EXHIBIT 1002

US007704984B2

(12) **United States Patent**
Boissonneault

(10) **Patent No.: US 7,704,984 B2**
(45) **Date of Patent: Apr. 27, 2010**

(54) **EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1382 days.

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A61K 31/56 (2006.01)
A61K 31/58 (2006.01)

(52) **U.S. Cl.** **514/170**; 514/843

(58) **Field of Classification Search** 514/170, 514/843

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,921,843	A	5/1990	Pasquale	
4,962,098	A	10/1990	Boissonneault	
5,010,070	A	4/1991	Boissonneault	
5,280,023	A	1/1994	Ehrlich et al.	
5,510,341	A	4/1996	Ehrlich et al.	
5,552,394	A	9/1996	Hodgen	
5,747,480	A	5/1998	Gast	
5,756,490	A	5/1998	Lachnit et al.	
5,888,543	A	3/1999	Gast	
5,898,032	A	4/1999	Hodgen	
6,027,749	A	2/2000	Schmidt-Gollwitzer et al.	
6,479,475	B1	11/2002	Gast	
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FOREIGN PATENT DOCUMENTS

WO	WO 98/04268	*	2/1998
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Loose-Mitchell and Stancel, Chapter 58—Estrogen and Progestins, "Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed." Hardman JG, Limbird LE, and Gilman AG, Eds., McGraw-Hill, 2001, 1597-1634 (pp. 1597, 1618, 1623, and 1624 provided).*

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Assistant Examiner—Paul Zarek
(74) *Attorney, Agent, or Firm*—Fitzpatrick, Cella, Harper and Scinto

(57) **ABSTRACT**

A method of contraception that provides for sequentially administering to a female of child bearing age: (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 22 to about 26 days; (b) a second composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 2 to about 3 days and an optional third composition that is a placebo provided that (i) if estrogen administration is continuous then the first composition is administered for 25 to 26 days, the second composition is administered for 2 to 3 days and no third composition is administered and (ii) if estrogen administration is not continuous then the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days. The total cycle length is 28 days, with the first composition administered on day 1 of the menstrual cycle, defined as the first day of menstrual bleeding, or on the first Sunday after the first day of the menstrual cycle.

9 Claims, No Drawings

EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention is directed to an estrogenic/progestogenic contraceptive regimen with continuous and/or extended dosing of the estrogenic component. The inventive regimen provides for low daily estrogenic hormone exposure without compromising contraceptive efficacy or cycle control. A contraceptive kit that may be used to practice the method of the invention is also disclosed.

2. Related Background Art

Contraceptive compositions containing both estrogenic and progestogenic compounds are known to be effective in controlling ovulation and conception. The progestogenic component of the composition is primarily responsible for the contraceptive efficacy of the composition, while the estrogenic component is included primarily to reduce undesired side effects, such as breakthrough bleeding or spotting. It is thought that small amounts of estrogen help stabilize the endometrium and allow cyclic withdrawal bleeding, similar to the natural menstrual cycle.

The earliest of these estrogenic/progestogenic contraceptive compositions was administered monophasically (fixed dose) and contained a relatively high level of estrogenic component. U.S. Pat. No. 4,921,843 relates to the administration of an estrogen-only component from day 2 to day 7 of the menstrual cycle, followed by administration of a combination of estrogen and progestin from day 7 to day 28 of the menstrual cycle. U.S. Pat. No. 5,280,023 and U.S. Pat. No. 5,510,341 describe the administration of an estrogen-only component for 5 to 14 days at the beginning of the cycle, followed by 23 to 14 days of an estrogen/gestagen combination. U.S. Pat. No. 5,756,490 discloses combination preparations with 23 or 24 daily units of an estrogen and gestagen, and 4 to 10 daily units of estrogen only. Similarly, U.S. Pat. No. 6,027,749 discloses an estrogen-only component administered for 5, 6, or 7 days. U.S. Pat. No. 5,552,394 discloses administration of tablets that contain both estrogen and progestin for 24 days followed by 4 days of placebo.

U.S. Pat. No. 4,962,098 is directed to a multiphasic contraceptive regimen and describes a triphasic method of contraception using a progestin/estrogen combination in which the amount of estrogen is increased stepwise over the three phases wherein the first phase is 4-7 days, the second phase is 5-8 days and the third phase is 7-12 days. Preferably, administration of the contraceptive compositions for the three phases combined will be 21 days followed by a 7 day placebo period. For all three phases, the progestin is 0.5 to 1.5 mg of norethindrone acetate, while about 10 to 30 mcg of ethinyl estradiol is used in the first phase, about 20 to 40 mcg of ethinyl estradiol is used in the second phase and 30 to 50 mcg of ethinyl estradiol is employed in the third phase.

U.S. Pat. No. 5,747,480 also discloses a multiphasic regimen wherein the progestin component is levonorgestrel. U.S. Pat. No. 5,888,543 discloses various regimens wherein a combination of progestin and estrogen are administered in a monophasic or multiphasic regimen (varied dose, e.g., biphasic or triphasic). In one embodiment, a combination of a progestin composition and an estrogen composition is administered such that the daily dosage of the second phase progestin is greater than the daily dosage of progestin in the first phase and the daily dosage of the second phase estrogen is greater than or equal to the daily dosage of estrogen in the first phase. U.S. Pat. No. 6,479,475 describes multiphasic regimens with 23-25 consecutive days of hormone administration, followed by a 3-5 day hormone-free interval.

U.S. Pat. No. 5,898,032 discloses an extended oral contraceptive regimen wherein estrogen and progestin are administered in a combined dosage form, preferably monophasically, for 60 to 110 consecutive days, followed by an administration free period of 3 to 10 days. The amount of estrogen and progestin administered daily are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively. In one particular embodiment, the combined dosage form is administered for 84 days followed by 7 pill free days. Following this particular regimen is said to result in four treatments and menstrual cycles during the year. However, extended oral contraceptive regimens tend to suffer from poor initial cycle control. Another disadvantage is that once breakthrough bleeding is under control, the user becomes functionally amenorrheic. This does not reassure the user that she is not pregnant.

One constant goal in the oral contraceptive art has been to reduce the hormone levels of such compositions without reducing contraceptive efficacy and increasing undesired side effects. Since the risk is acute thrombosis (as opposed to atherosclerosis), minimizing daily exposure of estrogen is a therapeutic goal. However, as estrogen doses decreased, the incidences of unwanted breakthrough bleeding or spotting have generally increased. Therefore, there remains a need for an oral contraceptive regimen that maintains contraceptive efficacy and provides adequate cycle control with a low daily dose of the estrogenic component.

SUMMARY OF THE INVENTION

The present invention is directed to a method of contraception that comprises the steps of sequentially administering to a female of child-bearing age: (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to 20 mcg of ethinyl estradiol for about 22 to about 26 days; (b) a second composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol and substantially free of a progestin for about 2 to about 3 days; and (c) an optional third composition that is a placebo, wherein the sequential administration of the first composition, the second composition and the optional third composition, when present, is performed on a daily basis over a 28 day cycle. If estrogen administration is continuous during the cycle then the first composition is monophasically administered for 25 to 26 days, the second composition is administered for 2 to 3 days and no third composition is administered, while if estrogen administration is extended, but not continuous, then the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days. The sequential administration is begun on the first day of the female's menstrual cycle.

One particular embodiment of this invention is directed to a method of contraception that provides for sequentially administering to a female of child bearing age (a) a composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 25 or about 26 days; and (b) a composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 3 to about 2 days for a total cycle length of 28 days. No placebo is administered in this embodiment. The sequential administration of the first composition may be repeated the day following the comple-

tion of the administration of the second composition to provide for continuous administration of estrogen.

Yet another embodiment of this invention is directed to a method of contraception that provides for sequentially administering to a female of childbearing age (a) a composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg ethinyl estradiol for about 22 to about 24 days; (b) a composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg ethinyl estradiol for about 2 to 3 days; and (c) a placebo tablet for about 1 to about 4 days for a total cycle length of 28 days. This embodiment provides for extended, but not continuous, administration of estrogen. The sequential administration of the first composition may be repeated the day following the completion of the administration of the placebo to provide for continuous contraception.

In preferred embodiments of the invention, the amount of estrogenic component remains the same in both phases of administration, and the amount of progestin remains constant during the first phase of administration. The invention is also directed to a kit for practicing the method of this invention.

DETAILED DESCRIPTION OF THE INVENTION

By practicing the contraceptive method disclosed herein, a user advantageously improves control of menstrual bleeding while taking the contraceptive compositions of the invention. For the purposes of this invention, the designation "mcg" refers to micrograms and "mg" to milligrams.

In a preferred embodiment, the amount of estrogen administered is equivalent to 15 mcg per day of ethinyl estradiol, while the amount of progestin administered is equivalent to 1.0 mg norethindrone acetate per day during the combined estrogen/progestin phase.

The progestin may be selected, for example, from the group consisting of norethindrone acetate, drospirenone, trimegestone, norethindrone, levonorgestrel, desogestrel, 3-ketodesogestrel, gestodene, demogestone, dydrogesterone, medrogestone, medroxy progesterone, esters and mixtures thereof and the like. The most preferred progestin is norethindrone acetate. The estrogen may be selected, for example, from the group consisting of ethinyl estradiol, 17-β-estradiol, conjugated estrogens, mestranol, estrone and esters, prodrugs and salts thereof. An exemplary ester is estradiol acetate. Preferred salts of estrone include, but are not limited to the sodium and piperate salt. For the conjugated estrogens, 1.25 mg conjugated estrogens is equivalent to a daily dose of 15 mcg ethinyl estradiol. The most preferred estrogen is ethinyl estradiol. The amount of progestin and estrogen employed in each phase will be that amount which is equivalent in potency to the ranges of norethindrone acetate and ethinyl estradiol, respectively, that are set forth herein. Determination of equivalent potency is well understood and readily accomplished by those of ordinary skill in the art.

The third composition, if present is a placebo, i.e., a non-steroidal component. The non-steroidal placebo may comprise an iron supplement. Suitable iron supplements include, for example, ferrous fumarate, ferrous sulfate, ferrous gluconate, iron polysaccharides, and mixtures thereof. The preferred iron supplement is ferrous fumarate, most preferably a daily placebo dosage will be equivalent to not more than about 75 mg ferrous fumarate.

One goal of the extended estrogen dosing contraceptive regimen is to minimize daily exposure to estrogen from either exogenous or endogenous sources. Without wishing to be bound by theory, it is believed that continuous dosage of low amounts of estrogen may suppress FSH (follicle-stimulating hormone) and minimize follicular recruitment and therefore minimize estrogen contribution from the developing follicle. The cyclic addition of a progestin component suppresses both leutenizing hormone and ovulation while maintaining the integrity of the endometrium. Discontinuation of the progestin provides a withdrawal bleed.

The limitations of continuous low dose estrogen and progestin is irregular bleeding patterns due to a lack of an adequate withdrawal bleed. Although a higher dose 24-day regimen provides an adequate withdrawal bleed and fewer bleeding days, follicular suppression may not be optimal. The present invention provides in one embodiment that by extending the estrogen/progestin dosing beyond 24 days (e.g., 25-26 days) and utilizing estrogen alone for the rest of the cycle results in superior follicular suppression, less endogenous estrogen and therefore a more predictable withdrawal bleed of fewer days. Alternatively, in yet another embodiment dosing estrogen/progestin for 22-24 days and estrogen alone for 2-3 days with the addition of a placebo for the remainder of the cycle will allow follicular suppression while improving the reliability of a withdrawal bleed. These regimens allow for lower daily exposure to estrogen, while not compromising cycle control, and fewer days of cyclic withdrawal bleeding. If cyclic bleeding is predictable and a modest event, this natural episode provides reassurance to reproductive women that they are not pregnant and the extended cycle monophasic continuous dosing described in U.S. Pat. No. 5,898,032 provides little or no advantage.

The compositions used in this invention are administered using a suitable daily dosage form. Tablets, pills, capsules, and caplets are exemplary dosage forms. Suitable carriers with which the compositions can be administered include lactose, starch, cellulose derivatives and the like used in suitable amounts. Lactose is a preferred carrier. Mixtures of carriers, e.g. lactose, microcrystalline cellulose and starch, may also be used. In general, any pharmaceutically-acceptable additive which does not interfere with the function of the active components can be used in one or more of the compositions. These additives include conventional additives, e.g., fillers, colorants, polymeric binders, and the like.

The terms "method" and "kit" are used herein to encompass any drug delivery system via the use of which the invention outlined above can be effectively administered to human females. The contraceptive kit of this invention is a package containing the daily dosages of the compositions for practicing the method of this invention. Various types of packages for holding contraceptives are well known and it is contemplated that any such packaging may be used or altered for use in the practice of the present invention. For example, a single cycle package of the present invention for use in continuous estrogen dosing would preferably include about 25 to about 26 monophasic daily dosages of the first composition and about 2 to about 3 daily dosages of the second composition, with a total of 28 dosages. A single cycle package of the present invention for use in extended, but not continuous, estrogen dosing would preferably include about 22 to about 24 daily dosages of the first composition, about 2 to 3 daily dosages of the second composition and 1 to 4 daily dosages of the third composition, with a total of 28 dosages. The kit will also include instructions and/or indicia indicating that the first daily dosage of the first composition should be administered on the first day of the menstrual cycle, which is defined as the

first day of menstrual bleeding, or on the first Sunday after the first day of the menstrual cycle.

EXAMPLES

The following examples are used to explain the invention in more detail. The dosage units are formulated conventionally using tablets, pills, coated tablets, and the like.

Example 1

Continuos Estrogen Contraceptive Regimen

	Day						
	1	2	3	4	5	6	7
Composition	C	C	C	C	C	C	C
	Day						
	8	9	10	11	12	13	14
Composition	C	C	C	C	C	C	C
	Day						
	15	16	17	18	19	20	21
Composition	C	C	C	C	C	C	C
	Day						
	22	23	24	25	26	27	28
Composition	C	C	C	C	E	E	E

Day 1 is first day of bleeding.
C = 1.0 milligrams Norethindrone Acetate and 15 micrograms Ethinyl Estradiol
E = 15 micrograms Ethinyl Estradiol

Example 2

Extended Estrogen Contraceptive Regimen

	Day						
	1	2	3	4	5	6	7
Composition	C	C	C	C	C	C	C
	Day						
	8	9	10	11	12	13	14
Composition	C	C	C	C	C	C	C
	Day						
	15	16	17	18	19	20	21
Composition	C	C	C	C	C	C	C
	Day						
	22	23	24	25	26	27	28
Composition	C	C	C	E	E	P	P

Day 1 is first day of bleeding.
C = 1.0 milligrams Norethindrone Acetate and 15 micrograms Ethinyl Estradiol
E = 15 micrograms Ethinyl Estradiol
P = Placebo

While the invention has been described above with reference to specific embodiments thereof, it is apparent that many changes, modifications, and variations can be made without departing from the inventive concept disclosed herein. Accordingly, it is intended to embrace all such changes, modifications, and variations that fall within the spirit and broad scope of the appended claims. All patent applications, patents, and other publications cited herein are incorporated by reference in their entirety.

What is claimed is:

1. A method of contraception comprising the steps of sequentially administering to a female of child-bearing age:

(a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate wherein the progestin is selected from norethindrone acetate or norethindrone and 5 to 15 mcg of ethinyl estradiol for 24 days;

(b) a second composition containing 5 to 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days; and

(c) a third composition that is a placebo,

wherein the sequential administration of the first composition, the second composition and the third composition, is performed on a daily basis over a 28 day cycle.

2. The method according to claim **1**, wherein the sequential administration is repeated beginning the day after completion of the 28 day cycle.

3. The method according to claim **1**, wherein the progestin in the first composition is norethindrone acetate.

4. The method according to claim **3**, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

5. The method according to claim **1**, wherein the placebo contains about 75 mg of ferrous fumarate.

6. The method according to claim **4**, wherein the amount of ethinyl estradiol in the first and second composition is the same.

7. A method of contraception comprising the steps of sequentially administering to a female of child bearing age:

(a) a first composition containing about 0.3 to about 1.5 mg norethindrone acetate and 5 to 15 mcg ethinyl estradiol for 24 days;

(b) a second composition containing 5 to 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days;

(c) a third composition that is a placebo for 2 days,

wherein the sequential administration of the first composition, the second composition and the third composition is performed on a daily basis over a 28 day cycle.

8. The method according to claim **7**, wherein the first composition contains about 1 mg of norethindrone acetate.

9. The method according to claim **7**, wherein the amount of ethinyl estradiol in the first and second composition is the same.

* * * * *

Docket No. 4567-4002

Express Mail No. EV 460 048 236 US

27123
↑CUSTOMER NUMBER↑

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UTILITY APPLICATION AND FEE TRANSMITTAL §(1.53(B))

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing is the patent application of

Inventor(s) names and addresses:

(1) Roger M. Boissonneault
5 North Bridge Drive
Long Valley, NJ 07853

citizenship: USA

☐ Additional inventors are listed on a separate sheet

For: Extended Estrogen Dosing Contraceptive Regimen

Enclosed Are:

1 page title sheet
10 page(s) of specification
1 page(s) of Abstract
4 page(s) of claims (Claims 1-23)
____ sheets of ☐ Formal ☐ Informal drawings
11 page(s) of Declaration and Power of Attorney

- ☐ Unsigned
- ☒ Newly Executed
- ☐ Copy from prior application
- ☐ Deletion of inventors including Signed Statement under 37 C.F.R. §1.63(d)(2)

☒ **REQUEST AND CERTIFICATION UNDER 35 U.S.C. §122(b)(2)(B)(i) (form PTO/SB/35)**
As indicated on the attached Request and Certification, Applicant(s) certify that the invention disclosed in the attached application HAS NOT and WILL NOT be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing. Applicant(s) therefore request(s) that the attached application NOT be published under 35 U.S.C. §122(b).

☐ Incorporation by Reference:
- ☐ The entire disclosure of the prior application, from which a copy of the combined Declaration and Power of Attorney is supplied herein, is considered as being part of the disclosure of the accompanying application and is incorporated herein by reference.

☐ Deletion of Inventors (37 C.F.R. §1.63(d) and §1.33(b)

Signed statement attached deleting inventor(s) named in the prior application serial no. _____, filed _____.

☐ Microfiche Computer Program (Appendix)
- ☐ page(s) of Sequence Listing
- ☐ computer readable disk containing Sequence Listing
- ☐ Statement under 37 C.F.R. §1.821(f) that computer and paper copies of the Sequence Listing are the same

☒ Assignment Papers (assignment cover sheet and assignment documents)
- ☒ A check in the amount of $40.00 for recording the Assignment
- ☐ Charge the Assignment Recordation Fee to Deposit Account No. 13-4500, Order No. _____.
- ☐ Assignment Papers filed in the parent application Serial No. _____

☐ Certification of chain of title pursuant to 37 C.F.R. §3.73(b)

☐ Priority is claimed under 35 U.S.C. §119 for:
Application No(s). _____, filed _____, in _____ (country).
- ☐ Certified Copy of Priority Document(s) [_____]
  - ☐ filed herewith
  - ☐ filed in application Serial No. _____, filed _____.
- ☐ English translation document(s) [_____]
  - ☐ filed herewith
  - ☐ filed in application Serial No. _____, filed _____.

☐ Priority is claimed under 35 U.S.C. §119(e) for:
Provisional Application No. _____, filed _____.

☐ Information Disclosure Statement
- ☐ Copy of [_____] cited references
- ☐ PTO Form-1449
- ☐ References cited in parent application Serial No. _____, filed _____.

☐ Related Case Statement under 37 C.F.R. §1.98(a)(2)(iii)
- ☐ A copy of related pending U.S. Application(s) Serial No(s): _____, filed _____, respectively, is attached hereto.
- ☐ A copy of related pending U.S. Application(s) entitled, _____, filed _____ to inventor(s) _____, respectively, is attached hereto.
- ☐ A copy of each related application(s) was submitted in parent application serial no. _____, filed _____.

