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Xiromed, LLC

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

MERCK SHARP & DOHME B.V.; N.V. ORGANON; ORGANON USA LLC; and ORGANON LLC, Plaintiffs, v. XIROMED PHARMA ESPAÑA, S.L. and XIROMED, LLC;	Civil Action No. 2:25-2254 (CCC)(LDW) **DEFENDANTS XIROMED PHARMA ESPAÑA, S.L. and XIROMED, LLC's AMENDED ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Xiromed Pharma España, S.L. and Xiromed, LLC (together, "the Xiromed Defendants"[1]), by and through their undersigned counsel, provide the following answers, separate defenses and counterclaims to the Complaint for Patent Infringement ("Complaint") (Civ. No. 25-cv-2254, D.I. 1) filed by Plaintiffs Merck Sharp & Dohme B.V., N.V. Organon, Organon USA LLC, and Organon LLC (collectively "Plaintiffs"). This pleading is based upon the Xiromed Defendants' knowledge as to their own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), the Xiromed Defendants deny all allegations in the Complaint except those admitted specifically below.

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, and 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), arising from Xiromed's submission of an Abbreviated New Drug Application ("ANDA"), No. 217698 ("Xiromed's ANDA"), with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a purported generic version of NEXPLANON® (etonogestrel implant, 68 mg/implant) prior to the expiration of U.S. Patent Nos. 8,722,037 ("the '037 patent") and 9,757,552 ("the '552 patent") (together, "the patents-in-suit"). NEXPLANON® was first approved by FDA in 2011 and is a progestin indicated for use by women to prevent pregnancy.

ANSWER: Xiromed Pharma España, S.L. admits that it submitted ANDA No. 217698 ("Xiromed's ANDA" or the "Xiromed ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of a generic version of NEXPLANON® (etonogestrel implant, 68 mg/implant) ("the ANDA Product") prior to the expiration of the '037 and the '552 patents (together, "the patents-in-suit"). The Xiromed Defendants further admit that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of

[1] The parties entered a stipulation to dismiss Insud Pharma, S.L.U. ("Insud") from this case (ECF No. 13), but the Court has not yet ordered Insud's dismissal.

the United States, 35 U.S.C. § 100 *et. seq.*, but denies that Plaintiffs are entitled to relief. The Xiromed Defendants admit that the FDA's website indicates that NEXPLANON® was approved by the FDA in 2011. The Xiromed Defendants lack information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations set forth in this paragraph, and therefore, deny the same.

PARTIES

2. Plaintiff Merck B.V. is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands. Merck B.V. is a wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 126 E. Lincoln Ave, Rahway, New Jersey 07065. Merck B.V. is the owner and assignee of the patents-in-suit.

ANSWER: The Xiromed Defendants lack information or knowledge sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph, and therefore, deny the same.

3. Plaintiff N.V. Organon is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Kloosterstraat 6, 5349 AB Oss, Netherlands. N.V. Organon has rights to practice and enforce the patents-in-suit as an exclusive licensee in the United States.

ANSWER: The Xiromed Defendants lack information or knowledge sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph, and therefore, deny the same.

4. Plaintiff Organon USA is a limited liability company organized and existing under the laws of the State of New Jersey with its principal place of business at 30 Hudson Street, Jersey City, New Jersey 07302. Organon USA is the holder of New Drug Application ("NDA") No. 021529 for NEXPLANON® (etonogestrel implant, 68 mg/implant).

ANSWER: The Xiromed Defendants admit that the FDA's website indicates that Organon USA LLC is the holder of NDA No. 021529 for NEXPLANON® (etonogestrel implant, 68

mg/implant). The Xiromed Defendants lack information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations set forth in this paragraph, and therefore, deny the same.

5. Plaintiff Organon LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 30 Hudson Street, Jersey City, New Jersey 07302. Organon LLC is responsible for marketing and selling the NEXPLANON® product in the United States.

ANSWER: The Xiromed Defendants lack information or knowledge sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph, and therefore, deny the same.

6. On information and belief, Defendant Xiromed España is a limited liability company organized and existing under the laws of Spain, with a place of business at Calle de Manuel Pombo Angulo, 28, 3rd floor, Hortaleza, 28050, Madrid, Spain.

ANSWER: Xiromed España is a limited liability company organized and existing under the laws of Spain, with a place of business at Calle de Manuel Pombo Angulo, 28, 3rd floor, 28050, Madrid, Spain.

7. On information and belief, Defendant Xiromed, LLC is a limited liability company organized and existing under the laws of the State of New Jersey with its principal place of business at 180 Park Ave, Suite 101, Florham Park, New Jersey 07932.

ANSWER: Admitted.

8. On information and belief, Defendant Insud is a single-member limited liability company organized and existing under the laws of Spain, with a principal place of business at Calle de Manuel Pombo Angulo, 28, 3rd floor, Hortaleza, 28050, Madrid, Spain. On information and belief, Insud is the ultimate parent of both Xiromed España and Xiromed, LLC. On information and belief, Xiromed España and Xiromed, LLC are the business entities through which Insud markets and sells generic drug products in the U.S. market.

ANSWER: This paragraph contains legal conclusions and is directed to an entity who was, at the time of filing, a separate Defendant to this action. The parties have stipulated to a dismissal

of Insud from this litigation. Therefore, no response is required from the Xiromed Defendants.

9. On information and belief, Defendants are in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

ANSWER: The Xiromed Defendants provide affordable, high-quality pharmaceuticals which deliver enhanced value to patients, customers and the healthcare system. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

10. By a letter dated February 20, 2025 ("Xiromed Notice Letter"), Xiromed notified Plaintiffs that Xiromed had submitted to the FDA Xiromed's ANDA for approval to market and sell in the United States a purported generic version of NEXPLANON® (etonogestrel implant, 68 mg/implant) (referred to herein as the "Xiromed ANDA Product"), prior to the expiration of the patents-in-suit.

ANSWER: Admitted that Xiromed Pharma España, S.L. provided a Notice Letter referencing NEXPLANON® and the patents-in-suit dated February 20, 2025.

11. On information and belief, Defendants have acted and continue to act in concert with respect to the preparation, submission, and prosecution of Xiromed's ANDA, as well as the preparation and submission of the Xiromed Notice Letter.

ANSWER: Xiromed Pharma España, S.L. admits that it submitted the Xiromed ANDA and provided a Notice Letter. Xiromed, LLC is the U.S. Agent for the Xiromed ANDA. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

12. On information and belief, Defendants know and intend that upon approval of Xiromed's ANDA, Defendants will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Xiromed ANDA Product throughout the United States, including in New Jersey. On information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the Xiromed ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Defendants participated, assisted, and cooperated in carrying out the acts detailed in this Complaint.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants do not contest personal jurisdiction in this Court for purposes of this action only. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

13. On information and belief, following any FDA approval of Xiromed's ANDA, Defendants will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Xiromed ANDA Product throughout the United States, including in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants do not contest personal jurisdiction in this Court for purposes of this action only. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

JURISDICTION AND VENUE

14. Plaintiffs incorporate each of the preceding paragraphs 1-13 as if fully set forth

herein.

ANSWER: To the extent an answer to this paragraph is required, the Xiromed Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

15. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 & 1338(a).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*. and asserts subject matter jurisdiction over this action. The Xiromed Defendants deny that there is any actual infringement of the patents-in-suit. The Xiromed Defendants deny any remaining allegations in this paragraph.

16. Xiromed España is subject to personal jurisdiction in New Jersey because, among other things, Xiromed España itself, including by and through its affiliate Xiromed, LLC, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Xiromed España itself, and through its affiliate Xiromed, LLC, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Xiromed España is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Xiromed, LLC, and therefore the activities of Xiromed, LLC in this jurisdiction are attributable to Xiromed España. Xiromed España also directed and sent the Xiromed Notice Letter to Organon USA at its headquarters in Jersey City, New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed Pharma España, S.L. admits that it sent a copy of the Notice Letter to Organon USA at Jesey City, New Jersey and that it does not contest personal jurisdiction in this Court for the purposes of this action only. Xiromed Pharma España, S.L. denies

any remaining allegations set forth in this paragraph.

