Rebekah Conroy
Stone Conroy LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: 973-400-4181
rconroy@stoneconroy.com

Attorneys for Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVOFEM BIOSCIENCES, INC., EVOFEM, INC., and EVOFEM BIOSCIENCES OPERATIONS, INC., **Plaintiff,** **v.** **PADAGIS ISRAEL PHARMACEUTICALS LTD., PADAGIS US LLC, and PADAGIS LLC,** **Defendants.**	**Civil Action No. 3:23-cv-3003-ZNQ-DEA** **DEFENDANTS' ANSWER AND DEFENSES TO COMPLAINT FOR PATENT INFRINGEMENT AND DEFENDANTS' COUNTERCLAIMS** **(Filed Electronically)**

Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Padagis"), by its undersigned attorneys, submits this Answer and Defenses and Counterclaims in response to the Complaint for Patent Infringement of Plaintiffs Evofem Biosciences, Inc., Evofem, Inc., and Evofem Biosciences Operations, Inc. ("Plaintiffs"). Padagis denies all allegations in Plaintiffs' Complaint except those specifically admitted below. This pleading is based upon Padagis's knowledge of its own activities, and upon information and belief as to the activities of others.

Nature of the Action

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Padagis of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of the vaginal gel product currently marketed under the trade name PHEXXI® prior to the expiration of U.S. Patent Nos. 10,568,855 ("the '855 patent"), 11,337,989 ("the '989 patent"), and 11,439,610 ("the '610 patent") (collectively, "the Patents-in-Suit").

RESPONSE: Padagis admits that the Complaint purports to state an action against Padagis for alleged infringement of U.S. Patent Nos. 10,568,855 ("the '855 patent"), 11,337,989 ("the '989 patent"), and 11,439,610 ("the '610 patent") (collectively, "the Patents-in-Suit") under 35 U.S.C. §§ 100, *et seq.*, but Padagis denies the allegations have any merit. Padagis further admits that it filed Abbreviated New Drug Application ("ANDA") No. 217960 ("Padagis's ANDA") seeking regulatory approval to market its proposed generic a combination of lactic acid, citric acid, and potassium bitartrate drug product ("Padagis's Proposed Product") as described therein. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

Parties

2. Plaintiff Evofem Biosciences, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

RESPONSE: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies the same.

3. Plaintiff Evofem, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

RESPONSE: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

4. Plaintiff Evofem Biosciences Operations, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

RESPONSE: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

5. On information and belief, Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis Israel") is a corporation organized and existing under the laws of Israel, having a place of business at 1 Rakefet St., Shoham, 608500, Israel.

RESPONSE: Padagis admits that Padagis Israel is a corporation organized and existing under the laws of Israel, having a place of business at 1 Rakefet St., Shoham, 608500, Israel.

6. On information and belief, Defendant Padagis US LLC ("Padagis US") is a limited liability company organized and existing under the laws of Delaware, having a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

RESPONSE: Padagis admits that Padagis US is a limited liability company organized and existing under the laws of Delaware, having a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

7. On information and belief, Defendant Padagis LLC ("Padagis LLC") is a limited liability company organized and existing under the laws of Delaware, having a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

RESPONSE: Padagis admits that Padagis LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

8. On information and belief, Padagis Israel is a wholly owned subsidiary of Padagis LLC.

RESPONSE: Padagis admits that Padagis Israel is a wholly owned subsidiary of Padagis LLC.

9. On information and belief, Padagis US is a wholly owned subsidiary of Padagis LLC.

RESPONSE: Padagis admits that Padagis US is a wholly owned subsidiary of Padagis LLC.

Jurisdiction and Venue

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that this Court has subject-matter jurisdiction only over claims asserted under 35 U.S.C. § 271(e)(2)(A). Padagis denies that this Court has subject-matter jurisdiction over any other asserted claims. Padagis denies any remaining allegations of this paragraph.

11. As set forth in Paragraphs 12-15 below, this Court has personal jurisdiction over Padagis Israel by virtue of, among other things, its systematic and continuous contacts with the State of New Jersey.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

12. On information and belief, Padagis Israel is in the business of, among other things, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. On information and belief, Padagis Israel directly or indirectly develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Padagis ANDA Product (as defined below).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

13. On information and belief, Padagis Israel purposefully has conducted and continues to conduct business in this judicial district.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

14. On information and belief, Padagis Israel has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Bausch Health Ireland Ltd. et al. v. Padagis Israel Pharms. Ltd. et al.*, No. 2:22-cv-04248 (D.N.J.)