☐ Preliminary Amendment

☒ Return receipt postcard (MPEP 503)

☐ This is a ☐ continuation ☐ divisional ☐ continuation-in-part of prior application serial no. _____, filed _____, to which priority under 35 U.S.C. §120 is claimed.

☐ Cancel in this application original claims _____ of the parent application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

☐ A Preliminary Amendment is enclosed. (Claims added by this Amendment have been properly numbered consecutively beginning with the number following the highest numbered original claim in the prior application).

☐ The status of the parent application is as follows:

☐ A Petition for Extension of Time and a Fee therefor has been or is being filed in the parent application to extend the term for action in the parent application until _____.

☐ A copy of the Petition for Extension of Time in the co-pending parent application is attached.

☐ No Petition for Extension of Time and Fee therefor are necessary in the co-pending parent application.

☐ Please abandon the parent application at a time while the parent application is pending or at a time when the petition for extension of time in that application is granted and while this application is pending has been granted a filing date, so as to make this application co-pending.

☐ Transfer the drawing(s) from the parent application to this application

☐ Amend the specification by inserting before the first line the sentence:
This is ☐ continuation ☐ divisional ☐ continuation-in-part of co-pending application Serial No. _____, filed _____.

I. CALCULATION OF APPLICATION FEE					
Basic Fee ($300/$150)					$ 300
Examination Fee ($200/$100)					$ 200
Search Fee ($500/$250)					$ 500
	Number Filed		Number Extra	Rate	
Total Claims	33 - 20 =		13 x	($50/$25)	$ 650
Independent Claims	2 - 3 =		x	($200/$100)	$
☒ Multiple Dependent Claims	If marked, add fee of $360/$180				$ 360
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof		Fee	
- 100 =	/ 50 =	(round up to the whole number)		($250/$125)	$
				TOTAL:	$ 2010

914238 v1

☐ Small entity status is or has been claimed. Reduced fees under 37 C.F.R. §1.9 (f) paid herewith $____.

☒ A check in the amount of $2010 in payment of the application filing fees is attached.

☐ Charge fee to Deposit Account No. 13-4500, Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for filing this application pursuant to 37 CFR §1.16, **including all extension of time fees pursuant to 37 C.F.R. § 1.17 for maintaining copendency** with the parent application, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4567-4002. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: April 22, 2005

By: 

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Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Boissonneault, Roger M.

Group Art Unit: tba

Serial No.: tba

Examiner: tba

Filed: April 22, 2005

For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

EXPRESS MAIL CERTIFICATE

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Express Mail Label No.: EV 460 048 236 US

Date of Deposit: April 22, 2005

I hereby certify that the following attached paper(s) and/or fee

1. Utility Application and Fee Transmittal (4 pages + duplicate page)
2. Request and Certification Under 35 USC 112(b)(2)(B)(i) (1 page)
3. Assignment Recordation Cover Sheet and Assignment (3 pages + duplicate page)
4. Declaration signed by inventor (11 pages)
5. Application: cover sheet (1 page), specification (10 pages), Claims 1-23 (4 pages), abstract (1 page)
6. Check for $2010 and check for $40
7. return postcard

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Michael A. Willis
(Typed or printed name of person mailing papers(s) and/or fee)

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914242 v1

Docket No. 4567-4002

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27123
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UTILITY APPLICATION AND FEE TRANSMITTAL §(1.53(B))

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Sir:

Transmitted herewith for filing is the patent application of

Inventor(s) names and addresses:

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For: Extended Estrogen Dosing Contraceptive Regimen

Enclosed Are:

1 page title sheet
10 page(s) of specification
1 page(s) of Abstract
4 page(s) of claims (Claims 1-23)
____ sheets of ☐ Formal ☐ Informal drawings
11 page(s) of Declaration and Power of Attorney

- ☐ Unsigned
- ☒ Newly Executed
- ☐ Copy from prior application
- ☐ Deletion of inventors including Signed Statement under 37 C.F.R. §1.63(d)(2)

☒ **REQUEST AND CERTIFICATION UNDER 35 U.S.C. §122(b)(2)(B)(i) (form PTO/SB/35)**
As indicated on the attached Request and Certification, Applicant(s) certify that the invention disclosed in the attached application HAS NOT and WILL NOT be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing. Applicant(s) therefore request(s) that the attached application NOT be published under 35 U.S.C. §122(b).

☐ Incorporation by Reference:
- ☐ The entire disclosure of the prior application, from which a copy of the combined Declaration and Power of Attorney is supplied herein, is considered as being part of the disclosure of the accompanying application and is incorporated herein by reference.

☐ Deletion of Inventors (37 C.F.R. §1.63(d) and §1.33(b)

Signed statement attached deleting inventor(s) named in the prior application serial no. _____, filed _____.

☐ Microfiche Computer Program (Appendix)
- ☐ page(s) of Sequence Listing
- ☐ computer readable disk containing Sequence Listing
- ☐ Statement under 37 C.F.R. §1.821(f) that computer and paper copies of the Sequence Listing are the same

☒ Assignment Papers (assignment cover sheet and assignment documents)
- ☒ A check in the amount of $40.00 for recording the Assignment
- ☐ Charge the Assignment Recordation Fee to Deposit Account No. 13-4500, Order No. _____.
- ☐ Assignment Papers filed in the parent application Serial No. _____

☐ Certification of chain of title pursuant to 37 C.F.R. §3.73(b)

☐ Priority is claimed under 35 U.S.C. §119 for:
Application No(s). _____, filed _____, in _____ (country).
- ☐ Certified Copy of Priority Document(s) [_____]
  - ☐ filed herewith
  - ☐ filed in application Serial No. _____, filed _____.
- ☐ English translation document(s) [_____]
  - ☐ filed herewith
  - ☐ filed in application Serial No. _____, filed _____.

☐ Priority is claimed under 35 U.S.C. §119(e) for:
Provisional Application No. _____, filed _____.

☐ Information Disclosure Statement
- ☐ Copy of [_____] cited references
- ☐ PTO Form-1449
- ☐ References cited in parent application Serial No. _____, filed _____.

☐ Related Case Statement under 37 C.F.R. §1.98(a)(2)(iii)
- ☐ A copy of related pending U.S. Application(s) Serial No(s): _____, filed _____, respectively, is attached hereto.
- ☐ A copy of related pending U.S. Application(s) entitled, _____, filed _____ to inventor(s) _____, respectively, is attached hereto.
- ☐ A copy of each related application(s) was submitted in parent application serial no. _____, filed _____.

☐ Preliminary Amendment

☒ Return receipt postcard (MPEP 503)

☐ This is a ☐ continuation ☐ divisional ☐ continuation-in-part of prior application serial no. _____, filed _____, to which priority under 35 U.S.C. §120 is claimed.

☐ Cancel in this application original claims _____ of the parent application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

☐ A Preliminary Amendment is enclosed. (Claims added by this Amendment have been properly numbered consecutively beginning with the number following the highest numbered original claim in the prior application).

☐ The status of the parent application is as follows:

☐ A Petition for Extension of Time and a Fee therefor has been or is being filed in the parent application to extend the term for action in the parent application until _____.

☐ A copy of the Petition for Extension of Time in the co-pending parent application is attached.

☐ No Petition for Extension of Time and Fee therefor are necessary in the co-pending parent application.

☐ Please abandon the parent application at a time while the parent application is pending or at a time when the petition for extension of time in that application is granted and while this application is pending has been granted a filing date, so as to make this application co-pending.

☐ Transfer the drawing(s) from the parent application to this application

☐ Amend the specification by inserting before the first line the sentence:
This is ☐ continuation ☐ divisional ☐ continuation-in-part of co-pending application Serial No. _____, filed _____.

I. CALCULATION OF APPLICATION FEE					
Basic Fee ($300/$150)					$ 300
Examination Fee ($200/$100)					$ 200
Search Fee ($500/$250)					$ 500
	Number Filed		Number Extra	Rate	
Total Claims	33 - 20 =		13 x	($50/$25)	$ 650
Independent Claims	2 - 3 =		x	($200/$100)	$
☒ Multiple Dependent Claims	If marked, add fee of $360/$180				$ 360
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof		Fee	
- 100 =	/ 50 =	(round up to the whole number)		($250/$125)	$
				TOTAL:	$ 2010

914238 v1

☐ Small entity status is or has been claimed. Reduced fees under 37 C.F.R. §1.9 (f) paid herewith $____.

☒ A check in the amount of $2010 in payment of the application filing fees is attached.

☐ Charge fee to Deposit Account No. 13-4500, Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for filing this application pursuant to 37 CFR §1.16, **including all extension of time fees pursuant to 37 C.F.R. § 1.17 for maintaining copendency** with the parent application, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4567-4002. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: April 22, 2005

By: 

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Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Boissonneault, Roger M.

Group Art Unit: tba

Serial No.: tba

Examiner: tba

Filed: April 22, 2005

For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

EXPRESS MAIL CERTIFICATE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Express Mail Label No.: EV 460 048 236 US

Date of Deposit: April 22, 2005

I hereby certify that the following attached paper(s) and/or fee

1. Utility Application and Fee Transmittal (4 pages + duplicate page)
2. Request and Certification Under 35 USC 112(b)(2)(B)(i) (1 page)
3. Assignment Recordation Cover Sheet and Assignment (3 pages + duplicate page)
4. Declaration signed by inventor (11 pages)
5. Application: cover sheet (1 page), specification (10 pages), Claims 1-23 (4 pages), abstract (1 page)
6. Check for $2010 and check for $40
7. return postcard

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Michael A. Willis
(Typed or printed name of person mailing papers(s) and/or fee)

Michael Willis
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914242 v1

United States Non-Provisional Patent Application

of

Roger M. Boissonneault, Long Valley, NJ

for:

Extended Estrogen Dosing Contraceptive Regimen

TITLE

EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] This invention is directed to an estrogenic/progestogenic contraceptive regimen with continuous and/or extended dosing of the estrogenic component. The inventive regimen provides for low daily estrogenic hormone exposure without compromising contraceptive efficacy or cycle control. A contraceptive kit that may be used to practice the method of the invention is also disclosed.

Related Background Art

[0002] Contraceptive compositions containing both estrogenic and progestogenic compounds are known to be effective in controlling ovulation and conception. The progestogenic component of the composition is primarily responsible for the contraceptive efficacy of the composition, while the estrogenic component is included primarily to reduce undesired side effects, such as breakthrough bleeding or spotting. It is thought that small amounts of estrogen help stabilize the endometrium and allow cyclic withdrawal bleeding, similar to the natural menstrual cycle.

[0003] The earliest of these estrogenic/progestogenic contraceptive compositions was administered monophasically (fixed dose) and contained a relatively high level of estrogenic component. U.S. Patent No. 4,921,843 relates to the administration of an estrogen-only component from day 2 to day 7 of the menstrual cycle, followed by administration of a combination of estrogen and progestin from day 7 to day 28 of the menstrual cycle. U.S. Patent No. 5,280,023 and U.S. Patent No. 5,510,341 describe the administration of an estrogen-only component for 5 to 14 days at the beginning of the cycle, followed by 23 to 14 days of an estrogen/gestagen combination. U.S. Patent No. 5,756,490 discloses combination preparations with 23 or 24 daily units of an estrogen and gestagen, and 4 to 10 daily units of estrogen only. Similarly, U.S. Patent No. 6,027,749 discloses an estrogen-only component administered for 5, 6, or 7 days. U.S. Patent No. 5,552,394 discloses administration of tablets that contain both estrogen and progestin for 24 days followed by 4 days of placebo.

[0004] U.S. Patent No. 4,962,098 is directed to a multiphasic contraceptive regimen and describes a triphasic method of contraception using a progestin/estrogen combination in which the amount of estrogen is increased stepwise over the three phases wherein the first phase is 4-7 days, the second phase is 5-8 days and the third phase is 7-12 days. Preferably, administration of the contraceptive compositions for the three phases combined will be 21 days followed by a 7 day placebo period. For all three phases, the progestin is 0.5 to 1.5 mg of norethindrone acetate, while about 10 to 30 mcg of ethinyl estradiol is used in the first phase, about 20 to 40 mcg of ethinyl estradiol is used in the second phase and 30 to 50 mcg of ethinyl estradiol is employed in the third phase.

[0005] U.S. Patent No. 5,747,480 also discloses a multiphasic regimen wherein the progestin component is levonorgestrel. U.S. Patent No. 5,888,543 discloses various regimens wherein a combination of progestin and estrogen are administered in a monophasic or multiphasic regimen (varied dose, e.g., biphasic or triphasic). In one embodiment, a combination of a progestin composition and an estrogen composition is administered such that the daily dosage of the second phase progestin is greater than the daily dosage of progestin in the first phase and

the daily dosage of the second phase estrogen is greater than or equal to the daily dosage of estrogen in the first phase. U.S. Patent No. 6,479,475 describes multiphasic regimens with 23-25 consecutive days of hormone administration, followed by a 3-5 day hormone-free interval.

[0006] U.S. Patent No. 5,898,032 discloses an extended oral contraceptive regimen wherein estrogen and progestin are administered in a combined dosage form, preferably monophasically, for 60 to 110 consecutive days, followed by an administration free period of 3 to 10 days. The amount of estrogen and progestin administered daily are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively. In one particular embodiment, the combined dosage form is administered for 84 days followed by 7 pill free days. Following this particular regimen is said to result in four treatments and menstrual cycles during the year. However, extended oral contraceptive regimens tend to suffer from poor initial cycle control. Another disadvantage is that once breakthrough bleeding is under control, the user becomes functionally amenorrheic. This does not reassure the user that she is not pregnant.

[0007] One constant goal in the oral contraceptive art has been to reduce the hormone levels of such compositions without reducing contraceptive efficacy and increasing undesired side effects. Since the risk is acute thrombosis (as opposed to atherosclerosis), minimizing daily exposure of estrogen is a therapeutic goal. However, as estrogen doses decreased, the incidences of unwanted breakthrough bleeding or spotting have generally increased. Therefore, there remains a need for an oral contraceptive regimen that maintains contraceptive efficacy and provides adequate cycle control with a low daily dose of the estrogenic component.

SUMMARY OF THE INVENTION

[0008] The present invention is directed to a method of contraception that comprises the steps of sequentially administering to a female of child-bearing age: (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to 20 mcg of ethinyl estradiol for about 22 to about 26 days; (b) a second

composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol and substantially free of a progestin for about 2 to about 3 days; and (c) an optional third composition that is a placebo, wherein the sequential administration of the first composition, the second composition and the optional third composition, when present, is performed on a daily basis over a 28 day cycle. If estrogen administration is continuous during the cycle then the first composition is monophasically administered for 25 to 26 days, the second composition is administered for 2 to 3 days and no third composition is administered, while if estrogen administration is extended, but not continuous, then the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days. The sequential administration is begun on the first day of the female's menstrual cycle.

[0009] One particular embodiment of this invention is directed to a method of contraception that provides for sequentially administering to a female of child bearing age (a) a composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 25 or about 26 days; and (b) a composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 3 to about 2 days for a total cycle length of 28 days. No placebo is administered in this embodiment. The sequential administration of the first composition may be repeated the day following the completion of the administration of the second composition to provide for continuous administration of estrogen.

[0010] Yet another embodiment of this invention is directed to a method of contraception that provides for sequentially administering to a female of childbearing age (a) a composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg ethinyl estradiol for about 22 to about 24 days; (b) a composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg ethinyl estradiol for about 2 to 3 days; and (c) a placebo tablet for

about 1 to about 4 days for a total cycle length of 28 days. This embodiment provides for extended, but not continuous, administration of estrogen. The sequential administration of the first composition may be repeated the day following the completion of the administration of the placebo to provide for continuous contraception.

[0011] In preferred embodiments of the invention, the amount of estrogenic component remains the same in both phases of administration, and the amount of progestin remains constant during the first phase of administration. The invention is also directed to a kit for practicing the method of this invention.

DETAILED DESCRIPTION OF THE INVENTION

[0012] By practicing the contraceptive method disclosed herein, a user advantageously improves control of menstrual bleeding while taking the contraceptive compositions of the invention. For the purposes of this invention, the designation "mcg" refers to micrograms and "mg" to milligrams.

[0013] In a preferred embodiment, the amount of estrogen administered is equivalent to 15 mcg per day of ethinyl estradiol, while the amount of progestin administered is equivalent to 1.0 mg norethindrone acetate per day during the combined estrogen/progestin phase.

[0014] The progestin may be selected, for example, from the group consisting of norethindrone acetate, drospirenone, trimegestone, norethindrone, levonorgestrel, desogestrel, 3-ketodesogestrel, gestodene, demogestone, dydrogesterone, medrogestone, medroxy progesterone, esters and mixtures thereof and the like. The most preferred progestin is norethindrone acetate. The estrogen may be selected, for example, from the group consisting of ethinyl estradiol, 17-β-estradiol, conjugated estrogens, mestranol, estrone and esters, prodrugs and salts thereof. An exemplary ester is estradiol acetate. Preferred salts of estrone include, but are not limited to the sodium and piperate salt. For the conjugated estrogens, 1.25 mg conjugated estrogens is equivalent to a daily dose of 15 mcg ethinyl estradiol. The most preferred estrogen is ethinyl estradiol. The amount of

progestin and estrogen employed in each phase will be that amount which is equivalent in potency to the ranges of norethindrone acetate and ethinyl estradiol, respectively, that are set forth herein. Determination of equivalent potency is well understood and readily accomplished by those of ordinary skill in the art.

[0015] The third composition, if present is a placebo, i.e., a non-steroidal component. The non-steroidal placebo may comprise an iron supplement. Suitable iron supplements include, for example, ferrous fumarate, ferrous sulfate, ferrous gluconate, iron polysaccharides, and mixtures thereof. The preferred iron supplement is ferrous fumarate, most preferably a daily placebo dosage will be equivalent to not more than about 75 mg ferrous fumarate.

[0016] One goal of the extended estrogen dosing contraceptive regimen is to minimize daily exposure to estrogen from either exogenous or endogenous sources. Without wishing to be bound by theory, it is believed that continuous dosage of low amounts of estrogen may suppress FSH (follicle-stimulating hormone) and minimize follicular recruitment and therefore minimize estrogen contribution from the developing follicle. The cyclic addition of a progestin component suppresses both leutenizing hormone and ovulation while maintaining the integrity of the endometrium. Discontinuation of the progestin provides a withdrawal bleed.

[0017] The limitations of continuous low dose estrogen and progestin is irregular bleeding patterns due to a lack of an adequate withdrawal bleed. Although a higher dose 24-day regimen provides an adequate withdrawal bleed and fewer bleeding days, follicular suppression may not be optimal. The present invention provides in one embodiment that by extending the estrogen/progestin dosing beyond 24 days (e.g., 25-26 days) and utilizing estrogen alone for the rest of the cycle results in superior follicular suppression, less endogenous estrogen and therefore a more predictable withdrawal bleed of fewer days. Alternatively, in yet another embodiment dosing estrogen/progestin for 22-24 days and estrogen alone for 2-3 days with the addition of a placebo for the remainder of the cycle will allow follicular suppression while improving the reliability of a withdrawal bleed. These regimens allow for lower daily exposure to estrogen, while not compromising cycle control, and fewer days of cyclic withdrawal bleeding. If cyclic bleeding is

predictable and a modest event, this natural episode provides reassurance to reproductive women that they are not pregnant and the extended cycle monophasic continuous dosing described in U.S. Patent No. 5,898,032 provides little or no advantage.

[0018] The compositions used in this invention are administered using a suitable daily dosage form. Tablets, pills, capsules, and caplets are exemplary dosage forms. Suitable carriers with which the compositions can be administered include lactose, starch, cellulose derivatives and the like used in suitable amounts. Lactose is a preferred carrier. Mixtures of carriers, e.g. lactose, microcrystalline cellulose and starch, may also be used. In general, any pharmaceutically-acceptable additive which does not interfere with the function of the active components can be used in one or more of the compositions. These additives include conventional additives, e.g., fillers, colorants, polymeric binders, and the like.

