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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THERAPEUTICSMD, INC. and MAYNE PHARMA LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 20-3485 (BRM)(SDA) (consolidated) **Filed Electronically**

PLAINTIFFS' ANSWER TO DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S COUNTERCLAIMS (C.A. No. 21-12794)

Plaintiffs TherapeuticsMD, Inc. ("TherapeuticsMD") and Mayne Pharma LLC ("Mayne," and together with TherapeuticsMD, "Plaintiffs"), by and through their undersigned attorneys, hereby answer the Counterclaims of Defendant Teva Pharmaceuticals USA, Inc. ("Defendant") filed in Civil Action No. 21-12794 on January 7, 2025 (ECF No. 152, Civil Action No. 20-3485):

PARTIES

1. Teva USA 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.

ANSWER: Upon information and belief, admitted.

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: Admitted.

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

ANSWER: Admitted.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 4 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that Defendant's counterclaims purport to arise under the Declaratory Judgment Act. Plaintiffs deny the remaining allegations of paragraph 4.

5. 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).

ANSWER: Paragraph 5 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that this Court has subject matter jurisdiction over Defendant's counterclaims, but deny that the counterclaims are valid or sustainable. Plaintiffs deny the remaining allegations of paragraph 5.

6. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants TherapeuticsMD, Inc. and Mayne Pharma LLC because, among other reasons, it

subjected itself to the jurisdiction of this Court by filing its Complaint here.

ANSWER: Paragraph 6 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs do not contest personal jurisdiction for the purpose of this case only. Plaintiffs deny the remaining allegations in paragraph 6.

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

ANSWER: Paragraph 7 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that venue is proper in this District for the purpose of this case only. Plaintiffs deny the remaining allegations of paragraph 7.

8. There is an actual and justiciable controversy between the parties as to the infringement of U.S. Patent No. 10,888,516 ("the '516 patent" or "patent-in-suit").

ANSWER: Paragraph 8 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that a justiciable controversy presently exists between Plaintiffs and Teva USA concerning Teva USA's infringement of the '516 patent and concerning the validity of the '516 patent. Plaintiffs deny the remaining allegations of paragraph 8.

FACTUAL BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. 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.

ANSWER: Paragraph 9 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that the Federal Food, Drug,

and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, sets forth rules that the FDA follows. Plaintiffs deny the remaining allegations of paragraph 9.

10. 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.

ANSWER: Paragraph 10 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. § 355 provides, among other things, that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." Plaintiffs deny the remaining allegations of paragraph 10.

11. 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).

ANSWER: Paragraph 11 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. §355(b)(1), (c)(2) and 21 C.F.R. § 314.53(b)(1), (c)(2) set forth, among other things, certain requirements for filing an NDA. Plaintiffs deny the remaining allegations of paragraph 11.

12. 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).

ANSWER: Paragraph 12 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 C.F.R. § 314.53(e)

provides that "FDA will publish in the list the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant, and for each method-of-use patent, the description of the method of use claimed by the patent as required by 314.53(c)(2)(ii)(P)(3)." Plaintiffs deny the remaining allegations of paragraph 12.

13. 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.

ANSWER: Paragraph 13 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. § 355(b)(1) provides that "[t]he applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences." Plaintiffs deny the remaining allegations in paragraph 13.

B. FDA Approval of New Generic Drugs

14. 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.

ANSWER: Paragraph 14 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit only that "[i]n 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA." Plaintiffs lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, deny them.

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

ANSWER: Paragraph 15 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that a generic manufacturer may submit an ANDA to FDA under 21 U.S.C. § 355. Plaintiffs deny the remaining allegations in paragraph 15.

16. 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).

ANSWER: Paragraph 16 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. § 355(j)(2) provides, among other things, that "[a]n abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each

patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Plaintiffs deny the remaining allegations in paragraph 16.

17. 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).

ANSWER: Paragraph 17 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. § 355(j)(2) provides, among other things, that "[a]n abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Plaintiffs deny the remaining allegations in paragraph 17.

18. 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).

ANSWER: Paragraph 18 states one or more legal conclusions to which no response is

required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. § 355(j)(2)(B) provides, among other things, that "[a]n applicant required under this subparagraph to give notice shall give notice to—(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and (II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice)." Plaintiffs deny the remaining allegations in paragraph 18.

19. 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).

ANSWER: Paragraph 19 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. § 355(j)(5)(B)(iii) provides, among other things, that "[i]f the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action." Plaintiffs deny the remaining allegations in paragraph 19.