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

15. Alternatively, if the exercise of personal jurisdiction over Padagis Israel in this Court is not held to be proper, then, on information and belief, this Court has personal jurisdiction over Padagis Israel pursuant to Federal Rule of Civil Procedure 4(k)(2) because Padagis Israel has extensive contacts with the United States, including but not limited to the above-described commercial contact, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Padagis Israel is consistent with the laws of the United States and the United States Constitution.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

16. As set forth in Paragraphs 17-21 below, this Court has personal jurisdiction over Padagis US by virtue of, among other things, its systematic and continuous contacts with the State of New Jersey.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal

jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

17. On information and belief, Padagis US is in the business of, among other things, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. On information and belief, Padagis US directly or indirectly develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Padagis ANDA Product (as defined below).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

18. On information and belief, Padagis US purposefully has conducted and continues to conduct business in this judicial district.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

19. On information and belief, Padagis US is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Entity ID No. 0600473527.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that Padagis US is registered to do business in New Jersey under Business ID No. 0600473527. Padagis denies any remaining allegations of this paragraph.

20. On information and belief, Padagis US is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5006088.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that Padagis US is registered in New Jersey as a

manufacturer and wholesaler under registration number 5006088. Padagis denies any remaining allegations of this paragraph.

21. On information and belief, Padagis US has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., GW Research Ltd. v. Teva Pharms., Inc. et al.*, No. 2:23-cv-00018 (D.N.J.); *Bausch Health Ireland Ltd. et al. v. Padagis Israel Pharms. Ltd. et al.*, No. 2:22-cv-4248 (D.N.J.).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that Padagis US has consented to personal jurisdiction in this Court for the limited purposes of those actions and has filed counterclaims in this Court. Padagis denies any remaining allegations of this paragraph.

22. As set forth in Paragraphs 23-25 below, this Court has personal jurisdiction over Padagis LLC by virtue of, among other things, its systematic and continuous contacts with the State of New Jersey.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

23. On information and belief, Padagis LLC is in the business of, among other things, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. On information and belief, Padagis LLC directly or indirectly develops, manufactures, markets, and/or sells generic drug products throughout the United States and in this judicial district through its subsidiaries, and this judicial district is a likely destination for the Padagis ANDA Product (as defined below).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

24. On information and belief, Padagis LLC purposefully has conducted and continues to conduct business in this judicial district, at least through its wholly owned subsidiaries Padagis Israel and Padagis US.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

25. On information and belief, Padagis LLC has previously submitted to the jurisdiction of this Court. *See, e.g., Bausch Health Ireland Ltd. et al. v. Padagis Israel Pharms. Ltd. et al.*, No. 2:22-cv-04248 (D.N.J.).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

26. On information and belief, Padagis Israel, Padagis US, and Padagis LLC hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products. On information and belief, Padagis LLC exercises control over Padagis Israel and Padagis US.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

27. On information and belief, Padagis has taken the significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Padagis ANDA Product (as defined below), that will be purposefully directed at New Jersey and elsewhere. The filing of the Padagis ANDA (as defined below) constitutes a formal act that reliably indicates plans to engage in the manufacturing, marketing, selling, and distributing of the Padagis ANDA Product (as defined below).

RESPONSE: Padagis admits that it filed Padagis's ANDA seeking regulatory approval to market Padagis's Proposed Product as described therein. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

28. On information and belief, Padagis intends to direct sales of the Padagis ANDA Product (as defined below) into New Jersey, among other places, once it has received final FDA approval to market it.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

29. On information and belief, Padagis will engage in marketing of the Padagis ANDA Product (as defined below) in New Jersey upon approval of the Padagis ANDA (as defined below).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

30. In addition, jurisdiction is proper in this district with respect to Padagis Israel, Padagis US, and Padagis LLC because all three have agreed in writing not to contest personal jurisdiction in the United States District Court for the District of New Jersey for purposes of this action, and thus have consented to personal jurisdiction in this district for the purposes of this action.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

31. On information and belief, venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

32. Venue is proper in this judicial district as to Padagis Israel, because Padagis Israel is a foreign corporation, and this judicial district has personal jurisdiction over Padagis Israel