[0019] The terms "method" and "kit" are used herein to encompass any drug delivery system via the use of which the invention outlined above can be effectively administered to human females. The contraceptive kit of this invention is a package containing the daily dosages of the compositions for practicing the method of this invention. Various types of packages for holding contraceptives are well known and it is contemplated that any such packaging may be used or altered for use in the practice of the present invention. For example, a single cycle package of the present invention for use in continuous estrogen dosing would preferably include about 25 to about 26 monophasic daily dosages of the first composition and about 2 to about 3 daily dosages of the second composition, with a total of 28 dosages. A single cycle package of the present invention for use in extended, but not continuous, estrogen dosing would preferably include about 22 to about 24 daily dosages of the first composition, about 2 to 3 daily dosages of the second composition and 1 to 4 daily dosages of the third composition, with a total of 28 dosages. The kit will also include instructions and/or indicia indicating that the first daily dosage of the first composition should be administered on the first day of the menstrual cycle, which is defined as the first day of menstrual bleeding, or on the first Sunday after the first day of the menstrual cycle.

EXAMPLES

[0020] The following examples are used to explain the invention in more detail. The dosage units are formulated conventionally using tablets, pills, coated tablets, and the like.

Example 1: Continuous Estrogen Contraceptive Regimen

Day	1	2	3	4	5	6	7
Composition	C	C	C	C	C	C	C
Day	8	9	10	11	12	13	14
Composition	C	C	C	C	C	C	C
Day	15	16	17	18	19	20	21
Composition	C	C	C	C	C	C	C
Day	22	23	24	25	26	27	28
Composition	C	C	C	C	E	E	E

Day 1 is first day of bleeding.

C= 1.0 milligrams Norethindrone Acetate and 15 micrograms Ethinyl Estradiol

E= 15 micrograms Ethinyl Estradiol

Example 2: Extended Estrogen Contraceptive Regimen

Day	1	2	3	4	5	6	7
Composition	C	C	C	C	C	C	C
Day	8	9	10	11	12	13	14
Composition	C	C	C	C	C	C	C
Day	15	16	17	18	19	20	21
Composition	C	C	C	C	C	C	C
Day	22	23	24	25	26	27	28
Composition	C	C	C	E	E	P	P

Day 1 is first day of bleeding.

C= 1.0 milligrams Norethindrone Acetate and 15 micrograms Ethinyl Estradiol

E= 15 micrograms Ethinyl Estradiol

P= Placebo

[0021] While the invention has been described above with reference to specific embodiments thereof, it is apparent that many changes, modifications, and variations can be made without departing from the inventive concept disclosed herein. Accordingly, it is intended to embrace all such changes, modifications, and variations that fall within the spirit and broad scope of the appended claims. All patent applications, patents, and other publications cited herein are incorporated by reference in their entirety.

WHAT IS CLAIMED IS:

1. A method of contraception comprising the steps of sequentially administering to a female of child-bearing age:

(a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 22 to about 26 days;

(b) a second composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol and substantially free of a progestin for about 2 to about 3 days; and

(c) an optional third composition that is a placebo,

wherein the sequential administration of the first composition, the second composition and the optional third composition, when present, is performed on a daily basis over a 28 day cycle and further provided that (i) if estrogen administration is continuous during the sequence then the first composition is monophasic and is administered for 25 to 26 days and the second composition is administered for 2 to 3 days and (ii) if estrogen administration is not continuous during the sequence then the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days.

2. The method according to claim 1, wherein the sequential administration is repeated beginning the day after completion of the 28 day cycle.

3. The method according to claim 1, wherein the first composition is administered for 25 to 26 days, the second composition is administered for 2 to 3 days and no third composition is administered in the cycle.

4. The method according to claim 1, wherein the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days of the cycle.

5. The method according to claim 1, wherein the progestin is selected from the group consisting of norethindrone acetate, drospirenone, trimegestone, norethindrone, levonorgestrel, desogestrel, 3-ketodesogestrel, gestodene, demogestone, dydrogesterone, medrogestone, medroxy progesterone, esters and mixtures thereof.

6. The method according to claim 1, wherein the estrogen is selected from the group consisting of ethinyl estradiol, 17-β-estradiol, conjugated estrogens, mestranol, estrone, and esters, prodrugs and salts thereof.

7. The method according to any one of claims 3 and 4, wherein the progestin in the first composition is norethindrone acetate.

8. The method according to claim 7, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

9. The method according to any one of claims 3 and 4, wherein the estrogen in the first and second composition is ethinyl estradiol.

10. The method according to claim 9, wherein the amount of ethinyl estradiol in the first and second composition is about 15 mcg.

11. The method according to any one of claims 3 and 4, wherein (i) the first composition contains about 1.0 mg of norethindrone acetate and about 15 mcg of ethinyl estradiol, and (ii) the second composition contains about 15 mcg of ethinyl estradiol.

12. The method according to claim 1, wherein the placebo contains about 75 mg of ferrous fumarate.

13. A contraceptive kit comprising a package containing daily dosages of:

(a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol;

(b) a second composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol and substantially free of a progestin; an

(c) an optional third composition that is a placebo,

wherein the package contains 22 to 26 daily dosages of the first composition, 2 to 3 daily dosages of the second composition, optionally 1 to 4 daily dosages of the third composition, and a total amount of daily dosages of the first composition, second composition and optional third composition, when present, is 28 and further provided that (i) when the kit contains no third composition then the package contains 25 to 26 monophasic daily dosages of the first composition and 2 to 3 daily dosages of the second composition and (ii) when the kit contains 1 to 4 daily dosages of the third composition then the package contains 22 to 24 daily dosages of the first composition and 2 to 3 daily dosages of the second composition.

14. The kit according to claim 13, wherein the package contains 25 to 26 daily dosages of the first composition and 2 to 3 daily dosages of the second composition.

15. The kit according to claim 13, wherein the package contains 22 to 24 daily dosages of the first composition, 2 to 3 daily dosages of the second composition and 1 to 4 daily dosages of the third composition.

16. The kit according to claim 13, wherein the progestin is selected from the group consisting of norethindrone acetate, drospirenone, trimegestone, norethindrone, levonorgestrel, desogestrel, 3-ketodesogestrel, gestodene, demogestone, dydrogesterone, medrogestone, medroxy progesterone, esters and mixtures thereof.

17. The kit according to claim 13, wherein the estrogen is selected from the group consisting of ethinyl estradiol, 17-β-estradiol, conjugated estrogens, mestranol, estrone, and esters, prodrugs and salts thereof.

18. The kit according to any one of claims 14 and 15, wherein the progestin in the first composition is norethindrone acetate.

19. The kit according to claim 18, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

20. The kit according to any one of claims 14 and 15, wherein the estrogen in the first and second composition is ethinyl estradiol.

21. The kit according to claim 20, wherein the amount of ethinyl estradiol in the first and second composition is about 15 mcg.

22. The kit according to any one of claims 14 and 15, wherein (i) the first composition contains about 1.0 mg of norethindrone acetate and about 15 mcg of ethinyl estradiol, and (ii) the second composition contains about 15 mcg of ethinyl estradiol.

23. The kit according to claim 13, wherein the placebo contains about 75 mg of ferrous fumarate.

ABSTRACT

[0022] A method of contraception that provides for sequentially administering to a female of child bearing age: (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 22 to about 26 days; (b) a second composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 2 to about 3 days and an optional third composition that is a placebo provided that (i) if estrogen administration is continuous then the first composition is administered for 25 to 26 days, the second composition is administered for 2 to 3 days and no third composition is administered and (ii) if estrogen administration is not continuous then the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days. The total cycle length is 28 days, with the first composition administered on day 1 of the menstrual cycle, defined as the first day of menstrual bleeding, or on the first Sunday after the first day of the menstrual cycle.

Docket No. 4567-4002

COMBINED DECLARATION AND POWER OF ATTORNEY FOR ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Extended Estrogen Dosing Contraceptive Regimen

the specification of which

a. ☒ is attached hereto

b. ☐ was filed on as application Serial No. and was amended on . (if applicable).

PCT FILED APPLICATION ENTERING NATIONAL STAGE

c. ☐ was described and claimed in International Application No. filed on and as amended on . (if any).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56.

I hereby specify the following as the correspondence address to which all communications about this application are to be directed:

SEND CORRESPONDENCE TO:

☒ The address associated with the Customer Number **27123**

-OR-

☐ Address Shown (see below)

DIRECT TELEPHONE CALLS TO:

(212) 415-8700

914200 v1

☐ I hereby claim foreign priority benefits under Title 35, United States Code § 119 (a)-(d) or under § 365(b) of any foreign application(s) for patent or inventor's certificate or under § 365(a) of any PCT international application(s) designating at least one country other than the U.S. listed below and also have identified below such foreign application(s) for patent or inventor's certificate or such PCT international application(s) filed by me on the same subject matter having a filing date within twelve (12) months before that of the application on which priority is claimed:

☐ The attached 35 U.S.C. § 119 claim for priority for the application(s) listed below forms a part of this declaration.

Country/PCT	Application Number	Date of filing (day, month, yr)	Date of issue (day, month, yr)	Priority Claimed
				☐ Y ☐ N
				☐ Y ☐ N
				☐ Y ☐ N

☐ I hereby claim the benefit under 35 U.S.C. § 119(e) of any U.S. provisional application(s) listed below.

Provisional Application No.	Date of filing (day, month, yr)

ADDITIONAL STATEMENTS FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART OR PCT APPLICATION(S) DESIGNATING THE U.S.

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or under § 365(c) of any PCT international application(s) designating the U.S. listed below.

US/PCT Application Serial No.	Filing Date	Status (patented, pending, abandoned)/ U.S. application no. assigned (For PCT)

US/PCT Application Serial No.	Filing Date	Status (patented, pending, abandoned)/ U.S. application no. assigned (For PCT)

☐ In this continuation-in-part application, insofar as the subject matter of any of the claims of this application is not disclosed in the above listed prior United States or PCT international application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

Docket No. 4567-4002

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or Imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint:

☒ Practitioners associated with the Customer Number **27123**

-OR-

☐ Practitioner(s) named below:

Name	Registration Number

☐ I hereby authorize the U.S. attorneys and/or agents named hereinabove to accept and follow instructions from as to any action to be taken in the U.S. Patent and Trademark Office regarding this application without direct communication between the U.S. attorneys and/or agents and me. In the event of a change in the person(s) from whom instructions may be taken I will so notify the U.S. attorneys and/or agents named hereinabove.

Full name of sole or first inventor: Roger M. Boissonneault

Inventor's signature* _____ 4/22/05 Date

Residence: 5 North Bridge Drive, Long Valley, NJ 07853

Citizenship: USA

Post Office Address: 5 North Bridge Drive, Long Valley, NJ 07853

Full name of second inventor: ____

Inventor's signature* _____ _____ Date

Residence: ____

Citizenship: ____

Post Office Address:

☐ ATTACHED IS ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR SIGNATURE BY THIRD AND SUBSEQUENT INVENTORS FORM.

Full name of third inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of fourth inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of fifth inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of sixth inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of seventh inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of eighth inventor _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of ninth inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of tenth inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

Full name of eleventh inventor: _____

Inventor's signature* _____ _____ Date

Residence: _____

Citizenship: _____

Post Office Address: _____

*Before signing this declaration, each person signing must:

1. Review the declaration and verify the correctness of all information therein; and

2. Review the specification and the claims, including any amendments made to the claims.

After the declaration is signed, the specification and claims are not to be altered.

To the inventor(s):

The following are cited in or pertinent to the declaration attached to the accompanying application:

Title 37, Code of Federal Regulation, §1.56

Duty to disclose information material to patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability. A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard,

giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the National or PCT international filing date of the continuation-in-part application.

Title 35, U.S. Code § 101

Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Title 35 U.S. Code § 102

Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless --

(a) the invention 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 patent,

(b) the invention was patented or described in a printed publication in this or foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) The invention was described in--

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national

application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a); or

(f) he did not himself invent the subject matter sought to be patented, or

(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Title 35, U.S. Code § 103

103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(b) (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)—

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means--

(A) a process of genetically altering or otherwise inducing a single- ormulti-celled organism to--

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Title 35, U.S. Code § 112 (in part)

Specification

The specification shall 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 to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Title 35, U.S. Code, § 119

Benefit of earlier filing date in foreign country; right of priority

(a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

(b) (1) No application for patent shall be entitled to this right of priority unless a claim is filed in the Patent and Trademark Office, identifying the foreign application by specifying the application number on that foreign application, the intellectual property authority or country in or for which the application was filed, and the date of filing the application, at such time during the pendency of the application as required by the Director.

(2) The Director may consider the failure of the applicant to file a timely claim for priority as a waiver of any such claim. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed claim under this section.

(3) The Director may require a certified copy of the original foreign application, specification, and drawings upon which it is based, a translation if not in the English language, and such other

information as the Director considers necessary. Any such certification shall be made by the foreign intellectual property authority in which the foreign application was filed and show the date of the application and of the filing of the specification and other papers.

(c) In like manner and subject to the same conditions and requirements, the right provided in this section may be based upon a subsequent regularly filed application in the same foreign country instead of the first filed foreign application, provided that any foreign application filed prior to such subsequent application has been withdrawn, abandoned, or otherwise disposed of, without having been laid open to public inspection and without leaving any rights outstanding, and has not served, nor thereafter shall serve, as a basis for claiming a right of priority.

(d) Applications for inventors' certificates filed in a foreign country in which applicants have a right to apply, at their discretion, either for a patent or for an inventor's certificate shall be treated in this country in the same manner and have the same effect for purpose of the right of priority under this section as applications for patents, subject to the same conditions and requirements of this section as apply to applications for patents, provided such applicants are entitled to the benefits of the Stockholm Revision of the Paris Convention at the time of such filing.

(e) (1) An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this subsection during the pendency of the application.

(2) A provisional application filed under section 111(b) of this title may not be relied upon in any proceeding in the Patent and Trademark Office unless the fee set forth in subparagraph (A) or (C) of section 41(a)(1) of this title has been paid.

(3) If the day that is 12 months after the filing date of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, the period of pendency of the provisional application shall be extended to the next succeeding secular or business day.

(f) Applications for plant breeder's rights filed in a WTO member country (or in a foreign UPOV Contracting Party) shall have the same effect for the purpose of the right of priority under subsections (a) through (c) of this section as applications for patents, subject to the same conditions and requirements of this section as apply to applications for patents.

(g) As used in this section--

(1) the term "WTO member country" has the same meaning as the term is defined in section 104(b)(2) of this title; and

(2) the term "UPOV Contracting Party" means a member of the International Convention for the Protection of New Varieties of Plants.

Title 35, U.S. Code, § 120

Benefit or earlier filing date in the United States

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. ***No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.***

Please read carefully before signing the Declaration attached to the accompanying Application. If you have any questions, please contact Morgan & Finnegan, L.L.P.

CLAIMS ONLY	SERIAL NO. 11/122,90	FILING DATE
	APPLICANT(S)	

CLAIMS

	AS FILED		AFTER 1ST AMENDMENT		AFTER 2ND AMENDMENT							
	IND	DEP	IND	DEP	IND	DEP		IND	DEP	IND	DEP	IND	DEP
1	1						51						
2		1					52						
3		1					53						
4		1					54						
5		1					55						
6		1					56						
7		2					57						
8		2					58						
9		2					59						
10		3					60						
11		2					61						
12		11					62						
13	1						63						
14		1					64						
15		1					65						
16		1					66						
17		1					67						
18		2					68						
19		2					69						
20		2					70						
21		0					71						
22		2					72						
23		1					73						
24							74						
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42							92						
43							93						
44							94						
45							95						
46							96						
47							97						
48							98						
49							99						
50							100						
TOTAL IND.	2						TOTAL IND.						
TOTAL DEP.	31						TOTAL DEP.						
TOTAL CLAIMS	33						TOTAL CLAIMS						

11/20

PTO-2202 (Replication only) (1/03)

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

04/26/2005 MWOLDGE1 00000011 11112290

01 FC:1011	300.00	OP
02 FC:1111	500.00	OP
03 FC:1311	200.00	OP
04 FC:1202	650.00	OP
05 FC:1203	360.00	OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 489-267/59033

PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 8, 2004

11112290

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS 23		
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	33 minus 20=	* 13
INDEPENDENT CLAIMS	2 minus 3 =	* -
MULTIPLE DEPENDENT CLAIM PRESENT		☑

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	150.00	OR	BASIC FEE	300.00
X$ 25=		OR	X$50=	650
X100=		OR	X200=	
+180=		OR	+360=	360
TOTAL		OR	TOTAL	1310

CLAIMS AS AMENDED - PART II

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

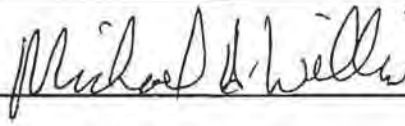
REQUEST AND CERTIFICATION UNDER 35 U.S.C. 122(b)(2)(B)(i)

Application No.	tba
Filing Date	April 22, 2005
First Named Inventor	Boissonneault
Group Art Unit	tba
Examiner Name	tba
Atty Docket No.	4567-4002

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing. I hereby request that the attached application not be published under 35 U.S.C. §122(b).

This request is signed in compliance with 37 C.F.R. §1.33(b) and is being submitted with the application **at the time of filing**.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature		Date April 22, 2005	
Name (Print/Type)	Michael A. Willis	Reg. No. (Atty/Agent)	53,913

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. §122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. §122(b)(2)(B)(iii)).**

04-24-06

Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Roger M. BOISSONNEAULT

Group Art Unit: 1614

Serial No.: 11/112,290

Examiner: TBA

Filed: April 22, 2005

For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

EXPRESS MAIL CERTIFICATE

Mail Stop PGPUB
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Express Mail Label No.: EV 826870709 US

Date of Deposit: April 21, 2006

I hereby certify that the following attached paper(s) and/or fee

1. Request to Rescind Previous NonPublication Request;
2. Transmittal of Request to Rescind Previous NonPublication Request; and
3. Postcard.

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Albert Isles
(Typed or printed name of person mailing papers(s) and/or fee)

Albert Isles
(Signature of person mailing paper(s) and/or fee)

Correspondence Address:
MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101
(212) 415-8700 Telephone
(212) 415-8701 Facsimile

988064 v1

Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Roger M BOISSONNEAULT

Group Art Unit: 1614

Serial No.: 11/112,290

Examiner: TBA

Filed: April 22, 2005

For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

TRANSMITTAL OF REQUEST TO RESCIND PREVIOUS NONPUBLICATION REQUEST UNDER 35 USC 122 (b)(2)(B)(ii); NOTICE OF FOREIGN FILING 35 USC 122(b)(2)(B)(iii)

Mail Stop PGPUB
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is/are the following items in the above-identified application:

☒ **REQUEST TO RESCIND PREVIOUS NONPUBLICATION REQUEST UNDER 35 USC 122(b)(2)(B)(ii); NOTICE OF FOREIGN FILING 35 USC 122(b)(2)(B)(iii)**

☐ A check for the required fee of $_____ is enclosed.

☐ Please charge the required fee of $_____ to Deposit Account No. **13-4500**, Order No. _____.

☒ The Commissioner is hereby authorized to charge any fees which may be required by this paper, or credit any overpayment to Deposit Account No. **13-4500**, Order No. **4567-4002**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: April 21, 2006

By: _____
Michael A. Willis
Registration No. 53,913

Correspondence Address:

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988055 v1

REQUEST TO RESCIND PREVIOUS NONPUBLICATION REQUEST 35 U.S.C. §122(b)(2)(B)(ii) NOTICE OF FOREIGN FILING 35 U.S.C. §122(b)(2)(B)(iii)		
	Application No.	11/112,290
	Filing Date	April 22, 2005
	First Named Inventor	BOISSONNEAULT
	Group Art Unit	1614
	Examiner Name	TBA
	Atty Docket No.	4567-4002

I hereby rescind the previous request that the above-identified application not be published under 35 U.S.C. §122(b)(2)(B)(iii).

