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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORKX	
AMERICAN INFERTILITY OF NEW YORK, P.C., d/b/a The Center for Human Reproduction, and FERTILITY NUTRACEUTICALS, LLC,	Civ. Action No.: 21 CV 5566
Plaintiffs, -against-	COMPLAINT JURY TRIAL DEMANDED
CNY FERTILITY, PLLC, d/b/a CNY Fertility Center,	
Defendant.	
X	

Plaintiffs American Infertility of New York, P.C., d/b/a The Center for Human Reproduction ("American Infertility") and Fertility Nutraceuticals, LLC ("FNC" and collectively, "plaintiffs"), by their attorneys, La Reddola, Lester & Associates, LLP, for their complaint against CNY Fertility, PLLC, d/b/a CNY Fertility Center ("CNY" or "defendant"), allege:

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. FNC is a Delaware limited liability company having a place of business at 1411 Broadway, 16th Floor, New York, New York 10018.

3. Upon information and belief, CNY is a New York professional limited liability company conducting business in the United States and in the State of New York. CNY has its main offices, corporate headquarters, and a place of business at 195 Intrepid Lane, Syracuse, New York 13205 and conducts business in three other locations in the State of New York.

Jurisdiction and Venue

- 4. 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*.
- 5. Upon information and belief, defendant is subject to this Court's personal jurisdiction because it is a New York professional limited liability company, it maintains its main offices and corporate headquarters in the State of New York, 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.
- 6. Upon information and belief, defendant 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," a copy of which is attached as Exhibit 1) and U.S. Patent No. 9,375,436 (the "'436 patent," a copy of which is attached as Exhibit 2), by promoting, marketing, making, having made, distributing, selling, offering for sale, otherwise making available, prescribing, recommending, using, and inducing other to use, within the State of New York and elsewhere throughout the United States, the patented invention by administering and/or inducing others to administer an androgen including, but not limited to, 'Fountain DHEA' that contains

dehydroepiandrosterone (DHEA), in accordance with all of the limitations of at least one claim of each of the '400 and '436 patents (the "infringing method").

- 7. Upon information and belief, defendant is also subject to this Court's personal jurisdiction in accordance with due process because it is engaging in, and continues to engage in, promoting, marketing, having made, using, distributing, offering for sale, prescribing, providing, advertising and/or selling services, including the infringing method, in the State of New York and this judicial district, which infringing method is promoted, marketed, sold, offered for sale, used, induced for use, prescribed, recommended, and administered in accordance with all of the limitations of at least one of the claims of each of the '400 and '436 patents.
- 8. Upon information and belief, defendant has an interactive website on which it markets, advertises, distributes, promotes, prescribes, recommends, sells, offers for sale, uses, and/or induces the sale and use of the infringing method to be administered in accordance with the limitations of at least one of the claims of each of the '400 and '436 patents, which website is used, and/or accessible, in the State of New York and this judicial district.
- 9. Specifically, the infringing method is advertised, marketed, described in detail, distributed, prescribed, recommended, promoted for sale and use, and linked to a specific site for sale of Fountain DHEA on defendant's internet website at http://cnyfertility.com/dhea-for-fertility and is being practiced, induced for use, sold, offered for sale, and made in the United States. (See Exhibit 3).
- 10. On its website, defendant specifically instructs patients to administer and use DHEA, and specifically Fountain DHEA from Fountain DHEA, LLC for fertility purposes including to improve egg quality, increase the number of eggs in an in-vitro fertilization (IVF)

cycle, increase pregnancy rates and successful IVF outcomes, and reduce miscarriage rates and aneuploidy. (*See* Exhibit 3, p. 2). On its website, defendant specifically recommends, instructs, administers, prescribes, and uses, or induces patients to administer and use DHEA and specifically Fountain DHEA at dosages of 75 mg per day in micronized doses of 25 mg for at least 6-8 weeks, but preferably 4-5 months, prior to a fertility treatment cycle. (*See* Exhibit 3, pp. 7 and 9).