20. 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).

ANSWER: Plaintiffs lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, deny them.

21. 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.*

ANSWER: Paragraph 21 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that 21 U.S.C. § 355(j)(5)(B)(iii) provides, among other things, that "(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on— (aa) the date on which the court enters judgment reflecting the decision; or (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed; (II) if before the expiration of such period the district court decides that the patent has been infringed— (aa) if the judgment of the district court is appealed, the approval shall be made effective on— (AA) the date on which the court of appeals decides that the patent is invalid or not infringed

(including any substantive determination that there is no cause of action for patent infringement or invalidity); or (BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or (bb)if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35; (III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or (IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).” Plaintiffs deny the remaining allegations in paragraph 21.

C. Teva USA’s ANDA

22. 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 ’516 patent.

ANSWER: Upon information and belief, admitted.

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

ANSWER: Admitted that in December 2022, TherapeuticsMD completed transactions with Mayne pursuant to which: (i) TherapeuticsMD granted Mayne an exclusive, sublicensable,

perpetual, irrevocable license to the Patents-in-Suit; and (ii) transferred to Mayne ownership of New Drug Application ("NDA") No. 208564, which was approved by the U.S. Food and Drug Administration ("FDA") for the manufacture and sale of Imvexxy® (estradiol vaginal inserts) 4 mcg and 10 mcg.

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

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

25. On information and belief, TherapeuticsMD submitted the '516 patent for listing in the Orange Book in connection with NDA No. 208564.

ANSWER: Plaintiffs admit that the FDA's "Orange Book" lists the '516 patent as covering Imvexxy®. Plaintiffs further state that the FDA's "Orange Book" lists U.S. Patent Nos. 9,180,091, 9,289,382, 10,258,630, 10,398,708, 10,471,072, 10,537,581, 10,568,891, 10,668,082, 10,806,697, 10,835,487, 10,888,516, 11,065,197, 11,116,717, 11,123,283, 11,241,445, 11,246,875, 11,266,661, 11,304,959, 11,351,182, and 11,497,709 as covering Imvexxy®.

26. Teva USA's ANDA includes a Paragraph IV certification with respect to the '516 patent.

ANSWER: Admitted that Teva USA sent TherapeuticsMD a letter dated May 13, 2021 stating 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 '516 patent. Plaintiffs deny the remaining allegations in paragraph 26.

27. On May 13, 2021, Teva USA sent a Notice Letter ("Teva USA's Notice Letter") to Plaintiff TherapeuticsMD providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '516 patent is not infringed, directly or indirectly, either literally or under the doctrine of equivalents, by the commercial manufacture use, offer for sale, and/or sale of Teva USA's Proposed Products.

ANSWER: Admitted that Teva USA sent TherapeuticsMD a letter dated May 13, 2021 stating 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 '516 patents. Plaintiffs deny that Teva USA's Notice Letter contains a detailed statement of the factual and legal bases for its opinion that the '516 patent is not infringed, directly or indirectly, either literally or under the doctrine of equivalents, by the commercial manufacture, use, offer for sale, and/or sale of Teva USA's Proposed Products. Plaintiffs further deny that the '516 patent would not be infringed by the commercial manufacture, use, offer for sale, and/or sale of Teva USA's Proposed Products. Plaintiffs deny the remaining allegations in paragraph 27.

28. Teva USA's Notice Letter also contained an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) to allow TherapeuticsMD the opportunity to review the relevant portions of Teva USA's ANDA.

ANSWER: Plaintiffs admit that TherapeuticsMD received a letter dated May 13, 2021 that purportedly included an offer of conditional access to Teva USA's ANDA. Plaintiffs deny the remaining allegations in paragraph 28.

29. TherapeuticsMD filed a complaint against Teva USA on June 21, 2021 in

TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc., et al., Civil Action No. 2:21-cv-12794-BRM-SDA (D.N.J.), alleging that Teva USA has infringed and will infringe the '516 patent by filing ANDA No. 214137 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA.

ANSWER: Admitted.

30. On July 13, 2023, the Court added Mayne Pharma LLC ("Mayne") as a plaintiff in Civil Action No. 2:21-cv-12794-BRM-ESK (D.N.J.).

ANSWER: Admitted.

31. As a consequence of the foregoing, there is an actual and justiciable controversy between Teva USA, on the one hand, and TherapeuticsMD and Mayne, on the other hand, as to whether the claims of the '516 patent 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.