This document is being submitted within forty-five (45) days of April 17, 2006, the foreign filing date of the application (35 U.S.C. §122(b)(2)(B)(iii)).

This request is signed in compliance with 37 C.F.R. §1.33(b).

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	Michael A Willis	Date	April 21, 2006
Name (Print/Type)	Michael A. Willis	Reg. No. (Atty/Agent)	53,913

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P.O. Box 1450
Alexandria, VA 22313-1450

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
11/112,290	04/22/2005	Roger M. Boissonneault	4567-4002

CONFIRMATION NO. 5820

MORGAN & FINNEGAN, L.L.P.
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New York, NY 10281-2101

Date Mailed: 04/27/2006

Communication Regarding Rescission Of Nonpublication Request and/or Notice of Foreign Filing

Applicant's rescission of the previously-filed nonpublication request and/or notice of foreign filing is acknowledged. The paper has been reflected in the Patent and Trademark Office's (USPTO's) computer records so that the earliest possible projected publication date can be assigned.

The projected publication date is 10/26/2006.

If applicant rescinded the nonpublication request before or on the date of "foreign filing,"[1] then no notice of foreign filing is required.

If applicant foreign filed the application after filing the above application and before filing the rescission, and the rescission did not also include a notice of foreign filing, then a notice of foreign filing (not merely a rescission) is required to be filed within 45 days of the date of foreign filing. See 35 U.S.C. § 122(b)(2)(B)(iii), and Clarification of the United States Patent and Trademark Office's Interpretation of the Provisions of 35 U.S.C. § 122(b)(2)(B)(ii)-(iv), 1272 Off. Gaz. Pat. Office 22 (July 1, 2003).

If a notice of foreign filing is required and is not filed within 45 days of the date of foreign filing, then the application becomes abandoned pursuant to 35 U.S.C. § 122(b)(2)(B)(iii). In this situation, applicant should either file a petition to revive or notify the Office that the application is abandoned. See 37 CFR 1.137(f). Any such petition to revive will be forwarded to the Office of Petitions for a decision. Note that the filing of the petition will not operate to stay any period of reply that may be running against the application.

Questions regarding petitions to revive should be directed to the Office of Petitions at (571) 272-3282. Questions regarding publications of patent applications should be directed to the patent application publication hotline at (703) 605-4283 or by e-mail pgpub@uspto.gov.

[1] Note, for purpose of this notice, that "foreign filing" means "filing an application directed to the same invention in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing".

PART 1 - ATTORNEY/APPLICANT COPY

NOTICE OF FOREIGN FILING
35 U.S.C. §122(b)(2)(B)(iii)

Application No.	11/112,290
Filing Date	April 22, 2005
First Named Inventor	BOISSONNEAULT
Group Art Unit	1614
Examiner Name	TBA
Atty Docket No.	4567-4002

On April 21, 2006, Applicants submitted a *Request to Rescind Previous Non-Publication Request (35 U.S.C. §122(b)(2)(B)(iii)) and Notice of Foreign Filing (35 U.S.C. §122(b)(2)(B)(iii))*.

On April 27, 2006, Applicants received from the USPTO a *Communication Regarding Rescission of Nonpublication Request and/or Notice of Foreign Filing*.

Further to Applicants' April 21, 2006 submission, Applicants inform the USPTO that Applicants filed a PCT application claiming priority to US 11/112,290 with the USTPO as receiving office on April 17, 2006. A serial number for the PCT application is not yet available.

This document is being submitted within forty-five (45) days of April 17, 2006, the foreign filing date of the application (35 U.S.C. §122(b)(2)(B)(iii)).

This request is signed in compliance with 37 C.F.R. §1.33(b).

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	Michael A. Willis	Date	May 24, 2006
Name (Print/Type)	Michael A. Willis	Reg. No. (Atty/Agent)	53,913

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995132 v1

05-26-06 DW

Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Roger M. BOISSONNEAULT

Group Art Unit: 1614

Serial No.: 11/112,290

Examiner: TBA

Filed: April 22, 2005

For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

EXPRESS MAIL CERTIFICATE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Express Mail Label No.: EV 826872293 US

Date of Deposit: May 24, 2006

I hereby certify that the following attached paper(s) and/or fee

1. Transmittal of Notice of Foreign Filing (1 page + duplicate page)
2. Notice of Foreign Filing (1 page)
3. Postcard.

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Michael A. Willis
(Typed or printed name of person mailing papers(s) and/or fee)

Michael A. Willis
(Signature of person mailing paper(s) and/or fee)

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Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Roger M BOISSONNEAULT

Group Art Unit: 1614

Serial No.: 11/112,290

Examiner: TBA

Filed: April 22, 2005

For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

TRANSMITTAL OF NOTICE OF FOREIGN FILING
35 USC 122(b)(2)(B)(iii)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is/are the following items in the above-identified application:

☒ **NOTICE OF FOREIGN FILING 35 USC 122(b)(2)(B)(iii)**

☐ A check for the required fee of $_____ is enclosed.

☐ Please charge the required fee of $_____ to Deposit Account No. **13-4500**, Order No. _____.

☒ The Commissioner is hereby authorized to charge any fees which may be required by this paper, or credit any overpayment to Deposit Account No. **13-4500**, Order No. **4567-4002**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: May 24, 2006

By: _____
Michael A. Willis
Registration No. 53,913

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Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	11/112,290	Confirmation No.:	5820
Applicant(s):	Roger M. BOISSONNEAULT	Group Art Unit:	1614
		Examiner:	San Ming R. HUI
Filed:	April 22, 2005		
		Customer No.:	27123
For:	EXTENDED ESTROGEN DOSING CONTRACEPTIVE PROGRAM		

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☒ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:

   GASPARD, U. et al., "New Forms of Hormonal Contraception"; *Journal de Gynécologie, Obstétrique et Biologie de al Reproduction*, May 2000, vol. 29, no. 3, p. 288-291.

2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.

3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. _____, filed _____.

4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:

   ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or

☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or

☒ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or

☐ 37 C.F.R. §1.97(b)(4) before the mailing date of a first office action after the filing of an RCE under §1.114.

5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.

6. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):

☐ A check in the amount of $180.00 is enclosed in payment of the fee.

☐ Charge the fee to Deposit Account No. **13-4500**, Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:

a. one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and

b. the fee due under 37 C.F.R. §1.17(p) which is paid as set forth in paragraph 11 below.

8. ☐ This Information Disclosure Statement is being filed in compliance with:

a. ☐ 37 C.F.R. §1.313(b)(3) or §1.313(c)(1), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h);

b. ☐ 37 C.F.R. §1.313(c)(2) or §1.313(c)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Request for Continued Examination (RCE) or a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h).

c. ☐ The fee due under 37 C.F.R. §§1.17(h) is paid as set forth in paragraph 11 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

10. ☒ This document is accompanied by ☒ a Search Report ☐ Communication which was cited in a corresponding ☒ PCT (PCT/US2006/014367) or ☐ Foreign counterpart application

11. ☐ A check in the amount of $ is enclosed in payment of the fees due under 37 C.F.R. §§1.17(h) and 1.17(p).

☐ Charge the fees due under 37 C.F.R. §§1.17(h) and 1.17(p) to Deposit Account No. **13-4500**, Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. **13-4500**, Order No. 4567-4002. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: April 30, 2007

By: _____
Keith J. McWha
Registration No. 44,235

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FORM PTO-1449A INFORMATION DISCLOSURE CITATION	Attorney Docket: 4567-4002	Serial No.: 11/112,290
	Applicant: Roger M. BOISSONNEAULT	
	Filing Date: April 22, 2005	Group Art Unit: 1614

U.S. PATENT / PUBLICATION DOCUMENTS

Examiner Initial		Patent/Publication Number	Publication/Issue Date	Name	Filing Date
	1.	4,921,843	May 1, 1990	Pasquale	Oct. 20, 1988
	2.	5,280,023	Jan. 19, 1994	Ehrlich et al.	Feb. 10, 1992
	3.	5,510,341	Apr. 23, 1996	Ehrlich et al.	Oct. 6, 1993
	4.	5,756,490	May 26, 1998	Lachnit et al.	Mar. 30, 1995
	5.	6,027,749	Feb. 22, 2000	Schmidt-Gollwitzer et al.	Jun. 27, 1996
	6.	5,552,394	Sep. 3, 1996	Hodgen	Jul. 22, 1994
	7.	4,962,098	Oct. 9, 1990	Boissonneault	Apr. 20, 1989
	8.	5,747,480	May 5, 1998	Gast	Apr. 17, 1997
	9.	5,888,543	Mar. 30, 1999	Gast	Jul. 2, 1997
	10.	6,479,475	Nov. 12, 2002	Gast	Jul. 2, 1997
	11.	5,898,032	Apr. 27, 1999	Hodgen	Jun. 23, 1997
	12.	5,010,070	Apr. 23, 1991	Boissonneault	May 22, 1990
	13.				
	14.				

FOREIGN PATENT DOCUMENTS

Examiner Initial		Patent Number	Publication Date	Country	Copy Filed	Translation
	15.	WO 2006/115871 A1	Nov. 2, 2006	WIPO	☒ Yes	☐ Yes ☐ No ☐ Abstract ☒ N/A
	16.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	17.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	18.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	19.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	20.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A

Examiner	Date Considered
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

FORM PTO-1449B INFORMATION DISCLOSURE CITATION	Attorney Docket: 4567-4002	Serial No.: 11/112,290
	Applicant: Roger M. BOISSONNEAULT	
	Filing Date: April 22, 2005	Group Art Unit: 1614

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	1.	MIRCETTE STUDY GROUP, "An open-label, multicenter, noncomparative safety and efficacy study of Mircette™, a low dose estrogen-progestin oral contraceptive"; *American Journal of Obstetrics and Gynecology*, July 1998, vol. 179, no. 1, p. S2-S8
	2.	GASPARD, U. et al., "New Forms of Hormonal Contraception"; *Journal de Gynécologie, Obstétrique et Biologie de al Reproduction*, May 2000, vol. 29, no. 3, p. 288-291.
	3.	European Patent Office, International Search Report for PCT/US2006/014367, August 25, 2006
	4.	
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	21.	
	22.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

1057501 v1

Electronic Acknowledgement Receipt

EFS ID:	1731100
Application Number:	11112290
International Application Number:	
Confirmation Number:	5820
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Correspondence Address:	MORGAN & FINNEGAN, L.L.P. - 3 World Financial Center - New York NY 10281-2101 US 212-415-8701 -
Filer:	Keith McWha/Andrew Cohen
Filer Authorized By:	Keith McWha
Attorney Docket Number:	4567-4002
Receipt Date:	30-APR-2007
Filing Date:	22-APR-2005
Time Stamp:	20:19:49
Application Type:	Utility

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	4567-4002_IDS.pdf	531602	no	5
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO06115871_ISR.pdf	727513	no	18
Warnings:					
Information:					
3	NPL Documents	Gaspard.pdf	22494	no	4
Warnings:					
Information:					
4	NPL Documents	Mircette.pdf	1329886	no	9
Warnings:					
Information:					
5	Foreign Reference	ISR.pdf	134321	no	3
Warnings:					
Information:					
		Total Files Size (in bytes):	2745816		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

27123
CUSTOMER NUMBER

Docket No. 4567-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Roger M. BOISSONNEAULT	Confirmation No.:	5820
Serial No.:	11/112,290	Group Art Unit:	1614
Filed:	April 22, 2005	Examiner:	San Ming R. HUI
For:	EXTENDED ESTROGEN DOSING CONTRACEPTIVE PROGRAM		

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to an examination on the merits, applicant respectfully requests entry of the following Preliminary Amendment.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remark/Arguments begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (original) A method of contraception comprising the steps of sequentially administering to a female of child-bearing age:

(a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 22 to about 26 days;

(b) a second composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol and substantially free of a progestin for about 2 to about 3 days; and

(c) an optional third composition that is a placebo,

wherein the sequential administration of the first composition, the second composition and the optional third composition, when present, is performed on a daily basis over a 28 day cycle and further provided that (i) if estrogen administration is continuous during the sequence then the first composition is monophasic and is administered for 25 to 26 days and the second composition is administered for 2 to 3 days and (ii) if estrogen administration is not continuous during the sequence then the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days.

2. (original) The method according to claim 1, wherein the sequential administration is repeated beginning the day after completion of the 28 day cycle.

3. (original) The method according to claim 1, wherein the first composition is administered for 25 to 26 days, the second composition is administered for 2 to 3 days and no third composition is administered in the cycle.

4. (original) The method according to claim 1, wherein the first composition is administered for 22 to 24 days, the second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days of the cycle.

5. (original) The method according to claim 1, wherein the progestin is selected from the group consisting of norethindrone acetate, drospirenone, trimegestone, norethindrone, levonorgestrel, desogestrel, 3-ketodesogestrel, gestodene, demogestone, dydrogesterone, medrogestone, medroxy progesterone, esters and mixtures thereof.

6. (original) The method according to claim 1, wherein the estrogen is selected from the group consisting of ethinyl estradiol, 17-β-estradiol, conjugated estrogens, mestranol, estrone, and esters, prodrugs and salts thereof.

7. (original) The method according to any one of claims 3 and 4, wherein the progestin in the first composition is norethindrone acetate.

8. (original) The method according to claim 7, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

9. (original) The method according to any one of claims 3 and 4, wherein the estrogen in the first and second composition is ethinyl estradiol.

10. (original) The method according to claim 9, wherein the amount of ethinyl estradiol in the first and second composition is about 15 mcg.

11. (original) The method according to any one of claims 3 and 4, wherein (i) the first composition contains about 1.0 mg of norethindrone acetate and about 15 mcg of ethinyl estradiol, and (ii) the second composition contains about 15 mcg of ethinyl estradiol.

12. (original) The method according to claim 1, wherein the placebo contains about 75 mg of ferrous fumarate.

13. (currently amended) A contraceptive kit comprising a package containing daily dosages of:

(a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol;

(b) a second composition containing an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol and substantially free of a progestin; ~~an~~ and

(c) an optional third composition that is a placebo,

wherein the package contains 22 to 26 daily dosages of the first composition, 2 to 3 daily dosages of the second composition, optionally 1 to 4 daily dosages of the third composition, and a total amount of daily dosages of the first composition, second composition and optional third composition, when present, is 28 and further provided that (i) when the kit contains no third composition then the package contains 25 to 26 monophasic daily dosages of the first composition and 2 to 3 daily dosages of the second composition and (ii) when the kit contains 1 to 4 daily dosages of the third composition then the package contains 22 to 24 daily dosages of the first composition and 2 to 3 daily dosages of the second composition.

14. (original) The kit according to claim 13, wherein the package contains 25 to 26 daily dosages of the first composition and 2 to 3 daily dosages of the second composition.

15. (original) The kit according to claim 13, wherein the package contains 22 to 24 daily dosages of the first composition, 2 to 3 daily dosages of the second composition and 1 to 4 daily dosages of the third composition.

16. (original) The kit according to claim 13, wherein the progestin is selected from the group consisting of norethindrone acetate, drospirenone, trimegestone, norethindrone, levonorgestrel, desogestrel, 3-ketodesogestrel, gestodene, demogestone, dydrogesterone, medrogestone, medroxy progesterone, esters and mixtures thereof.

17. (original) The kit according to claim 13, wherein the estrogen is selected from the group consisting of ethinyl estradiol, 17-β-estradiol, conjugated estrogens, mestranol, estrone, and esters, prodrugs and salts thereof.

18. (original) The kit according to any one of claims 14 and 15, wherein the progestin in the first composition is norethindrone acetate.

19. (original) The kit according to claim 18, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

20. (original) The kit according to any one of claims 14 and 15, wherein the estrogen in the first and second composition is ethinyl estradiol.

21. (original) The kit according to claim 20, wherein the amount of ethinyl estradiol in the first and second composition is about 15 mcg.

22. (original) The kit according to any one of claims 14 and 15, wherein (i) the first composition contains about 1.0 mg of norethindrone acetate and about 15 mcg of ethinyl estradiol, and (ii) the second composition contains about 15 mcg of ethinyl estradiol.

23. (original) The kit according to claim 13, wherein the placebo contains about 75 mg of ferrous fumarate.

24. (new) The method according to claim 1, wherein the amount of estrogen in the first and second composition is an amount equivalent to about 5 to about 15 mcg of ethinyl estradiol.

25. (new) The method according to claim 24, wherein the estrogen in the first and second composition is ethinyl estradiol.

26. (new) The kit according to claim 13, wherein the amount of estrogen in the first and second composition is an amount equivalent to about 5 to about 15 mcg of ethinyl estradiol.

27. (new) The kit according to claim 26, wherein the estrogen in the first and second composition is ethinyl estradiol.

28. (new) A method of contraception comprising the steps of sequentially administering to a female of child bearing age:

(a) a first composition containing about 0.3 to about 1.5 mg norethindrone acetate and about 5 to about 15 mcg ethinyl estradiol for 24 days;

(b) a second composition containing about 5 to about 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days;

(c) a third composition that is a placebo for 2 days,

wherein the sequential administration of the first composition, the second composition and the third composition is performed on a daily basis over a 28 day cycle.

29. (new) The method according to claim 28, wherein the first composition contains about 1 mg of norethindrone acetate.

30. (new) A contraceptive kit comprising a package containing daily dosages of:

(a) a first composition containing about 0.3 to about 1.5 mg norethindrone acetate and about 5 to about 15 mcg of ethinyl estradiol;

(b) a second composition containing about 5 to about 15 mcg of ethinyl estradiol and substantially free of a progestin; and

(c) a third composition that is a placebo,

wherein the package contains 24 daily dosages of the first composition, 2 daily dosages of the second composition and 2 daily dosages of the third composition.

31. (new) The kit according to claim 30, wherein the first composition contains about 1 mg of norethindrone acetate.

REMARKS

Claims 1-31 are pending after entry of this paper.

Claim 13 has been amended to correct a typographical error. Claims 24-31 have been newly added. Support for new claims 24-31 may be found throughout the instant specification and the claims as originally filed.

With respect to new method claims 24-25 and 28-29, original claim 1 recites that the first and second composition each contain "an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol," and original claim 10 recites that the first and second composition contain about 15 mcg of the estrogen ethinyl estradiol. Likewise, with respect to new kit claims 26-27 and 30-31, original claim 13 recites that the first and second composition each contain "an estrogen in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol," and original claim 21 recites that the first and second composition contain about 15 mcg of the estrogen ethinyl estradiol. Accordingly, original claims 10 and 21 essentially narrow original claims 1 and 13, respectively, from *the range of about 5 to about 20 mcg* on the one hand to *about 15 mcg* on the other.

Applicant respectfully submits that one of ordinary skill in the art would appreciate that the applicant was in possession of the invention now claimed in claims 24-31. Specifically, in view of the relationship between original claims 1 and 13 and original claims 10 and 21, one of ordinary skill in the art would appreciate that the applicant contemplated and invented a method and kit where the first and second composition contain estrogen in an amount equivalent to about 5 mcg to about 15 mcg of ethinyl estradiol. Applicant notes MPEP § 2163.02, which states that "[t]he subject matter of the claim need not be described literally (i.e.,

using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement."

Support for the progestin in the first composition being norethindrone acetate, as recited in claims 28 and 30, can be found in original claims 7 and 18, respectively.

Support for administering the first composition for 24 days, the second composition for 2 days, and the third composition for 2 days, as recited in claim 28, can be found, for example, at page 10 (Example 2) of the instant specification. Likewise, support for a kit containing 24 daily dosages of the first composition, 2 daily dosages of the second composition, and 2 daily dosages of the third composition, as recited in claim 30, can be found, for example, at page 10 (Example 2) of the instant specification.