- 11. On its website, defendant specifically recommends and induces its patients to purchase DHEA from Fountain DHEA, LLC and provides a hyperlink for patients to be able to place an order and purchase the Fountain DHEA product from defendant's website, which DHEA product is sold in a 90-day supply (270 capsules) of 25 mg doses to be taken three times a day. (*See* Exhibit 3, pp. 8-9).
- 12. On its website, defendant intentionally and blatantly markets, promotes, advertises, prescribes, recommends, offers for sale, sells, uses, administers and/.or induces the use and administration of DHEA (and specifically Fountain DHEA) and the practice of the infringing method in accordance with the specific limitation of at least one of the claims of the '400 and '436 patents using headings in its DHEA Table of Contents such as "Fast Facts about DHEA for Fertility," "Who should take DHEA for Fertility," "DHEA for Fertility Dosage" and "CNY Recommended DHEA." (*See* Exhibit 3, pp. 2, 6, 7, 8-9).
- 13. Upon information and belief, defendant not only promotes, markets, administers, prescribes, recommends, offers for sale, sells, uses, and induces the use and practice of the infringing method including the use and administration of DHEA and specifically Fountain

DHEA from Fountain DHEA, LLC for patented purposes on its website, but it also does so at its four clinics throughout the State of New York and its two clinics in other states.

- 14. Only a few months prior to defendant's infringing activities, in or about December 2020, an employee of defendant, who represented himself as William Kiltz, the Director of Marketing and/or the Head of Business Development for defendant and the nephew of defendant's Founder and Director, Robert Kiltz, M.D., communicated with representatives of FNC to obtain a license from FNC for defendant and a company called "Molecular Fertility" for the sale and use of DHEA in accordance with the patented methods.
- 15. William Kiltz represented himself to be the President of Molecular Fertility, a company formed as part of defendant's marketing strategy to be an online supplement store to sell and distribute supplement products to defendant's patients and customers and other customers.
- 16. FNC offered terms which were rejected by William Kiltz and FNC did not provide such a license.
- 17. Only a few months thereafter, defendant began the infringing activities described above on its website and at its clinics.
- 18. Upon information and belief, William Kiltz and Richard Kiltz incorporated or directed the incorporation of Fountain DHEA, LLC as a limited liability company in the State of Wyoming.
- 19. Fountain DHEA, LLC only sells one product: DHEA for use in the infringing method.

- 20. Upon further information and belief, Fountain DHEA, LLC makes, sells, offers for sale, uses, promotes, recommends, and administers its DHEA product at defendant's direction and pursuant to defendant's website's hyperlink, prescriptions, referrals and recommendations in accordance with its infringing method described above.
- 21. Upon information and belief, CNY, Molecular Fertility and Fountain DHEA, LLC are owned and/or controlled by the same person(s).
- 22. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b).

 Defendant resides in this judicial district because it is subject to the court's personal jurisdiction in the State of New York in this civil action. Defendant is organized in New York. Defendant conducts business and treats patients in New York. Defendant engaged in, and continues to engage in, the manufacturing, promoting, recommending, practicing, marketing, making, having made, using, inducing the use of, offering for sale, practicing, administering, inducing the administration and/or practice of, prescribing, advertising and/or selling services, including the infringing method, in New York. The infringing method is sold, offered for sale, made, prescribed, advertised, recommended, promoted, practiced, used, induced for use, and administered in accordance with the limitations of at least one of the claims of the '400 and '406 patents. Therefore, the complained of acts of patent infringement occurred, and continue to occur, in New York.
- 23. Upon information and belief, defendant induced, continues to induce, contributes to, and continues to contribute to, infringement of the '400 and '436 patents by manufacturing, having manufactured, promoting, recommending, marketing, making, having made, practicing, using, inducing the use of, administering, inducing the administration of, distributing,

prescribing, offering for sale, advertising and/or selling the infringing method in this judicial district, which expressly includes administration of DHEA, specifically Fountain DHEA, in accordance with the limitations of at least one of the claims of each of the '400 and '436 patents.

The Patents-in-Suit

- 24. 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. A copy of the '400 patent is attached as Exhibit 1.
- 25. 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.
- 26. The '400 patent is generally directed to a method for improving the quality of embryos, pregnancy rates and reduction of miscarriage rates and aneuploidy by administrating an androgen, such as DHEA, for at least two months. (*See* Exhibit 1).
- 27. On June 28, 2016, the U.S. Patent and Trademark Office duly and validly issued the '436 patent, entitled "Androgen Treatment in Females," naming Norbert Gleicher and David H. Barad as inventors.
- 28. The '436 patent is a continuation-in-part of application nos. 12/575,426, filed on Oct. 7, 2009, 12/610,215, filed Oct. 30, 2009, and 12/123,877, filed on May 20, 2008, which is a continuation-in-part of application nos. 11/680,973, filed on Mar. 1, 2007, 11/269,310, filed on Nov. 8, 2005, now U.S. Pat. No. 7,615,544, and no. 10/973,192, filed Oct. 26, 2004.

