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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THERAPEUTICSMD, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Honorable Brian R. Martinotti, U.S.D.J. Civil Action No. 2:20-cv-3485-BRM-ESK Civil Action No. 2:20-cv-8809-BRM-ESK Civil Action No. 2:20-cv-11087-BRM-ESK Civil Action No. 2:20-cv-17496-BRM-ESK (Consolidated)

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA" or "Teva"[1]), by and through the undersigned attorneys, submits its amended answer, affirmative defenses, and counterclaims to the Complaint for patent infringement of Plaintiff TherapeuticsMD, Inc. ("Plaintiff" or "TherapeuticsMD"). Teva denies all allegations in Plaintiff's Complaint except those admitted

[1] The Complaint uses "Teva" to collectively include Teva USA and Teva Pharmaceutical Industries, Ltd., ("Teva Ltd.") which is no longer a party to this case. Pursuant to the Stipulation submitted on December 8, 2020 (ECF No. 9) and so ordered on December 8, 2020 (ECF No. 10), the parties have stipulated to dismissal of the action against Teva Ltd. Accordingly, all responses herein are made solely on behalf of Teva USA, and no response is made on behalf of Teva Ltd.

specifically below. This pleading is based upon Teva's knowledge of its own activities, and upon information and belief as to the activities of others.

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 No. 10,806,697 ("the '697 patent") (attached as Exhibit A) and U.S. Patent No. 10,835,487 ("the '487 patent") (attached as Exhibit B) (collectively, the "patents-in-suit").

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that the Complaint purports to bring an action for infringement under the Patent Laws of the United States, Title 35 of the United States Code. Teva admits that what appears to be copies of U.S. Patent No. 10,806,697 ("the '697 patent") and U.S. Patent No. 10,835,487 ("the '487 patent") are attached as Exhibits A and B, respectively, to the Complaint. Teva denies that Plaintiff is entitled to any relief in this action. Teva denies any remaining allegations in this paragraph.

THE PARTIES

2. TherapeuticsMD, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33487.

ANSWER: Upon information and belief, Teva admits that Plaintiff TherapeuticsMD is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33487.

3. TherapeuticsMD, Inc. is the owner of New Drug Application ("NDA") No. 208564, which was approved by the U.S. Food and Drug Administration ("FDA") for the manufacture and sale of Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg.

ANSWER: Upon information and belief, Teva admits that Plaintiff TherapeuticsMD is the holder of NDA No. 208564 for Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg. Teva denies any remaining allegations in this paragraph.

4. TherapeuticsMD, Inc. is the current owner and assignee of each of the ten (10) patents listed in FDA's publication titled "Approved Drug Products with Therapeutics Equivalence Evaluations" (commonly known as the "Orange Book") as covering TherapeuticsMD's Imvexxy®, of which two (2) are the patents-in-suit.

ANSWER: Upon information and belief, Teva admits that ten patents are listed in the Orange Book for Imvexxy®, including the '697 and '487 patents. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

5. Upon information and belief, defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basal Street, Petach Tikva, 4951033, Israel.

ANSWER: To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Further answering, Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva, Israel 4951033. Teva denies any remaining allegations in this paragraph.

6. Upon information and belief, Teva Ltd. represented in its SEC filings that it is the "leading generic pharmaceutical company in the United States" and, in 2019, it "led the U.S. generics market in total prescriptions and new prescriptions." Teva Ltd.'s Form 10-K for the fiscal year ending in December 31, 2019, at 5, 60.

ANSWER: To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Further answering, in Teva Ltd.'s Security and Exchange Commission Annual Report (Form 10-K) for the fiscal year ending in December 31, 2019, Teva Ltd. stated, "[w]e are the leading generic drug company in the United States" and "[i]n 2019, we led the U.S. generics market in total prescriptions and new prescriptions, with approximately 388 million total prescriptions (based on trailing twelve months), representing

10.5% of total U.S. generic prescriptions according to IQVIA data." Teva denies any remaining allegations in this paragraph.

7. Upon information and belief, Teva Ltd. operates through a global network of subsidiaries that it directly or indirectly owns and controls, including defendant Teva USA. In its most recent SEC form 10-K, Teva Ltd. stated that it "operate[s] [its] business through three segments: North America, Europe and International Markets." Id. at 2. In particular, Teva Ltd. stated that "Anda, [its] distribution business in the United States, distributes generic, specialty and [over the counter] pharmaceutical products from various third party manufacturers to independent retail pharmacies, pharmacy retail chains, hospitals and physician offices in the United States." Id. at 3.

