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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THERAPEUTICSMD, INC. and MAYNE PHARMA LLC, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	Civil Action No. _____ (Filed Electronically)

COMPLAINT

Plaintiffs TherapeuticsMD, Inc. ("TherapeuticsMD") and Mayne Pharma LLC ("Mayne") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants Sun Pharmaceutical Industries Ltd. ("Sun Pharma Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun Pharma Inc.") (collectively, "Sun" or "Defendants"), allege:

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").

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.

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.

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.

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 Imvexxy®, of which all twenty (20) are the Patents-in-Suit.

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.

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.

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/.

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.

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/.

11. Sun Pharma Ltd.'s website states: "Our U.S. business makes up 30% of our global revenue." https://sunpharma.com/usa/.

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.

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

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.

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.

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.

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.

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).

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.

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]

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

[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).

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.

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.

23. Upon information and belief, 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.

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.

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.

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.

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.

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.

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.

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

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.

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

FACTS COMMON TO ALL COUNTS

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

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.

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.

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

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®.

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."

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."

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

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

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

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®.

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.

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.

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.

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."

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.

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."

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.

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.

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 Imvexxy®. The Orange Book lists December 20, 2033 as the expiration date of the '091 patent.

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.

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 Imvexxy®. The Orange Book lists November 21, 2032 as the expiration date of the '382 patent.

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.

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 Imvexxy®. The Orange Book lists December 20, 2033 as the expiration date of the ’630 patent.

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.

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.

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.

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.

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.

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.

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.

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 Imvexxy®. The Orange Book lists June 18, 2033 as the expiration date of the ’891 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 Imvexxy®. The Orange Book lists June 18, 2033 as the expiration date of the ’717 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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

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.

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

FIRST COUNT
(Defendants' Infringement of the '091 patent)

96. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

116. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

THIRD COUNT

(Defendants' Infringement of the '630 patent)

137. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

FOURTH COUNT
(Defendants' Infringement of the '708 patent)

154. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

174. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

191. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

211. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

EIGTH COUNT
(Defendants' Infringement of the '082 patent)

231. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

248. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

269. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

286. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

306. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

326. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

346. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

366. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

383. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

403. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

424. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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

444. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

458. Defendants have actual knowledge of the '182 patent, as evidenced by the Notice Letter.

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

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.

TWENTIETH COUNT
(Defendants' Infringement of the '709 patent)

461. Plaintiffs repeat and reallege each of the foregoing paragraphs 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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

475. Defendants have actual knowledge of the '709 patent, as evidenced by the Notice Letter.

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

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment declaring that the Patents-in-Suit are enforceable and not invalid;

B. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the Patents-in-Suit by submitting to FDA ANDA No. 214303 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, importation, offer to sell, or sale of Defendants' ANDA Product before the expiration of the Patents-in-Suit;

C. A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product before the expiration of the Patents-in-Suit (including any regulatory extensions) would directly and/or indirectly infringe the Patents-in-Suit;

D. An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 214303 shall be no earlier than the date on which the last of the Patents-in-Suit expire (including any regulatory extensions);

E. An Order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person or entity in active concert or participation or privity with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States, of Defendants' ANDA Product until the expiration of the Patents-in-Suit (including any regulatory extensions);

F. An Order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person or entity in active concert or participation or privity with Defendants, from seeking,

obtaining, or maintaining approval of ANDA No. 214303 until the expiration of the Patents-in-Suit (including any regulatory extensions);

G. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Plaintiffs damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, any product that is the subject of ANDA No. 214303, prior to the expiration of the Patents-in-Suit (including any regulatory extensions);

H. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the Patents-in-Suit is willful and awarding Plaintiffs enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, any product that is the subject of ANDA No. 214303, prior to the expiration of the Patents-in-Suit (including any regulatory extensions);

I. A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Plaintiffs their attorneys' fees and costs; and

J. Such other and further relief as this Court may deem just and proper.

Dated: July 24, 2024

By: s/ William C. Baton

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned *TherapeuticsMD, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 20-3485 (BRM)(SDA)(consolidated) (D.N.J.) and *TherapeuticsMD, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 21-12794 (BRM)(SDA) (D.N.J.) are related to the matter in controversy because the matter in controversy involves the same plaintiffs and some of the same patents, and because Defendants are seeking FDA approval to market generic versions of the same pharmaceutical product.

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

Dated: July 24, 2024

By: s/ William C. Baton

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