- 29. The '436 patent is generally directed to a method for reducing aneuploidy rates, and therefore reduce miscarriage rates and improve pregnancy rates in human embryos by administrating an androgen, such as DHEA or testosterone, for at least four weeks. (*See* Exhibit 2).
- 30. American Infertility is the assignee and owner of, and FNC is the exclusive licensee of, all right, title and interest in and to the '400 and '436 patents, 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 and '436 patents.
- 31. American Infertility owned, and FNC exclusively licensed, the '400 and '436 patents throughout the period of defendant's infringing acts and still own and exclusively license the '400 and '436 patents.
- 32. At all relevant times herein, the '400 and '436 patents are valid and enforceable patents.

FIRST CLAIM (Patent Infringement)

- 33. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 to 32 as though fully set forth herein.
- 34. Defendant 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 and '436 patents, by manufacturing, having manufactured, promoting, prescribing, recommending, marketing, making, having made, using, inducing the use of, administering, inducing the

administration of, distributing, offering for sale, advertising, selling and/or otherwise making available the infringing method to be administered in accordance with the limitations of these claims without license, permission and/or authorization from American Infertility.

- 35. Upon information and belief, defendant was aware of the '400 and '436 patents.
- 36. 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."
- 37. Claim 3 of the '400 patent is a "method according to claim 1, wherein said androgen is dehydroepiandrosterone [DHEA]."
- 38. 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."
- 39. 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."
- 40. Claim 1 of the '436 patent is for a "method of reducing aneuploidy rates in human embryos, said method comprising: administering an androgen selected from the group consisting of DHEA and testosterone to a human female for at least four weeks without concurrent administration of gonadotropin."
- 41. Claim 3 of the '436 patent is for a "method according to claim 1, wherein said androgen is DHEA, micronized, pharmaceutical grade and is orally administered."
- 42. Claim 4 of the '436 patent is for a "method according to claim 1, wherein said method decreases miscarriage rates."

- 43. Defendant's website and promotional material markets, advertises, distributes, sells and/or offers for sale, prescribes, promotes, recommends, practices, uses, induces the use of, administers, or induces the administration of DHEA in accordance with the infringing method to be administered in accordance with the limitations of at least one of the claims of each of the '400 and '436 patents.
- 44. Specifically, the infringing method is advertised, marketed, distributed, recommended, offered for sale and sold, used or induced for use, administered or induced for administration on defendant's internet website at http://cnyfertilty.com/dhea-for-fertility and is being made, sold and used in the United States, including the State of New York. (Copies of screenshots of the defendant's website with the recommended sale of DHEA to be used in accordance with the infringing method are attached as Exhibit 3).
- 45. The infringing method and the recommended DHEA product are being sold specifically to improve egg quality, reduce an euploidy, increase the number of eggs retrieved in IVF cycles, increase pregnancy rates, reduce miscarriage rates, and generally to improve fertility and increase the IVF success rate.
- 46. The DHEA is being sold in bottles containing a 90-day supply (270 capsules) of 25 mg capsules (*see* Exhibit 4, website page for the infringing product, Fountain DHEA) with directions on defendant's website for patients to administer the DHEA for at least 6-8 weeks, and preferably 4-5 months, in 75 mg per day dosages (3 times per day). (*See* Exhibits 3, p. 3 ("The standard dosage of DHEA for fertility is 25 mg 3 times a day for a total of 75 mg per day") and p. 7 ("One should aim for at least 6-8 weeks of DHEA supplementation prior to a fertility treatment cycle. That said, the effects of DHEA increase over time and reach their peak after

approximately 4-5 months")). Therefore, the DHEA is recommended for use by defendant and purchased and sold to practice and perform the infringing method.