ANSWER: Teva admits that Teva USA is an indirect wholly-owned subsidiary of Teva Ltd. To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Further answering, in Teva Ltd.'s Security and Exchange Commission Annual Report (Form 10-K) for the fiscal year ending in December 31, 2019, Teva Ltd. stated, "[w]e operate our business through three segments: North America, Europe and International Markets" and "Anda, our distribution business in the United States, distributes generic, specialty and OTC pharmaceutical products from various third party manufacturers to independent retail pharmacies, pharmacy retail chains, hospitals and physician offices in the United States." Teva denies any remaining allegations in this paragraph.

8. As of December 31, 2019, Teva Ltd.'s "generic products pipeline" included "251 product applications awaiting FDA approval" where "70% of [these] pending applications include a paragraph IV patent challenge." *Id.* at 63. Upon information and belief, Teva Ltd.'s "generic products pipeline" includes the generic pharmaceutical products for which Teva USA is the named Abbreviated New Drug Application ("ANDA") applicant.

ANSWER: To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Further answering, in Teva Ltd.'s Security and Exchange Commission Annual Report (Form 10-K) for the fiscal year ending in

December 31, 2019, Teva Ltd. stated, "[o]ur generic products pipeline in the United States includes, as of December 31, 2019, 251 product applications awaiting FDA approval, including 79 tentative approvals. This total reflects all pending ANDAs, supplements for product line extensions and tentatively approved applications and includes some instances where more than one application was submitted for the same reference product" and "[a]pproximately 70% of pending applications include a paragraph IV patent challenge and we believe we are first to file with respect to 95 of these products, or 116 products including final approvals where launch is pending a settlement agreement or court decision." Teva denies any remaining allegations in this paragraph.

9. Upon information and belief, Teva 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 Teva USA, 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 Teva USA, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Further answering, Teva admits that Teva has sought approval to commercially market, offer for sale, and sell the products described in the Teva ANDA ("Teva's Proposed Products") throughout the United States, including in the State of New Jersey. Teva denies any remaining allegations in this paragraph.

10. Upon information and belief, defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware having principal places of business located at 400 Interpace Parkway, Parsippany, New Jersey 07054 and 1090 Horsham Road, North Wales, Pennsylvania 19454.

ANSWER: Teva admits that Teva USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva denies any remaining allegations in this paragraph.

11. Upon information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd. Upon information and belief, Teva USA acts at the direction of, under the control of, and for the benefit of Teva Ltd., and is controlled and/or dominated by Teva Ltd. Upon information and belief, Teva USA and Teva Ltd. have at least one officer and/or director in common.

ANSWER: Teva admits that Teva USA is an indirect wholly-owned subsidiary of Teva Ltd. To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Teva denies any remaining allegations in this paragraph.

12. Upon information and belief, Teva USA 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 Teva 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 Teva Ltd., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Further answering, Teva admits that Teva Ltd. is a global pharmaceutical company, of which Teva USA is an indirect wholly-owned subsidiary. Teva admits that part of Teva USA's business is the manufacture and sale of generic medicines that are distributed in the United States, including in the State of New Jersey. Teva denies the remaining allegations of this paragraph.

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

ANSWER: To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Further answering, Teva admits that part of Teva USA's business is the manufacture and sale of generic medicines for which Teva USA is the named ANDA applicant. Teva denies the remaining allegations of this paragraph.

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that the Complaint cites the patent laws of the United States generally. Teva does not contest subject matter jurisdiction for purposes of this case only. Teva denies the remaining allegations of this paragraph.

15. Teva USA has already consented to personal jurisdiction and venue in a related matter, TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., C.A. No. 20-3485 (BRM) (ESK) (consolidated), in its Answer filed on June 15, 2020 and Amended Answer filed on July 2, 2020. See 20-3485 (BRM) (ESK), ECF Nos. 10, 20.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Teva does not contest personal jurisdiction and venue for purposes of this case only. Teva denies the remaining allegations of this paragraph.

