as though fully set forth herein.

25. Counter Defendants have asserted the '630 patent against Sun.

26. Counter Defendants allege, and Sun denies, that the '630 patent is valid.

27. The '630 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

28. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '630 patent.

29. Sun is entitled to a judicial declaration that the '630 patent is invalid.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,398,708)

30. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 29 of the Counterclaims as though fully set forth herein.

31. Counter Defendants have asserted the '708 patent against Sun.

32. Counter Defendants allege, and Sun denies, that the '708 patent is valid.

33. The '708 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

34. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '708 patent.

35. Sun is entitled to a judicial declaration that the '708 patent is invalid.

COUNT V
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,471,072)

36. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 35 of the Counterclaims as though fully set forth herein.

37. Counter Defendants have asserted the '072 patent against Sun.

38. Counter Defendants allege, and Sun denies, that the '072 patent is valid.

39. The '072 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

40. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '072 patent.

41. Sun is entitled to a judicial declaration that the '072 patent is invalid.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,537,581)

42. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 41 of the Counterclaims as though fully set forth herein.

43. Counter Defendants have asserted the '581 patent against Sun.

44. Counter Defendants allege, and Sun denies, that the '581 patent is valid.

45. The '581 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

46. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '581 patent.

47. Sun is entitled to a judicial declaration that the '581 patent is invalid.

COUNT VII
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,568,891)

48. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 47 of the Counterclaims as though fully set forth herein.

49. Counter Defendants have asserted the '891 patent against Sun.

50. Counter Defendants allege, and Sun denies, that the '891 patent is valid.

51. The '891 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

52. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '891 patent.

53. Sun is entitled to a judicial declaration that the '891 patent is invalid.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,668,082)

54. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 53 of the Counterclaims as though fully set forth herein.

55. Counter Defendants have asserted the '082 patent against Sun.

56. Counter Defendants allege, and Sun denies, that the '082 patent is valid.

57. The '082 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

58. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '082 patent.

59. Sun is entitled to a judicial declaration that the '082 patent is invalid.

COUNT IX
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,806,697)

60. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 59 of the Counterclaims as though fully set forth herein.

61. Counter Defendants have asserted the '697 patent against Sun.

62. Counter Defendants allege, and Sun denies, that the '697 patent is valid.

63. The '697 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

64. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '697 patent.

65. Sun is entitled to a judicial declaration that the '697 patent is invalid.

COUNT X
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,835,487)

66. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 65 of the Counterclaims as though fully set forth herein.

67. Counter Defendants have asserted the '487 patent against Sun.

68. Counter Defendants allege, and Sun denies, that the '487 patent is valid.

69. The '487 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

70. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '487 patent.

71. Sun is entitled to a judicial declaration that the '487 patent is invalid.

COUNT XI
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,888,516)

72. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 71 of the Counterclaims as though fully set forth herein.

73. Counter Defendants have asserted the '516 patent against Sun.

74. Counter Defendants allege, and Sun denies, that the '516 patent is valid.

75. The '516 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

76. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '516 patent.

77. Sun is entitled to a judicial declaration that the '516 patent is invalid.

COUNT XII

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,065,197)

78. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 77 of the Counterclaims as though fully set forth herein.

79. Counter Defendants have asserted the '197 patent against Sun.

80. Counter Defendants allege, and Sun denies, that the '197 patent is valid.

81. The '197 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

82. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '197 patent.

83. Sun is entitled to a judicial declaration that the '197 patent is invalid.

COUNT XIII

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,116,717)

84. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 83 of the Counterclaims as though fully set forth herein.

85. Counter Defendants have asserted the '717 patent against Sun.

86. Counter Defendants allege, and Sun denies, that the '717 patent is valid.

87. The '717 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

88. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '717 patent.

89. Sun is entitled to a judicial declaration that the '717 patent is invalid.

COUNT XIV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,123,283)

90. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 89 of the Counterclaims as though fully set forth herein.

91. Counter Defendants have asserted the '283 patent against Sun.

92. Counter Defendants allege, and Sun denies, that the '283 patent is valid.

93. The '283 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

94. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '283 patent.

95. Sun is entitled to a judicial declaration that the '283 patent is invalid.

COUNT XV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,241,445)

96. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 95 of the Counterclaims as though fully set forth herein.

97. Counter Defendants have asserted the '445 patent against Sun.

98. Counter Defendants allege, and Sun denies, that the '445 patent is valid.

99. The '445 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

100. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '445 patent.

101. Sun is entitled to a judicial declaration that the '445 patent is invalid.

COUNT XVI
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,246,875)

102. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 101 of the Counterclaims as though fully set forth herein.

103. Counter Defendants have asserted the '875 patent against Sun.

104. Counter Defendants allege, and Sun denies, that the '875 patent is valid.

105. The '875 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

106. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '875 patent.

107. Sun is entitled to a judicial declaration that the '875 patent is invalid.

COUNT XVII

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,266,661)

108. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 107 of the Counterclaims as though fully set forth herein.

109. Counter Defendants have asserted the '661 patent against Sun.

110. Counter Defendants allege, and Sun denies, that the '661 patent is valid.

111. The '661 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

112. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '661 patent.

113. Sun is entitled to a judicial declaration that the '661 patent is invalid.

COUNT XVIII

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,304,959)

114. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 113 of the Counterclaims as though fully set forth herein.

115. Counter Defendants have asserted the '959 patent against Sun.

116. Counter Defendants allege, and Sun denies, that the '959 patent is valid.

117. The '959 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

118. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '959 patent.