ANSWER: Paragraph 31 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that a justiciable controversy presently exists between Plaintiffs and Teva USA concerning Teva USA's infringement of the '516 patent. Aside from baseless invalidity allegations, Teva USA's Notice Letter does not include any noninfringement contentions with respect to the '516 patent. Teva USA's Notice Letter does not include any unenforceability contentions with respect to any claim of any patent. Plaintiffs deny the remaining allegations of paragraph 31.

COUNT I
(Declaration of Noninfringement of the '516 Patent)

32. Teva USA re-alleges and incorporates the allegations of paragraphs 1-31 as if fully set forth herein.

ANSWER: Plaintiffs repeat and incorporate by reference their replies to paragraphs 1-

31 as if fully set forth herein.

33. Plaintiffs allege ownership, title, and/or interest to the '516 patent and has brought claims against Teva USA alleging infringement of the '516 patent.

ANSWER: Admitted.

34. The manufacture, use, or sale of Teva USA's Proposed Products would not infringe any valid or enforceable claim of the '516 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

ANSWER: Denied.

35. On May 13, 2021, Teva USA sent a Notice Letter ("Teva USA's Notice Letter") to Plaintiff TherapeuticsMD providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '516 patent is not infringed, directly or indirectly, either literally or under the doctrine of equivalents, by the commercial manufacture use, offer for sale, and/or sale of Teva USA's Proposed Products.

ANSWER: Admitted that Teva USA sent TherapeuticsMD a letter dated May 13, 2021 stating that Teva USA's ANDA has been submitted under § 505(j) of the FDCA, with a paragraph IV certification, 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 '516 patent. Although Teva USA's Notice Letter states that the '516 patent "will not be infringed by the commercial manufacture, use or sale of the Estradiol product described in Teva's ANDA," Plaintiffs deny that Teva USA's Notice Letter contains a detailed statement of the factual and legal bases for that opinion. Plaintiffs deny the remaining allegations in paragraph 35.

36. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Plaintiffs, 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 ’516 patent.

ANSWER: Paragraph 36 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that a justiciable controversy presently exists between Plaintiffs and Teva USA concerning Teva USA’s infringement of the ’516 patent and the validity of the ’516 patent. Plaintiffs deny the remaining allegations in paragraph 36.

37. 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 ’516 patent.

ANSWER: Denied.

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.

ANSWER: Denied.

COUNT II
(Declaration of Invalidity of the ’516 Patent)

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

ANSWER: Plaintiffs repeat and incorporate by reference their replies to paragraphs 1-38 as if fully set forth herein.

40. Plaintiffs allege ownership, title, and/or interest to the ’516 patent and has brought claims against Teva USA alleging infringement of the ’516 patent.

ANSWER: Admitted.

41. One or more of the claims of the ’516 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

ANSWER: Denied.

42. On May 13, 2021, Teva USA sent a Notice Letter to Plaintiff TherapeuticsMD providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '516 patent is invalid.

ANSWER: Admitted that Teva USA sent TherapeuticsMD a letter dated May 13, 2021 stating that Teva USA's ANDA has been submitted under § 505(j) of the FDCA, with a paragraph IV certification, 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 '516 patent. Although Teva USA's Notice Letter states that the '516 patent "invalid," Plaintiffs deny that Teva USA's Notice Letter contains a detailed statement of the factual and legal bases for that opinion. Plaintiffs deny the remaining allegations in paragraph 42.

43. A present, genuine, and justiciable controversy exists between Teva USA and Plaintiffs regarding, *inter alia*, the validity of claims of the '516 patent.

ANSWER: Paragraph 43 states one or more legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that a justiciable controversy presently exists between Plaintiffs and Teva USA concerning Teva USA's infringement of the '516 patent and the validity of the '516 patent. Plaintiffs deny the remaining allegations in paragraph 43.

44. Teva USA is entitled to a declaration that claims of the '516 patent are invalid.

ANSWER: Denied.

45. 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.

ANSWER: Denied.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that the Court:

i. Enter judgment that Defendant is not entitled to any relief requested in its Counterclaims and dismiss Defendant's Counterclaims with prejudice;

ii. Grant Plaintiffs the relief sought in Plaintiffs' Complaint (ECF No. 1 in Civil Action No. 21-12794);

iii. Award Plaintiffs reasonable attorney fees, costs, and expenses a permitted by law; and

iv. Grant Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: January 28, 2025

By: s/ William C. Baton

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