16. This Court has personal jurisdiction over Teva USA at least because, upon information and belief: (i) Teva USA maintains a principal place of business in New Jersey located at 400 Interpace Parkway, Parsippany, New Jersey 07054; (ii) Teva USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Teva USA, together with its parent Teva Ltd., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Teva USA, together with its parent Teva Ltd., has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) Teva USA has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in hundreds of prior litigations,

and previously consented to personal jurisdiction and venue in this Judicial District[2]; and (vi) Teva USA's February 18, 2020 notice of paragraph IV certification, Teva USA's June 2, 2020 notice of paragraph IV certification, and Teva USA's August 5, 2020 notice of paragraph IV certification (collectively, "Teva's Notice Letters") identified the correspondence address for Teva USA's offer of confidential access as 400 Interpace Parkway, Parsippany, NJ 07054.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Teva USA does not contest personal jurisdiction for purposes of this case only. Teva admits that Teva USA maintains a principal place of business in New Jersey located at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva further admits that Teva USA has been sued and has litigated in the District of New Jersey federal courts. Teva also admits that Teva USA has asserted claims or counterclaims in this Judicial District in the following cases: *Teva Pharmaceuticals USA, Inc., et al. v. Sandoz Inc., et al.*, Civil Action No. 3-17-cv-00275; *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 3-17-cv-00517; *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 2-15-cv-00471; *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, Civil Action No. 2-15-cv-00472; *Adapt Pharma Operations Ltd., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 2-18-cv-09880;

[2] This Court has personal jurisdiction over Teva Ltd. and Teva USA because Teva Ltd. and Teva USA 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.*, *Teva Pharmaceuticals USA, Inc., et al. v. Sandoz Inc., et al.*, No. 3-17-cv-00275 (FLW)(DEA) (D.N.J.) (Teva USA and Teva Ltd. filed complaint for patent infringement); *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 3-17-cv-00517 (FLW)(DEA) (D.N.J.) (same); *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2-15-cv-00471 (CCC)(MF) (D.N.J.) (same); *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 2-15-cv-00472 (CCC)(MF) (D.N.J.) (same); *Adapt Pharma Operations Ltd., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2-18-cv-09880 (JLL)(JAD) (D.N.J) (Teva USA and Teva Ltd. did not contest jurisdiction); *Janssen Pharmaceuticals, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2-18-cv-00734 (CCC)(MF) (D.N.J.) (same); *Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 3-17-cv-11510 (MAS)(LHG) (D.N.J.) (Teva USA and Teva Ltd. filed counterclaims and did not contest jurisdiction).

Janssen Pharmaceuticals, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al., Civil Action No. 2-18-cv-00734; *Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 3-17-cv-11510. Teva denies any remaining allegations in this paragraph.

17. Upon information and belief, Teva USA 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 Number 0100250184. Upon information and belief, Teva USA is registered with the State of New Jersey's Department of Health as a drug & medical device "manufacturer and wholesaler" and "wholesaler" with Registration Numbers 5000583 and 5003436, respectively.

ANSWER: Teva admits that Teva USA is registered in the State of New Jersey's Department of Health under manufacturer wholesale registration number 5000583 and wholesale registration number 5003436. Teva further admits that Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services under entity identification number 0100250184. Teva denies the remaining allegations of this paragraph.

18. In Teva's Notice Letters, Teva USA asserts that it prepared, submitted, and filed with FDA, pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), ANDA No. 214137, seeking approval to engage in the commercial manufacture, use, and/or sale of Estradiol Vaginal Insert 4 mcg and 10 mcg ("Defendants' ANDA Product") before the expiration of TherapeuticsMD's United States Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; and 10,668,082 throughout the United States, including in this Judicial District.

ANSWER: Teva admits that Teva USA sent Notice Letters to Plaintiff dated February 18, 2020; June 2, 2020; and August 5, 2020 regarding ANDA No. 214137, and disclosed that ANDA No. 214137 contains Paragraph IV certifications to the '091, '382, '630, '708, '072, '581, '891 patents, and '082 patents. Teva further admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Teva denies the remaining allegations of this paragraph.

19. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if ANDA No. 214137 receives final approval, Defendants' ANDA Product will be manufactured, sold, distributed, and/or used by Defendants in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Teva USA does not contest personal jurisdiction for purposes of this case only. To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Teva denies the remaining allegations of this paragraph.

20. Upon information and belief, Teva USA's acts of preparing and filing ANDA No. 214137 and directing notice of its ANDA submission to Plaintiff were performed at the direction of, with the authorization of, and with the cooperation, participation, assistance, and, at least in part, the benefit of Teva Ltd. 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 '697 and '487 patents 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, Teva Ltd. and Teva USA reasonably anticipate being sued in New Jersey.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

21. Therefore, this Court has personal jurisdiction over Teva Ltd. because, among other things: (a) Teva Ltd. has purposefully directed its activities and the activities of Teva USA, its wholly owned subsidiary, at residents and corporate entities within the State of New Jersey; (b) the claims set forth herein as to Teva Ltd. arise out of or relate to those activities; (c) Teva Ltd.'s contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Teva Ltd.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action. Teva denies the remaining allegations of this paragraph

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Teva states that Teva does not contest that venue is proper in this Court for the purposes of this action only.