17. Xiromed España, in concert with Xiromed, LLC, has committed an act of infringement in this judicial district by filing Xiromed's ANDA with the intent to make, use, sell, offer for sale, and/or import the Xiromed ANDA Product in or into this judicial district, prior to the expiration of the patents-in-suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed Pharma España, S.L. does not contest personal jurisdiction in this Court for the purposes of this action only. Xiromed Pharma España, S.L. denies any remaining allegations set forth in this paragraph.

18. Additionally, this Court has personal jurisdiction over Xiromed España because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Xiromed España is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Xiromed España has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Xiromed's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Xiromed España satisfies due process.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed Pharma España, S.L. does not contest personal jurisdiction in this Court for the purposes of this action only. Xiromed Pharma España, S.L. denies any remaining allegations set forth in this paragraph.

19. On information and belief, Xiromed España has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g., American Regent, Inc. v. Xiromed, LLC et al.*, No. 2:24-cv-07811-BRM-CLW (D.N.J. July 16, 2024) (consolidated into *In re Selenious Acid Litigation*, No. 2:24-cv-07791).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed Pharma España, S.L. does not contest jurisdiction in this Court for the purposes of this action only and states that pleadings in previous actions speak

for themselves. Xiromed Pharma España, S.L. denies any remaining allegations set forth in this paragraph.

20. This Court has personal jurisdiction over Xiromed, LLC because Xiromed, LLC is a limited liability company organized under the laws of the State of New Jersey and having a principal place of business in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed, LLC does not contest personal jurisdiction in this Court for the purposes of this action only. Additionally, Xiromed, LLC admits that it is organized under the State of New Jersey and has a principal place of business in Florham Park, NJ. Xiromed, LLC denies any remaining allegations set forth in this paragraph.

21. Xiromed, LLC is also subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Xiromed, LLC is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID. No. 0600430486. On information and belief, Xiromed, LLC is registered with the New Jersey Department of Health as a drug manufacturer (Drug and Medical Device Certificate of Registration Number 5004977).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed, LLC does not contest personal jurisdiction in this Court for the purposes of this action only. Xiromed, LLC admits that it is registered to do business in New Jersey under Business ID No. 0600430486 and has Drug and Medical Device Certificate of Registration Number 5004977. Xiromed, LLC denies any remaining allegations set forth in this paragraph.

22. On information and belief, Xiromed, LLC develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed, LLC does not contest personal jurisdiction in this Court for the purposes of this action only. By way of further response, Xiromed, LLC states that Xiromed, LLC is focused on commercializing high quality generic pharmaceutical products for the US market. In addition to its commercial portfolio of generics available in the US, Xiromed, LLC has a robust portfolio of generic pharmaceutical products in various stages of development, including injectable, inhalation and complex generic products. Xiromed, LLC denies any remaining allegations set forth in this paragraph.

23. On information and belief, Xiromed, LLC has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g., American Regent, Inc. v. Xiromed, LLC et al.*, No. 2:24-cv-07811-BRM-CLW (D.N.J. July 16, 2024) (consolidated into *In re Selenious Acid Litigation*, No. 2:24-cv-07791).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed, LLC does not contest jurisdiction in this Court for the purposes of this action only and states that pleadings in previous actions speak for themselves. Xiromed, LLC denies any remaining allegations set forth in this paragraph.

24. Insud is subject to personal jurisdiction in New Jersey because, among other things, Insud itself, as well as by and through its subsidiaries and generic arms Xiromed España and Xiromed, LLC, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Insud itself, and through its subsidiaries and generic arms Xiromed España and Xiromed, LLC, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Insud is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Xiromed España and Xiromed, LLC, and therefore the activities of Xiromed España and Xiromed, LLC in this jurisdiction are attributable to Insud. Insud, through its subsidiaries and generic arms Xiromed España and Xiromed, LLC, also directed and sent the Xiromed Notice Letter to Organon USA at its headquarters in Jersey City, New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required and is directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent a response is required, denied.

25. Insud, in concert with Xiromed España and Xiromed, LLC, has committed an act of infringement in this judicial district by filing Xiromed's ANDA with the intent to make, use, sell, offer for sale, and/or import the Xiromed ANDA Product in or into this judicial district, prior to the expiration of the patents-in-suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required and is directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent a response is required, denied.

26. Additionally, this Court has personal jurisdiction over Insud because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Insud is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Insud has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Xiromed's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Insud satisfies due process.

ANSWER: This paragraph contains legal conclusions to which no answer is required and is directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent a response is required, denied.

27. Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Xiromed ANDA Product, that will be purposefully directed at New Jersey and elsewhere in the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, the Xiromed Defendants do not contest jurisdiction in this Court for the purposes of this action only. Additionally, Xiromed Pharma España, S.L. admits that it submitted the Xiromed ANDA and provided a Notice Letter. Xiromed, LLC is the U.S. Agent for the Xiromed ANDA. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

28. On information and belief, Defendants have systematic and continuous contacts with New Jersey; have established distribution channels for drug products in New Jersey; regularly and continuously conduct business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in New Jersey; and derive substantial revenue from the sale of drug products in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants do not contest jurisdiction in this Court for the purposes of this action only. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

29. On information and belief, if Xiromed's ANDA is approved, Defendants will manufacture, market, promote, sell, offer for sale, import, use, and/or distribute the Xiromed ANDA Product within the United States, including in New Jersey, consistent with Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Defendants regularly do business in New Jersey, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Defendants' generic pharmaceutical products are used and/or consumed within and

throughout the United States, including in New Jersey. On information and belief, the Xiromed ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the patents-in-suit in the event that the Xiromed ANDA Product is approved before the patents-in-suit expire.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants do not contest jurisdiction in this Court for the purposes of this action only. Xiromed Pharma España, S.L. admits that it submitted the Xiromed ANDA and provided a Notice Letter. Xiromed, LLC is the U.S. Agent for the Xiromed ANDA. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

30. On information and belief, Defendants derive substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by Defendants and/or for which Xiromed España, Xiromed, LLC, and/or Insud is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Xiromed España, Xiromed, LLC and/or Insud is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants do not contest jurisdiction in this Court for the purposes of this action only. Xiromed Pharma España, S.L. admits that it submitted the Xiromed ANDA and provided a Notice Letter. Xiromed, LLC is the U.S. Agent for the Xiromed ANDA. To the extent Insud is included in the term "Defendants," such allegations are directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

31. Venue is proper in this Court as to Xiromed España because Xiromed España is a foreign entity that may be sued in any judicial district, including in the District of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed Pharma España, S.L. does not contest venue in this Court for the purposes of this action only. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

32. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Xiromed, LLC, because, on information and belief, Xiromed, LLC is organized under the laws of the State of New Jersey, has a regular and established place of business in New Jersey, and because, on information and belief, Xiromed, LLC has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing Xiromed's ANDA in New Jersey and/or with the intention of seeking to market the Xiromed ANDA Product nationwide, including within New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed, LLC admits that it is organized under the laws of the State of New Jersey and has a principal place of business in Florham Park, New Jersey. Additionally, Xiromed, LLC does not contest venue in this Court for the purposes of this action only. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

33. Venue is proper in this Court as to Insud because Insud is a foreign entity that may be sued in any judicial district, including in the District of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

ANSWER: This paragraph contains legal conclusions and is directed to an entity that the parties have stipulated be dismissed from this action. Therefore, no response is required from the Xiromed Defendants.

