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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report

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(54) Title: HORMONE REPLACEMENT FORMULATION

(57) Abstract: The basic formulation comprises a combination of three estrogens, 2-hydroxyestrone, 17-beta-estradiol and estriol, and a metabolite of an estrogen, 2-methoxyestradiol, in specified amounts. Amounts of folic acid, DHEA, testosterone, Vitamin B6, Di-Indolyl Methane, melatonin and progesterone, as well as selenium and cobalt can be added in specific amounts to the basic formulation. 2-Hydroxyestradiol, another metabolic, can also be added.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US07/62556

A. CLASSIFICATION OF SUBJECT MATTER
 IPC: **A61K 31/56(2006.01),9/24(2006.01),31/00(2006.01);A61J 1/00(2006.01)**

 USPC: 514/170,179;424/473,472;604/892.1;206/438,538,539,570,828
 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 U.S. : 514/170,179;424/473,472;604/892.1;206/438,538,539,570,828

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---------------|---|------------------------|
| X --- Y | US 2004/0180866 A1 (Mamchur) 16 September 2004 (16.09.2004), abstract, paragraphs 5, 38, 50, 88, 89, 149-158. | 1-11 ----- 12-13 |
| Y | US 2004/0265355 A1 (Shalaby) 30 December 2004 (30.12.2004), page 2, paragraph 12. | 12-13 |
| Y | US 6,708,822 B1 (Muni) 23 March 2004 (23.03.2004), abstract. | 1-13 |

Further documents are listed in the continuation of Box C. See patent family annex.

| | | |
|---|-----|--|
| * Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
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| "O" document referring to an oral disclosure, use, exhibition or other means | | |
| "P" document published prior to the international filing date but later than the priority date claimed | | |

Date of the actual completion of the international search: 07 January 2008 (07.01.2008)
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Name and mailing address of the ISA/US: Mail Stop PCT, Attn: ISA/US, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, Facsimile No. (571) 273-3201
 Authorized officer: David Fox, Felicia D. Roberts, Telephone No. 571-273-1600

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US07/62556

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
 2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
 3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

 4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
- Remark on Protest**
- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
 - The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
 - No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US07/62556

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-11, drawn to an estrogen formulation for use in hormone replacement therapy.

Group II, claim(s) 12-13, drawn to a method of hormone replacement therapy.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are linked by the technical feature of a composition comprising an estrogen formulation for use in hormonal replacement therapy. However, this feature is not special because it does not constitute an advance over the prior art. I. Muni (US 6,708,822 B1) teaches compounded pharmaceuticals used in hormone replacement therapy (see abstract). Therefore, Groups I and II do not meet the requirement of unity of invention.