IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL NO. 11-5048 and 12-2928

WARNER CHILCOTT CO., LLC, Plaintiff, -vs- LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants. WARNER CHILCOTT CO., LLC, Plaintiff, -vs- WATSON LABORATORIES, INC., Defendant.	TRANSCRIPT OF PROCEEDINGS TRIAL

Trenton, New Jersey
October 7, 2013

B E F O R E:

THE HONORABLE JOEL A. PISANO
UNITED STATES DISTRICT COURT JUDGE

Pursuant to Section 753 Title 28 United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above-entitled proceedings.

S/Joanne M. Caruso, CSR, CRR
Official Court Reporter
(908)334-2472

THE COURT: Miss Breen, is that what you like to be called?

MS. BORG-BREEN: Caryn Borg-Breen. It's a hyphenated name.

THE COURT: Yes, I know that. I didn't know if you wanted both.

MS. BORG-BREEN: It's actually my husband's last name.

THE COURT: How are you?

MS. BORG-BREEN: I'm doing pretty well, your Honor. At this time, Lupin would call its first witness, Dr. Kurt T. Barnhart.

THE COURT: Dr. Barnhart.

MS. BORG-BREEN: He is a board certified obstetrician and gynecologist who will be presenting testimony on behalf of Lupin supporting prior art.

Permission to approach?

THE COURT: Sure.

K U R T B A R N H A R T, sworn.

THE COURT: Good morning, sir.

THE WITNESS: Good morning.

Can I clarify two important things before we start?

THE COURT: Wait until Miss Borg-Breen gets back. What have you given here?

MS. BORG-BREEN: We have two binders of exhibits and

A Yes, often in scientific --
Q Cartoon?
A That's a word we use scientifically all the time to show it's not data, it's an example.
Q Cartoon was the word you used, sir?
A That was the word I used.
Q Let's talk about the '050 patent now.
Can we have DTX-3 and four, Mr. Brooks?
You discussed this yesterday as well, correct?
A I did.
Q Can we have column two, lines 47 through 49?
A Which DTX is this, I'm sorry?
Q DTX-384.
Do you see that at column two, lines 47 through 49, it says, "The present invention relates to chewable palatable oral contraceptive tablets for administering an oral contraceptive agent to human females"?
A That's correct.
Q And the inventor stated, and now I'm at column three, lines 55 through 60, "In principle, virtually any oral contraceptive agent used in human medicine could be employed in accordance with the principles of the invention. The oral contraceptive agent may be an estrogen, a progestin or combination of an estrogen and a progestin."
Do you see that, sir?

US006667050B1

(12) **United States Patent**
Boissonneault et al.

(10) **Patent No.: US 6,667,050 B1**
(45) **Date of Patent: Dec. 23, 2003**

(54) **CHEWABLE ORAL CONTRACEPTIVE**

(75) Inventors: **Roger M. Boissonneault**, Long Valley, NJ (US); **Tina M. deVries**, Long Valley, NJ (US)

(73) Assignee: **Galen (Chemicals) Limited**, Dunlaoghaire (IE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/879,028**

(22) Filed: **Jun. 12, 2001**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/286,908, filed on Apr. 6, 1999.

(51) **Int. Cl.**[7] **A61K 47/00**

(52) **U.S. Cl.** **424/439**; 424/400; 424/440; 424/441; 424/464; 424/484; 424/489; 514/841; 514/843

(58) **Field of Search** 424/400, 439, 424/440, 441, 464, 484, 489; 514/841, 843

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,960,911	A		6/1976	Suschitzky et al.
4,036,983	A		7/1977	Rutherford et al.
4,038,413	A		7/1977	Suschitzky et al.
4,136,162	A		1/1979	Fuchs et al.
4,512,986	A		4/1985	Reel et al.
4,684,534	A		8/1987	Valentine
5,135,744	A		8/1992	Alexander et al.
5,569,456	A		10/1996	Gorinskyt
5,576,014	A		11/1996	Mizumoto et al.
5,747,480	A	*	5/1998	Gast 514/170

* cited by examiner

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(57) **ABSTRACT**

The present invention relates to a chewable, palatable oral contraceptive tablet, comprising an oral contraceptive agent, a chewable carrier suitable for human consumption, and not comprising a ferrocene compound, as well as use of these tablets in a method of human female oral contraception, and in a method of enhancing compliance with a human female oral contraceptive regimen.

60 Claims, No Drawings

CHEWABLE ORAL CONTRACEPTIVE

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of U.S. patent application Ser. No. 09/286,908, filed Apr. 6, 1999.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable.