THE PATENTS-IN-SUIT

34. The ’037 patent is entitled “X-Ray Visible Drug Delivery Device” and is attached as Exhibit A.

ANSWER: The Xiromed Defendants admit that a purported copy of the ’037 patent is attached to the Complaint as Exhibit A. The Xiromed Defendants admit that on its face, the ’037 patent is entitled “X-Ray Visible Drug Delivery Device.” To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

35. The ’037 patent was duly and legally issued on May 13, 2014.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit that on its face, the ’037 patent indicates it was issued on May 13, 2014 but the Xiromed Defendants deny that the ’037 patent was duly and legally issued.

36. The ’037 patent is directed generally to X-ray visible implant compositions comprising crystalline etonogestrel (also known as 3-ketodesogestrel) or desogestrel for subdermal administration.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

37. The FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) currently lists the expiration of the ’037 patent as September 28, 2027.

ANSWER: The Xiromed Defendants admit that the ’037 patent is presently listed in the FDA’s Orange Book with an expiration date of September 28, 2027.

38. The ’552 patent is entitled “Applicator for Inserting an Implant” and is attached as Exhibit B.

ANSWER: The Xiromed Defendants admit that a purported copy of the ’552 patent is

attached to the Complaint as Exhibit B. The Xiromed Defendants admit that on its face, the '552 patent is entitled "Applicator for Inserting an Implant." To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

39. The '552 patent was duly and legally issued on September 12, 2017.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit that on its face, the '552 patent indicates it was issued on September 12, 2017 but the Xiromed Defendants deny that the '552 patent was duly and legally issued.

40. The '552 patent is directed generally to an applicator for subdermally inserting an implant containing etonogestrel that prevents the unintended exit of the implant from the applicator or damage to the implant prior to or during insertion in a patient.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

41. The Orange Book currently lists the expiration of the '552 patent as July 28, 2030.

ANSWER: The Xiromed Defendants admit that the '552 patent is presently listed in the FDA's Orange Book with an expiration date of July 28, 2030.

THE NEXPLANON® DRUG PRODUCT

42. NEXPLANON® is a groundbreaking innovation in the field of contraception. Organon USA is the holder of NDA No. 021529, under which the FDA approved the commercial marketing of NEXPLANON® (etonogestrel implant, 68 mg/implant) on May 13, 2011, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit that the FDA's website indicates

that Organon USA LLC is the holder of NDA No. 021529 for NEXPLANON® (etonogestrel implant, 68 mg/implant) with an approval date of May 13, 2011. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

43. NEXPLANON® has two primary components: (1) a matchstick-sized, radiopaque implant containing etonogestrel, a synthetic hormone that prevents pregnancy by inhibiting ovulation, and (2) a novel applicator device used to insert the implant subcutaneously at the proper location in the upper arm. Once inserted, a single NEXPLANON® implant systemically delivers an ongoing low dose of etonogestrel into the bloodstream for up to three (3) years, which then prevents ovulation in the ovaries. When used correctly, NEXPLANON® is over ninety-nine (99) percent effective at preventing pregnancy. A true and correct copy of the current prescribing information for NEXPLANON® is attached as Exhibit C.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit that a purported copy of the prescribing information for NEXPLANON® is attached to the Complaint as Exhibit C. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

44. NEXPLANON®, as well as methods of using NEXPLANON®, are covered by one or more claims of the patents-in-suit. The ’037 and ’552 patents are listed with NDA No. 021529 in the FDA’s Orange Book.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit that the FDA’s Orange Book lists the ’037 and ’552 patents in connection with NDA No. 021529. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

45. On information and belief, Xiromed has submitted, or caused the submission of, Xiromed's ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Xiromed ANDA Product, as a purported generic version of NEXPLANON®, prior to the expiration of the patents-in-suit.

ANSWER: The Xiromed Defendants admit that Xiromed Pharma España, S.L has submitted Xiromed's ANDA No. 217698 to the FDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Xiromed ANDA Product prior to expiration of the patents-in-suit. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

46. On information and belief, the FDA has not yet approved Xiromed's ANDA.

ANSWER: Admitted.

47. In the Xiromed Notice Letter, Xiromed notified Plaintiffs of the submission of Xiromed's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Xiromed ANDA Product prior to the expiration of the patents-in-suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit the Xiromed Notice Letter notified Plaintiffs of the submission of Xiromed's ANDA No. 217698 to the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Xiromed ANDA Product prior to the expiration of the patents-in-suit. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

48. On information and belief, the Reference Listed Drug for Xiromed's ANDA is NEXPLANON®. NEXPLANON® is indicated for use by women to prevent pregnancy.

ANSWER: The Xiromed Defendants admit that the Reference Listed Drug for Xiromed's ANDA No. 217698 is NEXPLANON® (NDA No. 021529). The approved uses of NEXPLANON® are indicated in the approved labeling of NEXPLANON; that labeling speaks for itself. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

49. On information and belief, the Xiromed ANDA Product contains 68 mg etonogestrel per implant.

ANSWER: Admitted.

50. On information and belief, Xiromed, through its own actions and through the actions of its agents, affiliates, and subsidiaries, prepared and submitted Xiromed's ANDA, and intends to further prosecute Xiromed's ANDA. On information and belief, if the FDA approves Xiromed's ANDA, Xiromed will manufacture, offer for sale, or sell the Xiromed ANDA Product within the United States, or will import the Xiromed ANDA Product into the United States. On information and belief, if the FDA approves Xiromed's ANDA, Xiromed will directly manufacture, use, offer for sale, sell, or import the Xiromed ANDA and/or actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Xiromed ANDA Product in or into the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Xiromed admits that Xiromed Pharma España, S.L has submitted Xiromed's ANDA No. 217698 to the FDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Xiromed ANDA Product prior to expiration of the patents-in-suit. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

51. Plaintiffs bring this action within forty-five (45) days of receipt of the Xiromed Notice Letter. Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C.

§ 355(j)(5)(B)(iii).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, the Xiromed Defendants admit this Complaint was brought within forty-five (45) days of receipt of the Xiromed Notice Letter. To the extent there are any allegations not addressed by the foregoing, the Xiromed Defendants deny any remaining allegations of this paragraph.

COUNT I - INFRINGEMENT OF THE '037 PATENT

52. Plaintiffs incorporate each of the preceding paragraphs 1-51 as if fully set forth herein.

ANSWER: To the extent an answer to this paragraph is required, the Xiromed Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

53. The Xiromed ANDA Product, and the use of the Xiromed ANDA Product, is covered by one or more claims of the '037 patent including, but not limited to, claim 1 of the '037 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

54. In the Xiromed Notice Letter, Xiromed did not contest infringement of claims 1-24 of the '037 patent. If Xiromed had a factual or legal basis to contest infringement of those claims of the '037 patent, then it was required by applicable regulations to state such a basis in the Xiromed Notice Letter. *See* 21 C.F.R. § 314.52 (requiring a Paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug as to which the applicant has submitted a Paragraph IV Certification). Thus, Xiromed has conceded infringement of the '037 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

55. Xiromed's submission of Xiromed's ANDA with a Paragraph IV Certification for

the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Xiromed ANDA Product in or into the United States before the expiration of the '037 patent is an act of infringement of the '037 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

56. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will infringe one or more claims of the '037 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

57. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will induce infringement of one or more claims of the '037 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute the Xiromed ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Xiromed will knowingly and intentionally accompany the Xiromed ANDA Product with a product labeling or product insert that will include instructions for using or administering the Xiromed ANDA Product, which are substantially similar to the instructions in the prescribing information for NEXPLANON®, attached as Exhibit C, and which, if followed, will infringe the '037 patent. Accordingly, Xiromed will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and/or other end users of the Xiromed ANDA Product to directly infringe the '037 patent. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will intentionally encourage acts of direct infringement with knowledge of the '037 patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

58. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will contributorily infringe one or more claims of the '037 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, Xiromed has had and continues to have knowledge that the Xiromed ANDA Product is especially adapted for a use that

infringes one or more claims of the ’037 patent, including at least claim 1, and that there is no substantial non-infringing use for the Xiromed ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

COUNT II – INFRINGEMENT OF THE ’552 PATENT

59. Plaintiffs incorporate each of the preceding paragraphs 1-58 as if fully set forth herein.

ANSWER: To the extent an answer to Paragraph 59 is required, the Xiromed Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

60. The Xiromed ANDA Product, and the use of the Xiromed ANDA Product, is covered by one or more claims of the ’552 patent including, but not limited to, claim 14 of the ’552 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

61. In the Xiromed Notice Letter, Xiromed did not contest the validity of claims 1-25 of the ’552 patent. If Xiromed had a factual or legal basis to contest validity of those claims of the ’552 patent, then it was required by applicable regulations to state such a basis in the Xiromed Notice Letter. *See* 21 C.F.R. § 314.52 (requiring a Paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug as to which the applicant has submitted a Paragraph IV Certification). Thus, Xiromed has conceded validity of the ’552 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

62. Xiromed’s submission of Xiromed’s ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Xiromed ANDA Product in or into the United States before the expiration of the ’552 patent is an act of infringement of the ’552 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

63. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will infringe one or more claims of the '552 patent under 35 U.S.C. § 271(a), including at least claim 14, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

64. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will induce infringement of one or more claims of the '552 patent under 35 U.S.C. § 271(b), including at least claim 14, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute the Xiromed ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Xiromed will knowingly and intentionally accompany the Xiromed ANDA Product with a product labeling or product insert that will include instructions for using or administering the Xiromed ANDA Product, which are substantially similar to the instructions in the prescribing information for NEXPLANON®, attached as Exhibit C, and which, if followed, will infringe the '552 patent. Accordingly, Xiromed will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and/or other end users of the Xiromed ANDA Product to directly infringe the '552 patent. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will intentionally encourage acts of direct infringement with knowledge of the '552 patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied.

65. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will contributorily infringe one or more claims of the '552 patent under 35 U.S.C. § 271(c), including at least claim 14, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, Xiromed has had and continues to have knowledge that the Xiromed ANDA Product is especially adapted for a use that infringes one or more claims of the '552 patent, including at least claim 14, and that there is no substantial non-infringing use for the Xiromed ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, denied.

RESPONSE TO PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief for which no response is required. To the extent a response is required, the Xiromed Defendants deny that Plaintiffs are entitled to any relief.

SEPARATE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Defendants request that judgment be entered in their favor, dismissing the Complaint with prejudice, awarding Defendants' attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting further relief as the Court may deem just and proper. Defendants do not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Defendants reserve the right to assert other defenses and/or to otherwise supplement or amend this Answer upon discovery of facts or evidence rendering such action appropriate in accordance with the Federal Rules of Civil Procedure and Local Civil Rules of the U.S. District Court for the District of New Jersey.

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of the ’037 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

THIRD DEFENSE

The Xiromed Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’037 patent. If the products that are the subject of ANDA No. 217698 were marketed, the Xiromed Defendants would not infringe any valid and enforceable claim of the ’037 patent.

FOURTH DEFENSE

The Xiromed Defendants have not, do not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’037 patent. If the products that are the subject of ANDA No. 217698 were marketed, the Xiromed Defendants would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’037 patent .

FIFTH DEFENSE

Plaintiffs are barred from asserting the claims of the ’037 patent in whole or in part, either literally or by application of the doctrine of equivalents, by the doctrine of prosecution history estoppel, judicial estoppel, inequitable conduct, unclean hands, and/or other equitable doctrines.

SIXTH DEFENSE

The claims of the '552 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

SEVENTH DEFENSE

The Xiromed Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '552 patent. If the products that are the subject of ANDA No. 217698 were marketed, the Xiromed Defendants would not infringe any valid and enforceable claim of the '552 patent.

EIGHTH DEFENSE

The Xiromed Defendants have not, do not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '552 patent. If the products that are the subject of ANDA No. 217698 were marketed, the Xiromed Defendants would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '552 patent.

NINTH DEFENSE

Plaintiffs are barred from asserting the claims of the '552 patent in whole or in part, either literally or by application of the doctrine of equivalents, by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

TENTH DEFENSE

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

ELEVENTH DEFENSE

Any activities reasonably related to the development and submission of information to the FDA regarding Xiromed's ANDA are protected by the safe harbor of 35 U.S.C. § 271(e)(1).

TWELFTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For their Counterclaims against Merck Sharp & Dohme B.V. ("Merck"); N.V. Organon; Organon USA LLC ("Organon USA"); and Organon LLC (collectively, "Counterclaim Defendants/Plaintiffs"), Xiromed Pharma España, S.L. and Xiromed, LLC (collectively, "the Xiromed Defendants" or "Counterclaim Plaintiffs/Defendants"), states as follows:

THE PARTIES

1. On information and belief and as it pled in its Complaint, Merck Sharp & Dohme B.V. is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands. On information and belief and as it pled in its Complaint, Merck B.V. is a wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 126 E. Lincoln Ave, Rahway, New Jersey 07065.

2. On information and belief and as it pled in its Complaint, N.V. Organon is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Kloosterstraat 6, 5349 AB Oss, Netherlands. N.V. On information and belief and as it pled in its Complaint, Organon has rights to practice and enforce the patents-in-suit as an exclusive licensee in the United States.

3. On information and belief and as it pled in its Complaint, Organon USA is a limited liability company organized and existing under the laws of the State of New Jersey with its principal place of business at 30 Hudson Street, Jersey City, New Jersey 07302. On information and belief and as it pled in its Complaint, Organon USA is the holder of New Drug Application ("NDA") No. 021529 for NEXPLANON (etonogestrel implant, 68 mg/implant).

4. On information and belief and as it pled in its Complaint, Organon LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 30 Hudson Street, Jersey City, New Jersey 07302. On information and belief and as it pled in its Complaint, Organon LLC is responsible for marketing and selling the NEXPLANON product in the United States.

5. Xiromed, LLC is a limited liability company organized and existing under the laws of the State of New Jersey with its principal place of business at 180 Park Ave, Suite 101, Florham Park, New Jersey 07932.

6. Xiromed Pharma España S.L. is a limited liability company organized and existing under the laws of Spain, with a place of business at Calle de Manuel Pombo Angulo, 28, 3rd floor, 28050, Madrid, Spain.

JURISDICTION AND VENUE

7. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Counterclaim Defendants/Plaintiffs on the basis of, *inter alia*, their contacts with New Jersey relating to the subject matter of this action, including having filed the Complaint in the underlying suit.

9. Venue is proper under 28 U.S.C. §§ 1391 and 1400 and as a result of Plaintiffs' filing of the Complaint in the underlying suit.

BACKGROUND

10. Upon information and belief, Organon USA holds approved New Drug Application ("NDA") No. 021539 for NEXPLANON (etonogestrel implant, 68 mg/implant).

11. An NDA must include, among other things, the number of any patent that 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 authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

12. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

13. On information and belief, U.S. Patent No. 8,722,037 ("the '037 patent"), entitled "X-Ray Visible Drug Delivery Device," issued on May 13, 2014.

14. On information and belief, based upon the United States Patent Office's assignment database, Merck Sharp & Dohme B.V. is the assignee of the '037 patent.

15. On information and belief, U.S. Patent No. 9,757,552 ("the '552 patent"), entitled "Applicator for Inserting an Implant," issued on September 12, 2017.

16. On information and belief, based upon the United States Patent Office's assignment database, Merck Sharp & Dohme B.V. is the assignee of the '552 patent.

17. On information and belief, after the issuance of the '037 and the '552 patents ("the patents-in-suit"), Counterclaim Defendants/Plaintiffs caused the patents-in-suit to be listed in the

Orange Book for NDA No. 217698.