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

33. Venue is proper as to Padagis Israel, Padagis US, and Padagis LLC because each has previously consented to venue in this judicial district.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

34. In addition, venue is proper in this district with respect to Padagis Israel, Padagis US, and Padagis LLC because all three have agreed in writing not to contest venue in this district for the purposes of this action, and thus have consented to venue in this district for the purposes of this action.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

Patents-in-Suit

35. On February 25, 2020, the '855 patent entitled "Compositions and Methods for Enhancing the Efficacy of Contraceptive Microbicides" was duly and legally issued. A true and correct copy of the '855 patent is attached to this Complaint as Exhibit A.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that a copy of what purports to be the '855 patent is attached to the Complaint as Exhibit A. Padagis states that the '855 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Padagis denies any remaining allegations of this paragraph.

36. The FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the expiration of the '855 Patent as March 15, 2033.

RESPONSE: Padagis admits the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the ostensible expiration of the '855 Patent as March 15, 2033. Padagis denies any remaining allegations of this paragraph.

37. Evofem, Inc. is the assignee of the '855 patent.

RESPONSE: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding assignment of the ’855 patent, and therefore denies the same. Padagis denies any remaining allegations of this paragraph.

38. On May 24, 2022, the ’989 patent entitled “Compositions and Methods for Inhibiting Inflammation and Diseases Using an Alginic Acid-Based Antimicrobial Compound” was duly and legally issued. A true and correct copy of the ’989 patent is attached to this Complaint as Exhibit B.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that a copy of what purports to be the ’989 patent is attached to the Complaint as Exhibit B. Padagis states that the ’989 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Padagis denies any remaining allegations of this paragraph.

39. The Orange Book lists the expiration of the ’989 Patent as March 15, 2033.

RESPONSE: Padagis admits the Orange Book lists the ostensible expiration of the ’989 Patent as March 15, 2033. Padagis denies any remaining allegations of this paragraph

40. Evofem, Inc. is the assignee of the ’989 patent.

RESPONSE: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding assignment of the ’989 patent, and therefore denies the same. Padagis denies any remaining allegations of this paragraph.

41. On September 13, 2022, the ’610 patent entitled “Compositions and Methods for Enhancing the Efficacy of Contraceptive Microbicides” was duly and legally issued. A true and correct copy of the ’610 patent is attached to this Complaint as Exhibit C.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that a copy of what purports to be the ’610 patent is attached to the Complaint as Exhibit C. Padagis states that the ’610 patent speaks for itself, and

Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Padagis denies any remaining allegations of this paragraph.

42. The Orange Book lists the expiration of the '610 Patent as March 15, 2033.

RESPONSE: Padagis admits the Orange Book lists the ostensible expiration of the '610 Patent as March 15, 2033. Padagis denies any remaining allegations of this paragraph

43. Evofem, Inc. is the assignee of the '610 patent.

RESPONSE: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding assignment of the '610 patent, and therefore denies the same. Padagis denies any remaining allegations of this paragraph.

Acts Giving Rise to the Action

44. Evofem, Inc. holds the approved New Drug Application ("NDA") No. 208352 for the vaginal gel product currently marketed under the trade name PHEXXI®.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that the FDA website indicates that Evofem, Inc. is the holder of New Drug Application ("NDA") No. 208352 for the vaginal gel product currently marketed under the trade name PHEXXI®. Padagis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies the same.

45. PHEXXI® is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

RESPONSE: Padagis admits that PHEXXI® is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

46. Pursuant to 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the Patents-in-Suit are listed in the Orange Book for PHEXXI®, and were so listed at the time the Padagis ANDA (defined below) was submitted to the FDA.

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that the Orange Book listed the Patents-in-Suit for PHEXXI® when the Padagis ANDA was submitted to the FDA. Padagis denies any remaining allegations of this paragraph.

47. Padagis notified Evofem by letter dated April 18, 2023 ("the Notice Letter") that it had submitted to the FDA ANDA No. 217960 ("the Padagis ANDA"), seeking approval from the FDA "to engage in the commercial manufacture, use, and/or sale of lactic acid, citric acid, and potassium bitartrate vaginal gel" ("the Padagis ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Patents-in-Suit.

