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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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AMERICAN INFERTILITY OF NEW YORK, P.C.,

Civil Action No.

Plaintiff,

COMPLAINT

-against-

**JURY TRIAL
DEMANDED**

MDR PHARMACEUTICAL CARE, LTD.,

Defendant.

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Plaintiff American Infertility of New York, P.C. (American Infertility), by its attorneys,
La Reddola, Lester & Associates, LLP, for its Complaint against defendant MDR
Pharmaceutical Care Ltd., alleges:

The Parties

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

2. Upon information and belief, Defendant MDR Pharmaceutical Care Ltd. (MDR)
is a foreign business corporation conducting business in the United States and having its
principal place of business at 17071 Ventura Boulevard, Suite 100, Encino, California 93116.

Jurisdiction and Venue

3. 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.*

4. Upon information and belief, MDR 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.

5. Upon information and belief, MDR 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 manufacturing, promoting, marketing, making, having made, using, distributing, offering for sale, advertising, selling and/or otherwise making available, within the State of New York and elsewhere throughout the United States, products, including, but not limited to, “Naturally Smart DHEA 25mg” (the Infringing Product), that contains dehydroepiandrosterone (DHEA) and is sold and administered in accordance with the limitations of at least one claim of each of the ‘400 and ‘436 patents.

6. Upon further information and belief, MDR 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. MDR is engaged in, and continues to engage in manufacturing, promoting, marketing, having made, using, distributing, offering for

sale, advertising and/or selling of goods and products, including the Infringing Product, in the State of New York and which is sold and administered in accordance with the limitations of at least one of the claims of each of the '400 and '436 patents.

7. Upon information and belief, MDR has an interactive website on which it markets, advertises, distributes, 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 each of the '400 and '436 patents, which website is used, and/or accessible, in the State of New York. Specifically, the Infringing Product is advertised, marketed, distributed, offered for sale and sold on MDR's Naturally Smart Vitamins internet web site at <http://www.naturallysmartvitamins.com> and is being sold throughout the United States. (*See* Exhibit 3).

8. The Infringing Product is being sold in a dosage of 25 mg of DHEA per capsule, with 90 capsules in each bottle. (Exhibit 3).

9. MDR's website also describes that the Infringing Product "may improve ovarian health and egg quality in women trying to conceive. Can be taken in conjunction with fertility treatments." (*See* Exhibit 4).

10. The extended information for the Infringing Product provides that "Naturally smart DHEA® can be used in conjunction with fertility treatments for women, and may improve ovarian health and increase the quality and quantity of eggs and embryos. Other benefits may include increased IVF pregnancy rates and decreased risk of miscarriage and chromosomal abnormalities in embryos." (*See* Exhibit 5). The website identifies MDR as the distributor of the Infringing Product and directs purchasers of the product to purchase the product from MDR. (*See* Exhibit 6).

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400. MDR is subject to personal jurisdiction in this judicial district in accordance with due process and/or the New York long arm statute. MDR engaged in, and continues to engage in, the manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising and/or 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 each of the '400 and '436 patents. Therefore, the complained of acts of patent infringement occurred, and continue to occur, within this judicial district.

12. Upon information and belief, MDR induced, and continues to induce, infringement of the '400 and '436 patents by manufacturing, promoting, marketing, making, having made, using, distributing, offering for sale, advertising and/or selling 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 each of the '400 and '436 patents.

The Patents-in-Suit

13. 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.

14. 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.

15. 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.

16. 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. A copy of the '436 patent is attached as Exhibit 2.

17. The '436 patent is a continuation-in-part of application nos. 12/575,426, filed on October 7, 2009, 12/610,215, filed October 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 March 1, 2007, 11/269,310, filed on November 8, 2005 now U.S. Pat. No. 7,615,544, and no. 10/973,192, filed October 26, 2004.

18. The '436 patent is generally directed to a method for reducing aneuploidy rates, and therefore reducing miscarriage rates and improving pregnancy rates in human embryos by administering an androgen, such as DHEA or testosterone, for at least four weeks.

19. American Infertility is the assignee and owner 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 patents and the right to seek and recover remedies for infringement of the '400 and '436 patents.

FIRST CLAIM
(Patent Infringement)

20. American Infertility repeats and realleges each and every allegation contained in paragraphs 1 to 19 as though fully set forth herein.

21. American Infertility owned the '400 and '436 patents throughout the period of MDR's infringing acts and still owns the '400 and '436 patents.

22. At all relevant times herein, the '400 and '436 patents are valid and enforceable patents.

23. MDR 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 each of the '400 and '436 patents, by manufacturing, promoting, marketing, making, having made, using, distributing, offering for sale, advertising, selling and/or otherwise making available the Infringing Product to be administered in accordance with the limitations of these claims without license, permission and/or authorization from American Infertility.

24. Upon information and belief, MDR was aware of the '400 and '436 patents.

25. 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."

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

27. 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."

28. 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."

29. 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.”

30. 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.”