18. Xiromed Pharma España, S.L. submitted Abbreviated New Drug Application ("ANDA") No. 217698 ("Xiromed's ANDA" or the "Xiromed ANDA") to obtain FDA approval to market generic versions of NEXPLANON (etonogestrel implant, 68 mg/implant) prior to the expiration of the '037 and '552 patents (the "patents-in-suit").

19. Pursuant to 21 U.S.C. § 355(j)(2)(B), Xiromed notified Counterclaim Defendants/Plaintiffs by letter dated February 20, 2025 (the "Xiromed Notice Letter") that Xiromed had submitted a Paragraph IV Certification for its ANDA with respect to the patents-in-suit. The Xiromed Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for the Xiromed Paragraph IV Certification that the claims of the patents-in-suit are invalid, not infringed, and/or unenforceable.

20. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), Xiromed offered Counterclaim Defendants/Plaintiffs confidential access to information from Xiromed's ANDA No. 217698 for the purpose of determining whether an infringement action under 21 U.S.C. § 355(j)(5)(B)(iii) can be brought against Xiromed relating to Xiromed's ANDA Product.

21. Counterclaim Defendants/Plaintiffs did not accept Xiromed's Offer of Confidential access.

22. On April 2, 2025, Counterclaim Defendants/Plaintiffs filed the instant lawsuit alleging infringement of the patents-in-suit without having reviewed Xiromed's ANDA.

COUNT I

(Declaratory Judgment of Invalidity of the '037 Patent)

23. The Xiromed Defendants re-allege and incorporate by reference the allegations in Paragraphs 1 through 22 of their Counterclaims as though fully set forth herein.

24. Merck Sharp & Dohme B.V. alleges ownership of the '037 patent. Collectively with N.V. Organon, Organon USA LLC and Organon LLC, Merck Sharp & Dohme B.V. has brought claims against the Xiromed Defendants, alleging infringement of the '037 patent.

25. One or more claims of the '037 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

26. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Xiromed's ANDA and/or the commercial marketing of Xiromed's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '037 patent.

27. The Xiromed Defendants are entitled to a declaration that all claims of the '037 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

COUNT II

(Declaratory Judgment of Unenforceability of the '037 Patent)

28. The Xiromed Defendants re-allege and incorporate by reference the allegations in Paragraphs 1 through 27 of their Counterclaims as though fully set forth herein.

29. Upon information and belief, the claims of the '037 Patent are unenforceable, in whole or in part, due to inequitable conduct committed by Counterclaim Defendants/Plaintiffs and their attorneys, in coordination with the named inventors of the '037 Patent, during prosecution of the '037 Patent at the United States Patent and Trademark Office ("USPTO").

30. Upon information and belief, the individuals responsible for the inequitable conduct include at least the two named inventors, Harm Veenstra ("Veenstra"), and Wouter De Graaff ("De Graaff"); Counterclaim Defendants/Plaintiffs' attorneys, including at least Susan

Hess ("Hess"), Patricia Chisholm ("Chisholm"), and Janet Fair ("Fair"); and other individual(s) employed by Counterclaim Defendants/Plaintiffs who were responsible for overseeing the prosecution of the '037 Patent.

31. The inequitable conduct barring enforcement of the '037 Patent includes a pattern of deliberate misrepresentations to the USPTO as to the state of and teachings of the prior art, as well as failure to disclose material prior art to the USPTO. This pattern of misrepresentations represents egregious misconduct. Additionally, the circumstantial evidence demonstrates a deliberate intent to deceive the USPTO to gain allowance of the '037 Patent.

32. Specifically, the Counterclaim Defendants/Plaintiffs took the position during prosecution of the '037 Patent that it would not have been obvious to incorporate a radio-opaque (or "radiopaque") substance into a long-acting contraceptive device for use in a human. Then, they took the exact opposite position in a petition for *inter partes* review ("IPR") of another company's patents. In light of all the circumstances, the single most reasonable inference to be drawn from Counterclaim Defendants/Plaintiffs' later reversal of position is that they earlier had a specific intent to deceive the USPTO to obtain the '037 Patent.

Merck Added a Single, Commonly Used Component to IMPLANON to Develop NEXPLANON

33. Organon USA, Inc., which later became a subsidiary of Merck & Co., Inc., initially filed and received approval of NDA 21-529 for an etonogestrel implant with the trade name IMPLANON. *See* Ex. 1, July 17, 2006 NDA 021529 Approval Letter. IMPLANON was approved by FDA on July 17, 2006. *Id.*

34. What became known as NEXPLANON was filed as a supplement to the IMPLANON NDA approximately three years later on July 29, 2009. *See* Ex. 2, Excerpts of May 13, 2011 Approval Package. As FDA noted, NEXPLANON was "a new radiopaque version of

the etonogestrel implant for the indication of 'use by women to prevent pregnancy' and a new device for insertion of the implant." *Id*. at 5 (Approval Letter at 1). In particular, the FDA noted that the only difference between the NEXPLANON implant and the IMPLANON implant is the addition of a radiopaque component, *i.e*., barium sulfate. *Id*. at 12 (Summary Review at 2) ("The new radiopaque etonogestrel implant (also referred to as Nexplanon) ***is identical to Implanon*** with the exception that ***15 mg of barium sulfate has been added*** to the core matrix of the implant rod…." (emphasis added)).

35. NEXPLANON was approved by FDA on May 13, 2011. *Id*. at 1 (Cover Page). IMPLANON has been discontinued. *See* Ex. 3, Orange Book entry for Implanon, NDA No. 021529.[2]

36. The '037 Patent is indicated on its face to have issued on May 13, 2014, three years after NEXPLANON's approval. The '037 Patent was submitted to the FDA for listing in the Orange Book in relation to NEXPLANON two days later, on May 15, 2014. *See* Ex. 4, Orange Book entry for NEXPLANON, NDA No. 021529.[3]

37. The '037 Patent is generally directed to a radio-opaque etonogestrel implant. As such, the only difference between the claims of the '037 Patent and the prior art IMPLANON device is the inclusion of barium sulfate, a material that renders the implant radio-opaque, in the core of the etonogestrel implant. The addition of this radio-opaque substance allows the implant to be visualized in the body using X-rays. *See, e.g*., '037 Patent at 3:24-27 ("The object of the invention is to add a radio-opaque element to a contraceptive/HRT implant such as Implanon®

[2] Available at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021529#4404

[3] Available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&Appl_No=021529&Appl_type=N

providing the possibility to identify and locate it in the body by X-ray techniques…").

38. During prosecution of the '037 Patent, the inventors and Organon's attorneys consistently asserted that one skilled in the art would ***not*** have considered incorporating a radio-opaque material in a controlled-release contraceptive device. For example, they asserted that it was unexpected that incorporating the radio-opaque material in the core did not affect the release of etonogestrel. *See, e.g.*, Ex. 5, Feb. 3, 2010 Amendment at 10 ("[O]ne of skill in the art would not reasonably expect that the incorporation of radio-opaque material into a controlled-release contraceptive device would not affect the hormone release from the controlled-release contraceptive device")(emphasis in original); *see also id*. at 11; Ex. 6, July 20, 2010 Amendment generally and particularly at 10-13; Ex. 12, Sept. 12, 2012 Amendment and Response at 10; Ex. 7, December 18, 2012 Amendment to Support Request for Continued Examination (RCE) Under the Provisions of 37 CFR § 1.114 at 12.