RESPONSE: Padagis admits that it sent written notice of a Paragraph IV Certification ("Padagis's Notice Letter") to Plaintiffs. Padagis admits that it filed Padagis's ANDA seeking regulatory approval to market Padagis's Proposed Product as described therein. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

48. The Notice Letter indicated that the Padagis ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the Patents-in-Suit ("Paragraph IV Certification").

RESPONSE: Padagis admits that Padagis's Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the Patents-in-Suit ("Paragraph IV Certification"). Padagis further states that Padagis's Notice Letter speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's Notice Letter. Padagis denies any remaining allegations of this paragraph.

49. The Notice Letter does not allege non-infringement for any claim of the Patents-in-Suit.

RESPONSE: Padagis denies the allegations of this paragraph including because Padagis's Notice Letter sets forth why the claims of the Patents-in-Suit are invalid, and an invalid claim

cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

50. By not identifying non-infringement defenses for any claim of the Patents-in-Suit in the Notice Letter, Padagis admitted that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product meets all limitations of all claims in the Patents-in-Suit.

RESPONSE: Padagis denies the allegations of this paragraph.

51. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101 or 102, or unenforceability for any claim of the Patents-in-Suit.

RESPONSE: Padagis denies the allegations of this paragraph including because there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

52. By not identifying invalidity defenses under 35 U.S.C. §§ 101 or 102, or unenforceability defenses for the Patents-in-Suit in the Notice Letter, Padagis admitted that the claims of the Patents-in-Suit are not invalid under 35 U.S.C. §§ 101 and 102, and are enforceable.

RESPONSE: Padagis denies the allegations of this paragraph.

53. Evofem is commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

RESPONSE: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits Padagis sent Padagis's Notice Letter on April 18, 2023, and that Evofem filed this action on June 1, 2023. Padagis denies any remaining allegations of this paragraph.

Count I: Infringement of the '855 Patent

54. Evofem realleges and incorporates by reference the allegations contained in the preceding paragraphs.

RESPONSE: Padagis repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

55. The Notice Letter does not allege that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product will not infringe any claim of the '855 patent.

RESPONSE: Padagis denies the allegations of this paragraph including because Padagis's Notice Letter sets forth why the claims of the Patents-in-Suit are invalid, and an invalid claim cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

56. The Notice Letter does not identify any limitation of the claims of the '855 patent that is absent from the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product.

RESPONSE: Padagis denies the allegations of this paragraph including because Padagis's Notice Letter sets forth why the claims of the Patents-in-Suit are invalid, and an invalid claim cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j)

or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

57. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of the '855 patent by submitting the Padagis ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product in the United States prior to the expiration of the '855 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

58. Padagis's actions, including but not limited to, the development of the Padagis ANDA Product, and the filing of the Padagis ANDA with the Paragraph IV Certification, reliably indicate that Padagis has made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import the Padagis ANDA Product, giving rise to an actual case or controversy between the parties over whether Padagis's future manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '855 patent will constitute infringement of the '855 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

59. On information and belief, Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '855 patent would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '855 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

60. On information and belief, the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '855 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

61. On information and belief, Padagis intends to, and will, actively induce infringement of at least one of the claims of the '855 patent after approval of the Padagis ANDA.

RESPONSE: Padagis denies the allegations of this paragraph.

62. On information and belief, Padagis knows that the Padagis ANDA Product and its proposed labeling are especially made or adapted for use in infringing at least one of the claims of the '855 patent and that the Padagis ANDA Product and its proposed labeling is not suitable for substantial non-infringing use.

RESPONSE: Padagis denies the allegations of this paragraph.

63. On information and belief, Padagis intends to, and will, contribute to infringement of at least one of the claims of the '855 patent after approval of the Padagis ANDA.

RESPONSE: Padagis denies the allegations of this paragraph.

64. On information and belief, Padagis has acted with full knowledge of the '855 patent and without a reasonable basis for believing that it would not be liable for infringing the '855 patent, actively inducing infringement of the '855 patent, and contributing to the infringement by others of the '855 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

65. On information and belief, Padagis intends to, and will, actively induce infringement of at least one of the claims of the '855 patent after approval of the Padagis ANDA.

RESPONSE: Padagis denies the allegations of this paragraph.