FACTS COMMON TO ALL COUNTS

23. TherapeuticsMD's Imvexxy® is sold and marketed under NDA No. 208564, which was approved by FDA as a New Product on May 29, 2018.

ANSWER: Teva admits, on information and belief, that TherapeuticsMD holds New Drug Application ("NDA") No. 208564 for Imvexxy®, which was approved by the FDA on May 29, 2018. Teva denies the remaining allegations of this paragraph.

24. Because TherapeuticsMD conducted efficacy clinical trials to secure FDA approval of Imvexxy®, FDA granted Imvexxy® three years of regulatory exclusivity.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

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

ANSWER: Teva admits, on information and belief, that the product packaging for Imvexxy® indicates it is supplied as a vaginal insert with either 4 mcg or 10 mcg of estradiol. Teva further admits, on information and belief, that the same product packaging indicates that estradiol is the active ingredient in Imvexxy. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

26. NDA No. 208564 pertains to Imvexxy® 4 mcg and 10 mcg.

ANSWER: Teva admits, on information and belief, that NDA No. 208564 relates to Imvexxy® 4 mcg and 10 mcg.

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

ANSWER: Upon information and belief, Teva admits that the prescribing label for Imvexxy® provides some description of the use of Imvexxy®. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

28. FDA's Orange Book lists ten (10) patents as covering TherapeuticsMD's Imvexxy®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), these ten (10) patents were submitted to FDA with or after the approval of NDA No. 208564. These ten (10) patents are listed in the Orange Book as covering Imvexxy®.

ANSWER: Upon information and belief, Teva admits that at least ten patents are listed in the Orange Book for Imvexxy®, including the '697 and '487 patents. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

29. Teva USA sent Teva's Notice Letters to TherapeuticsMD, purportedly pursuant to § 505(j)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations, regarding ANDA No. 214137. In these letters, Teva USA states that Teva USA's ANDA has been submitted under § 505(j) of the FDCA, with paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of Estradiol Vaginal Insert 4 mcg and 10 mcg, before the expiration of United States Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; and 10,668,082. United States Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; and 10,668,082 are eight (8) of the ten (10) patents listed in FDA's Orange Book as covering Imvexxy®.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that it sent a letter to Plaintiff dated February 18, 2020 regarding ANDA No. 214137, and disclosed that ANDA No. 214137 contains

Paragraph IV certifications for the '091, '382, '630, '708, and '072 patents. Teva further admits that it sent a letter to Plaintiff dated June 2, 2020 regarding ANDA No. 214137, and disclosed that ANDA No. 214137 contains Paragraph IV certifications for the '581 and '891 patents. Teva further admits that it sent a letter to Plaintiff dated August 5, 2020 regarding ANDA No. 214137, and disclosed that ANDA No. 214137 contains Paragraph IV certifications for the '082 patent. Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Upon information and belief, Teva admits that the '091, '382, '630, '708, '072, '581, '891, and '082 patents, among others, are listed in the Orange Book for Imvexxy®. Teva denies the remaining allegations of this paragraph.

30. TherapeuticsMD filed a complaint against Teva USA and Teva Ltd. in this Court on April 1, 2020 alleging infringement of United States Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072. TherapeuticsMD, Inc. v. Teva USA, Inc., C.A. No. 20- 3485 (BRM) (ESK), ECF No. 1. TherapeuticsMD filed a second complaint against Teva USA and Teva Ltd. in this Court on July 13, 2020 alleging infringement of United States Patent Nos. 10,537,581 and 10,568,891. TherapeuticsMD, Inc. v. Teva USA, Inc., C.A. No. 20-8809 (BRM) (ESK), ECF No. 1. TherapeuticsMD filed a third complaint against Teva USA and Teva Ltd. In this Court on August 21, 2020 alleging infringement of United States Patent No. 10,668,082. TherapeuticsMD, Inc. v. Teva USA, Inc., C.A. No. 20-11087 (BRM) (ESK), ECF No. 1. These three actions have been consolidated for all purposes, including trial, under Civil Action No. 20-3485 (consolidated). TherapeuticsMD, Inc. v. Teva USA, Inc., C.A. No. 20-3485 (BRM) (ESK) (consolidated), ECF No. 43.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that TherapeuticsMD filed a complaint against Teva USA on April 1, 2020 in *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al*., Civil Action No. 2:20-cv-03485 (D.N.J.), alleging that Teva USA has infringed and will infringe the '091, '382, '630, '708, and '072 patents by filing ANDA No. 214137 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA. Teva further admits that TherapeuticsMD filed a complaint against Teva USA on July 13, 2020 in

TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al., Civil Action No. 2:20-cv-08809 (D.N.J.), alleging that Teva USA has infringed and will infringe the '581 and '891 patents by filing ANDA No. 214137 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA. Teva further admits that TherapeuticsMD filed a complaint against Teva USA on August 21, 2020 in *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al*., Civil Action No. 2:20-cv-11087 (D.N.J.), alleging that Teva USA has infringed and will infringe the '082 patent by filing ANDA No. 214137 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA. Teva admits that *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al*., Civil Action No. 2:20-cv-03485 (D.N.J.); *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al*., Civil Action No. 2:20-cv-08809 (D.N.J.); and *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al*., Civil Action No. 2:20-cv-11087 (D.N.J.) have been consolidated for all purposes, including discovery, case management, and trial, subject to further order of the Court, under Civil Action No. 2:20-cv-03485 (D.N.J.). Teva denies the remaining allegations of this paragraph.

31. Teva USA sent Teva's Notice Letters to TherapeuticsMD, purportedly pursuant to § 505(j)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations, regarding ANDA No. 214137.

ANSWER: Teva admits that Teva USA sent Notice Letters to Plaintiff dated February 18, 2020; June 2, 2020; and August 5, 2020 regarding ANDA No. 214137, pursuant to § 505(j)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations.

32. Teva's Notice Letters state that Teva USA's ANDA has been submitted under § 505(j) of the FDCA, with paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of Estradiol Vaginal Insert 4 mcg and 10 mcg, before the expiration of United States Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; and 10,668,082. United States Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; and 10,668,082 are eight (8) of the ten (10) patents listed in FDA's Orange Book as covering Imvexxy®.

ANSWER: Teva admits the allegations in this paragraph.

33. Upon information and belief, Teva USA's ANDA was submitted under § 505(j)(2) of the FDCA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that United States Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; and 10,668,082 are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Defendants' ANDA Product.

ANSWER: Teva admits the allegations in this paragraph.

34. Upon information and belief, the proposed prescribing information for Defendants' ANDA Product includes a header titled, "Indications and Usage," and states that Defendants' ANDA Product is for treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

ANSWER: Teva admits that the proposed prescribing information for Teva's Proposed Products includes a header titled "Indications and Usage" and provides some description of the indications and usage of Teva's Proposed Products. Teva denies the remaining allegations of this paragraph.

35. Upon information and belief, the proposed prescribing information for Defendants' ANDA Product includes a header titled, "Dosage and Administration," and states that Defendants' ANDA Product should be administered intvaginally; insert with the smaller end up for a depth of about two inches into the vaginal canal. Insert 1 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). Generally, women should be started at the 4 mcg dosage strength. Dosage adjustment should be guided by the clinical response.

ANSWER: Teva admits that the proposed prescribing information for Teva's Proposed Products includes a header titled "Dosage and Administration" and provides some description of the dosage and administration of Teva's Proposed Products. Teva denies the remaining allegations of this paragraph.

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

ANSWER: Teva admits that the proposed prescribing information for Teva's Proposed Products includes a header titled "Description" and provides some description of the composition of Teva's Proposed Products. Teva denies the remaining allegations of this paragraph.

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

ANSWER: Teva admits that the proposed prescribing information for Teva USA's ANDA No. 214137 includes an indication for the treatment for moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. Teva denies the remaining allegations in this paragraph.

38. 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 inventors.

ANSWER: Teva admits that the '697 patent, entitled "Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods," was issued by the USPTO on October 20, 2020. Teva admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the '697 patent. Teva denies that the '697 patent was duly and legally issued. Teva denies any remaining allegations in this paragraph.

39. Pursuant to 21 U.S.C. § 355(b)(1), 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®.

ANSWER: Teva admits that the '697 patent is listed in the Orange Book for Imvexxy®. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

40. The expiration date of the '697 Patent is November 21, 2032.

ANSWER: Teva admits that the Orange Book lists the patent expiration for the '697 patent as November 21, 2032.

41. 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 inventors.

ANSWER: Teva admits that the ’487 patent, entitled “Vaginal Inserted Estradiol Pharmaceutical Compositions and Methods,” was issued by the USPTO on November 17, 2020. Teva admits that TherapeuticsMD, Inc. is listed as the assignee on the face of the ’487 patent. Teva denies that the ’487 patent was duly and legally issued. Teva denies any remaining allegations in this paragraph.