39. These arguments worked, convincing the USPTO to issue the '037 patent. In the Examiner's Notice of Allowance, the Examiner identified three pieces of prior art, including U.S. Pat. No. 4,957,119 ("de Nijs"), which discloses the IMPLANON implant, but stated that de Nijs' etonogestrel implant did not include radio-opaque material. The Examiner then pointed to two other pieces of art that included radio-opaque material but stated that neither one suggested using radio-opaque material (or particularly barium sulfate) with contraceptive devices. Ex. 8, February 12, 2014 Second Notice of Allowance at 2; Ex. 9, August 2, 2013 First Notice of Allowance at 2. Thus, in allowing the claims of the '037 Patent, the Examiner specifically noted and relied on the lack of art incorporating radio-opaque material in a hormonal implant.

40. Upon information and belief, Organon's prosecuting attorneys and the '037 Patent inventors were aware that, prior to the filing date of the application for the '037 Patent, there was

a publicly known, long history of incorporating radio-opaque material into hormonal contraceptives. However, neither Organon's prosecuting attorneys nor the '037 Patent inventors disclosed this material prior art to the USPTO.

41. The evidence of their knowledge is that Counterclaim Defendants/Plaintiffs later correctly represented the material prior art before the USPTO, but only when it benefitted them during different proceedings challenging another party's patents. Counterclaim Defendants/Plaintiffs' later statements about the state of the art and knowledge of skilled artisans directly contradict what they said about the state of the art and the knowledge of skilled artisans to obtain the '037 Patent. The only reasonable inference is that they willfully and intentionally misled the USPTO about material prior art during prosecution of the '037 Patent.

42. In particular, on June 5, 2017, Microspherix LLC filed suit against Merck & Co., Inc., Merck Sharpe & Dohme Corp., N.V. Organon, and Merck Sharp & Dohme B.V., asserting that Counterclaim Defendants/Plaintiffs' NEXPLANON product infringed four patents: U.S. Pat. Nos. 9,636,402 (the "'402 Patent"), 6,514,193 (the "'193 Patent"), 9,636,401 (the "'401 Patent"), and 8,821,835 (the "'835 Patent"). *See* 7 In its Complaint, Microspherix alleged that the '037 Patent, which is listed in the Orange Book in conjunction with Counterclaim Defendants/Plaintiffs' NEXPLANON product, was evidence of Counterclaim Defendants/Plaintiffs' infringement of the '193 (*see, e.g., id.* at ¶ 150), the '401 (*see, e.g., id.* at ¶¶ 217, 239-244, 246), and the '835 Patents (*see, e.g., id.* at ¶¶ 284-287, 300-305, 307).

43. During the pendency of Microspherix's district court litigation against Counterclaim Defendants/Plaintiffs, Counterclaim Defendants/Plaintiffs filed four IPR petitions, challenging the validity of each of the patents asserted by Microspherix: IPR2018-00393 (challenging the '402 patent), IPR2018-00402 (challenging the '401 patent), IPR2018-00602

(challenging the '835 patent), and IPR2018-01288 (challenging the '193 patent) (collectively, "the Microspherix IPRs").

44. Notably, when challenging Microspherix's patents, which had earlier priority dates than did the '037 Patent, Counterclaim Defendants/Plaintiffs, through their expert Dr. Robert Langer, alleged that because barium sulfate was ***well-known for use as a radiopaque marker for contraceptive implants***, it would have been obvious to incorporate barium sulfate as a marker for such a device:

> ***There is a long history of barium sulfate being added to contraceptive and/or hormone-releasing devices to provide another mechanism, in addition to ultrasound and MRI, to locate the device inside a subject's body.*** For example, Thiery 2000 refers to the "famous spiral-shaped IUD" Perma-spiral (Gynecoil®) developed in 1960 by Dr. Lazar Marguiles, explaining that "[b]y molding barium sulfate into the plastic the Marguiles spiral was made radio-opaque so that its position could be traced on the X-ray plate." Thiery 2000 (Ex. 1036) at 149. Another IUD, a "T-shaped progesterone-releasing" device called "Progestasert" was introduced in the 1970s. *Id.* Progestasert was "constructed of a polyethylene short arm" that was "radiolucent" and a hollow vertical long arm" containing "a reservoir of progesterone, together with barium sulfate for radiopacity." Botash 1997 (Ex. 1037) at 374. As Botash notes, ultrasound was the "primary modality employed" for confirming the location of the device, but barium sulfate was added so that a radiograph could be used when the device was "not visualized sonographically." *Id.; see also* U.S. Pat. No. 5,788,980 (Ex. 1042) at 4:22-26 (describing estradiol releasing vaginal rings comprising a polymer matrix and "an X-ray contrast medium such as barium sulfate … for identification purposes.").

Ex. 11, IPR2018-01288, Exhibit 1002 (Langer Declaration), at ¶ 137 (emphasis added).

45. Plaintiffs adopted and relied on these statements by Dr. Langer in their Petition for *Inter Partes* Review, citing not only paragraph 137 of Dr. Langer's declaration but other prior art references to argue that a person of skill in the art would have been motivated to use a radio-opaque marker:

> Second, a POSA working with De Nijs's disclosure of a cylindrical hormone-eluting implant would have been motivated to incorporate Schopflin's teaching of including a radiopaque marker because it was known in the art to use radiopaque markers both to allow for precise placement of implants and to track their location within the body. *Id.*, ¶ 133, 137; Thiery 2000 (Ex. 1036) at 149; Botash 1997 (Ex. 1037) at 374; U.S. Pat. No.

5,788,980 (Ex. 1042) at 4:22-26.

Ex. 17, IPR2018-01288, Petition for *Inter Partes* Review at 58-59.

46. Upon information and belief, Counterclaim Defendants/Plaintiffs, including their attorneys and the named inventors of the ’037 Patent, were aware at the time of prosecution of the ’037 Patent of the same material prior art that Counterclaim Defendants/Plaintiffs raised in the Microspherix IPRs, but failed to disclose that art during prosecution of the ’037 Patent in an intent to deceive the USPTO.

47. Furthermore, as noted previously, the Examiner’s Notice of Allowance of the ’037 Patent’s claims twice noted that de Nijs did not include a radio-opaque material while the two references addressing radio-opaqueness did not involve hormonal contraceptives. That reason for allowance is directly contradicted by the Langer Declaration submitted by Counterclaim Defendants/Plaintiffs. Langer’s cited references, which showed the long history of incorporating a radiopaque component into hormonal implants, would have provided the link that the Examiner found missing, and thus would have been “but for” material with regard to allowance of the claims.

48. Furthermore, upon information and belief, since Organon’s prosecuting attorneys and the inventors of the ’037 Patent knew of this “long history” and did not supply that information to the USPTO at any time, including in their Request for Continuing Examination filed after the Examiner’s First Notice of Allowance, withholding that prior art also constituted an act of egregious misconduct that is material by definition.

Merck’s Representatives Engaged in a Deliberate Pattern of Misrepresentations to the USPTO Rising to the Level of Egregious Misconduct

49. In addition to failing to disclose material prior art to the USPTO during prosecution of the ’037 Patent, Counterclaim Defendants/Plaintiffs’ attorneys and the named inventors

engaged in a deliberate pattern of misrepresentation of the prior art, rising to the level of egregious misconduct.

50. Without waiver of the Xiromed Defendants' right to raise additional challenges, and as discovery may show, upon information and belief, Counterclaim Defendants/Plaintiffs, their attorneys, and/or the named inventors, deliberately made at least two additional material misrepresentations to the USPTO regarding the prior art, which the USPTO relied upon to allow the '037 Patent. Both of these misrepresentations relate to whether it would have been obvious for a person of ordinary skill in the art to add barium sulfate in the implant core of the prior art IMPLANON product.

51. ***First***, Counterclaim Defendants/Plaintiffs misrepresented the prior art by stating that it would have been surprising to find barium sulfate encapsulated within the microstructure of the polymer matrix instead of being encapsulated within the crystalline desogestrel or 3-kesodegestrel during manufacture of the implant rod. Specifically, Counterclaim Defendants/Plaintiffs, through their attorneys, represented to the USPTO that, since the claims of the '037 Patent are directed to a core having "a greater weight percent of desogestrel or 3-ketodesogestrel than the thermoplastic polymer," "one of ordinary skill would expect that some of the radio-opaque material would be present in the desogestrel or 3-ketodesogestrel," as opposed to encapsulated in the polymer matrix. Ex. 12, September 12, 2012 Applicant Remarks at 7.