Applicant therefore submits that no new matter has been introduced by these amendments. Entry of the above claim amendments is respectfully requested.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 4567-4002.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 4567-4002.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: October 29, 2008

By: /Andrew D. Cohen/
Andrew D. Cohen
Registration No. 61,508

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Docket No. 4567-4002

27123
↑CUSTOMER NUMBER↑

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	11/112,290	Confirmation No.:	5820
Applicant(s):	Roger M. BOISSONNEAULT	Group Art Unit:	1614
		Examiner:	San Ming R. HUI
Filed:	April 22, 2005		
		Customer No.:	27123

For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE PROGRAM

AMENDMENT FEE TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Amendment for the above-identified application.

☐ No additional fee is required.

☒ The additional fee has been calculated as shown below:

CLAIMS AS AMENDED

	Claims Remaining After Amendment	Highest No. Covered by Previous Payments	Extra	Rate	Additional Fee
Total Claims*	41	33	8	$52.00/ $26.00	$ 416
Independent Claims	4	3	1	$220.00/ $110.00	$ 220
Multiple Dependent Claims	(If claims added by amendment include Multiple Dependent Claim(s) and there was no Multiple Dependent Claim(s) in application before amendment add $390.00 to additional fee ($195.00 for small entity).				$
				TOTAL	$ 636

*Includes all independent and single dependent claims and all claims referred to in multiple dependent claims. See 37 C.F.R. §1.75(c).

☐ Small entity status is or has been claimed.
Reduced Fees Under 37 C.F.R. §1.9(f) paid herewith $_____

☐ _____ Pages Sequence Listing

☐ _____ Computer disk(s) containing substitute Sequence Listing

☐ Statement under 37 C.F.R. §1.825(b) that the computer and paper copies of the substitute Sequence Listing are the same.

☐ A check in the amount of $_____ to cover the filing fee is attached.

☒ Charge fee to Deposit Account No. **13-4500**, Order No. 4567-4002.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for filing this amendment, including all fees pursuant to 37 CFR §1.17 for its timely consideration, or credit any overpayment to Deposit Account No. **13-4500**, Order No. 4567-4002.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: October 29, 2008

By: /Andrew D. Cohen/
Andrew D. Cohen
Registration No. 61,508

Correspondence Address:
Address Associated With Customer Number:
27123

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Electronic Patent Application Fee Transmittal

Application Number:	11112290
Filing Date:	22-Apr-2005
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Filer:	Andrew Darion Cohen
Attorney Docket Number:	4567-4002

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	8	52	416
Independent claims in excess of 3	1201	1	220	220
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**636**

Electronic Acknowledgement Receipt

EFS ID:	4196045
Application Number:	11112290
International Application Number:	
Confirmation Number:	5820
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Correspondence Address:	MORGAN & FINNEGAN, L.L.P. - 3 World Financial Center - New York NY 10281-2101 US 212-415-8700 -
Filer:	Andrew Darion Cohen
Filer Authorized By:	
Attorney Docket Number:	4567-4002
Receipt Date:	29-OCT-2008
Filing Date:	22-APR-2005
Time Stamp:	13:49:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$636

RAM confirmation Number	7816
Deposit Account	134500
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2008-10-29_Preliminary_Amendment.pdf	305166 0c8b87037c321c405504b28ebfef17ce34683674	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	7
Applicant Arguments/Remarks Made in an Amendment	8	10

Warnings:					
Information:					
2	Miscellaneous Incoming Letter	2008-10-29_Claim_Fee.pdf	54352 1728582c5993da960536ee5a6c149fdb26e904e3	no	2
Warnings:					
Information:					
3	Fee Worksheet (PTO-06)	fee-info.pdf	31385 158f15ecd42133828f38238d7132b65053147121	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	390903		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/112,290	04/22/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	10/29/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 41	Minus	** 33	= 8	X $ =		OR	X $52=	416
	Independent (37 CFR 1.16(h))	* 4	Minus	***3	= 1	X $ =		OR	X $220=	220
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	636

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DORIS M. KING/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	4567-4002	5820

7590 12/30/2008

MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101

EXAMINER
ZAREK, PAUL E

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
12/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/112,290	BOISSONNEAULT, ROGER M.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claim 13 has been amended and Claims 24-31 have been added by the Applicant in correspondence filed on 10/29/2008. Claims 1-31 are currently pending.

Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 24, 25, 28, and 29, drawn to a method of contraception, classified in class 514, subclass 843.

II. Claims 13-23, 26, 27, 30, and 31, drawn to a contraceptive kit, classified in class 514, subclass 182.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition of Invention II can be administered to women for reasons wholly unrelated to contraception, such as determining the pharmacokinetic and pharmacodynamic profile of the drugs within the kit.

4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a

serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species

5. This application contains claims directed to the following patentably distinct species:

A progestin; and
An estrogen

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the following claims are generic:

Invention I: Claims 1-4, 12, and 24; and,
Invention II: Claims 13-15, 23, and 26.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search

queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/

Primary Examiner, Art Unit 1625

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112290	BOISSONNEAULT, ROGER M.
	Examiner	Art Unit
	Paul Zarek	1617

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/13/2008								
	1	÷								
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PATENT **Docket No.: 4567-4002**

27123
↑CUSTOMER NUMBER↑

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Roger M. Boissonneault		
		Group Art Unit:	1617
Serial No.:	11/112,290		
		Examiner:	Paul E. ZAREK
Filed:	April 22, 2005		
		Confirmation No.	5820
For:	EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN		

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In response to the Office Action dated December 30, 2008, in which pending claims 1-31 were subjected to restriction, the applicant provisionally elects to prosecute **Group I** (*i.e.*, claims 1-12, 24, 25, 28, and 29) as identified by the Examiner. As is set forth in detail below, this election is made with **traverse**. With respect to the species election, the applicant respectfully submits that the Examiner has misconstrued applicant's invention and based on the arguments set forth below, it is also respectfully submitted that the election of species restriction be withdrawn. Reconsideration of the requirement for restriction imposed in this case is respectfully requested in view of the following:

Remarks that begin on page 2 of this paper.

REMARKS

Claims 1-31 are pending in this application and have been subjected to restriction under 35 U.S.C. §121 because, in the Examiner's opinion, as set forth in the Detailed Action, the application contains claims directed to two patentably distinct inventions as follows:

Group I: claims 1-12, 24, 25, 28, and 29, drawn to a method of contraception, classified in class 514, subclass 843.

Group II: claims 13-23, 26, 27, 30, and 31, drawn to a contraceptive kit, classified in class 514, subclass 182.

As stated above, the applicant provisionally elects Group I, including claims 1-12, 24, 25, 28, and 29, for prosecution. Applicant respectfully disagrees with the restriction requirement imposed by the Examiner and the characterizations made of the claimed invention. Accordingly, this provisional election is made with traverse.

It is the Examiner's position that restriction is appropriate because the inventions contain claims that are not coextensive and have divergent subject matter. Applicant respectfully disagrees with the Examiner's position.

According to M.P.E.P. §803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent or distinct as claimed; **and**

(2) There must be serious burden on the Examiner if restriction is not required.

Applicant respectfully submits that both inventions of the restricted claims are properly presented in the same application because undue diverse searching would not be required and therefore all the claims should be examined together.

The Examiner has not shown that examination of all the pending claims would require undue searching and/or place a serious burden on the Examiner, which is a requisite showing for proper issuance of a restriction requirement. In fact, the applicant submits that to

properly search any one group, other group classifications must be considered as well to perform a comprehensive search.

There are only two inventions of art classified in class 514, with each invention further classified in only one subclass. To search prior art in two subclasses within the same class cannot be deemed "undue diverse searching." Accordingly, the Applicant respectfully traverses the requirement for restriction at least on the grounds that examining the identified groups would not be unduly burdensome.

Additionally, the Examiner requires that the applicant elect one of two (2) allegedly distinct species: a progestin and an estrogen. (*See 12/30/2008 Office Action*, page 4). It is respectfully submitted that the Examiner has misconstrued the instant claims. Contrary to the Examiner's assertion, applicant's claims are directed to methods of administering compositions with varying amounts of progestin and estrogen and, *inter alia*, the "sequential administration" of these various compositions, as recited in claim 1, or various amounts of "daily dosages" of these compositions, as recited in claim 13. Furthermore, applying the Examiner's rationale yields an irrational conclusion because it would require elements in at least claims 1 and 13 to be split. For example, claim 1 states, *inter alia*, "(a) a first composition containing **a progestin** in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate **and an estrogen** in an amount equivalent to about 5 to about 20 mcg of ethinyl estradiol for about 22 to about 26 days" (emphasis added). Clearly, the "first composition" requires various amounts of **both** progestin and estrogen. Following the Examiner's rationale, electing one of the alleged species would require dividing this element of the claim which, in turn, completely changes applicant's claimed invention. Thus, it is respectfully submitted that the Examiner misconstrued the invention and has erroneously required the applicant to elect one of two allegedly distinct species. Based on the above, it is respectfully submitted that the Examiner withdraw the election of species restriction.

If, however, the Examiner's intention was to require the applicant to elect a species of progestin **and** a species of estrogen, applicant elects the following species with traverse:

Progestin- norethindrone acetate

Estrogen- ethinyl estradiol

The applicant respectfully submits that the Requirement for Restriction is improper for at least the reasons stated, and requests that the Restriction Requirement be withdrawn and all presented claims be examined on the merits.

In view of the foregoing, the applicant respectfully submits that claims 1-31 as listed herein are properly presented in this application and that the claims are allowable over the prior art.

AUTHORIZATION

No fees are believed due in connection with this response and this paper is believed to be timely filed. However, should an extension of time be necessary, such extension is hereby petitioned. The Commissioner is authorized to charge any fees or credit any overpayments which may be required for this paper to Deposit Account Number 13-4500, Order No. 4567-4002.

In the event that a telephone conference would facilitate prosecution, the Examiner is invited to contact the undersigned at the number provided.

An early and favorable decision on the merits is respectfully requested.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Dated: January 28, 2009 By: 

Evelyn M. Kwon
Registration No. 54,246

Mailing address:
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Electronic Acknowledgement Receipt

EFS ID:	4690725
Application Number:	11112290
International Application Number:	
Confirmation Number:	5820
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Correspondence Address:	MORGAN & FINNEGAN, L.L.P. - 3 World Financial Center - New York NY 10281-2101 US 212-415-8700 -
Filer:	Evelyn Marian Kwon
Filer Authorized By:	
Attorney Docket Number:	4567-4002
Receipt Date:	28-JAN-2009
Filing Date:	22-APR-2005
Time Stamp:	15:24:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4567-4002RxnResp.pdf	157431 60f747c42e8df57d3c3b3b5263111cba1bb176d3	yes	4

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Response to Election / Restriction Filed	1	1
Applicant Arguments/Remarks Made in an Amendment	2	4

Warnings:	
Information:	
Total Files Size (in bytes):	157431

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	4567-4002	5820

7590 03/20/2009

MORGAN & FINNEGAN, L.L.P.
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New York, NY 10281-2101

EXAMINER
ZAREK, PAUL E

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/112,290	BOISSONNEAULT, ROGER M.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *13-23, 26, 27, 30, and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,24,25,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-31 are currently pending. This is the first Office Action on the merits of the claim(s).

Election/Restrictions

2. Applicant's election with traverse of Invention I drawn to a method of female contraception, and the species of norethindrone acetate and ethynyl estradiol in the reply filed on 01/28/2009 is acknowledged. The traversal is on the ground(s) that it would not be an undue search burden on Examiner to examine all claims. This is not found persuasive because the contraceptive kit of Invention I does not immediately render obvious a method of contraception. Art that would read on the kit would not necessarily read on the method. Moreover, the inventions are classified in different subclasses.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-12, 24, 25, 28, and 29 read on the elected invention. Claims 13-23, 26, 27, 30, and 31 are withdrawn as being drawn to a nonelected invention.

Priority

4. There are no priority documents associated with the immediate application. The effective filing date is 04/22/2005.

Claim Rejections - 35 USC § 112 (1st paragraph)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall 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 to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of female contraception comprising administration of a progestin and an estrogen, does not reasonably provide enablement for a method of female contraception comprising administration of an ester or prodrug of a progestin or estrogen that is not explicitly exemplified in the rejected claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07, set forth eight factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (MPEP § 2164.01(a))

a. *The breadth of the claim*: The rejected claims are drawn to a method of female contraception comprising the administration of a progestin and an estrogen, or esters, salts, or prodrugs, thereof. Esters are considered to be a species of prodrug;

b. *Nature of the invention*: The nature of the invention is a method of female contraception comprising administration of progestin and estrogen, or esters or prodrugs that are known (i.e. norethindrone acetate);

The state of the prior art: Estrogens and progestins are well known to be effective combined contraceptives (Loose-Mitchell and Stancel, Chapter 58 – Estrogen and Progestins, Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed., 2001, pg 1623, col 2, para 6, lines 1-3).

Prodrugs are known in the art and are utilized to improve the targeting or pharmacokinetics of a given drug. Van de Waterbeemd, et al. (Journal of Medicinal Chemistry, 2001), teach the myriad considerations one must keep in mind when designing prodrugs (pgs 1314-1327). Norethindrone acetate is a known prodrug of norethindrone, in which the norethindrone acetate is rapidly converted *in vivo* to norethindrone (Loose-Mitchell and Stancel, pg 18, col 1, para 2, lines 8-10);

c. *Level of one of ordinary skill in the art*: Scientists, physicians, and medicinal chemists investigating hormonal contraceptives would represent an ordinarily skilled artisan;

Level of predictability in the art: Numerous factors must be considered when attempting to create a prodrug. Van de Waterbeemd, et al., state that even with high-throughput screening and combinatorial chemistry, "the attrition of the eventual development candidates is still very high mainly due to toxicity and/or poor [pharmacokinetic] properties" (pg 1327, "Future Directions" paragraph 1, emphasis added). It cannot be known *a priori* whether a given molecule will be an effective prodrug. High-throughput computer modeling is not yet competent to reliably predict whether a given molecule would be an effective prodrug of a given drug. As such, "there remains a need for relatively low-throughput animal studies to extrapolate the likely

clinical pharmacokinetic profile (van de Waterbeemd, et al., pg 1328, paragraph 1). Van de Waterbeemd, et al., further teach that it is unclear which mathematical models would be most suited to predict pharmacokinetic properties of a given molecule in lieu of experimental data (pg 1328, paragraph 3). Finally, van de Waterbeemd, et al., discuss that "much needs to be learned about transporters influencing either active drug uptake or efflux of orally administered drugs. In addition, it will be important to develop screens to assess its extent" (pg 1328, "Conclusions);

d. *Amount of direction provided by the inventor*: Applicant does not define what would constitute prodrug, nor provide any generic guidance directing an art worker to make and use a prodrug of a progestin or estrogen;

e. *Existence of working examples*: All working examples utilize norethindrone acetate and ethinyl estradiol (which is not a prodrug); and,

f. *Quantity or experimentation needed to make or use the invention based on the content of the disclosure*: Predicting if a certain molecule is in fact a prodrug that produces the active compound metabolically, *in vivo*, at a therapeutic concentration and at a useful rate is filled with experimental uncertainty. Although attempts have been made to predict drug metabolism *de novo*, this is still an experimental science. For a compound to be a prodrug, it must meet three tests: A) it must itself be biologically inactive; B) it must be metabolized to a second substance, *in vivo*, at a rate and to an extent to produce that second substance at a physiologically meaningful concentration; and C) the second substance must be clinically effective. Determining whether a particular compound meets these three criteria in a clinical trial setting requires a large

quantity of experimentation. The instant specification does not provide enabling guidance sufficient that one of ordinary skill in the art would understand which of the potentially limitless candidates would be a legitimate prodrug of a progestin or estrogen. The prior art does not compensate for this deficiency. Undue and unpredictable experimentation would be required to use the invention as claimed. Therefore, the instant specification and prior art would not enable one of ordinary skill in the art at the time the invention was made to make and use the invention commensurate with the scope of the rejected claims.

Claim Rejections - 35 USC § 112 (2nd paragraph)

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation "esters and mixtures thereof" in line 4. Claim 6 recites the limitation "esters, prodrugs and salts thereof" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 5 and 6 depend upon Claim 1, in which only progestin and estrogen are contemplated. Esters, mixtures, prodrugs, or salts are not contemplated in Claim 1. Therefore, Claims 5 and 6 lack antecedent basis for these limitations.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 5, 6, 9, 10, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lachnit, et al. (US Patent No. 5,756,490, 1998, provided in IDS).

12. Claim 1 of the instant application is drawn to a method of female contraception comprising sequential administration over a 28 day cycle of (a) a first composition comprising a progestin in an amount equivalent to between about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to between about 5 and about 20 μg ethinyl estradiol for about 22 about 26 days; (b) a second composition comprising an estrogen in an amount equivalent to between about 5 and about 20 μg ethinyl estradiol and substantially free of a progestin for about 2 to about 3 days; and (c) an optional third composition that is a placebo, such that the placebo is only administered with the first and second compositions are together administered for fewer than 28 days. Claim 2 further limits the method to repeat after the completion of the aforementioned 28 day cycle. Claim 3 further limits the method of Claim 1 such that there is no placebo administered. Claims 5 and 6 limit the progestin and estrogen, respectively. Norethindrone and ethinyl estradiol are explicitly listed in these claims. Claims 9 and 10 limit the estrogen to ethinyl estradiol and about 15 μg of ethinyl estradiol, respectively.

Claim 24 limits the estrogen to be equivalent to between about 5 and about 15 μg of ethinyl estradiol. Claim 25 limits the estrogen of Claim 24 to ethinyl estradiol.

13. Lachnit, et al., teach a method of female contraception comprising administration of a first phase comprising both a progestin and an estrogen for 23-24 days followed by a second phase comprising an estrogen alone for 4-5 days, for a total 28 day cycle (col 5, Example 1). There is no placebo administered in this method. A preferred progestin is 0.35-0.75 mg norethindrone (termed norethisterone in this art). Lachnit, et al., do not disclose an equivalency between norethindrone and norethindrone acetate, Loose-Mitchell and Stancel (above) teach that norethindrone acetate is readily converted to norethindrone, *in vivo*, (pg 1618, col 1, para 2, lines 8-10). Therefore, a skilled artisan would recognize that 0.35-0.75 mg norethindrone is a equivalent 0.35-0.75 mg norethindrone acetate. A preferred estrogen is 10-40 μg ethinyl estradiol in the first phase, and 2-40 μg ethinyl estradiol in the second phase (col 5, lines 1-28). Therefore, Lachnit, et al., anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 4, 7, 8, 11, 12, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachnit, et al. (above), as applied to Claims 1-3, 5, 6, 9, 10, 24, and 25 in

view of Loose-Mitchell and Stancel (above) and Gast (International Application No. WO 98/04268).

16. Claim 4 further limits the method of Claim 1 such that the placebo is administered for 1-4 days of the cycle. Claims 7 and 8 limit the progestin to norethindrone acetate, and about 1 mg of norethindrone acetate, respectively. Claim 11 limits the composition to contain about 1 mg of norethindrone acetate and about 15 μg of ethinyl estradiol. Claim 12 limits the composition of the placebo to 75 mg of ferrous fumerate. Claim 28 is a method of female contraception comprising the same steps of Claim 1, wherein the progestin is norethindrone acetate, the estrogen is ethinyl estradiol, and there is a placebo administered. Claim 29 limits Claim 28 such that the dose of norethindrone acetate is about 1 mg.

17. Lachnit, et al., was discussed above. Briefly, Lachnit, et al., teach a method of female contraception comprising administration of 0.35-0.75 mg norethindrone and 10-40 μg ethinyl estradiol in the first phase and 2-40 μg ethinyl estradiol in the second phase. Lachnit, et al., disclose that a benefit of their disclosed method is that the subject can prevent the onset of menses (col 1, lines 52-53). Lachnit, et al., do not teach the presence of a placebo, a placebo of 75 mg ferrous fumerate, the progestin norethindrone acetate, or a progestin dose equivalent to about 1 mg norethindrone acetate.