66. The commercial manufacture, importation, use, sale, or offer for sale of the Padagis ANDA Product in violation of Evofem's patent rights will cause harm to Evofem for which damages are inadequate.

RESPONSE: Padagis denies the allegations of this paragraph.

67. Unless Padagis is enjoined from infringing the '855 patent, Evofem will suffer substantial and irreparable harm for which there is no adequate remedy at law.

RESPONSE: Padagis denies the allegations of this paragraph.

68. Evofem is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of the Padagis ANDA be a date that is not earlier than the expiration date of the '855 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

Count II: Infringement of the '989 Patent

69. Evofem realleges and incorporates by reference the allegations contained in the preceding paragraphs.

RESPONSE: Padagis repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

70. The Notice Letter does not allege that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product will not infringe any claim of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph including because Padagis's Notice Letter sets forth why the claims of the Patents-in-Suit are invalid, and an invalid claim cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

71. The Notice Letter does not identify any limitation of the claims of the '989 patent that is absent from the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product.

RESPONSE: Padagis denies the allegations of this paragraph including because Padagis's Notice Letter sets forth why the claims of the Patents-in-Suit are invalid, and an invalid claim cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

72. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of the '989 patent by submitting the Padagis ANDA to obtain approval to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product in the United States prior to the expiration of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

73. Padagis's actions, including but not limited to, the development of the Padagis ANDA Product, and the filing of the Padagis ANDA with the Paragraph IV Certification, reliably indicate that Padagis has made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import the Padagis ANDA Product, giving rise to an actual case or controversy between the parties over whether Padagis's future manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '989 patent will constitute infringement of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

74. On information and belief, Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '989 patent would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

75. On information and belief, the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

76. On information and belief, Padagis intends to, and will, actively induce infringement of at least one of the claims of the '989 patent after approval of the Padagis ANDA.

RESPONSE: Padagis denies the allegations of this paragraph.

77. On information and belief, Padagis knows that the Padagis ANDA Product and its proposed labeling are especially made or adapted for use in infringing at least one of the claims of the '989 patent and that the Padagis ANDA Product and its proposed labeling is not suitable for substantial non-infringing use.

RESPONSE: Padagis denies the allegations of this paragraph.

78. On information and belief, Padagis intends to, and will, contribute to infringement of at least one of the claims of the '989 patent after approval of the Padagis ANDA.

RESPONSE: Padagis denies the allegations of this paragraph.

79. The foregoing actions by Padagis constitute and/or will constitute infringement of at least one of the claims of the '989 patent, active inducement of infringement of at least one of the claims of the '989 patent, and contribution to the infringement by others of at least one of the claims of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

80. On information and belief, Padagis has acted with full knowledge of the '989 patent and without a reasonable basis for believing that it would not be liable for infringing the '989 patent, actively inducing infringement of the '989 patent, and contributing to the infringement by others of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

81. The commercial manufacture, importation, use, sale, or offer for sale of the Padagis ANDA Product in violation of Evofem's patent rights will cause harm to Evofem for which damages are inadequate.

RESPONSE: Padagis denies the allegations of this paragraph.

82. Unless Padagis is enjoined from infringing the '989 patent, Evofem will suffer substantial and irreparable harm for which there is no adequate remedy at law.

RESPONSE: Padagis denies the allegations of this paragraph.

83. Evofem is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of the Padagis ANDA be a date that is not earlier than the expiration date of the '989 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

Count III: Infringement of the '610 Patent

84. Evofem realleges and incorporates by reference the allegations contained in the preceding paragraphs.

RESPONSE: Padagis repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

85. The Notice Letter does not allege that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product will not infringe any claim of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph including because Padagis's Notice Letter sets forth why the claims of the Patents-in-Suit are invalid, and an invalid claim

cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

86. The Notice Letter does not identify any limitation of the claims of the '610 patent that is absent from the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product.

RESPONSE: Padagis denies the allegations of this paragraph including because Padagis's Notice Letter sets forth why the claims of the Patents-in-Suit are invalid, and an invalid claim cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Padagis's ANDA. Padagis denies any remaining allegations of this paragraph.

87. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of the '610 patent by submitting the Padagis ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product in the United States prior to the expiration of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

88. Padagis's actions, including but not limited to, the development of the Padagis ANDA Product, and the filing of the Padagis ANDA with the Paragraph IV Certification, reliably indicate that Padagis has made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import the Padagis ANDA Product, giving rise to an actual case or controversy between the parties over whether Padagis's future manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '610 patent will constitute infringement of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

89. On information and belief, Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '610 patent would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

90. On information and belief, the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

91. On information and belief, Padagis intends to, and will, actively induce infringement of at least one of the claims of the '610 patent after approval of the Padagis ANDA.

RESPONSE: Padagis denies the allegations of this paragraph.

92. On information and belief, Padagis knows that the Padagis ANDA Product and its proposed labeling are especially made or adapted for use in infringing at least one of the claims of the '610 patent and that the Padagis ANDA Product and its proposed labeling is not suitable for substantial non-infringing use.

RESPONSE: Padagis denies the allegations of this paragraph.

93. On information and belief, Padagis intends to, and will, contribute to infringement of at least one of the claims of the '610 patent after approval of the Padagis ANDA.

RESPONSE: Padagis denies the allegations of this paragraph.

94. The foregoing actions by Padagis constitute and/or will constitute infringement of at least one of the claims of the '610 patent, active inducement of infringement of at least one of the claims of the '610 patent, and contribution to the infringement by others of at least one of the claims of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

95. On information and belief, Padagis has acted with full knowledge of the '610 patent and without a reasonable basis for believing that it would not be liable for infringing the '610 patent, actively inducing infringement of the '610 patent, and contributing to the infringement by others of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

96. The commercial manufacture, importation, use, sale, or offer for sale of the Padagis ANDA Product in violation of Evofem's patent rights will cause harm to Evofem for which damages are inadequate.

RESPONSE: Padagis denies the allegations of this paragraph.

97. Unless Padagis is enjoined from infringing the '610 patent, Evofem will suffer substantial and irreparable harm for which there is no adequate remedy at law.

RESPONSE: Padagis denies the allegations of this paragraph.

98. Evofem is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of the Padagis ANDA be a date that is not earlier than the expiration date of the '610 patent.

RESPONSE: Padagis denies the allegations of this paragraph.

RESPONSE TO PRAYER FOR RELIEF

Padagis denies that Plaintiffs are entitled to any of the relief set forth in its "Prayer for Relief against Padagis" in the Complaint, or to any other relief for any remaining allegations set forth in the Complaint.

AFFIRMATIVE DEFENSES

Without any admission as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Padagis states the following defenses:

FIRST AFFIRMATIVE DEFENSE

Padagis does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, properly construed claim of U.S. Patent Nos. 10,568,855 ("the '855 patent"), 11,337,989 ("the '989 patent"), and 11,439,610 ("the '610 patent") (collectively, "the Patents-in-Suit") either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

The claims of the Patents-in-Suit are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, 116, and/or 120 thereof.

THIRD AFFIRMATIVE DEFENSE

On information and belief, by virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the issuance of the Patents-in-Suit, Plaintiffs are estopped from maintaining that Padagis infringes any valid claim of the Patents-in-Suit.

FOURTH AFFIRMATIVE DEFENSE

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

FIFTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over portions of the claims asserted against Padagis, in particular, any infringement claims Plaintiffs assert under 35 U.S.C. § 271(a), (b), and/or (c).

* * *

Padagis expressly reserves the right to supplement and/or amend its Answer to Plaintiff's Complaint, including but not limited to supplementation and/or amendment of its defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

COUNTERCLAIMS

Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Padagis"), for its counterclaims against Evofem Biosciences, Inc., Evofem, Inc., and Evofem Biosciences Operations, Inc. ("Counterclaim-Defendants"), alleges as follows:

1. These counterclaim actions are for declaratory judgment of invalidity and/or non-infringement of one or more claims of U.S. Patent Nos. 10,568,855 ("the '855 patent"), 11,337,989 ("the '989 patent"), and 11,439,610 ("the '610 patent") (collectively, "the Patents-in-Suit").

THE PARTIES

2. Padagis is a limited liability company organized and existing under the laws of Delaware with a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

3. On information and belief, Evofem Biosciences, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

4. On information and belief, Evofem, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

5. On information and belief, Evofem Biosciences Operations, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these counterclaim actions for declaratory judgment pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1338, 2201, and 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Padagis and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

7. The Court has personal jurisdiction over Counterclaim-Defendants based on the filing of this lawsuit in this jurisdiction and because, on information and belief, they are doing business in this jurisdiction.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II).