42. 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®.

ANSWER: Teva admits that the ’487 patent is listed in the Orange Book for Imvexxy®. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

43. The expiration date of the ’487 Patent is November 21, 2032.

ANSWER: Teva admits that the Orange Book lists the patent expiration for the ’487 patent as November 21, 2032. Teva denies any remaining allegations in this paragraph.

44. As of the date of this Complaint, Teva USA had not yet sent a letter to TherapeuticsMD stating that Teva USA’s ANDA contains a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the ’697 and ’487 patents listed in FDA’s Orange Book as covering Imvexxy®.

ANSWER: Teva admits that as of November 30, 2020, Teva USA had not yet sent a Notice Letter to Plaintiff regarding ANDA No. 214137, disclosing that ANDA No. 214137 contains Paragraph IV certifications to the ’697 and ’487 patents. Teva denies any remaining allegations in this paragraph.

45. Upon information and belief, Teva USA, at the direction and control of Teva Ltd., will submit ANDA No. 214137 with paragraph IV certifications to the ’697 and ’487 patents 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 and '487 patents.

ANSWER: Teva admits that Teva USA has submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

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

ANSWER: Teva incorporates by reference its responses to paragraphs 1-45 as if fully set forth herein.

47. Upon information and belief, Teva USA, purportedly at the direction and control of Teva Ltd., prepared ANDA No. 214137.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

48. Upon information and belief, Teva Ltd. provided material and significant support to Teva USA in the preparation of ANDA No. 214137.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

49. Upon information and belief, Teva USA, purportedly at the direction and control of Teva Ltd., submitted ANDA No. 214137 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 '697 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

50. Upon information and belief, ANDA No. 214137 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, seeking approval to market a generic version of the pharmaceutical product Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg. Teva denies the remaining allegations of this paragraph.

51. Upon information and belief, Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, seeking approval to market a generic version of the pharmaceutical product Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg. Teva denies the remaining allegations of this paragraph.

52. Under 35 U.S.C. § 271(e)(2)(A), Teva USA's submission of ANDA No. 214137 (at the direction and control of Teva Ltd.) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '697 patent is an act of infringement of the '697 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that an answer is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

53. Upon information and belief, Teva USA and Teva Ltd. 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. 214137 ever receives final FDA approval.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the

extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies that Plaintiff is entitled to any relief whatsoever. Teva denies the remaining allegations of this paragraph.

57. The acts of infringement set forth above will cause TherapeuticsMD irreparable harm for which there is no adequate remedy at law, unless Teva USA and Teva Ltd. are preliminarily and permanently enjoined by this Court.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

58. Upon information and belief, Defendants have made, and will continue to make, substantial preparations in the United States to manufacture, use, sell, offer to sell, and/or import Defendants' ANDA Product prior to the expiration of the '697 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the

extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

59. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of, Defendants' ANDA Product upon receipt of final FDA approval of ANDA No. 214137.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

60. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiff and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of, Defendants' ANDA Product according to ANDA No. 214137 will infringe one or more claims of the '697 patent under 35 U.S.C. § 271(a). Plaintiff thus is entitled to a declaration that the making, using, sale, offer for sale, and importation into the United States of Defendants' ANDA Product according to ANDA No. 214137 will infringe one or more claims of the '697 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

61. TherapeuticsMD repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Teva incorporates by reference its responses to paragraphs 1-60 as if fully set forth herein.

62. Upon information and belief, Teva USA, purportedly at the direction and control of Teva Ltd., prepared ANDA No. 214137.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

63. Upon information and belief, Teva Ltd. provided material and significant support to Teva USA in the preparation of ANDA No. 214137.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

64. Upon information and belief, Teva USA, purportedly at the direction and control of Teva Ltd., submitted ANDA No. 214137 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 '487 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the

allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

65. Upon information and belief, ANDA No. 214137 is based upon Imvexxy® (estradiol vaginal inserts), 4 mcg and 10 mcg, as its reference listed drug.

ANSWER: Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, seeking approval to market a generic version of the pharmaceutical product Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg. Teva denies the remaining allegations of this paragraph.

66. Upon information and belief, Defendants' ANDA Product is Estradiol Vaginal Insert, 4 mcg and 10 mcg.

ANSWER: Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, seeking approval to market a generic version of the pharmaceutical product Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg. Teva denies the remaining allegations of this paragraph.

