

Steven M. Lester
La REDDOLA, LESTER & ASSOCIATES, LLP
Attorneys for Plaintiff American Infertility
of New York, P.C.
600 Old Country Road, Suite 224
Garden City, New York 11530
(516) 357-0056
sml@llalawfirm.com

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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AMERICAN INFERTILITY OF NEW YORK, P.C. and
FERTILITY NUTRACEUTICALS, LLC,

Plaintiffs,

-against-

THERALOGIX, LLC, KRISTIN A. BENDIKSON, M.D.,
GLENN L. SCHATTMAN, M.D., and ROBERT
J. STILLMAN, M.D.,

Defendants.

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Civil Action No.

COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs American Infertility of New York, P.C. (American Infertility) and Fertility
Nutraceuticals, LLC, by their attorneys, La Reddola, Lester & Associates, LLP, for their
Complaint against Defendants Theralogix, LLC, Kristin A. Bendikson, M.D., Glenn L.
Schattman, M.D., and Robert J. Stillman, M.D., alleges:

The Parties

1. American Infertility is a New York professional corporation having a place of
business at 21 East 69th Street, New York, New York 10021.

2. Fertility Nutraceuticals, LLC is a Delaware limited liability company having a
place of business at 551 Madison Avenue, Suite 700, New York, New York 10022.

3. Upon information and belief, Defendant Theralogix, LLC is a Maryland limited liability company having a place of business at 401 East Jefferson Street, Suite 108, Rockville, Maryland 20850.

4. Theralogix, LLC has a Medical Advisory Board, which according to Theralogix's website, "oversees the formulation and development of all Theralogix nutritional supplements." Theralogix claims that its Medical Advisory Board "is comprised of leading academic physicians and scientists from diverse fields and specialties" and that the Board "meets regularly to review current research and provide guidance on all existing products and development of new products."

5. Theralogix, LLC has three individuals on its Medical Advisory Board for Reproductive Endocrinology and Women's Health.

6. Upon information and belief, Defendant Kristin A. Bendikson, M.D. is a resident of the State of California, and an Assistant Professor of Obstetrics and Gynecology and Assistant Fellowship Director of the Division of Reproductive Endocrinology and Infertility at the Keck School of Medicine of the University of Southern California, USC Fertility, Los Angeles, California. Defendant Bendikson is a member of Theralogix Medical Advisory Board for Reproductive Endocrinology and Women's Health.

7. Upon information and belief, Defendant Glenn M. Schattman, M.D. is a resident of the State of New York and an Associate Professor of Clinical Obstetrics and Gynecology and an Associate Professor of Clinical Reproductive Medicine at the Weill Cornell Medical College of Cornell University, New York, New York. Defendant Schattman is a member of Theralogix Medical Advisory Board for Reproductive Endocrinology and Women's Health.

8. Upon information and belief, Defendant Robert J. Stillman, M.D., is a resident of the State of Maryland and a Clinical Professor in the Department of Obstetrics and Gynecology at Georgetown University School of Medicine, and is the Medical Director of the Shady Grove Fertility Reproductive Science Center in Rockville, Maryland. Defendant Stillman is a member of Theralogix Medical Advisory Board for Reproductive Endocrinology and Women's Health.

9. Defendants Theralogix, LLC, Bendikson, Schattman and Stillman are hereinafter collectively referred to as Theralogix.

Jurisdiction and Venue

10. This Court has subject matter jurisdiction over this claim pursuant to 28 U.S.C. §§ 1331 and 1338 because this action arises under the United States patent laws, 35 U.S.C. § 101, *et seq.*

11. Upon information and belief, Theralogix is subject to this Court's personal jurisdiction because it regularly conducts business and/or solicits business, engages in other persistent course of conduct and/or derives substantial revenue from goods and/or services sold to persons and/or entities in the State of New York.

12. Upon information and belief, Theralogix directly infringed, continues to directly infringe, induced others to infringe, continues to induce others to infringe, contributed to infringement and continues to contribute to infringement, of U.S. Patent No. 8,067,400 (the '400 patent), by manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising, selling or otherwise making available, within the State of New York and elsewhere throughout the United States, products, including, but not limited to, DHEA

25 (the infringing product), that contains dehydroepiandrosterone (DHEA) and are administered in accordance with the claims of the '400 patent.

13. Upon information and belief, Theralogix is subject to this Court's personal jurisdiction in accordance with due process and/or the New York long arm statute because it is conducting substantial business in the State of New York because it engaged in, and continues to engage in, manufacturing, promoting, marketing, having made, using, importing, offering for sale, advertising and selling of goods and products, including the infringing product, in the State of New York.

