

William C. Baton  
Sarah A. Sullivan  
**SAUL EWING ARNSTEIN & LEHR LLP**  
One Riverfront Plaza  
1037 Raymond Blvd., Suite 1520  
Newark, NJ 07102  
wbaton@saul.com

*Attorneys for Plaintiff  
TherapeuticsMD, Inc.*

OF COUNSEL:

Edgar H. Haug  
Nicholas Giove  
Anna N. Lukacher  
**HAUG PARTNERS LLP**  
745 Fifth Avenue  
New York, NY 10151

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

THERAPEUTICSMD, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.  
and TEVA PHARMACEUTICAL  
INDUSTRIES LIMITED,

Defendants.

Civil Action No. \_\_\_\_\_

(Filed Electronically)

**COMPLAINT**

Plaintiff TherapeuticsMD, Inc. (“TherapeuticsMD” or “Plaintiff”), by its undersigned attorneys, for its Complaint against defendants Teva Pharmaceuticals USA, Inc. (“Teva USA”) and Teva Pharmaceutical Industries Limited (“Teva Ltd.”) (collectively, “Teva” or “Defendants”), alleges:

**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. 9,180,091 (“the ’091 patent”) (attached as Exhibit A), U.S. Patent No. 9,289,382 (“the ’382 patent”) (attached as

Exhibit B), U.S. Patent No. 10,258,630 (“the ’630 patent”) (attached as Exhibit C), U.S. Patent No. 10,398,708 (“the ’708 patent”) (attached as Exhibit D), and U.S. Patent No. 10,471,072 (“the ’072 patent”) (attached as Exhibit E) (collectively, the “patents-in-suit”).

### **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.

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<sup>®</sup> (estradiol vaginal inserts) 4 mcg and 10 mcg.

4. TherapeuticsMD, Inc. is the current owner and assignee of each of the seven (7) 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<sup>®</sup>, of which five (5) are the patents-in-suit.

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.

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.

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.

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.

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.

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.

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.

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.

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.

#### **JURISDICTION AND VENUE**

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

15. 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<sup>1</sup>; and (vi) Teva USA's February 18, 2020 notice of paragraph IV certification ("Notice Letter") identified the correspondence address for Teva USA's offer of confidential access as 400 Interpace Parkway, Parsippany, NJ 07054.

16. 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.

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<sup>1</sup> 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. Synthron 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).

17. In its Notice Letter, 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 the ’091, ’382, ’630, ’708, and ’072 patents throughout the United States, including in this Judicial District.

18. 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.

19. 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 ’091, ’382, ’630, ’708, and ’072 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.

20. 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.

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

### **FACTS COMMON TO ALL COUNTS**

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

23. Because TherapeuticsMD conducted efficacy clinical trials to secure FDA approval of Imvexxy<sup>®</sup>, FDA granted Imvexxy<sup>®</sup> three years of regulatory exclusivity.

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

25. NDA No. 208564 pertains to Imvexxy<sup>®</sup> 4 mcg and 10 mcg.

26. Imvexxy<sup>®</sup>'s recommended dosage is one vaginal insert daily for two weeks, followed by one insert twice weekly.

27. FDA's Orange Book lists seven (7) patents as covering TherapeuticsMD's Imvexxy<sup>®</sup>. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), these seven (7) patents were submitted to FDA with or after the approval of NDA No. 208564. These seven (7) patents are listed in the Orange Book as covering Imvexxy<sup>®</sup>.

28. Teva USA sent a letter to TherapeuticsMD dated February 18, 2020 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 (the “Notice Letter”).

29. The Notice Letter 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 the ’091, ’382, ’630, ’708, and ’072 patents. The ’091, ’382, ’630, ’708, and ’072 patents are five (5) of the seven (7) patents listed in FDA’s Orange Book as covering Imvexxy®.

30. Upon information and belief, Teva USA’s ANDA was submitted under § 505(j)(2) of the FDCA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’091, ’382, ’630, ’708, and ’072 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Defendants’ ANDA Product.

31. 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.

32. 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 intravaginally; 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.

33. 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.

34. 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.

35. 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 inventors.

36. 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®.

37. 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 inventors.

38. 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®.

39. 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 inventors.

40. 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®.

41. 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 inventors.

42. 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®.

43. 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 inventors.

44. 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®.

45. The Notice Letter does not state that Teva's ANDA contains a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for U.S. Patent No. 10,537,581 ("the '581 patent"), which is listed in FDA's Orange Book as covering Imvexxy®.

46. Teva USA did not send 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 '581 patent listed in FDA's Orange Book as covering Imvexxy®.

47. The '581 patent was listed in FDA's Orange Book as covering Imvexxy® as of February 13, 2020.

48. Upon information and belief, Teva was aware of the '581 patent before it sent its Notice Letter on February 18, 2020.

49. Upon information and belief, Teva was aware that the '581 patent was listed in the Orange Book as covering Imvexxy® before it sent its Notice Letter on February 18, 2020.

50. Upon information and belief, Teva USA's ANDA does not contain a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '581 patent.