ORANGE BOOK LISTINGS

9. On information and belief, on February 25, 2020, the United States Patent and Trademark Office ("USPTO") issued the '855 patent. On information and belief, Evofem, Inc. purports to be the assignee of the '855 patent. The '855 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to PHEXXI®.

10. On information and belief, on May 24, 2022, the USPTO issued the '989 patent. On information and belief, Evofem, Inc. purports to be the assignee of the '989 patent. The '989 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to PHEXXI®.

11. On information and belief, on September 13, 2022, the USPTO issued the '610 patent. On information and belief, Evofem, Inc. purports to be the assignee of the '610 patent. The '610 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to PHEXXI®.

PADAGIS'S ABBREVIATED NEW DRUG APPLICATION

12. Padagis filed Abbreviated New Drug Application ("ANDA") No. 217960 ("Padagis's ANDA") seeking regulatory approval to market its proposed generic a combination of lactic acid, citric acid, and potassium bitartrate drug product ("Padagis's Proposed Product") as described therein. In the ANDA, Padagis certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '855 patent, '989 patent, and '610 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Padagis's ANDA.

PRESENCE OF CONTROVERSY

13. On information and belief, Evofem, Inc. is the holder of New Drug Application ("NDA") No. 208352 for the vaginal gel product currently marketed under the trade name PHEXXI®.

14. On information and belief, prior to the filing of this action, Counterclaim-Defendants caused the FDA to list the '855 patent, '989 patent, and '610 patent in the Orange Book in connection with NDA No. 208352.

15. In a letter dated April 18, 2023 ("Padagis's Notice Letter"), Padagis notified Counterclaim-Defendants that Padagis's ANDA included a certification that the '855 patent, '989 patent, and '610 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Padagis's ANDA.

16. On June 1, 2023, Counterclaim-Defendants filed a patent infringement action against Padagis alleging infringement of the '855 patent, '989 patent, and '610 patent.

17. On information and belie, Counterclaim-Defendants have not caused the FDA to remove the Patents-in-Suit from the Orange Book in connection with NDA No. 208352.

18. By maintaining the listing of the Patents-in-Suit in the Orange Book, Counterclaim-Defendants represent that a claim of patent infringement of the Patents-in-Suit "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

19. In light of all the circumstances, there has been and is now an actual, substantial, and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court between Padagis and Counterclaim-Defendants as to whether Padagis's Produced Product would infringe any or all claims of the Patents-in-Suit and whether the claims of the Patents-in-Suit are valid and enforceable.

COUNT I.
Declaratory Judgment of Invalidity of the '855 Patent

20. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

21. The claims of the '855 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 120, and/or based on other judicially-created bases for invalidation.

22. The alleged invention of the '855 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.

23. The alleged invention of the '855 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

24. The '855 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

25. The alleged invention of the '855 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '855 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '855 patent and would have had a reasonable expectation of success in doing so.

26. The subject matter claimed in the '855 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

27. The '855 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

28. The claims of the '855 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

29. An actual and justiciable case or controversy exists between Padagis and Counter-Defendant as to whether the '855 patent is invalid.

30. Padagis is entitled to and seeks a declaration that the claims of the '855 patent are invalid.

COUNT II.
Declaratory Judgment of Non-Infringement of the '855 Patent

31. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

32. Counterclaim-Defendants have accused Padagis of infringing claims of the '855 patent in connection with Padagis's ANDA.

33. Padagis denies infringement of any valid, properly construed claim of the '855 patent, and alleges that the manufacture, use, sale, offer for sale or importation of Padagis's Proposed Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the '855 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

34. There is an actual, substantial, and continuing justiciable case or controversy between Padagis and Counterclaim-Defendants regarding infringement of the '855 patent in connection with the ANDA.

35. Padagis is entitled to and seeks a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Padagis's Proposed Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the '855 patent either directly or indirectly.

COUNT III.
Declaratory Judgment of Invalidity of the '989 Patent

36. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

37. The claims of the '989 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 120, and/or based on other judicially-created bases for invalidation.

38. The alleged invention of the '989 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.

39. The alleged invention of the ’989 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

40. The ’989 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

41. The alleged invention of the ’989 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’989 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’989 patent and would have had a reasonable expectation of success in doing so.