14. Theralogix has an interactive website on which it markets, advertises, sells and/or offers for sale the infringing product to be administered in accordance with the limitations of at least one of the claims of the '400 patent, which website is used, and/or accessible, in the State of New York.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400. Theralogix is subject to personal jurisdiction in this judicial district in accordance with due process and/or the New York long arm statute. Theralogix engaged in, and continues to engage in, the manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising and selling goods and products, including the infringing product, in this judicial district and are administered in accordance with the limitations of at least one of the claims of the '400 patent. Therefore, the complained of acts of patent infringement occurred, and continue to occur, within this judicial district.

16. Upon information and belief, Theralogix induced, and continues to induce, infringement of the '400 patent by manufacturing, promoting, marketing, making, having made,

using, importing, offering for sale, advertise and sell goods and products, including the infringing product, in this judicial district, to be administered in accordance with the limitations of at least one of the claims of the '400 patent.

The Patent-in-Suit

17. On November 29, 2011, the U.S. Patent and Trademark Office duly and validly issued the '400 patent, entitled "Androgen Treatment in Females," naming Norbert Gleicher, David H. Barad and Dwyn V. Harben as inventors and American Infertility as assignee. A copy of the '400 patent is attached as Exhibit 1.

18. The '400 patent is a continuation-in-part of application no. 10/973,192, filed on October 26, 2004, now abandoned, and a continuation-in-part of application no. 11/269,310, filed on November 8, 2005, now U.S. Patent No. 7,615,544, and a continuation-in-part of application no. 11/680,973, filed on March 1, 2007, now abandoned.

19. The '400 patent is generally directed to a method for improving the quality of embryos, pregnancy rates and reduction of miscarriage rates by administering an androgen, such as DHEA, for at least two months.

20. American Infertility is the assignee and owner of all right, title and interest in and to the '400 patent, including the right to assert all causes of action arising under said patent and the right to seek and recover remedies for infringement of the '400 patent.

21. Fertility Nutraceuticals is the licensee from American Infertility of, *inter alia*, the '400 patent, and Fertility Nutraceuticals has the right to bring an action for infringement of the '400 patent under such license.

FIRST CLAIM
(Patent Infringement)

22. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 to 21 as though fully set forth herein.

23. American Infertility owned the '400 patent throughout the period of Theralogix's infringing acts and still owns the '400 patent.

24. Fertility Nutraceuticals was the licensee of the '400 patent throughout the period of Theralogix's infringing acts and still licenses the '400 patent.

25. At all relevant times herein, the '400 patent is a valid and enforceable patent.

26. Theralogix directly infringed, continues to directly infringe, literally and/or under the doctrine of equivalents, induced others to infringe, continues to induce others to infringe, contributed to infringement and continues to contribute to infringement, within this judicial district and elsewhere throughout the United States, at least one of the claims of the '400 patent, by manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising, selling or otherwise making available the infringing product to be administered in accordance with the limitations of at least one of the claims of the '400 patent without license, permission and/or authorization from American Infertility.

27. Upon information and belief, Theralogix was aware of the '400 patent.

28. Claim 1 of the '400 patent is a "method of decreasing aneuploidy rates in human embryos comprising administering androgen to a female for at least two months."

29. Claim 3 of the '400 patent is a "method according to claim 1, wherein said androgen is dehydroepiandrosterone [DHEA]."

30. Claim 4 of the '400 patent is a "method according to claim 3, wherein said dehydroepiandrosterone administration comprises between 50 and 100 mg per day of said dehydroepiandrosterone."

31. Claim 6 of the '400 patent is for a "method of decreasing time to pregnancy and increasing pregnancy rates in females comprising administering an androgen for at least two months."

32. Theralogix promotional material for its DHEA 25 product refers to unspecified research which shows that 75 mg daily dosages of DHEA is effective to improve egg and embryo quality in women with diminished ovarian reserve. A copy of the DHEA 25 product brochure is attached as Exhibit 2.

33. Theralogix's website states that women wanting to get pregnant should take one 25 mg capsule of DHEA, three times per day, for at least six weeks. A screen shot of the Theralogix website is attached as Exhibit 3.

34. Although Theralogix's website recommends taking the 75 mg dosage for "at least six weeks before conception," Theralogix only sells the infringing product in a 90 day through that website. Theralogix website page showing how to order the 90 day, 270 capsule supply of DHEA 25 (25 mg per capsule at three capsules per day) is attached as Exhibit 4. There are no other quantities of capsules that may be ordered from Theralogix. Clearly, Theralogix is aware of the '400 patent, and its limitations, but intentionally sells a 90 day supply despite the statement on its website that its product should be taken for at least six weeks.

35. Theralogix's promotion, offer of sale and sale of 75 mg daily dosages and a 90 day supply of the infringing product, for the purposes set for therein, is administered, or to be

administered, in accordance with the limitations of at least claims 1, 3, 4 and/or 6 of the '400 patent.

36. By May 15, 2015 letter, the Hess Patent Law Firm LLC on behalf of American Infertility requested that Theralogix provide it with information regarding Theralogix's DHEA product sales, marketing, representations and the administration and prescription of DHEA.