51. Upon information and belief, Teva USA is not seeking final FDA approval of Teva USA's ANDA before the patent expiration of the '581 patent. As indicated in FDA's Orange Book, the patent expiration for the '581 patent is November 21, 2032.

52. The Notice Letter does not state that Teva's ANDA contains a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for U.S. Patent No. 10,568,891 ("the '891 patent"), which is listed in FDA's Orange Book as covering Imvexxy®.

53. Teva USA did not send 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 '891 patent listed in FDA's Orange Book as covering Imvexxy®.

54. Upon information and belief, Teva USA's ANDA does not contain a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '891 patent.

55. Upon information and belief, Teva USA is not seeking final FDA approval of Teva USA's ANDA before the patent expiration of the '891 patent. As indicated in FDA's Orange Book, the patent expiration for the '891 patent is June 18, 2033.

56. The Notice Letter does not include any invalidity contentions with respect to any claims of the '091 patent.

57. Other than asserting that "one cannot infringe an invalid patent," the Notice Letter does not include any additional noninfringement contentions with respect to any claims of the '382, '630, '708, and '072 patents.

58. 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)

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

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

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

62. 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 patents-in-suit.

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

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

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

66. 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." Likewise, 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 ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

67. Upon information and belief, as of the date of Notice Letter, Teva USA and Teva Ltd. 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).

68. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Teva USA sent a copy of the Notice Letter to TherapeuticsMD, Inc. at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431.

69. Under 35 U.S.C. § 271(e)(2)(A), Teva USA's, purportedly at the direction and control of Teva Ltd., submission of ANDA No. 214137 with a paragraph IV certification to the '091 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '091 patent is an act of infringement of the '091 patent.

70. 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.

71. 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 '091 patent's claims under 35 U.S.C. § 271.

72. 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 '091 patent under 35 U.S.C. § 271.

73. Upon information and belief, the factual and legal bases in the Notice Letter regarding the '091 patent do not establish good-faith bases to comply with 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).

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

75. 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.

**SECOND COUNT**  
(Defendants' Infringement of the '382 Patent)

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

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

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

79. 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 patents-in-suit.

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

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

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

83. 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.” Likewise, 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 ground supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

84. Upon information and belief, as of the date of Notice Letter, Teva USA and Teva Ltd. 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).

85. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Teva USA sent a copy of the Notice Letter to TherapeuticsMD, Inc. at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431.

86. Under 35 U.S.C. § 271(e)(2)(A), Teva USA’s, purportedly at the direction and control of Teva Ltd., submission of ANDA No. 214137 with a paragraph IV certification to the ’382 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants’ ANDA Product before the expiration of the ’382 patent is an act of infringement of the ’382 patent.

87. 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.

88. 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 '382 patent's claims under 35 U.S.C. § 271.

89. 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 '382 patent under 35 U.S.C. § 271.

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

91. 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.

### **THIRD COUNT**

(Defendants' Infringement of the '630 Patent)

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

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

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

95. 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 patents-in-suit.

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

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

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

99. 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." Likewise, 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 ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

100. Upon information and belief, as of the date of Notice Letter, Teva USA and Teva Ltd. 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).

101. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Teva USA sent a copy of the Notice Letter to TherapeuticsMD, Inc. at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431.

102. Under 35 U.S.C. § 271(e)(2)(A), Teva USA's, purportedly at the direction and control of Teva Ltd., submission of ANDA No. 214137 with a paragraph IV certification to the '630 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '630 patent is an act of infringement of the '630 patent.

103. 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.

104. 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 '630 patent's claims under 35 U.S.C. § 271.

105. 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 '630 patent under 35 U.S.C. § 271.

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

107. 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.

**FOURTH COUNT**  
(Defendants' Infringement of the '708 Patent)

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

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

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

111. 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 patents-in-suit.

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

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

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

115. 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.” Likewise, 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 ground supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

116. Upon information and belief, as of the date of Notice Letter, Teva USA and Teva Ltd. 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).

117. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Teva USA sent a copy of the Notice Letter to TherapeuticsMD, Inc. at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431.

118. Under 35 U.S.C. § 271(e)(2)(A), Teva USA’s, purportedly at the direction and control of Teva Ltd., submission of ANDA No. 214137 with a paragraph IV certification to the ’708 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants’ ANDA Product before the expiration of the ’708 patent is an act of infringement of the ’708 patent.

119. 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.

120. 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 '708 patent's claims under 35 U.S.C. § 271.

121. 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 '708 patent under 35 U.S.C. § 271.

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

123. 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.

#### **FIFTH COUNT**

(Defendants' Infringement of the '072 Patent)

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

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

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

127. 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 patents-in-suit.

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

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

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

131. 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." Likewise, 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 ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

132. Upon information and belief, as of the date of Notice Letter, Teva USA and Teva Ltd. 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).

133. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Teva USA sent a copy of the Notice Letter to TherapeuticsMD, Inc. at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431.