18. Loose-Mitchell and Stancel teach that norethindrone acetate is readily converted to norethindrone, *in vivo* (pg 1618, col 1, para 2, lines 8-10). Since it was known that norethindrone acetate is readily converted to norethindrone, one of ordinary skill in the art would have recognized that the two compounds would be obvious variants of each other. Loose-Mitchell and Stancel also teach that combined oral contraceptives commonly utilize the progestin

norethindrone at a dose of between 0.4-1.0 mg. Therefore, a skilled artisan would recognize that the dose of norethindrone taught by Lachnit, et al., could be easily increased to 1.0 mg without a loss in contraceptive efficacy. Loose-Mitchell and Stancel further teach that oral contraceptives are commonly administered with the presence of a placebo (pg 1624, col 1, para 2-para 3). Thus, Loose-Mitchell and Stancel teach that about 1 mg of norethindrone acetate can be administered in the contraceptive method taught by Lachnit, et al. Lachnit, et al., and Loose-Mitchell and Stancel, together, do not teach the addition of a third (placebo) phase, or a placebo comprising 75 mg ferrous fumerate.

19. Gast teaches a method of female contraception comprising a non-contraceptive placebo comprising 75 mg ferrous fumerate to be administered at the end of the 28 day cycle (pg 8, lines 24-27). One would have been motivated to include a placebo to induce menses in the female subject. The experience of a period would assure the female subject that she was not pregnant. Thus, Lichnit, et al., and Gast together teach the presence of a placebo comprising 75 mg of ferrous fumerate.

20. Therefore, for the above mentioned reasons, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Loose-Mitchell and Stancel and Gast to modify the method taught by Lichnit, et al., to include a progestin equivalent of about 1 mg norethindrone acetate and a placebo of 75 mg ferrous fumerate.

Conclusion

21. Claims 1-12, 24, 25, 28, and 29 are rejected

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625

Notice of References Cited	Application/Control No. 11/112,290	Applicant(s)/Patent Under Reexamination BOISSONNEAULT, ROGER M.	
	Examiner Paul Zarek	Art Unit 1617	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 98/04268	02-1998	WIPO	Gast	A61K 31/57
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Loose-Mitchell and Stancel, Chapter 58 – Estrogen and Progestins, "Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed." Hardman JG, Limbird LE, and Gilman AG, Eds., McGraw-Hill, 2001, 1597-1634 (pgs 1597, 1618, 1623, and 1624 provided).
	V	van De Waterbeemd H, Smith DA, Beaumont K, and Walker DK, "Property-based design: optimization of drug absorption and pharmacokinetics," Journal of Medicinal Chemistry, 04/2001,44(9), 1313-1333.
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 5820

SERIAL NUMBER	FILING or 371(c) DATE / RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/112,290	04/22/2005	514	1617	4567-4002

APPLICANTS
Roger M. Boissonneault, Long Valley, NJ;

**** CONTINUING DATA ***************************

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****
05/17/2005

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/PAUL E ZAREK/ Examiner's Signature	☐ Initials	NJ	0	23	2

ADDRESS

MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101
UNITED STATES

TITLE

Extended estrogen dosing contraceptive regimen

FILING FEE RECEIVED		
2646	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

FORM PTO-1449A INFORMATION DISCLOSURE CITATION	Attorney Docket: 4567-4002	Serial No.: 11/112,290
	Applicant: Roger M. BOISSONNEAULT	
	Filing Date: April 22, 2005	Group Art Unit: 1614

U.S. PATENT / PUBLICATION DOCUMENTS

Examiner Initial		Patent/Publication Number	Publication/Issue Date	Name	Filing Date
/PEZ/	1.	4,921,843	May 1, 1990	Pasquale	Oct. 20, 1988
	2.	5,280,023	Jan. 19, 1994	Ehrlich et al.	Feb. 10, 1992
	3.	5,510,341	Apr. 23, 1996	Ehrlich et al.	Oct. 6, 1993
	4.	5,756,490	May 26, 1998	Lachnit et al.	Mar. 30, 1995
	5.	6,027,749	Feb. 22, 2000	Schmidt-Gollwitzer et al.	Jun. 27, 1996
	6.	5,552,394	Sep. 3, 1996	Hodgen	Jul. 22, 1994
	7.	4,962,098	Oct. 9, 1990	Boissonneault	Apr. 20, 1989
	8.	5,747,480	May 5, 1998	Gast	Apr. 17, 1997
	9.	5,888,543	Mar. 30, 1999	Gast	Jul. 2, 1997
	10.	6,479,475	Nov. 12, 2002	Gast	Jul. 2, 1997
	11.	5,898,032	Apr. 27, 1999	Hodgen	Jun. 23, 1997
	12.	5,010,070	Apr. 23, 1991	Boissonneault	May 22, 1990
	13.				
	14.				

FOREIGN PATENT DOCUMENTS

Examiner Initial		Patent Number	Publication Date	Country	Copy Filed	Translation
/PEZ/	15.	WO 2006/115871 A1	Nov. 2, 2006	WIPO	☒ Yes	☐ Yes ☐ No ☐ Abstract ☒ N/A
	16.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	17.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	18.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	19.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A
	20.				☐ Yes	☐ Yes ☐ No ☐ Abstract ☐ N/A

Examiner	/Paul Zarek/	Date Considered	03/06/2009

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609.
Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to Applicant.

FORM PTO-1449B INFORMATION DISCLOSURE CITATION	Attorney Docket: 4567-4002	Serial No.: 11/112,290
	Applicant: Roger M. BOISSONNEAULT	
	Filing Date: April 22, 2005	Group Art Unit: 1614

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
/PEZ/	1.	MIRCETTE STUDY GROUP, "An open-label, multicenter, noncomparative safety and efficacy study of Mircette™, a low dose estrogen-progestin oral contraceptive"; *American Journal of Obstetrics and Gynecology*, July 1998, vol. 179, no. 1, p. S2-S8
/PEZ/	2.	GASPARD, U. et al., "New Forms of Hormonal Contraception"; *Journal de Gynécologie, Obstétrique et Biologie de al Reproduction*, May 2000, vol. 29, no. 3, p. 288-291.
/PEZ/	3.	European Patent Office, International Search Report for PCT/US2006/014367, August 25, 2006
	4.	
	5.	
	6.	
	7.	
	8.	
	9.	
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	22.	

Examiner Signature	/Paul Zarek/	Date Considered	03/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

1057501 v1

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112290	BOISSONNEAULT, ROGER M.
	Examiner	Art Unit
	Paul Zarek	1617

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search	03/06/2009	PEZ
Prosecution history of 11/078,300	03/06/2009	PEZ
IPRP of WO 06/115871	03/06/2009	PEZ

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112290	BOISSONNEAULT, ROGER M.
	Examiner	Art Unit
	Paul Zarek	1617

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/13/2008	03/06/2009							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
	4	÷	✓							
	5	÷	✓							
	6	÷	✓							
	7	÷	✓							
	8	÷	✓							
	9	÷	✓							
	10	÷	✓							
	11	÷	✓							
	12	÷	✓							
	13	÷	N							
	14	÷	N							
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	16	÷	N							
	17	÷	N							
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	21	÷	N							
	22	÷	N							
	23	÷	N							
	24	÷	✓							
	25	÷	✓							
	26	÷	N							
	27	÷	N							
	28	÷	✓							
	29	÷	✓							
	30	÷	N							
	31	÷	N							

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	20	roger near2 boissonneault.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/03/06 10:35
S2	23	(("4921843") or ("5280023") or ("5510341") or ("5756490") or ("6027749") or ("5552394") or ("4962098") or ("5747480") or ("5888543") or ("6479475") or ("5898032") or ("5010070")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2009/03/06 10:53
S3	2	("5898032").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2009/03/06 13:26

3/6/2009 3:16:53 PM
C:\Documents and Settings\pzarek\My Documents\EAST\Workspaces\11112290.wsp

02911.009860. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Paul E. Zarek
ROGER M. BOISSONNEAULT	)	
	:	Group Art Unit: 1617
Application No.: 11/112,290	)	
	:	Confirmation No. 5820
Filed: April 22, 2005	)	
	:	
For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN	) :	March 30, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUBMISSION OF REVOCATION AND NEW POWER OF ATTORNEY

Sir:

Submitted herewith is an executed Revocation And New Power Of Attorney in the above-identified patent.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

/Raymond R. Mandra/
Raymond R. Mandra
Attorney for Applicants
Registration No. 34,382

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3800
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

FCHS_WS 2997049v1

02911.009860.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Examiner: Paul E. Zarek
ROGER M. BOISSONNEAULT	)	Group Art Unit: 1617
Application No.: 11/112,290	)	Confirmation No. 5820
Filed: April 22, 2005	)	
For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REVOCATION AND NEW POWER OF ATTORNEY

Sir:

As assignee of record of the entire interest of the above-identified patent application, all powers of attorney previously given are hereby revoked and the attorneys associated with the firm and Customer Number provided below are hereby appointed to prosecute and transact all business in the Patent and Trademark Office connected therewith, and it is directed that all correspondence be addressed to the address associated with that Customer Number:

FITZPATRICK, CELLA, HARPER & SCINTO

Customer Number: 05514

ASSIGNEE CERTIFICATE UNDER 37 C.F.R. 3.73(b)

WARNER CHILCOTT COMPANY, INC., a corporation duly organized under the laws of Puerto Rico and having its principal place of business at P.O. Box 1005, Fajardo, Puerto Rico 00738, hereby certifies that it is the owner of all right, title, and interest in the above-identified application, by virtue of an Assignment from Inventor Roger M. Boissonneault of the above-identified application a copy of which is attached.

The undersigned is authorized to act on behalf of WARNER CHILCOTT COMPANY, INC.

Date: March 26, 2009

Name: Izumi Hara

Title: Secretary

Signature:

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

FCHS_WS 2988184v1

Electronic Acknowledgement Receipt

EFS ID:	5055749
Application Number:	11112290
International Application Number:	
Confirmation Number:	5820
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Correspondence Address:	MORGAN & FINNEGAN, L.L.P. - 3 World Financial Center - New York NY 10281-2101 US 212-415-8700 -
Filer:	Raymond Richard Mandra/DAVID NGUY
Filer Authorized By:	Raymond Richard Mandra
Attorney Docket Number:	4567-4002
Receipt Date:	30-MAR-2009
Filing Date:	22-APR-2005
Time Stamp:	11:17:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	SubRevocationAndPOA02911009860.pdf	3875 22b19f6368d644f2cc7a835710b93e01b84f38ee	no	1
Warnings:					
Information:					
2	Power of Attorney	ExecutedNewPOA02911009860.pdf	49882 76c4e50e054d908a4f70153177bd97a5d26c20ee	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	53757		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,290	04/22/2005	Roger M. Boissonneault	4567-4002

CONFIRMATION NO. 5820

MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101

POWER OF ATTORNEY NOTICE

OC000000035695016

Date Mailed: 05/07/2009

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/30/2009.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/smorland/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,290	04/22/2005	Roger M. Boissonneault	4567-4002

CONFIRMATION NO. 5820

5514
FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

POA ACCEPTANCE LETTER

OC000000035695022

Date Mailed: 05/07/2009

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/30/2009.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/smorland/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Paul E. Zarek
ROGER M. BOISSONNEAULT	)	
	:	Group Art Unit: 1617
Application No.: 11/112,290	)	
	:	Confirmation No. 5820
Filed: April 22, 2005	)	
	:	
For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN	)	
	:	July 13, 2009

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND PETITION FOR EXTENSION OF TIME

Sir:

Applicant petitions to extend the time for response to the Office Action dated March 20, 2009 to and including July 20, 2009. The extension fee of $130.00 has been paid herewith. Please charge any additional fee required for the extension, or credit any overpayment, to Deposit Account 50-3939.

In response to that Office Action, the Examiner is requested to amend the application as follows:

- Amendments to the claims are presented in the listing starting on page 2;
- Remarks are presented starting on page 9.

IN THE CLAIMS:

Please cancel Claims 3-6, 9-11, 13-24, 26-27 and 30-31, without prejudice or disclaimer of subject matter.

Please amend Claims 1, 7and 25 and add new claim 32 as indicated below. The following is a complete listing of claims and replaces all prior versions and listings of claims in the present application:

1. (Currently Amended) A method of contraception comprising the steps of sequentially administering to a female of child-bearing age:

(a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate wherein the progestin is selected from norethindrone acetate or norethindrone and ~~an estrogen in an amount equivalent to about~~ 5 to ~~about 20~~ 15 mcg of ethinyl estradiol for ~~about 22 to about 26~~ 24 days;

(b) a second composition containing ~~an estrogen in an amount equivalent to about~~ 5 to ~~about 20~~ 15 mcg of ethinyl estradiol and substantially free of a progestin for [[about]] 2 ~~to about 3~~ days; and

(c) ~~an optional~~ a third composition that is a placebo,

wherein the sequential administration of the first composition, the second composition and the ~~optional~~ third composition, ~~when present,~~ is performed on a daily basis over a 28 day cycle ~~and further provided that (I) if estrogen administration is continuous during the sequence then the first composition is monophasic and is administered for 25 to 26 days and the second composition is administered for 2 to 3 days and (ii) if estrogen administration is not continuous during the sequence then the first composition is administered for 22 to 24 days, the~~

~~second composition is administered for 2 to 3 days and the third composition is administered for 1 to 4 days~~.

2. (Original) The method according to claim 1, wherein the sequential administration is repeated beginning the day after completion of the 28 day cycle.

3. - 6. (Cancelled)

7. (Currently Amended) The method according to ~~any one of claims 3 and 4~~ claim 1, wherein the progestin in the first composition is norethindrone acetate.

8. (Original) The method according to claim 7, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

9. - 11. (Cancelled)

12. (Original) The method according to claim 1, wherein the placebo contains about 75 mg of ferrous fumarate.

13. - 24. (Cancelled)

25. (Currently Amended) The method according to claim [[24]] 8, wherein the amount of ethinyl estradiol ~~estrogen~~ in the first and second composition is ~~ethinyl estradiol~~ the same.

26. and 27. (Cancelled)

28. (Currently Amended) A method of contraception comprising the steps of sequentially administering to a female of child bearing age:

(a) a first composition containing about 0.3 to about 1.5 mg norethindrone acetate and [[about]] 5 to [[about]] 15 mcg ethinyl estradiol for 24 days;

(b) a second composition containing [[about]] 5 to [[about]] 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days;

(c) a third composition that is a placebo for 2 days,

wherein the sequential administration of the first composition, the second composition and the third composition is performed on a daily basis over a 28 day cycle.

29. (Previously Presented) The method according to claim 28, wherein the first composition contains about 1 mg of norethindrone acetate.

30. and 31. (Cancelled)

32. (New) The method according to claim 28, wherein the amount of ethinyl estradiol in the first and second composition is the same.

REMARKS

This application has been reviewed in light of the Office Action dated March 20, 2009. Claims 1, 2, 7, 8, 10-12, 14-22, 25, 27-29 and 32 are presented for examination, of which Claims 1 and 28 are in independent form. Claims 3-6, 9-11, 13-24, 26-27 and 30-31 have been cancelled without prejudice or disclaimer of the subject matter presented therein. New Claim 32 has been added to provide Applicants with a more complete scope of protection. Claims 1, 7, 25 and 28 have been amended to define Applicant's invention more clearly. Favorable reconsideration is requested.

Claims 5 and 6 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly being nonenabling. Claims 5 and 6 were also rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. These claims have been cancelled and therefore these rejections are now moot.

Claims 1-3, 5, 6, 9, 10, 24 and 25 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,756,490 (Lachnit et al.). In addition, Claims 4, 7, 8, 11, 12, 28 and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lachnit, in view of the Loose-Mitchell Stancel reference and International Application No. WO 98/04268 (Gast). These rejections are traversed, particularly in view of the amendments made herein.

Prior to discussing the merit of the rejections, Applicants believe it would be helpful to discuss the advantages of the present invention. The Examiner will first note that independent claim 1 has been amended to recite a particularly preferred embodiment of the invention whereby the first composition containing a progestin selected from norethindrone acetate or norethindrone and a low level of ethinyl estradiol is given for 24 days, followed by 2

days of low level ethinyl estradiol and 2 days of placebo. The level of ethinyl estradiol administered using a more preferred embodiment of the invention, i.e., 5 to 15 mcg, has been found to provide contraceptive efficacy despite an almost 25% to 75% reduction in ethinyl estradiol compared to conventional 24 day administration methods, while also providing an acceptable withdrawal bleed. Thus, the preferred embodiments of the presently claimed invention significantly reduces female exposure to estrogen and its well documented associated risks while providing contraceptive efficacy and an acceptable withdrawal bleed. It is respectfully submitted that a contraceptive regimen providing these advantages has not been disclosed or suggested in the prior art.

Lachnit describes a contraceptive composition having a first composition containing a progestin and an estrogen that is administered for 23 to 24 days and a second composition containing only estrogen that is administered for 4 to 8 days. No pill free days or placebo days, are disclosed or suggested. Accordingly, it is clear that there is no anticipation of the presently claimed invention.

With respect to obviousness, it is respectfully submitted that Lachnit would not have suggested the presently claimed contraceptive regimen. Lachnit does suggest that a preferred level of ethinyl estradiol in the first composition could be 15 to 25 mcg. This, however, would not have suggested that 5 to 15 mcg of ethinyl estradiol plus a progestin in a first composition administered for 24 days followed by two days of a second composition containing 5 to 15 mcg ethinyl estradiol and two days of a placebo, would be a highly effective combination, i,e., provide contraceptive efficacy and an acceptable withdrawal bleed.

While ethinyl estradiol ranges of the presently claimed invention and Lacknit meet at 15 mcg, this is a question of obviousness and not anticipation. Similarly, although the

presently claimed range is encompassed within the broad range of 10 mcg of 40 mcg of ethinyl estradiol, that range is so broad that it is nonsensical and would have provided no guidance to a person of skill in the art that a 5 to 15 mcg range of ethinyl estradiol could be effectively employed in the regimen of the presently claimed invention.

In that regard, a Declaration Under 37 C.F.R. §1.132 of Dr. Herman Ellman, is provided herewith. The declaration sets forth estrogen exposure of commercially available contraceptive products in comparison to an embodiment of the invention employing 10 mcg of ethinyl estradiol along with data showing that despite a very significant reduction of estrogen, contraceptive efficacy was obtained as measured using the Pearl Index. It is respectfully submitted that this showing that a regimen of the presently claimed invention having a total estrogen exposure of 0.26 mg of ethinyl estradiol per treatment cycle compared to commonly available commercial embodiments having 0.48 to 0.84 mg of ethinyl estradiol per treatment cycle clearly illustrates the advantageous significant reduction of ethinyl estradiol exposure provided by the presently claimed invention while maintaining contraceptive efficacy. It is respectfully submitted that the regimen of the present invention that provides such a significant reduction in estrogen exposure while maintaining contraceptive efficacy was not disclosed or suggested by the prior art of record.

In fact, Lachnit makes clear that the combination preparation according to its invention in which estrogen is continuously given, particularly at low doses, is important so as to avoid break through follicular development. Col. 4, lines 9-37. Thus, one skilled in the art would not have looked to introduce a placebo period into the regimen of Lachnit with a reasonable expectation that contraceptive efficacy would be maintained particularly when using a very low level of ethinyl estradiol. The Examiner relies on Gast to argue that it would have been

obvious to introduce a placebo into the regimen of Lachnit. This proposition is traversed as it runs completely counter to the teaching of Lachnit.

It should be noted at Col. 4, lines 38-45, of Lachnit that it is stated:

> The subsequent phase, in which dosage units that contain only one estrogenic component as a hormonal active ingredient are administered daily over 4 to 8 days, ensures withdrawal bleeding...