119. Sun is entitled to a judicial declaration that the '959 patent is invalid.

COUNT XIX
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,351,182)

120. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 119 of the Counterclaims as though fully set forth herein.

121. Counter Defendants have asserted the '182 patent against Sun.

122. Counter Defendants allege, and Sun denies, that the '182 patent is valid.

123. The '182 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

124. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '182 patent.

125. Sun is entitled to a judicial declaration that the '182 patent is invalid.

COUNT XX
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,497,709)

126. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 125 of the Counterclaims as though fully set forth herein.

127. Counter Defendants have asserted the '709 patent against Sun.

128. Counter Defendants allege, and Sun denies, that the '709 patent is valid.

129. The '709 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102 and 103.

130. Sun and Counter Defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '709 patent.

131. Sun is entitled to a judicial declaration that the '709 patent is invalid.

COUNT XXI

(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,180,091)

132. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 131 of the Counterclaims as though fully set forth herein.

133. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '091 patent.

134. Sun is entitled to a judicial declaration that the '091 patent is not infringed.

COUNT XXII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,289,382)

135. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 134 of the Counterclaims as though fully set forth herein.

136. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '382 patent.

137. Sun is entitled to a judicial declaration that the '382 patent is not infringed.

COUNT XXIII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,258,630)

138. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 137 of the Counterclaims as though fully set forth herein.

139. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '630 patent.

140. Sun is entitled to a judicial declaration that the '630 patent is not infringed.

COUNT XXIV

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,398,708)

141. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 140 of the Counterclaims as though fully set forth herein.

142. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '708 patent.

143. Sun is entitled to a judicial declaration that the '708 patent is not infringed.

COUNT XXV

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,471,072)

144. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 143 of the Counterclaims as though fully set forth herein.

145. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '072 patent.

146. Sun is entitled to a judicial declaration that the '072 patent is not infringed.

COUNT XXVI

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,537,581)

147. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 146 of the Counterclaims as though fully set forth herein.

148. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '581 patent.

149. Sun is entitled to a judicial declaration that the '581 patent is not infringed.

COUNT XXVII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,568,891)

150. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 149 of the Counterclaims as though fully set forth herein.

151. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '891 patent.

152. Sun is entitled to a judicial declaration that the '891 patent is not infringed.

COUNT XXVIII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,668,082)

153. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 152 of the Counterclaims as though fully set forth herein.

154. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '082 patent.

155. Sun is entitled to a judicial declaration that the '082 patent is not infringed.

COUNT XXIX

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,806,697)

156. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 155 of the Counterclaims as though fully set forth herein.

157. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '697 patent.

158. Sun is entitled to a judicial declaration that the '697 patent is not infringed.

COUNT XXX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,835,487)

159. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 158 of the Counterclaims as though fully set forth herein.

160. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '487 patent.

161. Sun is entitled to a judicial declaration that the '487 patent is not infringed.

COUNT XXXI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,888,516)

162. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 161 of the Counterclaims as though fully set forth herein.

163. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '516 patent.

164. Sun is entitled to a judicial declaration that the '516 patent is not infringed.

COUNT XXXII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,241,445)

165. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 164 of the Counterclaims as though fully set forth herein.

166. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '445 patent.

167. Sun is entitled to a judicial declaration that the '445 patent is not infringed.

COUNT XXXIII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,246,875)

168. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 167 of the Counterclaims as though fully set forth herein.

169. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '875 patent.

170. Sun is entitled to a judicial declaration that the '875 patent is not infringed.

COUNT XXXIV

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,266,661)

171. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 170 of the Counterclaims as though fully set forth herein.

172. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '661 patent.

173. Sun is entitled to a judicial declaration that the '661 patent is not infringed.

COUNT XXXV

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,351,182)

174. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 173 of the Counterclaims as though fully set forth herein.

175. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '182 patent.

176. Sun is entitled to a judicial declaration that the '182 patent is not infringed.

COUNT XXXVI

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,497,709)

177. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 176 of the Counterclaims as though fully set forth herein.

178. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of the drug product subject to Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '709 patent.

179. Sun is entitled to a judicial declaration that the '709 patent is not infringed.

PRAYER FOR RELIEF

WHEREFORE, Sun prays for the following relief:

- A. An order dismissing the Complaint, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;
- B. An order declaring, pursuant to one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, that each claim of the Patents-in-Suit is invalid;
- C. An order declaring that no valid and enforceable claim of the Patents-in-Suit is infringed by the submission of Sun's ANDA No. 214303 or by the making, use, sale, offer for sale, marketing, or importation into the United States of a drug product subject to Sun's ANDA;
- D. Denying Plaintiffs any award of damages, costs, or fees;
- E. An order declaring this case exceptional under 35 U.S.C. § 285 and awarding Sun its reasonable attorneys' fees, and costs under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon;
- F. Awarding Sun such other and further relief as this Court may deem just and proper.

Dated: September 30, 2024

By:

s/ Gregory D. Miller

Gregory D. Miller

Timothy P. Gonzalez

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Industries, Inc.*

LOCAL CIVIL RULE 11.2 and 40.1 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 30, 2024

s/ Gregory D. Miller
Gregory D. Miller

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive and declaratory relief.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: September 30, 2024

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that, on September 30, 2024, the foregoing document described as **DEFENDANTS' ANSWER TO COMPLAINT, SEPARATE DEFENSES AND COUNTERCLAIMS** was served on all counsel of record indicated below via electronic mail.

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*Attorneys for Plaintiffs TherapeuticsMD, Inc.
and Mayne Pharma LLC*

s/ Gregory D. Miller
Gregory D. Miller