134. Under 35 U.S.C. § 271(e)(2)(A), Teva USA's, purportedly at the direction and control of Teva Ltd., submission of ANDA No. 214137 with a paragraph IV certification to the '072 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '072 patent is an act of infringement of the '072 patent.

135. 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.

136. 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 '072 patent's claims under 35 U.S.C. § 271.

137. 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 '072 patent under 35 U.S.C. § 271.

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

139. 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.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

- A. A judgment declaring that the '091 patent is valid and enforceable;
- B. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '091 patent by submitting to FDA ANDA No. 214137 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '091 patent;
- 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 '091 patent (including any regulatory extension) would directly and/or indirectly infringe the '091 patent;
- 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. 214137 shall be no earlier than the date on which the '091 patent expires (including any regulatory extension);
- E. An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person 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 '091 patent (including any regulatory extension);

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding TherapeuticsMD 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. 214137, prior to the expiration of the '091 patent (including any regulatory extension);

G. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '091 patent is willful and awarding TherapeuticsMD 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. 214137, prior to the expiration of the '091 patent (including any regulatory extension);

H. A judgment declaring that the '382 patent is valid and enforceable;

I. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '382 patent by submitting to FDA ANDA No. 214137 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '382 patent;

J. 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 '382 patent (including any regulatory extension) would directly and/or indirectly infringe the '382 patent;

K. 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. 214137 shall be no earlier than the date on which the '382 patent expires (including any regulatory extension);

L. An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person 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 '382 patent (including any regulatory extension);

M. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding TherapeuticsMD 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. 214137, prior to the expiration of the '382 patent (including any regulatory extension);

N. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '382 patent is willful and awarding TherapeuticsMD 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. 214137, prior to the expiration of the '382 patent (including any regulatory extension);

O. A judgment declaring that the '630 patent is valid and enforceable;

P. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '630 patent by submitting to FDA ANDA No. 214137 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '630 patent;

Q. 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 '630 patent (including any regulatory extension) would directly and/or indirectly infringe the '630 patent;

R. 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. 214137 shall be no earlier than the date on which the '630 patent expires (including any regulatory extension);

S. An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person 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 '630 patent (including any regulatory extension);

T. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding TherapeuticsMD 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. 214137, prior to the expiration of the '630 patent (including any regulatory extension);

U. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '630 patent is willful and awarding TherapeuticsMD 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. 214137, prior to the expiration of the '630 patent (including any regulatory extension);

V. A judgment declaring that the '708 patent is valid and enforceable;

W. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '708 patent by submitting to FDA ANDA No. 214137 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '708 patent;

X. 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 '708 patent (including any regulatory extension) would directly and/or indirectly infringe the '708 patent;

Y. 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. 214137 shall be no earlier than the date on which the '708 patent expires (including any regulatory extension);

Z. An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person 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 '708 patent (including any regulatory extension);

AA. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding TherapeuticsMD 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. 214137, prior to the expiration of the '708 patent (including any regulatory extension);

BB. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '708 patent is willful and awarding TherapeuticsMD 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. 214137, prior to the expiration of the '708 patent (including any regulatory extension);

CC. A judgment declaring that the '072 patent is valid and enforceable;

DD. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '072 patent by submitting to FDA ANDA No. 214137 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Defendants' ANDA Product before the expiration of the '072 patent;

EE. 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 '072 patent (including any regulatory extension) would directly and/or indirectly infringe the '072 patent;

FF. 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. 214137 shall be no earlier than the date on which the '072 patent expires (including any regulatory extension);

GG. An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person 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 '072 patent (including any regulatory extension);

HH. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding TherapeuticsMD 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. 214137, prior to the expiration of the '072 patent (including any regulatory extension);

II. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '072 patent is willful and awarding TherapeuticsMD 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. 214137, prior to the expiration of the '072 patent (including any regulatory extension);

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

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

Dated: April 1, 2020

OF COUNSEL:

Edgar H. Haug

Nicholas Giove

Anna N. Lukacher

**HAUG PARTNERS LLP**

745 Fifth Avenue

New York, NY 10151

Respectfully submitted,

By: s/ William C. Baton

William C. Baton

Sarah A. Sullivan

**SAUL EWING ARNSTEIN & LEHR LLP**

One Riverfront Plaza

1037 Raymond Blvd., Suite 1520

Newark, NJ 07102

wbaton@saul.com

*Attorneys for Plaintiff*

*TherapeuticsMD, Inc.*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1**

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

Dated: April 1, 2020

Respectfully submitted,

OF COUNSEL:  
Edgar H. Haug  
Nicholas Giove  
Anna N. Lukacher  
**HAUG PARTNERS LLP**  
745 Fifth Avenue  
New York, NY 10151

By: s/ William C. Baton  
William C. Baton  
Sarah A. Sullivan  
**SAUL EWING ARNSTEIN & LEHR LLP**  
One Riverfront Plaza  
1037 Raymond Blvd., Suite 1520  
Newark, NJ 07102  
wbaton@saul.com

*Attorneys for Plaintiff  
TherapeuticsMD, Inc.*