52. Counterclaim Defendants/Plaintiffs also explained that "Applicants believe that having the percent weight of the thermoplastic polymer be less than 50% and/or equal to or less than the percent weight of the hormone contributes in allowing the device to demonstrate two unexpected features; (1) prevents the radio-opaque material from leaching out of the device and (2) enables the radio-opaque material to not affect the release rate of the desogestrel or 3-

ketodesogestrel as compared to the same device without a radio-opaque material." *Id.* In this way, Counterclaim Defendants/Plaintiffs intended to deceive the USPTO that there was something surprising about the way barium sulfate could be added to the existing IMPLANON device, leading to unexpected results.

53. Upon information and belief, the Examiner of the '037 Patent application did not understand how barium sulfate was incorporated into the implant core, and thus requested, and relied upon, Counterclaim Defendants/Plaintiffs' representations to understand the technology. Specifically, the Examiner initiated an interview with Counterclaim Defendants/Plaintiffs' attorney Janet Fair, which was conducted on May 29, 2013. Ex. 13, June 11, 2013 Examiner-Initiated Interview Summary. In the Examiner's summary of the interview, the Examiner stated, "Examiner called the Attorney to discuss the method of making the claimed X-ray implant. Examiner wanted to know if any of the process steps were critical in order to ensure the encapsulation of the barium sulfate in the polymer…. Applicant's representative explained that they have more data to demonstrate that those of skill in the art would not have expected the barium sulfate to be encapsulated in the polymer and would have expected it to leach out along with the drug and therefore was unexpected. Applicant's representative is going to submit the results in a supplemental amendment." *Id.*

54. The Applicant submitted additional references in an IDS with the Supplemental Amendment on June 7, 2013, arguing that they "further support[] the unexpected result that the radio-opaque material does not leach out of the device." Ex. 14, June 7, 2013, Applicant Arguments/Remarks Made in an Amendment at 6. Applicants further explained that "[i]t was unexpected that almost all of the radio-opaque material encapsulated within the polymer and hardly any radio-opaque [material] encapsulated in the hormone crystals since there is a greater

weight percent of desogestrel or 3-ketodesogestrel than the thermoplastic polymer." *Id.* at 8.

55. When allowing the '037 Patent, the USPTO credited Counterclaim Defendants/Plaintiffs' representations regarding the encapsulation of barium sulfate in the polymer matrix, and not within the desogestrel or 3-ketodesogestrel, as unexpected. Specifically, in the Notice of Allowance, the Examiner stated: "The claims are allowable over the prior art because the prior art does not teach, disclose nor make obvious a contraceptive implant comprising crystalline desogestrel or 3-ketodesogestrel, a radio-opaque agent substantially encapsulated in a thermoplastic polymer and a non-medicated thermoplastic polymer skin covering the core[sic]." Ex. 9, August 2, 2013 Notice of Allowance at 2; *see also* Ex. 8, February 12, 2014 Notice of Allowance at 2.

56. However, upon information and belief, Counterclaim Defendants/Plaintiffs were aware that in an implant device such as the device claimed by the '037 Patent, the addition of barium sulfate would necessarily be encapsulated by the polymer matrix and not in the crystalline desogestrel or 3-ketodesogestrel.

57. Specifically, Counterclaim Defendants/Plaintiffs were aware of the prior art reference, J.A.H. van Laarhoven et al., "Effect of supersaturation and crystallization phenomena on the release properties of a controlled release device based on EVA copolymer," Journal of Controlled Release 82:309-317 (2002)("van Laarhoven 2002"), which was authored by at least one individual employed by Counterclaim Defendants/Plaintiffs at the time of publication, and was cited by Counterclaim Defendants/Plaintiffs during prosecution of the '037 Patent for a different, misleading proposition.

58. Van Laarhoven 2002 explains that the IMPLANON device is manufactured by extruding coaxial fibers of a polymer at temperatures "far below the melting point of the drug,"

but well above room temperature. Ex. 15, Van Laarhoven 2002 at 310 (noting that the melting temperature of etonogestrel is 199°C, but the melting temperatures of ethylene vinylacetate (EVA), as used in the claimed invention of the '037 Patent, are within the range of 80°-100°C). Thus, as Counterclaim Defendants/Plaintiffs and their attorneys would have known, but did not explain to the USPTO, the etonogestrel would have remained in crystalline form during the formation of the implant core, while the polymer matrix melted for extrusion and resolidified around the crystalline drug. Moreover, the method of extrusion would avoid any aggregation of crystalline drug around the barium sulfate. Thus, a person of ordinary skill in the art would have expected that barium sulfate included during formation of the implant would be encapsulated and surrounded by the melted polymer, not by the crystalline drug.

59. ***Second***, Counterclaim Defendants/Plaintiffs misrepresented the prior art regarding the effect of barium sulfate on the release rate of desogestrel or 3-kesodegestrel in the claimed device. Specifically, Counterclaim Defendants/Plaintiffs asserted in multiple instances that a POSA would reasonably expect that "the incorporation of radio-opaque material into a controlled-release contraceptive device would affect the hormone release from the controlled-release contraceptive device." *See, e.g.*, Ex. 6, July 20, 2010 Applicant Remarks at 15-16. To support these assertions, Counterclaim Defendants/Plaintiffs, through their attorneys, cited references discussing the impact of additional components in matrix devices. *See, e.g.*, Ex. 7, December 18, 2012 Applicant Remarks at 8 (discussing the matrix systems in Taghizadeh et al., "Study of Progesterone Release Mechanisms form a Silicon Matrix by a New Analytical Method," Journal of Applied Polymer Science, Vol. 91, 3040-3043, (2004) (Taghizadeh 2004)); *see also* Ex. 14 June 7, 2013 Applicant Remarks at 6 (citing J.D. Bonny et al., "Matrix Type Controlled Release Systems: I. Effect of Percolation on Drug Dissolution Kinetics," Pharm. Acta Helv. 66, Nr. 5-6

(1991)(Bonny 1991) (discussing an orally administered matrix tablet)).

60. However, Counterclaim Defendants/Plaintiffs were aware that the implant device claimed by the '037 Patent is a reservoir device, not a matrix device, and thus the release rate of desogestrel or 3-kesodegestrel was controlled in a different manner, and not affected, by the presence of barium sulfate in the core. Thus, Counterclaim Defendants/Plaintiffs relied on prior art relating to different, unrelated delivery systems to mislead the USPTO regarding the impact of barium sulfate on the claimed delivery system.

61. Specifically, during prosecution of the '037 Patent, Counterclaim Defendants/Plaintiffs and at least one of the named inventors, De Graaff, were aware of a prior art reference published in 1990 entitled "New Methods of Drug Delivery," by Robert Langer, Science 249:4976, 1527-1533 (1990) ("Langer 1990"). *See* Ex. 16, Langer 1990. This is one of the references that Plaintiffs later relied on in the Microspherix IPRs. *See*, Ex. 17, IPR2018-01288, Petition for *Inter Partes* Review at 7-8 (citing reference 1026 in a discussion of reservoir systems). However, Counterclaim Defendants/Plaintiffs and named inventor De Graaff were aware of Langer 1990 well before the IPR. They cited Langer 1990 as a prior art reference at least as early as December 6, 2013 during prosecution of a separate patent application which issued as U.S. Pat. No. 9,345,686. *See*, Ex. 18, 9,345,686 Patent December 6, 2013 Information Disclosure Statement. Thus, Counterclaim Defendants/Plaintiffs and De Graaff were aware of Langer 1990 at least by December 6, 2013, before the February 12, 2014 Notice of Allowance issued for the '037 Patent.

62. Langer 1990 expressly teaches that while the drug release rate of matrix devices can be impacted by the inclusion of other components, the drug release rate of reservoir devices is controlled by the membrane surrounding the reservoir, such as the membrane included in the

'037 Patent claims. As Langer 1990 explains, reservoirs and matrices are two types of diffusion-controlled systems. Ex. 16, Langer 1990 at 1529 and Fig. 1A and 1B. Langer 1990 teaches that reservoir devices have a "drug core surrounded by a polymer film," whereas matrix devices effect diffusion by ensuring that "the drug is uniformly distributed through the polymeric system." *Id*. Langer 1990 explains that "reservoir systems are able to produce near-constant release rates, whereas matrix systems are inexpensive to manufacture." *Id*.

63. Other prior art references cited by Counterclaim Defendants/Plaintiffs during prosecution of the '037 Patent teach that IMPLANON, and thus the claimed invention of the '037 Patent, involve a membrane-controlled reservoir device. *See, e.g.,* Ex. 19, A.P. Sam, "Controlled Release Contraceptive Devices: A Status Report," Journal of Controlled Release 22: 35-46 (1992) ("Sam 1992") at 40; *see also* Ex. 15, van Laarhoven 2002 at 309 ("Extrusion technology has proven to be an elegant method for the production of controlled release reservoir systems. Based on this technology, Organon developed two controlled release systems, i.e., Implanon® and Nuvaring®.").

64. While Counterclaim Defendants/Plaintiffs did admit that IMPLANON is a reservoir device when discussing Sam 1992 and van Laarhoven 2002 (*see, e.g*., Ex. 6, July 20, 2010 Applicant Remarks at 16-17), they made no attempt to explain why reservoir devices differed from the matrix-based prior art they relied upon for their allegations of unexpected results, such as Bonny 1991 and Taghizadeh 2004. Instead, when Counterclaim Defendants/Plaintiffs discussed reservoir devices, Counterclaim Defendants/Plaintiffs misleadingly pointed to the inclusion of components in the *membrane* of the reservoir device, not the reservoir core, to argue that a POSA would not be motivated to add barium sulfate in the reservoir *core*. *See, e.g.*, Ex. 6, July 20, 2010 Remarks at 12 (citing Sam 1992 at 39 for the

observation that inclusion of silicon dioxide in the Silastic tubing (i.e., the outer membrane) of NORPLANT affected the release rates of hormone from the reservoir). However, as explained above, Counterclaim Defendants/Plaintiffs were aware that it is the *membrane* that controls the release of drug from a reservoir device, and so the fact that a component of the membrane would impact drug release rate would not inform a POSA's understanding of how a component of the reservoir *core* would impact drug release rate.

65. Contrary to Counterclaim Defendants/Plaintiffs' representations to the USPTO regarding the potential impact of barium sulfate on the drug release rate from matrix devices and the membrane of a reservoir device, Counterclaim Defendants/Plaintiffs were aware that there is a long history of barium sulfate being used in hormone-releasing reservoir devices with little to no effect on the release rate. For example, Counterclaim Defendants/Plaintiffs were aware that Sam 1992 disclosed that PROTAGESTERT, a reservoir device that had been commercially marketed since 1976, incorporated both progesterone and barium sulfate in the reservoir core without impact to the rate of release of progesterone. Ex. 19, Sam 1992 at 36-37. Counterclaim Defendants/Plaintiffs did not direct the Examiner's attention to this section of Sam 1992, however, and instead misled the Examiner by pointing to the discussion of silicon dioxide in the membrane of NORPLANT.

66. But for the intentional misrepresentations of the prior art by Counterclaim Defendants/Plaintiffs to the USPTO, the '037 Patent would not have been allowed.

67. Taken together, Counterclaim Defendants/Plaintiffs' pattern of conduct, including knowing omission of material prior art, and multiple knowing misrepresentations of the prior art, demonstrate evidence of specific intent to deceive the USPTO to gain allowance of the '037 Patent.

68. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the claims of the ’037 Patent are enforceable.

69. The Xiromed Defendants are entitled to a declaration that the claims of the ’037 Patent are unenforceable.

COUNT III

(Declaratory Judgment of Non-Infringement of the ’037 Patent)

70. The Xiromed Defendants re-allege and incorporate by reference the allegations in Paragraphs 1 through 69 of their Counterclaims as though fully set forth herein.

71. Merck Sharp & Dohme B.V. alleges ownership of the ’037 patent. Collectively with N.V. Organon, Organon USA LLC and Organon LLC, Merck Sharp & Dohme B.V. has brought claims against the Xiromed Defendants, alleging infringement of the ’037 patent.

72. The Xiromed Defendants have not and will not infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the ’037 patent and are not liable for such infringement.

73. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Xiromed’s ANDA and/or the commercial marketing of Xiromed’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’037 patent.

74. The Xiromed Defendants are entitled to a declaration that the manufacture, use, or sale of Xiromed’s ANDA Product would not infringe any valid or enforceable claim of the ’037 patent.

COUNT IV

(Declaratory Judgment of Invalidity or Unenforceability of the ' 522 Patent)

75. The Xiromed Defendants re-allege and incorporate by reference the allegations in Paragraphs 1 through 74 of their Counterclaims as though fully set forth herein.

76. Merck Sharp & Dohme B.V. alleges ownership of the '522 patent. Collectively with N.V. Organon, Organon USA LLC and Organon LLC, Merck Sharp & Dohme B.V. has brought claims against the Xiromed Defendants, alleging infringement of the '522 patent.

77. One or more claims of the '552 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

78. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Xiromed's ANDA and/or the commercial marketing of Xiromed's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '552 patent.

79. The Xiromed Defendants are entitled to a declaration that all claims of the '552 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

COUNT V

(Declaratory Judgment of Non-Infringement of the '552 Patent)

80. The Xiromed Defendants re-allege and incorporate by reference the allegations in Paragraphs 1 through 79 of their Counterclaims as though fully set forth herein.

81. Merck Sharp & Dohme B.V. alleges ownership of the '522 patent. Collectively with N.V. Organon, Organon USA LLC and Organon LLC, Merck Sharp & Dohme B.V. has

brought claims against the Xiromed Defendants, alleging infringement of the ’522 patent.

82. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Xiromed’s ANDA and/or the commercial marketing of Xiromed’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’552 patent.

83. The Xiromed Defendants have not and will not infringe, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’552 patent and are not liable for such infringement.

84. The Xiromed Defendants are entitled to a declaration that the manufacture, use, or sale of Xiromed’s ANDA Product would not infringe any valid or enforceable claim of the ’552 patent.

PRAYER FOR RELIEF

WHEREFORE, the Xiromed Defendants respectfully request judgment in their favor and against Counterclaim Defendants/Plaintiffs as follows:

a. Declaring that the filing of Xiromed’s ANDA No. 217698 (the “Xiromed ANDA” or “Xiromed’s ANDA”) has not infringed and does not infringe any valid and enforceable claim of the patents-in-suit;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of the Xiromed ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the patents-in-suit;

c. Declaring that each claim of the patents-in-suit is invalid and/or unenforceable;

d. Declaring this an exceptional case in favor of the Xiromed Defendants and awarding their attorneys’ fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and

rules in common law that would be appropriate;

e. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

By: s/_*Eric I. Abraham*_____
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DATED: July 24, 2025

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, that Defendants Xiromed Pharma España, S.L. and Xiromed, LLC are not aware of any other action in any court or any pending arbitration or administrative proceeding related to this matter.

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: July 24, 2025

s/ *Eric I. Abraham*

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CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Xiromed Pharma España, S.L. and Xiromed, LLC's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on July 24, 2025.

s/ *Eric I. Abraham*
Eric I. Abraham

DATED: July 24, 2025