67. Under 35 U.S.C. § 271(e)(2)(A), Teva USA's, submission of ANDA No. 214137 (at the direction and control of Teva Ltd.) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '487 patent is an act of infringement of the '697 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that an answer is required, Teva admits that Teva USA submitted ANDA No. 214137 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of the product that is the subject of ANDA No. 214137. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

68. Upon information and belief, Teva USA and Teva Ltd. 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. 214137 ever receives final FDA approval.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies that Plaintiff is entitled to any relief whatsoever. Teva denies the remaining allegations of this paragraph.

72. The acts of infringement set forth above will cause TherapeuticsMD irreparable harm for which there is no adequate remedy at law, unless Teva USA and Teva Ltd. are preliminarily and permanently enjoined by this Court.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

73. Upon information and belief, Defendants have made, and will continue to make, substantial preparations in the United States to manufacture, use, sell, offer to sell, and/or import Defendants' ANDA Product prior to the expiration of the '487 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

74. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Defendants' ANDA Product upon receipt of final FDA approval of ANDA No. 214137.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

75. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiff and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States, of Defendants' ANDA Product according to ANDA No. 214137 will infringe one or more claims of the '487 patent under 35 U.S.C. § 271(a). Plaintiff thus is entitled to a declaration that the making, using, sale, offer for sale, and importation into the United States of Defendants' ANDA Product according to ANDA No. 214137 will infringe one or more claims of the '487 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further answering, Teva denies that Teva Ltd. is a "Defendant" to this action. To the

extent the allegations in this paragraph are directed toward Teva Ltd., no response is required. Teva denies the remaining allegations of this paragraph.

PRAYER FOR RELIEF

The remainder of Plaintiff's Complaint is a prayer for relief, and does not require a response. To the extent any response is required, Teva denies that Plaintiff is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Teva hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Teva reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

First Affirmative Defense

The filing of Teva USA's ANDA has not infringed and does not infringe any valid and enforceable claim of U.S. Patent No. 10,806,697 ("the '697 patent") and U.S. Patent No. 10,835,487 ("the '487 patent") either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Affirmative Defense

The manufacture, use, sale, or offer for sale of Teva USA's proposed ANDA Product that is the subject of Teva USA's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claims of the '697 patent and the '487 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

Third Affirmative Defense

Claims of the '697 patent and the '487 patent are invalid under one or more provisions of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Fourth Affirmative Defense

The complaint fails to state a claim upon which relief can be granted.

Fifth Affirmative Defense

Teva's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

Teva has not willfully infringed any claim of the '697 or '487 patents.

Seventh Affirmative Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Plaintiff/Counterclaim-Defendant TherapeuticsMD, Inc ("TherapeuticsMD"), Defendant/Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA") states as follows:

PARTIES

1. Teva Pharmaceuticals USA, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. TherapeuticsMD, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33487.

JURISDICTION AND VENUE

3. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. These counterclaims arise under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant TherapeuticsMD, Inc. because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its Complaint here.

6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

7. There is an actual and justiciable controversy between the parties as to the infringement of U.S. Patent No. 10,806,697 ("the '697 patent") and U.S. Patent No. 10,835,487 ("the '487 patent").

FACTUAL BACKGROUND

A. FDA Approval of New Brand Name Drugs.

8. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

9. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

10. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

11. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

12. The FDA's duties with respect to the Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs.

13. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. See Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

14. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

15. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

16. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval

of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

17. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

18. Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

19. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

20. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. Teva USA's ANDA

21. Teva USA submitted its ANDA No. 214137 ("Teva USA's ANDA") seeking approval to engage in the commercial use, sale, offer for sale or importation into the United States of Estradiol Vaginal Insert 4 mcg and 10 mcg ("Teva USA's Proposed Products") before, *inter alia*, the expiration of the '697 and '487 patents.

22. On information and belief, FDA lists TherapeuticsMD as the holder of New Drug Application ("NDA") No. 208564.

23. On information and belief, NDA No. 208564 covers TherapeuticsMD's Imvexxy®.

24. On information and belief, TherapeuticsMD lists the '697 and '487 patents in the Orange Book in connection with NDA No. 208564.

25. TherapeuticsMD filed a complaint against Teva USA on November 30, 2020 in *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 2:20-cv-17496-BRM-ESK (D.N.J.), alleging that Teva USA has infringed and will infringe the '697 and '487 patents by filing ANDA No. 214137 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA.

26. As a consequence of the foregoing, there is an actual and justiciable controversy between Teva USA, on the one hand, and TherapeuticsMD, on the other hand, as to whether the claims of the '697 and '487 patents are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by Teva USA's ANDA No. 214137, or by the manufacture, use, or sale of the products described therein.