- 47. Defendant also promotes, advertises, prescribes, offers for sale and/or sells the infringing method by direct emails to its patients. A copy of a recent email to a patient of defendant is attached as Exhibit 5. The email advertises Fountain DHEA as costing "From \$60.00/90 days." Below the 90-day supply term is a hyperlink to the Fountain DHEA web site where the email recipient may purchase the DHEA product for use in the infringing method.
- 48. Defendant's promotion, advertising, prescribing, offer of sale, and/or sale of the infringing method includes instructions for patients and customers to purchase the Fountain DHEA product which contains 270 25 mg dose capsules, to be taken in a daily dosage of 75 mg per day (three times a day) for at least 6-8 weeks, and preferably 4-5 months, for the fertility purposes set forth in its website and other promotional material. Therefore, the infringing method is administered, or induced to be administered, in accordance with the limitations of at least one of the claims of each of the '400 and '436 patents.
- 49. Defendant has full knowledge of the patents in suit and tried to license the patents from plaintiffs.
 - 50. Defendant was unsuccessful in obtaining a license from plaintiffs.
- 51. Defendant then commenced the infringing activities set forth herein only after being unsuccessful in obtaining a license from plaintiffs.
- 52. Upon information and belief, defendant's founder and/or his nephew incorporated and/or arranged for the incorporation of Fountain DHEA for the sole purpose of selling DHEA to

be used in the infringing method as prescribed, recommended, used, practiced, administered, or induced for use and administration by and for defendant after defendant failed to obtain a license.

- 53. To date, defendant continues its infringing activities.
- 54. Upon information and belief, defendant took active and deliberate steps to induce and/or contribute to the infringement of the '400 and '436 patents by (i) advertising, distributing, prescribing, recommending and/or instructing others to purchase, use and/or administer DHEA in a manner that infringes (*i.e.* the infringing method) the '400 and '436 patents, including showing and directing consumers how to purchase, use and/or administer the DHEA for the patented purposes and methods (*i.e.* the infringing method) on defendant's promotional literature, brochures and/or on its website and (ii) forming Fountain DHEA, LLC and directing its patients to purchase Fountain DHEA for administration thereof in accordance with the patented methods and for the patented purposes (*i.e.* the infringing method). (Exhibits 3-4).
- 55. Upon information and belief, defendant knew or should have known that its actions infringe and would induce and/or contribute to the infringement of, the '400 and '436 patents.
 - 56. Defendant is willfully and intentionally infringing the '400 and '436 patents.
- 57. Defendant's unlawful acts of infringement as described herein constitute a violation of 35 U.S.C § 271(a), 35 U.S.C § 271(b) and/or 35 U.S.C. § 271(c).
- 58. As a direct and proximate consequence of defendant's direct and/or inducement of and/or contributory infringement of the '400 and '436 patents, plaintiffs suffered, and continue to suffer, irreparable injury and monetary damages pursuant to 36 U.S.C §§ 281, 283, 284, 285 and 287.

- 59. By reason of the foregoing, defendant's direct infringement, inducement of infringement, and/or contributory infringement of the '400 and '436 patents have caused and will continue to cause damages to plaintiffs.
- 60. Upon information and belief, plaintiff's direct, induced and/or contributory infringement of the '400 and '436 patents will continue unless enjoined by this Court.
- 61. By reason of the foregoing, plaintiffs seek damages and a trebling thereof and preliminary and permanent injunctions enjoining defendant from committing further acts of direct, induced, or contributory infringement of the '400 and '436 patents.

Jury Demand

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

Reservation of Rights

63. The above allegations and claims are based upon information known to plaintiffs, and/or upon their information and belief at this time. Plaintiffs' discovery and investigation in this action is continuing and they 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 CNY infringed and is infringing the '400 and '436 patents;
- B. Preliminary and permanently enjoining CNY 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 and/or contributory infringement of the '400 and '436 patents;

C. Awarding to plaintiffs their damages for CNY's direct and indirect infringement

of the '400 and '436 patents pursuant to 35 U.S.C. § 284;

D. Awarding to plaintiffs treble damages for CNY's willful and intentional

infringement of the '400 and '436 patents pursuant to 35 U.S.C. § 284;

E. Awarding to plaintiffs such pre-judgment and post-judgment interest as applicable

by law;

F. Awarding to plaintiffs their costs incurred in this action;

G. Given CNY's blatant and intentional acts of infringe, declaring this case

"exceptional" under 35 U.S.C. § 285, and awarding to plaintiffs their attorneys' fees in this

matter;

H. Requiring CNY to render an accounting to plaintiffs for CNY's profits or the

value of the business opportunities received from the foregoing acts of patent infringement; and

I. Granting to plaintiffs such other and further relief as this Court deems just and

proper.

Dated: Garden City, New York

June 25, 2021

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