REFERENCE TO MICROFICHE APPENDIX

Not Applicable.

BACKGROUND OF THE INVENTION

The present invention generally relates to an oral contraceptive delivery system, and in particular an oral contraceptive delivery system involving novel alternate dose forms to improve compliance.

The efficacy of oral contraceptives tends to be particularly patient compliance dependent, largely due to the lack of a disease state or symptoms to remind a human female patient (sometimes referred to simply as "patient" or "woman") to take a pill. The single most significant reason for failure with oral contraceptives is use, rather than method, failure. That is, unless the contraceptives are used according to the prescribed regimen, the contraceptives can fail to effectively help a patient avoid pregnancy. Further, in order to be most effective in preventing pregnancy and maintaining menstrual cycle control, proper compliance with an oral contraceptive dosage regimen requires that the oral contraceptives be taken at about the same time each day.

Various attempts have been made to improve patient compliance with contraceptive regimens. For example, it has been suggested that progestin rods can be inserted subdermally. This procedure has been described, for example, in U.S. Pat. No. 5,756,115. This technique has the significant disadvantage of requiring a surgical incision, a procedure that is highly disfavored by a relatively large segment of the patient population.

As another example, it has been suggested that DEPO-PROVERA® (Pharmacia, Inc.) medroxyprogesterone acetate can be injected subcutaneously every three months. This technique has been described, for example, in U.S. Pat. No. 4,639,439. This procedure has the disadvantage of requiring an injection via hypodermic needle, which is also a procedure that is disfavored by many patients.

In many cases, the patient prefers to carry the contraceptive pills on her person as a matter of lifestyle or personal discretion. This is especially true for younger patients, and it is not uncommon for such patients to exchange pills. Members of this population tend to view portable packaging of the pills, immediate access to the pills, and ease of pill use as significant benefits.

Prior proposed solutions to the compliance problem have tended to focus primarily or exclusively on optimizing compliance packaging, rather than on changes to the dosage form. It has been suggested that instead of being packaged in vials, contraceptive pills can be packaged in 21 or 28 day blister packages. It has also been suggested that the size of these packages can be reduced to improve portability and confidentiality.

Although oral contraceptive pills provided in a small blister package are somewhat more convenient to carry and to conceal, they are not necessarily easy to ingest. Access to water to facilitate contraceptive pill taking remains a problem. Most medications are typically stored in a medicine cabinet and therefore are likely to be near a water source. On the contrary, oral contraceptive pills are often carried on the person and a source of water is not always available when it is time to take the oral contraceptive pill. Additionally, a certain segment of the patient population will have trouble swallowing pills, irrespective of access to water.

The present invention provides an improved oral contraceptive tablet. The technology encompassed in the invention involves a chewable, palatable oral contraceptive tablet that has appropriate size and hardness for blister packaging and compliant use.

BRIEF SUMMARY OF THE INVENTION

One aspect of the present invention relates to a chewable, palatable oral contraceptive tablet, comprising an oral contraceptive agent, a chewable carrier suitable for human consumption, and not comprising a ferrocene compound.

Another aspect of this invention relates to a method of human female oral contraception, the method comprising providing a chewable, palatable oral contraceptive tablet comprising a contraceptively effective amount of an oral contraceptive agent, and a chewable carrier suitable for human consumption, and not comprising a ferrocene compound, and administering the tablet to a human female.

Yet another aspect of this invention relates to a method of enhancing compliance with a human female oral contraceptive regimen involving oral contraceptive tablets, the method comprising providing chewable, palatable oral contraceptive tablets comprising a contraceptively effective amount of an oral contraceptive agent, and a chewable carrier suitable for human consumption, and not comprising a ferrocene compound, and administering the tablets to the human female in accordance with the contraceptive regimen.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Not Applicable.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to chewable, palatable oral contraceptive tablets for administering an oral contraceptive agent to human females. The tablets of this invention may simply be chewed, and therefore are easy for a patient to ingest, even in the absence of a liquid. The oral contraceptive agent formulation of this invention improves dosage regimen compliance, and thereby enhances the desired contraceptive effect of the oral contraceptive. This invention also includes methods for administering the oral contraceptive formulations to a woman.

Definitions

The articles "a" and "an" are used herein to refer to one or more than one (i.e., to at least one) of the grammatical objects of the article. By way of example, "an element" means one element or more than one element.

The term "oral contraceptive agent," as used herein, refers to any compound or combination of compounds which, when administered orally, prevents pregnancy.

The term "estrogen," as used herein, refers to any natural or synthetic compound which exhibits an effect on the

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