COUNT I
(Declaration of Noninfringement of the '697 Patent)

27. Teva USA re-alleges and incorporates the allegations of paragraphs 1-26 as if fully set forth herein.

28. TherapeuticsMD alleges ownership, title, and/or interest to the '697 patent and has brought claims against Teva USA alleging infringement of the '697 patent.

29. The manufacture, use, or sale of Teva USA's Proposed Products would not infringe any valid or enforceable claim of the '697 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

30. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and TherapeuticsMD, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva USA's Proposed Products would infringe any valid or enforceable claim of the '697 patent.

31. Teva USA is entitled to a declaration that the manufacture, use, or sale of Teva USA's Proposed Products would not infringe any valid or enforceable claim of the '697 patent.

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

COUNT II
(Declaration of Invalidity of the '697 Patent)

33. Teva USA re-alleges and incorporates the allegations of paragraphs 1-32 as if fully set forth herein.

34. TherapeuticsMD alleges ownership, title, and/or interest to the '697 patent and has brought claims against Teva USA alleging infringement of the '697 patent.

35. One or more of the claims of the '697 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

36. A present, genuine, and justiciable controversy exists between Teva USA and TherapeuticsMD regarding, *inter alia*, the validity of claims of the '697 patent.

37. Teva USA is entitled to a declaration that claims of the '697 patent are invalid.

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

COUNT III
(Declaration of Noninfringement of the '487 Patent)

39. Teva USA re-alleges and incorporates the allegations of paragraphs 1-38 as if fully set forth herein.

40. TherapeuticsMD alleges ownership, title, and/or interest to the '487 patent and has brought claims against Teva USA alleging infringement of the '487 patent.

41. The manufacture, use, or sale of Teva USA's Proposed Products would not infringe any valid or enforceable claim of the '487 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

42. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and TherapeuticsMD, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva USA's Proposed Products would infringe any valid or enforceable claim of the '487 patent.

43. Teva USA is entitled to a declaration that the manufacture, use, or sale of Teva USA's Proposed Products would not infringe any valid or enforceable claim of the '487 patent.

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

COUNT IV
(Declaration of Invalidity of the '487 Patent)

45. Teva USA re-alleges and incorporates the allegations of paragraphs 1-44 as if fully set forth herein.

46. TherapeuticsMD alleges ownership, title, and/or interest to the '487 patent and has brought claims against Teva USA alleging infringement of the '487 patent.

47. One or more of the claims of the '487 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

48. A present, genuine, and justiciable controversy exists between Teva USA and TherapeuticsMD regarding, *inter alia*, the validity of claims of the '487 patent.

49. Teva USA is entitled to a declaration that claims of the '487 patent are invalid.

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

PRAYER FOR RELIEF

WHEREFORE, Teva Pharmaceuticals USA, Inc. ("Teva USA") respectfully requests that this Court enter a Judgment and Order in its favor and against TherapeuticsMD as follows:

1. declaring that Teva USA has not infringed any valid and enforceable claim of U.S. Patent No. 10,806,697;

2. declaring that the claims of U.S. Patent No. 10,806,697 are invalid;

3. declaring that Teva USA has not infringed any valid and enforceable claim of U.S. Patent No. 10,835,487;

4. declaring that the claims of U.S. Patent No. 10,835,487 are invalid;

5. declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 and awarding Teva USA its costs, expenses, and reasonable attorneys' fees in this action; and

6. awarding Teva USA any further and additional relief as the Court deems just and proper.

Dated: December 21, 2020

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding, with the exception of the following action:

- *TherapeuticsMD, Inc. v. Amneal Pharmaceuticals, Inc. et al.*, Civil Action No. 3:20-cv-05256-FLW-TJB (involving U.S. Patent No. 8,633,178, U.S. Patent No. 8,846,648, U.S. Patent No. 8,846,649, U.S. Patent No. 8,987,237, U.S. Patent No. 8,993,548, U.S. Patent No. 8,993,549, U.S. Patent No. 9,006,222, U.S. Patent No. 9,114,145, U.S. Patent No. 9,114,146, U.S. Patent No. 9,301,920, U.S. Patent No. 10,052,386, U.S. Patent No. 10,206,932, U.S. Patent No. 10,639,375, and U.S. Patent No. 10,675,288).

Dated: December 21, 2020

By: *s/ Liza M. Walsh*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Teva Pharmaceuticals USA, Inc., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: December 21, 2020

By: *s/ Liza M. Walsh*

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