42. The subject matter claimed in the ’989 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

43. The ’989 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

44. The claims of the ’989 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not

particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

45. An actual and justiciable case or controversy exists between Padagis and Counter-Defendant as to whether the '989 patent is invalid.

46. Padagis is entitled to and seeks a declaration that the claims of the '989 patent are invalid.

COUNT IV.
Declaratory Judgment of Non-Infringement of the '989 Patent

47. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

48. Counterclaim-Defendants have accused Padagis of infringing claims of the '989 patent in connection with Padagis's ANDA.

49. Padagis denies infringement of any valid, properly construed claim of the '989 patent, and alleges that the manufacture, use, sale, offer for sale or importation of Padagis's Proposed Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the '989 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

50. There is an actual, substantial, and continuing justiciable case or controversy between Padagis and Counterclaim-Defendants regarding infringement of the '989 patent in connection with the ANDA.

51. Padagis is entitled to and seeks a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Padagis's Proposed Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the '989 patent either directly or indirectly.

COUNT V.
Declaratory Judgment of Invalidity of the '610 Patent

52. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

53. The claims of the '610 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 120, and/or based on other judicially-created bases for invalidation.

54. The alleged invention of the '610 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.

55. The alleged invention of the '610 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

56. The '610 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

57. The alleged invention of the '610 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '610 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '610 patent and would have had a reasonable expectation of success in doing so.

58. The subject matter claimed in the ’610 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

59. The ’610 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

60. The claims of the ’610 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

61. An actual and justiciable case or controversy exists between Padagis and Counter-Defendant as to whether the ’610 patent is invalid.

62. Padagis is entitled to and seeks a declaration that the claims of the ’610 patent are invalid.

COUNT VI.
Declaratory Judgment of Non-Infringement of the ’610 Patent

63. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

64. Counterclaim-Defendants have accused Padagis of infringing claims of the ’610 patent in connection with Padagis’s ANDA.

65. Padagis denies infringement of any valid, properly construed claim of the '610 patent, and alleges that the manufacture, use, sale, offer for sale or importation of Padagis's Proposed Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the '610 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

66. There is an actual, substantial, and continuing justiciable case or controversy between Padagis and Counterclaim-Defendants regarding infringement of the '610 patent in connection with the ANDA.

67. Padagis is entitled to and seeks a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Padagis's Proposed Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the '610 patent either directly or indirectly.

DEMAND FOR JUDGMENT

WHEREFORE, Padagis prays that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs therein;

b) Declaring the claims of the Patents-in-Suit invalid;

c) Declaring that the filing of Padagis's ANDA or the manufacture, use, sale, offer for sale or importation of Padagis's Proposed Product has not, does not, and would not infringe any valid claim, if any, of the Patents-in-Suit, either directly or indirectly, either literally or under the doctrine of equivalents;

d) Granting Padagis judgment in its favor on Plaintiffs' claims;

e) Granting Padagis judgment in its favor on its counterclaims;

f) Awarding Padagis such other and further relief as the Court deems just and proper.

Dated: August 7, 2023

STONE CONROY LLC

/s/Rebekah Conroy
Rebekah Conroy
Stone Conroy LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: 973-400-4181
rconroy@stoneconroy.com

OF COUNSEL:

Mark Deming
Polsinelli PC
150 N. Riverside Plaza, Suite 3000
Chicago, IL 60606
(312) 819-1900

Attorneys for Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, Attorneys for Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC, by their undersigned counsel, hereby certify that to the best of its knowledge, this matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: August 7, 2023

STONE CONROY LLC

/s/Rebekah Conroy
Rebekah Conroy
Stone Conroy LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: 973-400-4181
rconroy@stoneconroy.com

OF COUNSEL:

Mark Deming
Polsinelli PC
150 N. Riverside Plaza, Suite 3000
Chicago, IL 60606
(312) 819-1900

Attorneys for Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Attorneys for Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC, by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: August 7, 2023

STONE CONROY LLC

/s/Rebekah Conroy
Rebekah Conroy
Stone Conroy LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: 973-400-4181
rconroy@stoneconroy.com

OF COUNSEL:

Mark Deming
Polsinelli PC
150 N. Riverside Plaza, Suite 3000
Chicago, IL 60606
(312) 819-1900

Attorneys for Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC