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IMPROVING FERTILITY HEALTH IN  
FEMALE AND MALE ANIMALS AND  
HUMANS****Publication Classification**(51) **Int. Cl.<sup>7</sup>** ..... **A61K 35/78**; A61K 33/04;  
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**MCLEAN, VA 22101 (US)**(21) **Appl. No.: 11/214,927**(22) **Filed: Aug. 31, 2005****Related U.S. Application Data**(62) Division of application No. 10/252,698, filed on Sep.  
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09/742,412, filed on Dec. 22, 2000, now Pat. No.  
6,497,885.(57) **ABSTRACT**

In a new pharmaceutical combination, the herb, *Vitex agnus-castus* (chasteberry), enhances hormone balance by increasing progesterone release and, therefore, ovulation frequency. The antioxidants, green tea, vitamin E, and selenium, improve overall reproductive health. L-arginine, an amino acid, stimulates the reproductive organs by improving circulation. Folic acid, vitamins B6 and B12, iron, zinc and magnesium help promote womens' fertility. Sperms are highly susceptible to free radical or oxidative damage from environmental toxicants and natural aging. Vitamins C and E, coenzyme Q10 and selenium are all potent antioxidants that help improve sperm counts and quality. Ferulic acid, an antioxidant found in Dong quai, also improves sperm quality. Zinc and B vitamins (B6, B12 and folate) are critical nutrients in male reproductive systems for hormone metabolism, sperm formation and motility. The amino acid, L-carnitine, promotes formation of healthy sperm.

## METHOD AND COMPOSITION FOR IMPROVING FERTILITY HEALTH IN FEMALE AND MALE ANIMALS AND HUMANS

### BACKGROUND OF THE INVENTION

[0001] Because of delayed child bearing, unhealthy diets and use of tobacco, caffeine, alcohol, drugs and environmental contaminants, difficulties in conceiving have been experienced.

[0002] Needs exist for pharmaceutical compounds that improve fertility in both women and men.

### SUMMARY OF THE INVENTION

[0003] This invention provides combinations of bioeffecting compounds for promoting fertility in men and women. The combinations include nutritional components that benefit fertility health. All the components have been studied separately, to determine their individual efficacy. The invention provides the first products to put these components together synergistically in women's and men's formulations.

[0004] As many as 15% of couples in the U.S. have difficulty conceiving a child. In about one third of these cases, it is the man that is infertile; in another third, the female has fertility issues. The remaining is due to a combination of male and female fertility issues, or unknown causes. In many of these cases, causes of infertility are treatable. Nutritional and lifestyle changes should be the first step to increasing chances for conception. Smoking and caffeine, drug and alcohol consumption, environmental toxicants, and stress are related to infertility in men and women. Reproductive organs are highly susceptible to free radical or oxidative damage from environmental toxicants and natural aging. A balanced, nutritional diet, and nutritional supplements with high antioxidant content can help reverse some of that damage. In women, hormone balance is critical to monthly ovulation and development of the corpus luteum (an ovarian follicle that release progesterone after release of the egg to prepare the uterus for implantation).

[0005] These and further and other objects and features of the invention are apparent in the disclosure, which includes the above ongoing written specification with the claims.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0006] The invention provides combinations of beneficial bioeffecting compounds for promoting fertility in women. The invention provides a scientifically validated herbal/nutritional blend for women to improve infertility by helping to regulate the menstrual cycle and correct hormone imbalance (corpus luteum insufficiency) without increased chances of multiple births associated with drug therapy. The combination of amino acids, herbs, vitamins and minerals improves overall health and helps with many of the deficiencies that decrease fertility.

[0007] The herb, Vitex agnus-castus (chasteberry), enhances hormone balance by increasing progesterone release and, therefore, ovulation frequency. The antioxidants, green tea, vitamin E, and selenium, improve overall reproductive health. L-arginine, an amino acid, stimulates the reproductive organs by improving circulation. Folic acid, vitamins B6 and B 12, iron, zinc and magnesium help promote womens' fertility.

[0008] The invention provides combinations of beneficial bioeffecting compounds for promoting fertility in men. Sperms are highly susceptible to free radical or oxidative damage from environmental toxicants and natural aging. Vitamins C and E, coenzyme Q10 and selenium are all potent antioxidants that help improve sperm counts and quality. Ferulic acid, an antioxidant found in Dong quai, also improves sperm quality. Zinc and B vitamins (B6, B12 and folate) are critical nutrients in male reproductive systems for hormone metabolism, sperm formation and motility. The amino acid, L-carnitine, promotes formation of healthy sperm.

[0009] The invention provides synergistic action of the combinations.

[0010] The two dietary supplements in male and female formulas are useful for men and women. Preferably, the distinct combinations are taken by both members of a couple in which the female age is between 21 and 46. The distinct combinations are useful for couples who have tried for 6 months or more, up to three years, to become pregnant without success. Preferably, patients take 2-4 capsules per day of the distinct formulas for three months. In women it is useful to record their basal temperature daily using thermometers and charts and to have their blood drawn for progesterone analysis at day 18-22 of the first menstrual cycle prior to taking the supplement. For men, it is useful to submit a sperm sample at the same time for analysis of count and motility. Prior to submitting sperm samples, 2-4 days abstinence is suggested for best results. No fevers over 101 degrees in the three months prior to taking the new combinations should be encountered. It is useful to repeat the analyses during the fourth menstrual cycle of the study. The first month is needed to develop baselines, followed by three months of taking the combinations product or placebo.

[0011] Preferred ranges of the combinations considered in percent by weight are:

Components	Minimum %	Maximum %
<u>Women's formula</u>		
Vitex (chasteberry)	2	10
L-arginine	40	60
Green tea	5	20
Vitamin E	5	20
Selenium	.01	1
Vitamins B6, B12	.01	1
Folic acid	.01	1
Iron	.1	5
Magnesium	10	40
Zinc	.1	5

[0012]

<u>Men's Formula</u>		
Components	Minimum %	Maximum %
L-carnitine	40	70
Ferulic acid in Dong Quai	.1	10
Vitamins C and E	10	30
Coenzyme coQ10	.1	5
Selenium	.01	1
Zinc	.1	10
B vitamins	.001	1

[0013] Acceptable ranges of womens' and mens' formulations are:

<u>Women's Formula</u>		
Components	Minimum %	Maximum %
Vitex (chasteberry)	1	20
L-arginine	20	70
Green tea	0	30
Vitamin E	0	30
Selenium	0	2
Vitamins B6, B12	0	2
Folic acid	0	2
Iron	0	7
Magnesium	5	50
Zinc	.01	10

[0014]

<u>Men's Formula</u>		
Components	Minimum %	Maximum %
L-carnitine	20	80
Ferulic acid in Dong Quai	0	20
Vitamins C and E	.01	40
Coenzyme coQ10	.01	10
Selenium	0	3
Zinc	.01	15
B vitamins	0	5

[0015] Examples of useful formulation in percent by weight are:

<u>Women's formula</u>	
Components	
Vitex (chasteberry)	5
L-arginine	50
Green tea	11
Vitamin E	11
Selenium	.03
Vitamins B6, B12	.03
Folic acid	.03
Iron	1
Magnesium	20
Zinc	1
	100%

[0016]

<u>Men's Formula</u>	
Components	
L-carnitine	60
Ferulic acid in Dong Quai	6
Vitamins C and E	25
Coenzyme coQ10	3
Selenium	6

-continued

<u>Men's Formula</u>	
Components	
Zinc	5
B Vitamins	4
	100%

[0017] While the invention has been described with references to specific embodiments, modifications and variations of the invention may be constructed without departing from the scope of the invention, which is defined in the following claims.

1-9. (canceled)

10. A supplement, comprising a herb, Vitex agnus-castus (chasteberry) for enhancing hormone balance, increasing progesterone release and ovulation frequency, antioxidants, green tea, vitamin E, and selenium for improving reproductive fertility, L-arginine, an amino acid for stimulating reproductive organs by improving circulation, folic acid, vitamins B6 and B12, iron, zinc and magnesium for promoting women's fertility.

11. A method of promoting fertility health in women comprising taking a dietary supplement of L-arginine, magnesium, green tea, vitamin E, Vitex agnus-castus, iron, zinc, selenium, vitamins B6 and B12 and folic acid.

12. The method of claim 11, wherein the dietary supplement further comprises the following components in percentages by weight: about 50% L-arginine, about 20% magnesium, about 5% green tea, about 11% vitamin E, about 5% Vitex, about 1% iron, about 1% zinc and less than about 1% of each selenium, vitamins B6 and B12 and folic acid.

13. The method of claim 11, wherein the components are present in the proportion in parts by weight of about 10 to 80% L-arginine, an amino acid, about 5 to 50% magnesium, about 5 to 50% antioxidants, including green tea, vitamin E or selenium, 2 to 20% Vitex agnus-castus (chasteberry), about 0.1 to 10% iron, about 0.1 to 10% zinc, about 0.001 to 1% folic acid, about 0.001 to 1% vitamins B6 and B12.

14. The method of claim 11, wherein the components are present in the proportion in parts by weight of about 40 to 80% L-arginine, an amino acid, about 20 to 50% antioxidants, including green tea, vitamin E or selenium, about 20 to 50% magnesium, about 4 to 20% Vitex agnus-castus (chasteberry), about 1 to 10% iron, about 1 to 10 % zinc, about 0.01 to 1% folic acid, and about 0.3 to 1% vitamins B6 and B12.

15. A method for promoting fertility health in women comprising taking a supplement having fertility promoting activity in females comprising in combination components in effective amounts of the following components present in proportions in parts by weights of about 10 to 80% L-arginine, an amino acid, about 5 to 50% magnesium, about 5 to 50% antioxidants, including green tea, vitamin E or selenium, 2 to 20% Vitex agnus-castus (chasteberry), about 0.1 to 10% iron, about 0.1 to 10% zinc, about 0.001 to 1% folic acid, about 0.001 to 1% vitamins B6 and B12.

16. A method for promoting fertility health in women comprising taking a supplement having fertility promoting activity in females comprising in combination components in effective amounts of the following components present in

proportions in parts by weights of about 40 to 80% L-arginine, an amino acid, about 20 to 50% antioxidants, including green tea, vitamin E or selenium, about 20 to 50% magnesium, about 4 to 20% Vitex agnus-castus (chasteberry), about 1 to 10% iron, about 1 to 10 % zinc, about 0.01 to 1% folic acid, and about 0.3 to 1% vitamins B6 and B12.

17. A method for promoting fertility health in women comprising taking a supplement having fertility promoting activity in females comprising in combination components in effective amounts of the following components present in proportions in parts by weights of about 10 to 80% L-arginine, an amino acid, about 10 to 50% magnesium, about 5 to 50% antioxidants, including green tea, vitamin E or selenium, about 1 to 20% Vitex agnus-castus (chasteberry), about 0.1 to 10% iron.

18. A method of promoting a women's fertility by taking a new supplement, comprising a herb, Vitex agnus-castus (chasteberry) for enhancing hormone balance, increasing progesterone release and ovulation frequency, antioxidants, green tea, vitamin E, and selenium for improving overall reproductive health, L-arginine, an amino acid for stimulating reproductive organs by improving circulation, folic acid, vitamins B6 and B12, iron, zinc and magnesium for promoting women's fertility.

19. A supplement for promoting women's fertility comprising an herb for enhancing hormone balance, increasing progesterone release and ovulation frequency and an amino acid for stimulating reproductive organs by improving circulation.

20. The supplement of claim 19, wherein the herb is Vitex agnus-castus.

21. The supplement of claim 20, wherein the amino acid is L-arginine.

22. The supplement of claim 21, further comprising one or more antioxidants for improving reproductive fertility.

23. The supplement of claim 22, wherein the antioxidants are selected from the group consisting of green tea, vitamin E, selenium, and combinations thereof.

24. The supplement of claim 22, further comprising folic acid.

25. The supplement of claim 24, further comprising vitamins B6 and B12.

26. The supplement of claim 25, further comprising iron, zinc and magnesium.

27. A method of promoting fertility health in women comprising taking a dietary supplement comprising an herb for enhancing hormone balance, increasing progesterone release and ovulation frequency and an amino acid for stimulating reproductive organs by improving circulation.

28. The method of claim 27, wherein the taking a dietary supplement comprises taking the supplement comprising L-arginine and Vitex agnus-castus.

29. The method of claim 27, wherein the taking a dietary supplement comprises taking the supplement comprising one or more antioxidants.

30. The method of claim 29, wherein the antioxidants are selected from the group consisting of green tea, vitamin E, selenium, and combinations thereof.

31. The method of claim 29, wherein the taking a dietary supplement comprises taking the supplement comprising iron, magnesium, zinc, and combinations thereof.

32. The method of claim 31, wherein the taking the supplement comprises taking the supplement comprising vitamins B6 and B12.

33. The method of claim 32, wherein the taking the supplement comprises taking the supplement comprising folic acid.

34. The method of claim 33, wherein the dietary supplement further comprises the following components in percentages by weight: about 50% L-arginine, about 20% magnesium, about 5% green tea, about 11% vitamin E, about 5% Vitex, about 1% iron, about 1% zinc and less than about 1% of each of selenium, vitamins B6 and B12 and folic acid.

35. The method of claim 33, wherein the components are present in the proportion in parts by weight of about 10 to 80% L-arginine, an amino acid, about 5 to 50% magnesium, about 5 to 50% antioxidants, including green tea, vitamin E or selenium, 2 to 20% Vitex agnus-castus (chasteberry), about 0.1 to 10% iron, about 0.1 to 10% zinc, about 0.001 to 1% folic acid, about 0.001 to 1% vitamins B6 and B12.

36. The method of claim 33, wherein the components are present in the proportion in parts by weight of about 40 to 80% L-arginine, an amino acid, about 20 to 50% antioxidants, including green tea, vitamin E or selenium, about 20 to 50% magnesium, about 4 to 20% Vitex agnus-castus (chasteberry), about 1 to 10% iron, about 1 to 10 % zinc, about 0.01 to 1% folic acid, and about 0.3 to 1% vitamins B6 and B12.

37. A method for promoting fertility health in women comprising taking a supplement having fertility promoting activity in females comprising in combination components in effective amounts present in proportions in parts by weights of about 10 to 80% L-arginine and about 2 to 20% Vitex agnus-castus.

38. The method of claim 37, further comprising in combination components in effective amounts present in proportions in parts by weights of about 5 to 50% magnesium, about 5 to 50% antioxidants including green tea, vitamin E or selenium, about 0.1 to 10% iron, about 0.1 to 10% zinc, about 0.001 to 1% folic acid, about 0.001 to 1% vitamins B6 and B12.

39. A method for promoting fertility health in women comprising taking a supplement having fertility promoting activity in females comprising in combination components in effective amounts present in proportions in parts by weights of about 40 to 80% L-arginine and about 4 to 20% Vitex agnus-castus.

40. The method of claim 39, further comprising in combination components in effective amounts present in proportions in parts by weights of about 20 to 50% antioxidants, including green tea, vitamin E or selenium, about 20 to 50% magnesium, about 1 to 10% iron, about 1 to 10 % zinc, about 0.01 to 1% folic acid, and about 0.3 to 1% vitamins B6 and B12.

41. A method for promoting fertility health in women comprising taking a supplement having fertility promoting activity in females comprising in combination components in effective amounts present in proportions in parts by weights of about 10 to 80% L-arginine and about 1 to 20% Vitex agnus-castus.

42. The method of claim 41, further comprising in combination components in effective amounts present in proportions in parts by weights of about 10 to 50% magnesium, about 5 to 50% antioxidants including green tea, vitamin E or selenium, about 0.1 to 10% iron.

43. A method of promoting a women's fertility by taking a new supplement, comprising an herb Vitex agnus-castus (chasteberry) for enhancing hormone balance, increasing

progesterone release and ovulation frequency, an amino acid L-arginine for stimulating reproductive organs by improving circulation, and antioxidants for improving overall reproductive health.

**44.** The method of claim 43, wherein the antioxidants are selected from the group consisting of green tea, vitamin E, selenium, and combinations thereof.

**45.** The method of claim 44, further comprising folic acid, vitamins B6 and B12, iron, zinc and magnesium for promoting women's fertility.

**46.** A supplement for improving fertility health comprising effective amounts of components of Vitex agnus-castus (chasteberry), green tea, and L-arginine for improving reproductive fertility, treating female infertility, enhancing hormone balance, stimulating reproductive organs, increasing progesterone release, increasing ovulation rate, and increasing pregnancy rate.

**47.** The supplement of claim 46, wherein the components are present in parts by weight of about 74% L-arginine, about 18.5% green tea, and about 7.4% Vitex agnus-castus (chasteberry).

**48.** The supplement of claim 46, wherein the components are present in parts by weight of about 10 to 80% L-arginine, about 5 to 50% green tea, and about 2 to 20% Vitex agnus-castus (chasteberry).

**49.** The supplement of claim 46, wherein the components are present in parts by weight of about 40 to 80% L-arginine, about 20 to 50% green tea, and about 4 to 20% Vitex agnus-castus (chasteberry).

**50.** A method for improving and promoting fertility health in women comprising taking a supplement having fertility

promoting activity in females comprising in combination components in parts by weights of about 10 to 80% L-arginine, about 5 to 50% green tea, and about 2 to 20% Vitex agnus-castus (chasteberry) for improving reproductive fertility, treating female infertility, enhancing hormone balance, stimulating reproductive organs, increasing progesterone release, increasing ovulation rate, and increasing pregnancy rate.

**51.** A method of improving and promoting fertility health in women comprising taking a dietary supplement of effective amounts of components of L-arginine, green tea, and Vitex agnus-castus (chasteberry) for improving reproductive fertility, treating female infertility, enhancing hormone balance, stimulating reproductive organs, increasing progesterone release, increasing ovulation rate, and increasing pregnancy rate.

**52.** The method of claim 51, wherein the dietary supplement comprises the components in percentages by weight of about 74% L-arginine, about 18.5% green tea, and about 7.4% Vitex agnus-castus (chasteberry).

**53.** The method of claim 51, wherein the components are present in the parts by weight of about 10 to 80% L-arginine, about 5 to 50% green tea, and about 2 to 20% Vitex agnus-castus (chasteberry).

**54.** The method of claim 51, wherein the components are present in parts by weight of about 40 to 80% L-arginine, about 20 to 50% green tea, and about 4 to 20% Vitex agnus-castus (chasteberry).

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