Accordingly, relying on this disclosure one skilled in the art would not have introduced a placebo into the regimen of Lachnit since this would seem completely contrary to the stated goal of Lachnit. Moreover, even if a person skilled in the art were to ignore the contrary teaching of Lachnit and introduce a placebo, there would have been no reasonable expectation that a regimen employing 5 to 15 mcg of ethinyl estradiol with norethindrone or norethindrone acetate for 24 days, followed by two days of 5 to 15 mcg of ethinyl estradiol without a progestin and then by a two day placebo period would have provided contraceptive efficacy with an acceptable withdrawal bleed. Again it is important to recognize that the presently claimed invention provides for contraceptive efficacy despite an advantageous 25% to 75% reduction in ethinyl estradiol used in presently available commercial products.

The Examiner uses Loose-Mitchell and Stancel to support the proposition that it would be obvious to substitute norethindrone acetate for the norethindrone disclosed in Lachnit. However, it is clear that the disclosure of these references does not overcome the deficiencies of Lachnit taken together with Gast.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Applicant's undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

/Raymond R. Mandra/
Raymond R. Mandra
Attorney for Applicant
Registration No. 34,382

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

FCHS_WS 3151298v1

02911.009860. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Paul E. Zarek
ROGER M. BOISSONNEAULT	)	
	:	Group Art Unit: 1617
Application No.: 11/112,290	)	
	:	Confirmation No. 5820
Filed: April 22, 2005	)	
	:	
For: EXTENDED ESTROGEN DOSINGCONTRACEPTIVE REGIMEN	)	
	:	
	)	

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

Herman Ellman declares and says that:

1. I am presently Senior Vice President, Clinical Development of Warner Chilcott (Warner Chilcott Company LLC is the assignee of the above-noted application). Prior to joining Warner Chilcott, I held the position of Medical Director for Women's Healthcare of Berlex Laboratories. I joined Warner Chilcott as Senior Vice President, Clinical Development in June 2000. I am responsible for clinical development and medical affairs activities in Warner Chilcott.

2. I am aware of the Office Action dated March 20, 2009 in which the Examiner has rejected claims 1-3, 5, 6, 9, 10, 24 and 25 as allegedly anticipated under 35

U.S.C. § 102(b) by U.S. Patent No. 5,756,490 (Lachnit) and claims 4, 7, 8, 11, 12, 28 and 29 as allegedly obvious over Lachnit in view of Loose-Mitchel and Stancel and Gast.

3. I commissioned and oversaw a clinical study looking at a contraceptive regimen comprising sequential administration for 24 days of a first composition comprising 1 mg norethindrone acetate (NETA) and 10 μg ethinyl estradiol (EE), followed by two days of a second composition comprising 10 μg ethinyl estradiol, followed by 2 days of a third composition comprising a placebo.

4. The present invention aims to reduce exposure to estrogens, while maintaining contraceptive efficacy. This is solved by administering a second composition of estrogen alone, immediately after an extended first composition of progestin and estrogen. This allows the total estrogen dose over each treatment cycle to be reduced while, surprisingly, maintaining contraceptive reliability.

5. The studied contraceptive regimen, comprising 2 days of 10 μg ethinyl estradiol alone, immediately after 24 days of 1 mg norethindrone acetate and 10 μg ethinyl estradiol, exposes the subject to a total of 0.26 mg ethinyl estradiol over the 28 days of each treatment cycle.

6. The Pearl Index is the number of pregnancies per 100 woman-years of use, assuming 13 28-day cycles per year. The Pearl Index is calculated by multiplying the number of pregnancies by 1300 and then dividing the total by the number of woman-cycles of treatment (only cycles in which no back-up contraceptive methods were used were included).

7. The table below shows the Pearl Indices of some oral contraceptive products recently approved by the FDA, as well as the total estrogen dose over each treatment cycle.

	Duration of each phase (days)	Progestin / Dose (mg)	Estrogen Dose (μg EE)	Total Estrogen Dose over each Composition (mg EE)	**Total Estrogen Dose over Treatment Cycle (mg EE)**	**Pearl Index**
Tricyclen-Lo™						
First Composition	7	NGM 0.18	25	0.175		
Second Composition	7	NGM 0.21	25	0.175		
Third Composition	7	NGM 0.25	25	0.175		
Placebo	7	-	-			
					0.525	**2.36**
Loestrin Fe 24™						
First Composition	24	NETA 1.0	20	0.48		
Placebo	4	-	-			
					0.48	**1.82**
Seasonale™						
First Composition	84	LNG 0.15	30	2.52		
Placebo	7	-	-			
					0.84*	**1.98**
LoSeasonique™						
First Composition	84	LNG 0.1	20	1.68		
Second Composition	7	-	10	0.07		
Placebo	-	-	-			
					0.58*	**2.74**
Present Regimen						
First Composition	24 days	NETA 1.0	10	0.24		
Second Composition	2 days	-	10	0.02		
Placebo	2 days	-	-			
					0.26	**2.54**

NETA = norethindrone acetate
EE = ethinyl estradiol
NGM = norgestimate
LNG = levonorgestrel

*Total dose of EE/ treatment cycle is derived by dividing amount delivered over 91 days (3 "cycles") by 3.

8. The FDA has recently been accepting Pearl Indices in the range of 1.82 to 2.75, as is shown in the table above. The Pearl Index of the present regime is 2.54, which is within the range recently accepted by the FDA. Products recently approved by the FDA have had a total estrogen dose per treatment cycle in the range of 0.48 mg ethinyl estradiol to 0.84 mg ethinyl estradiol. The total estrogen dose per treatment cycle is 0.26 mg ethinyl estradiol for the present regimen. Surprisingly, the Pearl Index for the present regimen is still within the range of Pearl Indices recently approved by the FDA, while the total exposure of estrogen has been substantially reduced from the previous minimum presently found in commercially available approved oral contraceptives of 0.48 mg ethinyl estradiol to the current dose of 0.26 mg ethinyl estradiol.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

July 10, 2009
Date

Herman Ellman, M.D.

FCHS_WS 3528109_1.DOC

Electronic Patent Application Fee Transmittal

Application Number:	11112290
Filing Date:	22-Apr-2005
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Filer:	Raymond Richard Mandra/DAVID NGUY
Attorney Docket Number:	02911.009860.

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	130	130

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**130**

Electronic Acknowledgement Receipt

EFS ID:	5689316
Application Number:	11112290
International Application Number:	
Confirmation Number:	5820
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Customer Number:	05514
Filer:	Raymond Richard Mandra/DAVID NGUY
Filer Authorized By:	Raymond Richard Mandra
Attorney Docket Number:	02911.009860.
Receipt Date:	13-JUL-2009
Filing Date:	22-APR-2005
Time Stamp:	15:58:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$130
RAM confirmation Number	2283
Deposit Account	503939
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		02911009860AMD.pdf	25342 8ddd3c33adf77f891395l5b35c83db50a6fe72fc	yes	9
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	4	
	Applicant Arguments/Remarks Made in an Amendment		5	9	
Warnings:					
Information:					
2	Rule 130, 131 or 132 Affidavits	02911009860Declaration.pdf	152825 f1fdb8ca6079608bf035c90b60b43d28910e32f5	no	4
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30168 cee25aa224906420d62ea0f1d0d46f6d21d14951	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	208335		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/112,290	04/22/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	07/13/2009	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 9	Minus	** 41	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***4	= 0	X $ =		OR	X $220=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DESHONNE T. MARTINO/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	02911.009860.	5820

5514 7590 11/02/2009

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
11/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/112,290	BOISSONNEAULT, ROGER M.	
	Examiner	Art Unit	
	Paul Zarek	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,8,12,25,28,29 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,8,12,25,28,29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 7, 25, and 28 have been amended, Claim 32 has been added, and Claims 3-6, 9-11, 13-24, 26, 27, 30, and 31 have been cancelled by the Applicant in correspondence filed on 07/13/2009. Claims 1, 2, 7, 8, 12, 25, 28, 29, and 32 are currently pending. This is the second Office Action on the merits of the claim(s).

RESPONSE TO ARGUMENTS

2. Claims 5 and 6 were rejected under 35 U.S.C. 112, first and second paragraphs. These rejections are moot in light of Applicant's cancellation of Claims 5 and 6.

3. Claims 1-3, 5, 6, 9, 10, 24, and 25 were rejected under 35 U.S.C. 102(b) as being anticipated by Lachnit, et al. (US Patent No. 5,756,490, 1998, provided in IDS). This rejection is moot in light of the amendment to Claim 1 and cancellation of claims 3, 5, 6, 9, 10, and 24.

4. Claims 4, 7, 8, 11, 12, 28, and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lachnit, et al. (above), as applied to Claims 1-3, 5, 6, 9, 10, 24, and 25 in view of Loose-Mitchell and Stancel (above) and Gast (International Application No. WO 98/04268). Examiner notes that Claims 4 and 11 were cancelled. Applicant traversed this rejection on the grounds that these prior art do not render obvious the instant invention as disclosed by the amended claims. Specifically, Applicant contends that: a) Lachnit, et al., teach a preferred level of ethinyl estradiol of between 15 and 25 μg, which does not read on the 5 to 15 μg range claimed; b) Lachnit, et al., do not teach or suggest a 2-4 day placebo; and, c) Lachnit, et

al., teaches that continuous administration (e.g. no placebo period) is important to avoid breakthrough follicular development, thus suggesting to the skilled artisan that there should be no break in steroid administration. Applicant correctly points out that Lachnit, et al., teach that low does ethinyl estradiol administered alone over 4-8 days ensures withdrawal bleeding. Induction of menses was utilized by Examiner as motivation to insert a placebo period in the method taught by Lachnit, et al. Applicant further contends that Loose-Mitchell and Stancel and Gast do not overcome the alleged deficiencies of Lachnit, et al. Respectfully, Examiner does not find Applicant's arguments persuasive.

5. Examiner disagrees with Applicant's interpretation of Lachnit, et al., regarding the preferred dose of ethinyl estradiol. Rather than suggesting 15-25 μg ethinyl estradiol as asserted by Applicant, Lachnit, et al., contemplate a range of 10 to 40 μg ethinyl estradiol in the first dose (col 5, line 5), and a range of 2 to 40 μg (col 5, line 27). This overlaps or encompasses the instantly claimed ranges of the first and second compositions, respectively. "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)" (MPEP § 2144.05(I)(A)). Gast teaches that in 1978 the World Health Organization recommended that oral contraceptives contain the "lowest possible dose levels of estrogen and progestin" (pg 1, lines 23-26). Hence, the art worker would be motivated to administer as low a dose of ethinyl estradiol as possible, that is, closer to 10 μg rather than 40 μg. Examiner notes that the first composition of both Lachnit, et al., and the instant invention are to be administered for 24 days. Lachnit, et al., renders obvious the amount of norethindrone (discussed in previous Office Action) and ethinyl estradiol claimed in the instant invention.

6. Instant Claim 1, from which Claims 7, 8, and 12 depend, was amended to require a 2 day placebo composition. Such a limitation was not contemplated in Lachnit, et al. However, breaks in steroid administration are common in the oral contraceptive art (see Gast, already of record). Indeed, the Ellman Declaration discloses that the presence of a placebo does not negatively affect the capacity of an oral contraceptive to reduce pregnancy. Tricyclen-Lo™, Loestrin Fe 24™, and Seasonale™ all contain a placebos, and all have Pearl Indices within the FDA-acceptable range. Thus, the skilled artisan would recognize that placebo compositions can be incorporated in oral contraceptive methods without reducing the methods' effectiveness.

7. Examiner acknowledges that the stated motivation to administer a placebo (e.g. to induce menses to assure the subject that she is not pregnant) can be achieved in the absence of a placebo, as disclosed by Lachnit, et al. However, menstruation may lead to anemia. Thus, the skilled artisan would be motivated offset any loss of iron during menstruation by administering a placebo comprising iron, such as ferrous fumarate (Hillman, Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed., 2001, pg 1495, col 2, para 2, lines 11-12; pg 1499, col 2, para 2). The art worker would understand that a placebo can be administered given the prevalence of placebo phases in the oral contraceptive art.

8. For the above reasons, the rejection of Claims 7, 8, 12, 28, and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lachnit, et al., in view of Loose-Mitchell and Stancel and Gast is maintained.

9. Amended Claims 1, 2, and 25, and newly added Claim 32 are examined on their merits and the following **FINAL** rejection is made.

Claim Rejections - 35 USC § 103

10. The text of Title 35, U.S.C. § 103(a) can be found in a prior Office action.

11. Claims 1, 2, 25, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachnit, et al. (above), in view of Loose-Mitchell and Stancel (above) and Gast (above).

12. Amended Claim 1 of the instant application is drawn to a method of female contraception comprising sequential administration over a 28 day cycle of (a) a first composition comprising a progestin in an amount equivalent to between about 0.3 to about 1.5 mg norethindrone acetate and an estrogen in an amount equivalent to between about 5 and about 20 μg ethinyl estradiol for 24 days; (b) a second composition comprising an estrogen in an amount equivalent to between about 5 and about 20 μg ethinyl estradiol and substantially free of a progestin for 2 days; and (c) a third composition that is a placebo, such that the placebo is administered for 2 days. Claim 2 further limits the method to repeat after the completion of the aforementioned 28 day cycle. Claims 25 and 32 limits the ethinyl estradiol of Claims 8 and 28, respectively, to be the same in the first and second compositions.

13. Lachnit, et al., Loose-Mitchell, and Gast were explained above and in the previous Office Action (mailed 03/20/2009). Briefly, Lachnit, et al., teach a method of female contraception comprising administration of 0.35-0.75 mg norethindrone and 10-40 μg ethinyl estradiol in the first phase and 2-40 μg ethinyl estradiol in the second phase. Lachnit, et al., do not teach the presence of a placebo, a placebo of 75 mg ferrous fumerate, the progestin norethindrone acetate, or progestin dose equivalent to about 1 mg norethindrone acetate. Loose-Mitchell and Stancel teach that norethindrone acetate is readily converted to norethindrone, *in vivo* (pg 1618, col 1,

para 2, lines 8-10). Gast teaches a method of female contraception comprising a non-contraceptive placebo comprising 75 mg ferrous fumerate to be administered at the end of the 28 day cycle (pg 8, lines 24-27).

14. As discussed above, placebo administration is well known in the oral contraceptive art. The skilled artisan would know that the presence of a placebo does not negatively affect the efficacy of the oral contraception (see Ellman Declaration). Moreover, the art worker would be motivated to provide a placebo that includes iron to reduce anemia associated with menses. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the method taught by Lachnit, et al., to achieve the instant invention.

Conclusion

15. Claims 1, 2, 7, 8, 12, 25, 28, and 29 remain rejected. Newly added Claim 32 is rejected.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1628

Notice of References Cited	Application/Control No. 11/112,290	Applicant(s)/Patent Under Reexamination BOISSONNEAULT, ROGER M.	
	Examiner Paul Zarek	Art Unit 1628	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Hillman RS, Chapter 54 Hematopoietic Agents Growth Factors, Minerals, and Vitamins, "Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed." Hardman JG, Limbird LE, and Gilman AG, Eds., McGraw-Hill, 2001, 1487-1518 (pgs 1487, 1495, and 1499 provided).
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112290	BOISSONNEAULT, ROGER M.
	Examiner	Art Unit
	Paul Zarek	1617

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/13/2008	03/06/2009	10/26/2009						
	1	÷	✓	✓						
	2	÷	✓	✓						
	3	÷	✓	-						
	4	÷	✓	-						
	5	÷	✓	-						
	6	÷	✓	-						
	7	÷	✓	✓						
	8	÷	✓	✓						
	9	÷	✓	-						
	10	÷	✓	-						
	11	÷	✓	-						
	12	÷	✓	✓						
	13	÷	N	-						
	14	÷	N	-						
	15	÷	N	-						
	16	÷	N	-						
	17	÷	N	-						
	18	÷	N	-						
	19	÷	N	-						
	20	÷	N	-						
	21	÷	N	-						
	22	÷	N	-						
	23	÷	N	-						
	24	÷	✓	-						
	25	÷	✓	✓						
	26	÷	N	-						
	27	÷	N	-						
	28	÷	✓	✓						
	29	÷	✓	✓						
	30	÷	N	-						
	31	÷	N	-						
	32			✓						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112290	BOISSONNEAULT, ROGER M.
	Examiner	Art Unit
	Paul Zarek	1617

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search	03/06/2009	PEZ
Prosecution history of 11/078,300	03/06/2009	PEZ
IPRP of WO 06/115871	03/06/2009	PEZ
EAST search	10/26/2009	PEZ

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	21	roger near2 boissonneault.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/10/26 10:45
S2	2	("5756490").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2009/10/26 10:45
S3	2	("5262408").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2009/10/26 11:32
S4	2	("6451778").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2009/10/26 11:43
S5	8	(michael near2 gast).in. and biphasic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/10/26 11:50

EAST Search History (Interference)

<This search history is empty>

10/26/2009 2:34:20 PM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Paul E. Zarek
ROGER M. BOISSONNEAULT	)	
	:	Group Art Unit: 1617
Application No.: 11/112,290	)	
	:	Confirmation No. 5820
Filed: April 22, 2005	)	
	:	
For: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN	)	
	:	January 14, 2010

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AFTER FINAL

Sir:

In response to the Office Action dated November 2, 2009, the Examiner is requested to reconsider his position in view of the following remarks:

- No amendments to the claims have been made, but they are presented in the listing starting on page 2, for the Examiner's convenience; and
- Remarks are presented starting on page 5.

IN THE CLAIMS:

The following is a complete listing of claims and no changes have been made.

1. (Previously Presented) A method of contraception comprising the steps of sequentially administering to a female of child-bearing age:

(a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate wherein the progestin is selected from norethindrone acetate or norethindrone and 5 to15 mcg of ethinyl estradiol for 24 days;

(b) a second composition containing 5 to 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days; and

(c) a third composition that is a placebo,

wherein the sequential administration of the first composition, the second composition and the third composition, is performed on a daily basis over a 28 day cycle.

2. (Previously Presented) The method according to claim 1, wherein the sequential administration is repeated beginning the day after completion of the 28 day cycle.

3. - 6. (Cancelled)

7. (Previously Presented) The method according to claim 1, wherein the progestin in the first composition is norethindrone acetate.

8. (Previously Presented) The method according to claim 7, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

9. - 11. (Cancelled)

12. (Previously Presented) The method according to claim 1, wherein the placebo contains about 75 mg of ferrous fumarate.

13. - 24. (Cancelled)

25. (Previously Presented) The method according to claim 8, wherein the amount of ethinyl estradiol in the first and second composition is the same.

26. and 27. (Cancelled)

28. (Previously Presented) A method of contraception comprising the steps of sequentially administering to a female of child bearing age:

(a) a first composition containing about 0.3 to about 1.5 mg norethindrone acetate and 5 to 15 mcg ethinyl estradiol for 24 days;

(b) a second composition containing 5 to 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days;

(c) a third composition that is a placebo for 2 days,

wherein the sequential administration of the first composition, the second composition and the third composition is performed on a daily basis over a 28 day cycle.

29. (Previously Presented) The method according to claim 28, wherein the first composition contains about 1 mg of norethindrone acetate.

30. and 31. (Cancelled)

32. (Previously Presented) The method according to claim 28, wherein the amount of ethinyl estradiol in the first and second composition is the same.

REMARKS

This application has been reviewed in light of the Office Action dated November 2, 2009. Claims 1, 2, 7, 8, 12, 25, 28, 29 and 32 are presented for examination, of which Claims 1 and 28 are in independent form. Favorable reconsideration is respectfully requested.

Applicants and the undersigned would like to thank Examiners Zarek and Hui for the kind courtesy of the Interview of January 13, 2010. In accordance with the Examiners' request, the prior art distinguishing comments constructively discussed at the Interview are provided below.

Claims 1, 2, 7, 8, 12, 25, 8, 29 and 32 stand rejected as allegedly obvious over U.S. Patent No. 5,756,490 (Lachnit et al.) in view of Loose-Mitchell and Stancel and Gast (International Application No. WO 98/04268). Applicants respectfully traverse the rejection for the reasons set forth herein.