37. In a May 28, 2015 email, Theralogix, by its Chief Executive Officer, responded to Mr. Hess that he needed more time to attend to the information requested and reply thereto. However, by June 16, 2015 letter, Arnold & Porter LLP, on behalf of Theralogix, responded to Mr. Hess by refusing to provide any of the information requested, and asserted that the Hess Patent Law Firm letter did not assert infringement, that there was no good faith basis to do so and that Theralogix's policy is to respect the intellectual property rights of others.

38. In addition, Theralogix's legal counsel's letter states that it will be making changes to its marketing materials and website regarding DHEA, including changes to the "characterizations of DHEA, its effects and its dosing."

39. To date, Theralogix continues its infringing activities.

40. Upon information and belief, Theralogix took active and deliberate steps to induce direct infringement of the '400 patent by advertising and instructing others to use and/or administer the infringing product in a manner that infringes the '400 patent, including showing and directing consumers how to use the infringing product on Theralogix's promotional literature, brochures and/or on its website.

41. Specifically, the product brochure and Theralogix's website at <http://www.theralogix.com> as shown in Exhibits 2-4 instruct customers to administer the

infringing product, DHEA, in dosages and for purposes and/or effects that are covered by at least one of the claims of the '400 patent. And Theralogix sells its DHEA 25 product only in a quantity for a 90 day supply.

42. Upon information and belief, Theralogix knew or should have known that its actions infringe, and would induce actual infringement of, the '400 patent.

43. Individual defendants Bendikson, Schattman and Stillman are members of the corporate defendant's Medical Advisory Board relating to Reproductive Endocrinology and Women's Health. Upon information and belief and according to Theralogix's website, individual defendants Bendikson, Schattman and Stillman oversaw the formulation and development of DHEA 25 and, therefore, knowingly directed the acts of infringement by the corporate defendant, Theralogix, LLC.

44. Upon information and belief, individual defendants Bendikson, Schattman and Stillman induced the infringing acts set forth in this Complaint, and with the specific intent of encouraging Theralogix's and other direct infringers' activities, knew or should have known their actions would induce actual infringement of the '400 patent.

45. Theralogix is intentionally infringing the '400 patent.

46. Theralogix's unlawful acts of infringement as described herein constitute a violation of 35 U.S.C § 271(a) and/or 35 U.S.C § 271(b).

47. As a direct and proximate consequence of Theralogix's direct and/or inducement of infringement of the '400 patent, Plaintiffs suffered, and continue to suffer, irreparable injury and monetary damages pursuant to 36 U.S.C §§ 281, 283, 284, 285 and 287.

48. Upon information and belief, Theralogix's direct infringement and/or inducement of infringement of the '400 patent will continue unless enjoined by this Court.

49. By reason of the foregoing, Plaintiffs seek damages and a trebling thereof and preliminary and permanent injunctions enjoining Theralogix from committing further acts of infringement of the '400 patent.

Jury Demand

50. Plaintiffs hereby demand a trial by jury on all issues so triable.

Reservation of Rights

51. The above allegations and claims are based upon information known to Plaintiffs, and/or upon Plaintiffs' information and belief at this time. Plaintiffs' discovery and investigation in this action is continuing and Plaintiffs reserve their right to supplement and/or amend such allegations and claims.

Demand for Relief

WHEREFORE, Plaintiffs demand judgment and an order:

- A. Adjudicating that Theralogix infringed the '400 patent;
- B. Preliminary and permanently enjoining Theralogix and its respective officers, directors, agents, affiliates, subsidiaries, parents, employees, and those persons and entities in active concert therewith, from committing further acts of direct infringement and/or inducement of infringement of the '400 patent;
- C. Awarding Plaintiffs damages for the Theralogix's infringement of the '400 patent pursuant to 35 U.S.C. § 284;

- D. Awarding Plaintiffs treble damages for Theralogix's willful and intentional infringement of the '400 patent pursuant to 35 U.S.C. § 284;
- E. Awarding Plaintiffs pre-judgment and post-judgment interest as applicable by law;
- F. Awarding Plaintiffs its costs incurred in this action;
- G. Declaring this case "exceptional" under 35 U.S.C. § 285, and awarding Plaintiffs its attorneys' fees in this matter;
- H. Requiring Theralogix to render an accounting to Plaintiffs for Theralogix's profits or the value of the business opportunities received from the foregoing acts of patent infringement; and
- I. Granting Plaintiffs such other and further relief as this Court deems just and proper.

Dated: Garden City, New York
June 25, 2015

La REDDOLA, LESTER &
ASSOCIATES, LLP

By: /s/ Steven M. Lester
Steven M. Lester
Attorney for Plaintiff
600 Old Country Road, Suite 224
Garden City New York 11530
(516) 357-0056