31. Claim 4 of the ‘436 patent is for a “method according to claim 1, wherein said method decreases miscarriage rates.”

32. MDR’s website and promotional material markets, advertises, distributes, 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 each of the ‘400 and ‘436 patents. Specifically, the Infringing Product is advertised, marketed, distributed, offered for sale and sold on MDR’s Naturally Smart Vitamins internet web site at <http://www.naturallysmartvitamins.com/> and is being sold throughout the United States, including the State of New York. (*See Exhibit 3*). The Infringing Product is being sold in a dosage of 25 mg of DHEA per capsule, with 90 capsules in each bottle. Therefore, the supply is over 60 days. A copy of a screenshot of the website with the Infringing Product brochure is attached as Exhibit 3.

33. The MDR website states that the Infringing Product “may improve ovarian health and egg quality in women trying to conceive. Can be taken in conjunction with fertility treatments.” A screenshot of the MDR website description for the Infringing Product is attached as Exhibit 4.

34. The website also provides extended information for the Infringing Product. It states: “Naturally smart DHEA® can be used in conjunction with fertility treatments for women, and may improve ovarian health and increase the quality and quantity of eggs and embryos. Other benefits may include increased IVF pregnancy rates and decreased risk of miscarriage and

chromosomal abnormalities in embryos.” A screen shot of the extended information for the Infringing Product from the MDR website is attached as Exhibit 5.

35. MDR only offers for sale and sells the Infringing Product in 25 mg dosages and in a 90 capsule bottle, such that the supply is more than a 60 day supply. A screenshot of the website identifying MDR as the distributor of the Infringing Product and directing purchasers of the Infringing Product to purchase it from MDR is attached as Exhibit 6. Apparently, there are no other quantities that can be so ordered from MDR. Clearly, MDR is aware of the ‘400 and ‘436 patents, and its limitations, but intentionally sells at least a 60 day supply of the Infringing Product.

36. MDR’s promotion, offer of sale, and/or sale of the Infringing Product in 25 mg dosages in a 90 capsule bottle, for the purposes set forth in its website and other promotional material, is administered, or to be administered, in accordance with the limitations of at least one of the claims of each of the ‘400 and ‘436 patents, including at least claim 6 of the ‘400 patent and claim 1 of the ‘436 patent.

37. By letter dated July 30, 2018, American Infertility, through its attorneys, provided detailed information regarding American Infertility’s patents, including the ‘400 and ‘436 patents and requested that MDR provide it with information regarding sales of the Infringing Product, quantities of such sales, marketing, representations and the administration and prescription of DHEA related to such sales. The letter requested a response within two weeks.

38. MDR did not respond to the July 30, 2018 letter and did not provide any of the information requested by American Infertility.

39. To date, MDR continues its infringing activities.

40. Upon information and belief, MDR took active and deliberate steps to induce infringement of the '400 and '436 patents by advertising, distributing and/or instructing others to purchase, use and/or administer the Infringing Product in a manner that infringes the '400 and '436 patents, including showing and directing consumers how to purchase, use and/or administer the Infringing Product for patented methods on MDR's promotional literature, brochures and/or on its website. (*See Exhibits 3-6*).

41. Upon information and belief, MDR knew or should have known that its actions infringe, and would induce infringement of, the '400 and '436 patents.

42. MDR is willfully and intentionally infringing the '400 and '436 patents.

43. MDR'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).

44. As a direct and proximate consequence of MDR's direct and/or inducement of infringement of the '400 and '436 patents, American Infertility suffered, and continues to suffer, irreparable injury and monetary damages pursuant to 35 U.S.C §§ 281, 283, 284, 285 and 287.

45. Upon information and belief, MDR's direct infringement and/or inducement of infringement of the '400 and '436 patents will continue unless enjoined by this Court.

46. By reason of the foregoing, American Infertility seeks damages and a trebling thereof and preliminary and permanent injunctions enjoining MDR from committing further acts of infringement of the '400 and '436 patents.

Jury Demand

47. American Infertility hereby demands a trial by jury on all issues so triable.

Reservation of Rights

48. The above allegations and claims are based upon information known to American Infertility, and/or upon American Infertility's information and belief at this time. American Infertility's discovery and investigation in this action is continuing and American Infertility reserves its right to supplement and/or amend such allegations and claims.

Demand for Relief

WHEREFORE, American Infertility demands judgment and an order:

- A. Adjudicating that MDR infringed the '400 and '436 patents;
- B. Preliminary and permanently enjoining MDR 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 and '436 patents;
- C. Awarding American Infertility damages for the MDR's infringement of the '400 and '436 patents pursuant to 35 U.S.C. § 284;
- D. Awarding American Infertility treble damages for MDR's willful and intentional infringement of the '400 and '436 patents pursuant to 35 U.S.C. § 284;
- E. Awarding American Infertility pre-judgment and post-judgment interest as applicable by law;
- F. Awarding American Infertility its costs incurred in this action;
- G. Declaring this case "exceptional" under 35 U.S.C. § 285, and awarding American Infertility its attorneys' fees in this matter;

H. Requiring MDR to render an accounting to American Infertility for MDR's profits or the value of the business opportunities received from the foregoing acts of patent infringement; and

I. Granting American Infertility such other and further relief as this Court deems just and proper.

Dated: Garden City, New York
September 18, 2018

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ASSOCIATES, LLP

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