As discussed at the Interview, the present claims are specifically directed to the surprising discovery that a contraceptive regimen using 5 to 15 mcg of ethinyl estradiol in a daily dose (24 days in combination with the progestin norethindrone acetate or norethindrone and 2 days with ethinyl estradiol only) provided contraceptive efficacy even with a 2 day placebo period. This regimen advantageously provides a 25 to 75% reduction in ethinyl estradiol exposure compared to conventional low dose 24 day methods using a daily dose of 20 mcg of ethinyl estradiol.

Lachnit, the primary reference, describes a combination preparation for use in female birth control. In particular, a first hormone component contains an estrogen and a progestin and is given for 23 to 24 days. A second hormone component only contains an estrogen and is given for 4 to 10 days. Significantly, Lachnit makes very clear that the total

number of hormone daily units is equal to the total number of days of the desired cycle, i.e., there is no pill free or placebo period. See Abstract.

The Examiner notes that Lachnit broadly describes a range of potential ethinyl estradiol dose of 10 to 40 mcg and a preferred range of 15 to 25 mcg in the first hormone component. Similary, Lachnit broadly describes a range of potential ethinyl estradiol dose in the second hormone component as 2 to 40 mcg and a preferred range of 10 to 25 mcg. It is also noted that Lachnit describes the preferred use of 17β-estradiol in the broad range of 1 to 6 mg or 17β-estradiol valerate in the same broad range. When all the ranges of potential estrogens are taken together with the many potential progestins listed and their potential ranges, it becomes apparent that Lachnit describes a significant number of potentially differing regimens. As discussed at the Interview, altering contraceptive regimens can lead unpredictable results. Thus, it is clear that Lachnit does not disclose a small number of possibilities with predictable results.

The Examiner had suggested that a person of ordinary skill would have been inclined to choose a low level of ethinyl estradiol from the broad range of ethinyl estradiol dosages described in Lachnit and simply introduce 2 days of placebo because placebos are known (citing Gast). As explained by Applicants, the change suggested by the Examiner would actually be contrary to the teaching of Lachnit.

In fact, significantly, Lachnit makes clear at Col. 6, line 60 to Col. 7, line 23 that the advantages of their invention are particularly significant when compared to prior compositions that have ethinyl estradiol doses less than 30 mcg and those with a pill free interval. In particular, Lachnit claims that their inventive regimens, which do not have a pill free period, result in a lower risk of breakthrough ovulation and considerably improved cycle control.

Accordingly, it is respectfully submitted that a person of ordinary skill in the art would not have selected a low level ethinyl estradiol dosage from the ranges described in Lachnit and introduced a pill free period or placebo period when this would run contrary to the very teaching of Lachnit, i.e., no pill free period or placebo period, to obtain the advantages described by Lachnit. Moreover, it respectfully submitted that a person of ordinary skill in the art would not have had a reasonable expectation of obtaining a successful contraceptive regimen by introducing a placebo period into a regimen of Lachnit in view of Lachnit's teachings, particularly considering the many possibilities described by Lachnit and unpredictable nature of contraceptive regimens. To the contrary, a person of ordinary skill would have expected, based on Lachnit, that such a change would have negatively impacted contraceptive efficacy and cycle control.

In his office action, the Examiner had also pointed to the declaration of Dr. Ellman as evidence that contraceptive regimens with placebos work. However, as pointed out to the Examiner, the only regimens within the table in paragraph 7 that has a low level of ethinyl estradiol as defined in the present claims is LoSeasonique™. Notably this regimen, which ends with 7 days of 10 mcg ethinyl estradiol, has no placebo period.

Wherefore, it is respectfully submitted that the art of record, whether taken alone or together, does not disclose or suggest the presently claimed invention. In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Applicant's undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

/Raymond R. Mandra/
Raymond R. Mandra
Attorney for Applicant
Registration No. 34,382

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

FCHS_WS 4608465_1.DOC

Electronic Acknowledgement Receipt

EFS ID:	6813143
Application Number:	11112290
International Application Number:	
Confirmation Number:	5820
Title of Invention:	Extended estrogen dosing contraceptive regimen
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Customer Number:	05514
Filer:	Raymond Richard Mandra/DAVID NGUY
Filer Authorized By:	Raymond Richard Mandra
Attorney Docket Number:	02911.009860.
Receipt Date:	14-JAN-2010
Filing Date:	22-APR-2005
Time Stamp:	17:05:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		02911009860AmendmentAfterFinal.pdf	28342 79e5689b5c97179169f5ac243f6315158225ad96	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	8
Warnings:			
Information:			
	Total Files Size (in bytes):	28342	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/112,290	04/22/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 01/14/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 9	Minus	** 41	= 0	X $ =		OR	X $52=	0
Independent (37 CFR 1.16(h))	* 2	Minus	***4	= 0	X $ =		OR	X $220=	0
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/MARY PEOPLES/

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/112,290	04/22/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	01/14/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 9	Minus	** 41	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***4	= 0	X $ =		OR	X $220=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/GOIGA N. DUCKETT/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	02911.009860.	5820

5514 7590 01/19/2010

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
01/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/112,290	BOISSONNEAULT, ROGER M.	
	Examiner	Art Unit	
	Paul Zarek	1628	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Paul Zarek*.

(2) *San-Ming Hui*.

(3)*Raymond Mandra*.

(4)*Herman Ellman*.

Date of Interview: *13 January 2010*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *1 and 28*.

Identification of prior art discussed: *Lachnit, et al. (US Patent no. 5,756,490*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Lachnit, et al., suggest a continuous administration of low-dose ethinyl estradiol (EE) is required for acceptable contraception. Lachnit, et al., do not teach or suggest both a low dose of EE and a placebo. Written response will be carefully reviewed*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/PEZ/	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

OK to Enter
/PEZ/
01/27/2010

REMARKS

This application has been reviewed in light of the Office Action dated November 2, 2009. Claims 1, 2, 7, 8, 12, 25, 28, 29 and 32 are presented for examination, of which Claims 1 and 28 are in independent form. Favorable reconsideration is respectfully requested.

Applicants and the undersigned would like to thank Examiners Zarek and Hui for the kind courtesy of the Interview of January 13, 2010. In accordance with the Examiners' request, the prior art distinguishing comments constructively discussed at the Interview are provided below.

Claims 1, 2, 7, 8, 12, 25, 8, 29 and 32 stand rejected as allegedly obvious over U.S. Patent No. 5,756,490 (Lachnit et al.) in view of Loose-Mitchell and Stancel and Gast (International Application No. WO 98/04268). Applicants respectfully traverse the rejection for the reasons set forth herein.

As discussed at the Interview, the present claims are specifically directed to the surprising discovery that a contraceptive regimen using 5 to 15 mcg of ethinyl estradiol in a daily dose (24 days in combination with the progestin norethindrone acetate or norethindrone and 2 days with ethinyl estradiol only) provided contraceptive efficacy even with a 2 day placebo period. This regimen advantageously provides a 25 to 75% reduction in ethinyl estradiol exposure compared to conventional low dose 24 day methods using a daily dose of 20 mcg of ethinyl estradiol.

Lachnit, the primary reference, describes a combination preparation for use in female birth control. In particular, a first hormone component contains an estrogen and a progestin and is given for 23 to 24 days. A second hormone component only contains an estrogen and is given for 4 to 10 days. Significantly, Lachnit makes very clear that the total

number of hormone daily units is equal to the total number of days of the desired cycle, i.e., there is no pill free or placebo period. See Abstract.

The Examiner notes that Lachnit broadly describes a range of potential ethinyl estradiol dose of 10 to 40 mcg and a preferred range of 15 to 25 mcg in the first hormone component. Similary, Lachnit broadly describes a range of potential ethinyl estradiol dose in the second hormone component as 2 to 40 mcg and a preferred range of 10 to 25 mcg. It is also noted that Lachnit describes the preferred use of 17β-estradiol in the broad range of 1 to 6 mg or 17β-estradiol valerate in the same broad range. When all the ranges of potential estrogens are taken together with the many potential progestins listed and their potential ranges, it becomes apparent that Lachnit describes a significant number of potentially differing regimens. As discussed at the Interview, altering contraceptive regimens can lead unpredictable results. Thus, it is clear that Lachnit does not disclose a small number of possibilities with predictable results.

The Examiner had suggested that a person of ordinary skill would have been inclined to choose a low level of ethinyl estradiol from the broad range of ethinyl estradiol dosages described in Lachnit and simply introduce 2 days of placebo because placebos are known (citing Gast). As explained by Applicants, the change suggested by the Examiner would actually be contrary to the teaching of Lachnit.

In fact, significantly, Lachnit makes clear at Col. 6, line 60 to Col. 7, line 23 that the advantages of their invention are particularly significant when compared to prior compositions that have ethinyl estradiol doses less than 30 mcg and those with a pill free interval. In particular, Lachnit claims that their inventive regimens, which do not have a pill free period, result in a lower risk of breakthrough ovulation and considerably improved cycle control.

Accordingly, it is respectfully submitted that a person of ordinary skill in the art would not have selected a low level ethinyl estradiol dosage from the ranges described in Lachnit and introduced a pill free period or placebo period when this would run contrary to the very teaching of Lachnit, i.e., no pill free period or placebo period, to obtain the advantages described by Lachnit. Moreover, it respectfully submitted that a person of ordinary skill in the art would not have had a reasonable expectation of obtaining a successful contraceptive regimen by introducing a placebo period into a regimen of Lachnit in view of Lachnit's teachings, particularly considering the many possibilities described by Lachnit and unpredictable nature of contraceptive regimens. To the contrary, a person of ordinary skill would have expected, based on Lachnit, that such a change would have negatively impacted contraceptive efficacy and cycle control.

In his office action, the Examiner had also pointed to the declaration of Dr. Ellman as evidence that contraceptive regimens with placebos work. However, as pointed out to the Examiner, the only regimens within the table in paragraph 7 that has a low level of ethinyl estradiol as defined in the present claims is LoSeasonique™. Notably this regimen, which ends with 7 days of 10 mcg ethinyl estradiol, has no placebo period.

Wherefore, it is respectfully submitted that the art of record, whether taken alone or together, does not disclose or suggest the presently claimed invention. In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

OK to Enter
/PEZ/
01/27/2010

Applicant's undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

/Raymond R. Mandra/
Raymond R. Mandra
Attorney for Applicant
Registration No. 34,382

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

FCHS_WS 4608465_1.DOC

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112290	BOISSONNEAULT, ROGER M.
	Examiner	Art Unit
	Paul Zarek	1628

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/13/2008	03/06/2009	10/26/2009	01/27/2010					
1	1	÷	✓	✓	=					
2	2	÷	✓	✓	=					
	3	÷	✓	-	-					
	4	÷	✓	-	-					
	5	÷	✓	-	-					
	6	÷	✓	-	-					
3	7	÷	✓	✓	=					
4	8	÷	✓	✓	=					
	9	÷	✓	-	-					
	10	÷	✓	-	-					
	11	÷	✓	-	-					
5	12	÷	✓	✓	=					
	13	÷	N	-	-					
	14	÷	N	-	-					
	15	÷	N	-	-					
	16	÷	N	-	-					
	17	÷	N	-	-					
	18	÷	N	-	-					
	19	÷	N	-	-					
	20	÷	N	-	-					
	21	÷	N	-	-					
	22	÷	N	-	-					
	23	÷	N	-	-					
	24	÷	✓	-	-					
6	25	÷	✓	✓	=					
	26	÷	N	-	-					
	27	÷	N	-	-					
7	28	÷	✓	✓	=					
8	29	÷	✓	✓	=					
	30	÷	N	-	-					
	31	÷	N	-	-					
9	32			✓	=					

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112290	BOISSONNEAULT, ROGER M.
	Examiner	Art Unit
	Paul Zarek	1628

SEARCHED

Class	Subclass	Date	Examiner
514	170, 843	01/27/2010	PEZ

SEARCH NOTES

Search Notes	Date	Examiner
EAST search	03/06/2009	PEZ
Prosecution history of 11/078,300	03/06/2009	PEZ
IPRP of WO 06/115871	03/06/2009	PEZ
EAST search	10/26/2009	PEZ
updated EAST search (including inventor search)	01/27/2010	PEZ
Patentability conference with Sreeni Padmanabhan and Brandon Fetterolf	01/27/2010	PEZ

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
510	170, 843	01/27/2010	PEZ

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NOTICE OF ALLOWANCE AND FEE(S) DUE

5514 7590 02/12/2010

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
ZAREK, PAUL E	
ART UNIT	PAPER NUMBER
1628	

DATE MAILED: 02/12/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	02911.009860.	5820

TITLE OF INVENTION: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	05/12/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

5514 7590 02/12/2010

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	02911.009860.	5820

TITLE OF INVENTION: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	05/12/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
ZAREK, PAUL E	1628	514-170000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	02911.009860.	5820

5514 7590 02/12/2010

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
ZAREK, PAUL E	
ART UNIT	PAPER NUMBER
1628	

DATE MAILED: 02/12/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 899 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 899 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	11/112,290	BOISSONNEAULT, ROGER M.	
	Examiner	Art Unit	
	Paul Zarek	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *14 January 2010*.

2. ☒ The allowed claim(s) is/are *1,2,7,8,12,25,28,29 and 32*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Acknowledgement is made of Applicant's After-Final reply received on 01/14/2010.

Status of the Claims

3. Claims 1, 2, 7, 8, 25, 28, 29, and 32 are currently pending.

RESPONSE TO ARGUMENTS

4. Claims 1, 2, 7, 8, 12, 25, 28, 29, and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lachnit, et al. (US Patent No. 5,756,490, 1998, provided in IDS), in view of Loose-Mitchell and Stancel (Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed., 2001), and Gast (International Application No. WO 98/04268). Applicant traversed this rejection on the grounds that the combination of Lachnit, et al., Loose-Mitchell and Stancel, and Gast do not teach or fairly suggest the claimed invention. Applicant contends that Lachnit, et al., teach that the contraceptive method disclosed therein (a first hormone component comprising a progestin and an estrogen and a second estrogen-only component) requires the absence of a placebo. Applicant further states that Lachnit, et al., specifically states that the advantages of that invention lie in the absence of a placebo period. Applicant asserts that one of ordinary skill in the art would not have selected a low level ethinyl estradiol in the dosage range disclosed by Lachnit, et al., and introduced a pill-free or placebo period. After careful consideration,

Examiner finds Applicant's arguments persuasive. Therefore, the rejection of Claims 1, 2, 7, 8, 12, 25, 28, 29, and 32 under 35 U.S.C. 103(a) as being unpatentable over Lachnit, et al., in view of Loose-Mitchell and Stancel, and Gast is withdrawn.

5. Applicant has overcome all standing rejections.

REASONS FOR ALLOWANCE

6. The following is an examiner's statement of reasons for allowance: The prior art does not anticipate or render obvious the claimed invention. After an extensive search of the art, Examiner found no art that teaches or suggests an ultra low dose of ethinyl estradiol (5-15 μg) and a placebo period of any length in a biphasic regimen lasting 28 days. For example, see Tables 1 and 2 in Rodriguez (US PreGrant Publication no. 2004/0176336.

Conclusion

7. Claims 1, 2, 7, 8, 12, 25, 28, 29, and 32 are allowed.

8. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642

Notice of References Cited	Application/Control No. 11/112,290	Applicant(s)/Patent Under Reexamination BOISSONNEAULT, ROGER M.	
	Examiner Paul Zarek	Art Unit 1628	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2004/0176336	09-2004	Rodriguez, Gustavo C.	514/170
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11112290	BOISSONNEAULT, ROGER M.
Examiner	**Art Unit**
Paul Zarek	1628

ORIGINAL		INTERNATIONAL CLASSIFICATION															
CLASS	SUBCLASS	CLAIMED										NON-CLAIMED					
514	170	A	6	1	K	31 / 56 (2006.0)											
CROSS REFERENCE(S)		A	6	1	K	31 / 58 (2006.0)											
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																
514	843																

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1														
2	2														
3	7														
4	8														
5	12														
6	25														
7	28														
8	29														
9	32														

/Paul Zarek/ Examiner.Art Unit 1628 (Assistant Examiner)	01/27/2010 (Date)	**Total Claims Allowed:** 9
/BRANDON J FETTEROLF/ Primary Examiner.Art Unit 1642 (Primary Examiner)	01/28/2010 (Date)	O.G. Print Claim(s) 1 O.G. Print Figure none

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	22	roger near2 boissonneault.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/01/27 15:03
L2	1097	514/170,843.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/01/27 15:09
L5	108	(low dose or low-dose) same ethinyl estradiol	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/01/27 15:43

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	644	514/170,843.ccls.	USPAT; UPAD	ADJ	ON	2010/01/27 15:09
L4	32	(low dose or low-dose) same ethinyl estradiol	USPAT; UPAD	ADJ	ON	2010/01/27 15:43

1/27/2010 3:49:23 PM
C:\Documents and Settings\pzarek\My Documents\EAST\Workspaces\11112290.wsp

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 5820

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/112,290	04/22/2005 RULE	514	1628	02911.009860.

APPLICANTS
Roger M. Boissonneault, Long Valley, NJ;

** CONTINUING DATA **********

** FOREIGN APPLICATIONS **********

** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **
05/17/2005

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/PAUL E ZAREK/ Examiner's Signature	☐ /PEZ/ Initials	NJ	0	23	2

ADDRESS
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800
UNITED STATES

TITLE
Extended estrogen dosing contraceptive regimen

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
2646	No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

5514 7590 02/12/2010

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/22/2005	Roger M. Boissonneault	02911.009860.	5820

TITLE OF INVENTION: EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	05/12/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
ZAREK, PAUL E	1628	514-170000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Fitzpatrick, Cella, Harper
2 and Scinto
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: WARNER CHILCOTT COMPANY, LLC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): FAJARDO, PUERTO RICO

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☒ Payment made concurrently herewith.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge ~~the required fee(s),~~ any deficiency, or credit any overpayment, to Deposit Account Number 06-1205 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Raymond R. Mandra/ Date March 4, 2010

Typed or printed name Raymond R. Mandra Registration No. 34,382

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	11112290
Filing Date:	22-Apr-2005
Title of Invention:	EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Filer:	Raymond Richard Mandra/Wendy Valdez
Attorney Docket Number:	02911.009860.

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	1501	1	1510	1510
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1810**

Electronic Acknowledgement Receipt

EFS ID:	7139200
Application Number:	11112290
International Application Number:	
Confirmation Number:	5820
Title of Invention:	EXTENDED ESTROGEN DOSING CONTRACEPTIVE REGIMEN
First Named Inventor/Applicant Name:	Roger M. Boissonneault
Customer Number:	05514
Filer:	Raymond Richard Mandra/DAVID NGUY
Filer Authorized By:	Raymond Richard Mandra
Attorney Docket Number:	02911.009860.
Receipt Date:	04-MAR-2010
Filing Date:	22-APR-2005
Time Stamp:	12:25:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1810
RAM confirmation Number	12375
Deposit Account	503939
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	02911009860_IssueFee.pdf	89437 b44cd5d83c3b4b1bf36af94701a910d4d834ed1e	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	32285 5fbfc255e717f2e32b3aafb7017540c5b8849279	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	121722		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,290	04/27/2010	7704984	02911.009860.	5820

5514 7590 04/07/2010

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1382 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Roger M. Boissonneault, Long Valley, NJ;

AO 120 (Rev. 08/10)

TO:	**Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313–1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the **U.S. District Court for the District of New Jersey** on the following:
____ Trademarks or **X** Patents. (____ the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
3:12–cv–02928–JAP–TJB	5/17/2012	TRENTON, NJ

PLAINTIFF	DEFENDANT
WARNER CHILCOTT COMPANY, LLC	WATSON LABORATORIES, INC.

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 5,552,394	9/3/1996	THE MEDICAL COLLEGE OF HAMPTON ROADS
2 US 7,704,984 B2	4/27/2010	WARNER CHILCOTT COMPANY, LLC
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ___ Amendment ___ Answer ___ Cross Bill ___ Other Pleading

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
William T. Walsh	s/ JAWEIA CAMPBELL	5/17/2012

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy