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IP Australia

AUSTRALIAN OFFICIAL JOURNAL

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PATENTS

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Contents

General Information

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GUIDE TO THE USE OF THIS JOURNAL

The Australian Official Journal of Patents (AOJP) reports all major events and actions which take place during the life cycle of an Australian patent and provides certain details of these actions as they relate to the patent or patent application involved. This guide sets out to teach the reader how to use the journal to access this information.

While there are many possible actions in the life of a patent, the majority of actions reported relate to the following events, which are the main stages in the progression of a patent application to a sealed patent:

(i) FILING -

This is the act of making an application. When the application is first filed certain details are published.

(ii) OPEN-TO-PUBLIC-INSPECTION (OPI) -

Approximately 18 months after first filing of an Australian or a corresponding foreign application, certain application documents, including the complete specification, become available to the public (Open-to-Public-Inspection or "OPI"). Relevant application details are published.

(iii) ACCEPTANCE –

This is the Commissioner's acceptance of a patent application. Once the Commissioner has accepted a patent application, certain details of the application are published in the AOJP. Notice of opposition may be filed within three months of advertisement of acceptance.

(iv) OPPOSITION –

If an opposition action is commenced against the grant of the patent, the six-figure acceptance number and the name of the opponent are published. If the opposition is to the Certification of an Innovation Patent, the patent number and the name of the opponent are published.

(v) SEALING –

Most accepted applications are not opposed. These proceed to sealing and become granted patents. Of the few that are opposed (less than 1%) most of these, after resolution of the opposition, proceed to sealing and become granted patents. Sealed patents are simply listed in order of their application number.

(vi) CERTIFICATION

This is the Commissioner's Certification after passing examination of a previously granted unexamined Innovation Patent.

In addition to the actions related to these stages, other actions reported include: assignments, lapsing or withdrawal of applications and ceasing or expiry of patents, voluntary amendments, extensions of time for certain actions and registration of licences.

How To Identify Information Using "INID" Numbers

Patents are published in many different countries and in many different languages. As a result, finding the information that you want (eg the filing date) on a patent document or in a journal can be quite difficult. There is an international system operating, however, which codifies this information in an unambiguous way, by assigning a specific number to each piece of information about the history of a patent. These numbers are called the **Internationally agreed Numbers for the Identification of Data** or INID numbers.

These numbers appear on all published patents and abstracts and are used throughout this journal to identify particular items of information. For example, the date on which a document is filed has the INID number (22), while the name of the applicant has the INID number of (71). These numbers are always expressed in parentheses and always immediately precede the information to which they relate. For example:

(22) 12.10.91

means that the filing date of the document which contains this reference is 12 October 1991. Learning the INID numbers for the information you want will help you find it quickly and easily.

A complete list of the INID numbers and the items to which they relate is provided at the end of this Guide.

How Australian Patent Documents are Numbered

Patent applications in Australia are assigned a number at the filing stage in their processing. Each Australian application will retain the same number throughout its life, though different numbers may be associated to the application. The number will incorporate the year of lodgment then a unique number within the appropriate range.

There will be number ranges for types of patents:
100,000 – 199,999 Innovation
200,000 – 799,999 Standard
800,000 – 899,999 Petty
900,000 – 999,999 Provisional

When searching for information and ordering documents it is vital that you understand the numbering systems.

1. **Provisional Applications** are given a ten-figure number

    e.g. 2002901123

    A provisional application number is identified by the INID number (21).

2. **Complete and Innovation Applications** are also given a ten-figure application number

    e.g. 2002200345 Standard

    2002100123 Innovation

There are prefixes applied to this number which indicate whether the application has been accepted:

A document corresponding to an unaccepted application has the prefix, AU-A; eg AU-A-2002200234.
A document corresponding to an accepted application carries the prefix AU-B; eg AU-B-2002200234.

Users need to be aware that an accepted document may differ from the corresponding unaccepted document. This is because amendment may occur between first publication (OPI) and second publication (acceptance).

A ten-figure application number is identified by the INID number (21).

NOTE: When ordering any patent document from us, whether accepted or not, please quote the ten-figure application number preceded by the appropriate prefix.

Arrangement of Information in the Journal

For each of the categories

(i) Provisional Applications Filed,

(ii) Complete Applications Filed,

iii) Applications Open to Public Inspection

(iv) Applications Entered National Phase

(v) Applications Accepted, and

(vi) Innovation Patent Certified.

The Journal lists the information published in that category in an alphabetical Name Index list based on the name of the applicant. These indices are useful if you wish to find information about applications made by a particular applicant.

In addition to the Name Index there is provided, for each of these categories, a Numerical Index This index lists the applications either in order of their five-figure Application Numbers, in the case of complete applications filed and applications OPI, or in order of their six-figure Document Number in the case of accepted applications. It provides, for each number, the name of the applicant. These indices are useful if you wish to track the progress of a particular patent application.

There are also IPC Indices provided for applications which are OPI and for applications which have been accepted. IPC stands for **I**nternational **P**atent **C**lassification. Each IPC "mark" is an alpha-numerical representation of a particular area of technology. These indices are in order of IPC mark, and within each mark provide either the five-figure application numbers of the application which are now OPI or the six-figure numbers of the cases now accepted. These indices are useful if you wish to check on patent activity in a particular technology.

Using the Indices

1. To Find Patent Information if You Know the Name of the Applicant.

Use the Name Indices. They will give you the following information identified by their INID number:

ITEM	INID No.
A) Provisional applications filed - Name Index	
The name of the applicant	(71)
The Provisional application number	(21)
The date of filing	(22)
The title of the invention	(54)

ITEM	INID No.
B) Complete applications filed - Name Index	
The name of the applicant	(71)
The number assigned to the application	(21)
The date of filing	(22)
Title of the invention	(54)
Number of priority document(s) if any	(31)
Date(s) of filing of priority documents	(32)
Country of which priority documents filed	(33)
PCT application number	(86)

ITEM	INID No.
C) Applications open to public inspection - Name Index	
The name of the applicant	(71)
The number of the document	(11)
The number assigned to the application	(21)
The date of filing	(22)
The title	(54)
The classification marks	(51)
Priority document number(s)	(31)
Date of filing of priority document(s)	(32)
Country in which priority document filed	(33)
Publication date of unexamined document	(43)
Inventors names if known	(72)
Patent Attorneys	(74)

ITEM	INID No.
D) Applications accepted - Name Index	
The name of the applicant	(71)
The number of the document	(11)
The number of the accepted document	(10)
The number assigned to the application	(21)
The date of filing	(22)
The title	(54)
The classification marks	(51)
PCT publication number	(87)
Priority document number	(31)
Date of filing of priority document(s)	(32)
Country in which priority document filed	(33)
Publication date of unexamined document	(43)

ITEM	INID No.
E) Patents Certified – Name Index	
The name of the applicant	(71)
The number of the accepted document	(10)
The number assigned to the application	(21)
The date of filing	(22)
The title	(54)
The classification marks	(51)
Priority document number	(31)
Date of filing of priority document(s)	(32)
Country in which priority document filed	(33)
Publication date of granted patent	(45)
Inventors names	(72)
Patent Attorneys	(74)
Related by division	(62)

You will notice at each stage of following application through that all applications are in alphabetical order of **Applicant**, not inventor.

2. To Find Information About a Patent Application if You Know its Number.

Use the appropriate numerical index. This will give you the name of the applicant from the number. You will then need to use the appropriate Name Index as above to find out other information about the Patent Application you are interested in.

The following Numerical Indices are available:

A) **Provisional** Applications filed.

B) **Complete** Applications filed.

C) Innovation Applications filed.

D) Applications **Open to Public Inspection.**

E) Applications **Accepted**.

F) Innovation Patent Certified

3. To Find Information About Patent Documents in the Area of Technology in which You are Interested if You Know the International Patent Classification Mark for that Area.

All patent applications are classified according to their subject matter using the International Patent Classification (IPC). Although the system is very detailed and covers all technologies, knowledge of the IPC marks of the technologies you are interested in will allow you to find patent documents in these technologies quite easily.

The indices to use are

A) Applications **OPI** - IPC Index

B) Applications **accepted** - IPC Index.

These indices give you the numbers of the applications which are either OPI or Accepted and are listed in order of their IPC marks.

Once you have the numbers of the documents that interest you, consult the relevant Number Index (see 2. above) to find the applicant's name, and then the Name Index (see 1. above) to find out the details of that application.

'INID' NUMBERS in use on Australian Patent Documents

'INID' is an acronym for '**I**nternationally agreed **N**umbers for the **I**dentification of **D**ata'.

(10) Document identification
- **(11)** Number of the document
- **(12)** Plain language designation of the kind of document
- **(19)** WIPO country code, or other identification, of the country publishing the document.

(20) Document filing data
- **(21)** Number(s) assigned to the application(s).
- **(22)** Date(s) of filing application(s)
- **(23)** Other date(s) of filing, including exhibition filing date and date of filing complete specification following provisional specification.
- **(24)** Date from which industrial property rights may have effect.

(30) Priority data
- **(31)** Number(s) assigned to priority application(s)
- **(32)** Date(s) of filing priority application(s)
- **(33)** Country (countries) in which the priority application(s) was (were) filed.

(40) Date(s) of making available to the public
- **(43)** Date of publication by printing or similar process of an unexamined document, on which no grant has taken place on or before the said date.
- **(44)** Date of publication by printing or similar process of an examined document, on which no grant has taken place on or before the said date.
- **(45)** Date of publication by printing or similar process of a document, on which grant or certification has taken place on or before the said date.

(50) Technical Information
- **(51)** International Patent Classification
- **(52)** Domestic or national classification

(54) Title of invention
(56) List of prior art documents, if separate from descriptive text
(57) Abstract or claim

(60) Reference(s) to other legally related domestic document(s)
(60) Related by cognate(s).
(61) Related by addition(s).
(62) Related by division(s).

(70) Identification of parties concerned with the document
(71) Name(s) of applicant(s)
(72) Name(s) of inventor(s) if know to be such
(74) Name(s) of attorney(s) or agent(s)
(75) Name(s) of inventor(s) who is (are) also applicant(s)

(80) Identification of data related to International Conventions other than the Paris Convention
(86) PCT Application Number
(87) PCT Publication Number

NOTE

(1) Australian patent documents published on or after 26 October 1978 should be referred to by the application number preceded by the prefix AU-A or AU-B.

AU-A = Pre-examination **AU-B** = Post-examination

(2) The classification used is the International Patent Classification and is identified by the INID code (51). Further editions of the classification are identified as $(51)_2$, $(51)_3$, $(51)_4$ and $(51)_5$.

(3) INID code 74 provides for the name of the patent attorney, or firm of attorneys, prosecuting an application.

Official Notice

COMMONWEALTH OF AUSTRALIA

Patents Act 1990
Patents Regulations 1991, Chapter 20

PATENTS AND TRADE MARKS ATTORNEYS DISCIPLINARY TRIBUNAL

IN RE HOWARD KENNETH SCHULZE
IN RE PHILLIP BOEHM

Tribunal: Mrs S. Higgins

Date: 23 February 2012

Place: Sydney

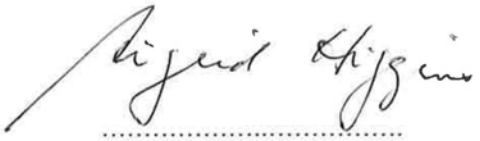
Decision:

1. The Tribunal has jurisdiction to hear and determine these proceedings.

2. Mr Schulze is guilty of unsatisfactory conduct in that he failed to resolve the conflict of interest between client A and client B on or after 11 September 2007 in breach of clause 4.2.8 of the Code of Conduct for Patent and Trade Mark Attorneys.

3. No orders as to disciplinary action are made in regard to Mr Schulz's unsatisfactory conduct.

4. The charge against Mr Boehm is dismissed.



Sigrid Higgins
Patent and Trade Marks Disciplinary Tribunal

Official Notice

Changes in PCT Fees

In accordance with the directives adopted by the PCT Assembly, new equivalent amounts in AUD will be established with effect from **1 April 2012**, As follows:

International PCT Fees

1.	**Transmittal** Fee	$150
2.	**International Search** Fee	$1900
3.	**International** Filing Fee	$1375
	If the application contains 30 Pages or less including the request form	
	PCT-EASY component of **PCT-SAFE** reduction	$103
	Electronic filings filed in PDF format	$207
	Electronic filings filed in XML format	$310
	PLUS	
	For Each page in the application in excess of 30 Sheets	$16
4.	Cost of Preparing **Certified Copy** of Basic Document	$100 per document
5.	Copies of **Specifications** cited in the International Search Report	$50 per copy

International Preliminary Examination Fees

1.	International Preliminary **Examination** Fee	
If the International Search was performed by IP Australia		$550
If the International search was not conducted by IP Australia		$780
2.	International Preliminary **Handling** Fee	$207

Total If Search performed by IP Australia
$757

Total if Search not performed by IP Australia
$987

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Web: www.ipaustralia.gov.au

Proceedings under the Patents Act 1990

Extensions of Time, Section 223

Applications Received

Notice of opposition under Section 223(6) to the undermentioned application(s) for an extension of time may be lodged at the Patent Office within the prescribed time.

747726 **Land Roller, Inc.** An application to extend the time from 24 Jan 2012 to 24 Feb 2012 in which to pay a renewal fee has been lodged . Address for service in Australia - Davies Collison Cave Level 15 1 Nicholson Street MELBOURNE VIC 3000

783694 **Mamet, C. and Mamet, A.** An application to extend the time from 4 Jul 2011 to 4 Mar 2012 in which to pay a renewal fee has been lodged . Address for service in Australia - Callinans PO Box 1189 HARTWELL VIC 3124

Applications Allowed - Section 223(2)

768534 **Pasquini, J.** The time in which to pay a renewal fee has been extended to 26 Aug 2011 . Address for service in Australia - Griffith Hack GPO Box 4164 SYDNEY NSW 2001

783335 **Sirkin, T.** The time in which to pay a renewal fee has been extended to 12 Oct 2011 . Address for service in Australia - Griffith Hack GPO Box 4164 SYDNEY NSW 2001

Amendments, Section 104

Amendments Made

695436 **TMA Corp. Pty Ltd** The nature of the amendment is as was notified in the Official Journal dated 29 Sep 2011

Amendments, Section 105

Court Order by the Federal Court of Australia, New South Wales Australian Letters Patent 770594 in the name of Garford PTY. LTD.
The amendments advertised in the Official Journal of Patents dated 20 October 2011 have been made in accordance with a Court Order dated 7 December 2011

Alteration Of Name In Register

663022 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

671803 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

683587 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

686879 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

693005 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

695784 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

715839 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

721064 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

725333 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

728172 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

729163 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

730768 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

732511 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

735103 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

737118 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

738158 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

750203 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

752765 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

760503 MEGMILK SNOW BRAND CO., LTD. The name of the patentee(s) has been changed to **MEGMILK SNOW BRAND Co., Ltd.**

762091 Siemens Water Technologies Corp. The name of the patentee(s) has been changed to **Siemens Industry, Inc.**

767067 France Telecom SA The name of the patentee(s) has

Alteration of Name in Register - cont'd

been changed to **France Telecom**

771158 HUYCK.WAGNER Austria GmbH The name of the patentee(s) has been changed to **HUYCK.WANGNER Austria GmbH**

778444 France Telecom SA The name of the patentee(s) has been changed to **France Telecom**

784087 MEGMILK SNOW BRAND CO., LTD. The name of the patentee(s) has been changed to **MEGMILK SNOW BRAND Co., Ltd.**

Notice of Intention to Amend pursuant to Order 34.41 of the Federal Court Rules

Australian Patent No 780330 in the name of Bayer Pharma Aktiengesellschaft

AUSTRALIA

Patents Act 1990

NOTICE

OF

APPLICATION TO AMEND LETTERS PATENT

PURSUANT TO SECTION 105

Bayer Pharma Aktiengesellschaft

of Building S105, 6th Floor, Room 621
Müllerstraße 178
13353 Berlin
GERMANY

hereby gives notice that it intends to apply under sub-section 105(1) of the *Patents Act 1990* for an Order directing the amendment of the Australian Letters Patent No. 780330 for an invention entitled "Pharmaceutical combination of ethinylestradiol and drospirenone for use as a contraceptive" in accordance with the Advertisement lodged herewith.

The Applicant's address for service is C/- Davies Collison Cave Law, Level 15, 1 Nicholson Street, Melbourne, VIC 3000.

DATED: 17 February 2012

Davies Collison Cave Law

DAVIES COLLISON CAVE LAW
Solicitors for the Applicant

TO: The Commissioner of Patents
Australian Industrial Property Organisation
PO Box 200
WODEN ACT 2600

SECTION 105 PATENTS ACT
Advertisement pursuant to Order 34.41 of the Federal Court Rules

IDENTITY OF PROCEEDINGS

Court: Federal Court of Australia
New South Wales District Registry
Proceeding No. NSD 236 of 2012

Parties: Bayer Pharma Aktiengesellschaft and Bayer Australia Limited (Applicants)

and

Generic Health Pty Ltd and Lupin Australia Pty Limited (Respondents)

PARTICULARS OF PROPOSED AMENDMENT

Bayer Pharma Aktiengesellschaft, the registered proprietor of Australian Letters Patent No. 780330 (the **Patent**), will seek an Order under Section 105(1) of the Patents Act 1990 directing the amendment of the Patent as follows:

1. Page 16, delete "from 2 mg to 4 mg" at the start of line 2 of claim 3 and insert "3 mg", as shown in annexure 1.

2. Page 16, insert "wherein the oral dosage form is a tablet, and" on lines 3 and 4 of claim 3, as shown in annexure 1.

3. Page 16, insert "900 ml of" on line 6 of claim 3, as shown in annexure 1.

4. Page 17, delete "any one of preceding claims" on line 1 of claim 8 and insert "claim 1 or 2", as shown in annexure 1.

5. Page 17, insert "are in tablet form and" at the start of line 4 of claim 11 and replace the word "comprises" with "comprise" at line 4 of claim 11 and delete the words "in an amount of from 2 mg to 4 mg" on lines 4 and 5 of claim 11, as shown in annexure 1.

6. Page 18, replace the word "unit" with "units" on line 6 of claim 11 and insert "900 ml of" on line 7 of claim 11, as shown in annexure 1.

7. Page 20, delete the words "any one of claims 9 to 23" on line 1 of claim 24 and insert "claim 9 or 10" on line 1 of claim 24 and delete "and is in the form of a in the form of a" and insert the words "are in" on line 2 of claim 24 and delete the word "a" before the words "pill" and "capsule" and insert the word "form" on line 2 of claim 24, as shown in annexure 1.

8. Page 20, insert "3 mg of" and delete the words "in an amount in the range of from 2 mg to 4 mg of" on line 2 of claim 27 and insert the word "wherein" on line 4 of claim

27 and delete the word "a" on line 5 of claim 27 and insert "tablet" and "and" and "tablet" on line 5 of claim 27 and insert "900 ml of" on line 6 of claim 27, as shown in annexure 1.

9. Page 20, delete "any one of claims 25 to 27" and insert "claim 25 or 26" on line 1 of claim 28.

10. Page 21, delete "an amount" and insert "3 mg" on line 2 of claim 32 and delete "in the range of from 2 mg to 4 mg" on lines 2 and 3 of claim 32 and insert "wherein" on line 5 of claim 32 and delete "a" and insert "tablet" on line 5 of claim 32 and insert the word "and" and "tablet" on line 6 of claim 32 and insert "900 ml of" on line 7 of claim 32, as shown in annexure 1.

11. Page 23, delete "drospirennoe" and insert "drospirenone" on line 2 of claim 45, as shown in annexure 1.

APPLICANTS' ADDRESS FOR SERVICE

Davies Collison Cave Law
Level 15, 1 Nicholson Street
MELBOURNE VIC 3000
Tel: (03) 9254 2888
Fax: (03) 9254 2880

Attention: Ian Pascarl and Penny Smith

RESPONDENTS' ADDRESS FOR SERVICE

Middletons
Level 26, 52 Martin Place
SYDNEY NSW 2000
Tel: (02) 9513 2327
Fax: (02) 9513 2399

Attention: Jane Owen

OPPOSITION

Any person or corporation intending to oppose the application not being a party to the proceedings must not later than 28 days after the publication of this advertisement, give written notice of that intention to each of the Commissioner of Patents, the Applicants Bayer Pharma Aktiengesellschaft and Bayer Australia Limited and the Respondents Generic Health Pty Ltd and Lupin Australia Pty Limited at the above addresses for service.

Annexure 1

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The claims defining the invention are as follows:

1. A pharmaceutical composition in oral dosage form comprising from 2 mg to 4 mg of micronised drospirenone and 0.01 mg to 0.05 mg of ethinylestradiol, together with one or more pharmaceutically acceptable carriers or excipients.

2. A pharmaceutical composition in oral dosage form comprising from 2 mg to 4 mg of drospirenone and 0.01 mg to 0.05 mg of ethinylestradiol, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone has a surface area of more than 10 000 cm^2/g,

3. A pharmaceutical composition in oral dosage form comprising:
~~from 2 mg to 4 mg~~3 mg of drospirenone and 0.01 mg to 0.05 mg of ethinylestradiol, together with one or more pharmaceutically acceptable carriers or excipients, wherein the oral dosage form is a tablet, and
wherein at least 70% of said drospirenone is dissolved from said composition within 30 minutes, as determined by USP XXIII Paddle Method II using 900 ml of water at 37°C as the dissolution media and 50 rpm as the stirring rate.

4. The composition according to any one of claims 2 or 3, wherein drospirenone is sprayed from a solution of drospirenone onto particles of an inert carrier.

5. The composition according to any one of preceding claims, wherein the ethinylestradiol is in micronized form or sprayed from a solution onto particles of an inert carrier.

6. The composition according to any one of preceding claims, wherein the one or more pharmaceutically acceptable excipients is a sugar, a sugar alcohol and/or a starch,
the sugar being selected from lactose, glucose and sucrose,
the sugar alcohol being selected from mannitol, sorbitol and xylitol,

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the starch being selected from wheat, corn or potato starch, modified starch and sodium starch glycolate.

7. The composition according to any one of preceding claims, wherein the one or more pharmaceutically acceptable excipients is selected from polyvinylpyrrolidone, cellulose derivatives, carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose and gelatine.

8. The composition according to ~~any one of preceding claims~~claim 1 or 2 in the form of a tablet, a pill or a capsule.

9. A pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units comprises a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg, and said drospirenone is in micronized form.

10. A pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units comprises a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg,
wherein said drospirenone has a surface area of more than 10 000 cm2/g.

11. A pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units are in tablet form and comprises a combination of 3 mg of drospirenone ~~in an amount of from 2 mg to 4 mg~~ and ethinylestradiol in an amount from 0.01 to 0.05 mg,

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wherein at least 70% of said drospirenone is dissolved from said dosage units within 30 minutes, as determined by USP XXIII Paddle Method II using 900 ml of water at 37°C as the dissolution media and 50 rpm as the stirring rate.

12. The preparation according to any one of claims 10 or 11, wherein drospirenone is sprayed from a solution of drospirenone onto particles of an inert carrier.

13. The preparation according to any one of claims 9 to 12, wherein the ethinylestradiol is in micronised form, or sprayed from a solution onto particles of an inert carrier.

14. The preparation according to any one of claims 9 to 13, which additionally comprises 7 or less daily dosage units containing no active agent intended for oral administration subsequent to the period of at least 21 consecutive days, the total number of daily dosage units being at least 28.

15. The preparation according to any one of claims 9 to 14, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 21, 22, 23 or 24, and wherein the number of daily dosage units containing no active agent is 7, 6, 5 or 4.

16. The preparation according to any one of claims 9 to 14, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 28, or a multiple of 28.

17. The preparation according to claim 16, wherein the multiple of 28 daily dosage units is 2 to 4 times 28.

18. The preparation according to any one of claims 16 or 17, which additionally comprises a number of daily dosage units comprising the combination of drospirenone and

ethinylestradiol of 21, 22, 23 or 24, and a number of daily dosage units containing no active agent of 7, 6, 5 or 4.

19. The pharmaceutical preparation according to any one of claims 9 to 14 intended for oral administration for a period of at least 28 consecutive days, wherein at least 21 of said daily dosage units comprises a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg, and wherein 7 or less of said daily dosage units contain ethinylestradiol alone in an amount from 0.01 to 0.05 mg.

20. The preparation according to claim 19, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 21, 22, 23 or 24, and wherein the number of daily dosage units comprising ethinylestradiol alone is 7, 6, 5 or 4.

21. The preparation according to any one of claims 9 to 13, wherein the number of daily dosage units comprising the combination of ethinylestradiol and drospirenone is for oral administration for a period of 2 or 3 times 28 consecutive days followed by administration of the combination of drospirenone and ethinylestradiol for 21, 22, 23 or 24 consecutve days, and subsequently administration of daily dosage units containing no active agent or administration of no daily dosage units, for 7, 6, 5 or 4 consecutive days.

22. The preparation according to any one of claims 9 to 21, wherein the combination of ethinylestradiol and drospirenone is in admixture with a sugar, a sugar alcohol and/or a starch,
the sugar being selected from lactose, glucose and sucrose,
the sugar alcohol being selected from mannitol, sorbitol and xylitol,
the starch being selected from wheat, corn or potato starch, modified starch and sodium starch glycolate.

23. The preparation according to any one of claims 9 to 23, wherein the combination of ethinylestradiol and drospirenone is in admixture with one or more pharmaceutically acceptable excipients selected from polyvinylpyrrolidone, cellulose derivatives,

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carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose and gelatine.

24. The preparation according to ~~any one of claims 9 to 23~~claim 9 or 10, wherein the daily dosage units ~~is in the form of a in the form of a~~are in tablet, ~~a~~ pill or ~~a~~ capsule form.

25. A method of inhibiting ovulation in a mammal, comprising orally administering, to said mammal micronised drospirenone in an amount in the range of from 2 mg to 4 mg of per day, together with ethinylestradiol in an amount of from 0.01 mg to 0.05 mg per day, said amounts being effective to inhibit ovulation in said mammal.

26. A method of inhibiting ovulation in a mammal, comprising orally administering, to said mammal drospirenone in an amount in the range of from 2 mg to 4 mg of per day, together with ethinylestradiol in an amount of from 0.01 mg to 0.05 mg per day, said amounts being effective to inhibit ovulation in said mammal, said drospirenone has a surface area of more than 10 000 cm2/g.

27. A method of inhibiting ovulation in a mammal, comprising orally administering, to said mammal 3 mg of drospirenone ~~in an amount in the range of from 2 mg to 4 mg of~~ per day together with ethinylestradiol in an amount of from 0.01 mg to 0.05 mg per day, said amounts being effective to inhibit ovulation in said mammal, wherein said drospirenone is in a tablet form, and wherein at least 70% of said drospirenone is dissolved from said tablet form within 30 minutes, as determined by USP XXIII Paddle Method II using 900 ml of water at 37°C as the dissolution media and 50 rpm as the stirring rate.

28. The method according to ~~any one of claims 25 to 27~~claim 25 or 26, wherein the amount of drospirenone is in the range of from 2.5 mg to 3.5 mg per day.

29. The method according to any one of claims 25 to 28, wherein the amount of ethinylestradiol is from 0.015 mg to 0.04 mg, per day.

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30. A method of preventing or treating androgen-induced disorders in a female mammal, comprising administering, to said mammal, an amount of micronised drospirenone in the range of from 2 mg to 4 mg per day, together with an amount of ethinylestradiol of from 0.01 mg to 0.05 mg per day, said amounts being effective to prevent or treat androgen-induced disorders in said mammal.

31. A method of preventing or treating androgen-induced disorders in a female mammal, comprising administering, to said mammal, an amount of drospirenone in the range of from 2 mg to 4 mg per day, together with an amount of ethinylestradiol of from 0.01 mg to 0.05 mg per day, said amounts being effective to prevent or treat androgen-induced disorders in said mammal, said drospirenone has a surface area of more than 10 000 cm2/g.

32. A method of preventing or treating androgen-induced disorders in a female mammal, comprising administering, to said mammal, ~~an amount~~3 mg of drospirenone ~~in the range of from 2 mg to 4 mg~~ per day, together with an amount of ethinylestradiol of from 0.01 mg to 0.05 mg per day, said amounts being effective to prevent or treat androgen-induced disorders in said mammal, wherein said drospirenone is in atablet form, and wherein at least 70% of said drospirenone is dissolved from said tablet form within 30 minutes, as determined by USP XXIII Paddle Method II using 900 ml of water at 37°C as the dissolution media and 50 rpm as the stirring rate.

33. The method according to any one of claims 30 to 32, wherein the androgen-induced disorder is acne.

34. The method according to any one of claims 25 to 29, comprising administering, to said mammal, on each day of at least 21 consecutive days, a daily dosage unit comprising a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg, followed by administering, on each day of 7 or less consecutive days, a daily dosage unit containing no active agent, or alternatively administering no daily dosage units for 7 or less consecutive days.

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35. The method according to claim 34, wherein the daily dosage units comprising the combination of drospirenone and ethinylestradiol are administered for 21, 22, 23 or 24 consecutive days, and wherein no daily dosage units or daily dosage units containing no active agent are administered for 7, 6, 5 or 4 consecutive days.

36. The method according to any one of claims 25 to 29, wherein the daily dosage units comprising the combination of drospirenone and ethinylestradiol are administered for 28 consecutive days.

37. The method according to any one of claims 25 to 29, wherein the daily dosage units comprising the combination of drospirenone and ethinylestradiol are administered for 2-4, times 28 consecutive days, followed by administration of the daily dosage units comprising the combination of drospirenone and ethinylestradiol for 21 consecutive days and subsequently administration of the daily dosage units containing no active agent, or alternatively no daily dosage units, for 7 consecutive days.

38. The method of claim 37, wherein the daily dosage units are administered for 2 or 3 times 28 consecutive days.

39. The method according to any one of claims 25 to 29 comprising administering, to said mammal, on each day of at least 21 consecutive days, a daily dosage unit comprising a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg, followed by administering, on each day of 7 or less consecutive days, a daily dosage unit containing ethinylestradiol alone in an amount of from 0.01 mg to 0.05 mg.

40. The method according to claim 39, wherein the daily dosage units comprising the combination of drospirenone and ethinylestradiol are administered for 21, 22, 23 or 24 consecutive days, and wherein the daily dosage units comprising ethinylestradiol alone are administered for 7, 6, 5 or 4 consecutive days.

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41. The method according to any one of claims 25 to 29, wherein the daily dosage units comprising the combination of drospirenone and ethinylestradiol are administered for 2-4, times 28 consecutive days, followed by administration of the daily dosage units comprising the combination of drospirenone and ethinylestradiol for 21 consecutive days and subsequently administration of the daily dosage units comprising ethinylestradiol alone for 7 consecutive days.

42. The method of claim 41, wherein the daily dosage units are administered for 2 or 3 times 28 consecutive days.

43. The method according to any one of claims 25 to 42, wherein drospirenone is sprayed from a solution onto particles of an inert carrier.

44. The method according to any one of claims 25 to 39, wherein the female mammal is a female human.

45. A pharmaceutical composition comprising as a first active agent ~~drospirennoe~~drospirenone and as a second active agent ethinylestradiol substantially as hereinbefore described with reference to Example 1.

Annexure 2

The claims defining the invention are as follows:

1. A pharmaceutical composition in oral dosage form comprising from 2 mg to 4 mg of micronised drospirenone and 0.01 mg to 0.05 mg of ethinylestradiol, together with one or more pharmaceutically acceptable carriers or excipients.

2. A pharmaceutical composition in oral dosage form comprising from 2 mg to 4 mg of drospirenone and 0.01 mg to 0.05 mg of ethinylestradiol, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone has a surface area of more than 10 000 cm^2/g,

3. A pharmaceutical composition in oral dosage form comprising:
3 mg of drospirenone and 0.01 mg to 0.05 mg of ethinylestradiol, together with one or more pharmaceutically acceptable carriers or excipients, wherein the oral dosage form is a tablet, and
wherein at least 70% of said drospirenone is dissolved from said composition within 30 minutes, as determined by USP XXIII Paddle Method II using 900 ml of water at 37°C as the dissolution media and 50 rpm as the stirring rate.

4. The composition according to any one of claims 2 or 3, wherein drospirenone is sprayed from a solution of drospirenone onto particles of an inert carrier.

5. The composition according to any one of preceding claims, wherein the ethinylestradiol is in micronized form or sprayed from a solution onto particles of an inert carrier.

6. The composition according to any one of preceding claims, wherein the one or more pharmaceutically acceptable excipients is a sugar, a sugar alcohol and/or a starch,
the sugar being selected from lactose, glucose and sucrose,
the sugar alcohol being selected from mannitol, sorbitol and xylitol,

the starch being selected from wheat, corn or potato starch, modified starch and sodium starch glycolate.

7. The composition according to any one of preceding claims, wherein the one or more pharmaceutically acceptable excipients is selected from polyvinylpyrrolidone, cellulose derivatives, carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose and gelatine.

8. The composition according to claim 1 or 2 in the form of a tablet, a pill or a capsule.

9. A pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units comprises a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg, and said drospirenone is in micronized form.

10. A pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units comprises a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg,
wherein said drospirenone has a surface area of more than 10 000 cm2/g.

11. A pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units are in tablet form and comprise a combination of 3 mg of drospirenone and ethinylestradiol in an amount from 0.01 to 0.05 mg,

wherein at least 70% of said drospirenone is dissolved from said dosage units within 30 minutes, as determined by USP XXIII Paddle Method II using 900 ml of water at 37°C as the dissolution media and 50 rpm as the stirring rate.

12. The preparation according to any one of claims 10 or 11, wherein drospirenone is sprayed from a solution of drospirenone onto particles of an inert carrier.

13. The preparation according to any one of claims 9 to 12, wherein the ethinylestradiol is in micronised form, or sprayed from a solution onto particles of an inert carrier.

14. The preparation according to any one of claims 9 to 13, which additionally comprises 7 or less daily dosage units containing no active agent intended for oral administration subsequent to the period of at least 21 consecutive days, the total number of daily dosage units being at least 28.

15. The preparation according to any one of claims 9 to 14, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 21, 22, 23 or 24, and wherein the number of daily dosage units containing no active agent is 7, 6, 5 or 4.

16. The preparation according to any one of claims 9 to 14, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 28, or a multiple of 28.

17. The preparation according to claim 16, wherein the multiple of 28 daily dosage units is 2 to 4 times 28.

18. The preparation according to any one of claims 16 or 17, which additionally comprises a number of daily dosage units comprising the combination of drospirenone and

ethinylestradiol of 21, 22, 23 or 24, and a number of daily dosage units containing no active agent of 7, 6, 5 or 4.

19. The pharmaceutical preparation according to any one of claims 9 to 14 intended for oral administration for a period of at least 28 consecutive days, wherein at least 21 of said daily dosage units comprises a combination of drospirenone in an amount of from 2 mg to 4 mg and ethinylestradiol in an amount from 0.01 to 0.05 mg, and wherein 7 or less of said daily dosage units contain ethinylestradiol alone in an amount from 0.01 to 0.05 mg.

20. The preparation according to claim 19, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 21, 22, 23 or 24, and wherein the number of daily dosage units comprising ethinylestradiol alone is 7, 6, 5 or 4.

21. The preparation according to any one of claims 9 to 13, wherein the number of daily dosage units comprising the combination of ethinylestradiol and drospirenone is for oral administration for a period of 2 or 3 times 28 consecutive days followed by administration of the combination of drospirenone and ethinylestradiol for 21, 22, 23 or 24 consecutve days, and subsequently administration of daily dosage units containing no active agent or administration of no daily dosage units, for 7, 6, 5 or 4 consecutive days.

22. The preparation according to any one of claims 9 to 21, wherein the combination of ethinylestradiol and drospirenone is in admixture with a sugar, a sugar alcohol and/or a starch,
the sugar being selected from lactose, glucose and sucrose,
the sugar alcohol being selected from mannitol, sorbitol and xylitol,
the starch being selected from wheat, corn or potato starch, modified starch and sodium starch glycolate.

23. The preparation according to any one of claims 9 to 23, wherein the combination of ethinylestradiol and drospirenone is in admixture with one or more pharmaceutically acceptable excipients selected from polyvinylpyrrolidone, cellulose derivatives,

carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose and gelatine.

24. The preparation according to claim 9 or 10, wherein the daily dosage units are in tablet, pill or capsule form.

25. A method of inhibiting ovulation in a mammal, comprising orally administering, to said mammal micronised drospirenone in an amount in the range of from 2 mg to 4 mg of per day, together with ethinylestradiol in an amount of from 0.01 mg to 0.05 mg per day, said amounts being effective to inhibit ovulation in said mammal.

26. A method of inhibiting ovulation in a mammal, comprising orally administering, to said mammal drospirenone in an amount in the range of from 2 mg to 4 mg of per day, together with ethinylestradiol in an amount of from 0.01 mg to 0.05 mg per day, said amounts being effective to inhibit ovulation in said mammal, said drospirenone has a surface area of more than 10 000 cm2/g.

27. A method of inhibiting ovulation in a mammal, comprising orally administering, to said mammal 3 mg of drospirenone per day together with ethinylestradiol in an amount of from 0.01 mg to 0.05 mg per day, said amounts being effective to inhibit ovulation in said mammal, wherein said drospirenone is in tablet form, and wherein at least 70% of said drospirenone is dissolved from said tablet form within 30 minutes, as determined by USP XXIII Paddle Method II using 900 ml of water at 37°C as the dissolution media and 50 rpm as the stirring rate.

28. The method according to claim 25 or 26, wherein the amount of drospirenone is in the range of from 2.5 mg to 3.5 mg per day.

29. The method according to any one of claims 25 to 28, wherein the amount of ethinylestradiol is from 0.015 mg to 0.04 mg, per day.

41. The method according to any one of claims 25 to 29, wherein the daily dosage units comprising the combination of drospirenone and ethinylestradiol are administered for 2-4, times 28 consecutive days, followed by administration of the daily dosage units comprising the combination of drospirenone and ethinylestradiol for 21 consecutive days and subsequently administration of the daily dosage units comprising ethinylestradiol alone for 7 consecutive days.

42. The method of claim 41, wherein the daily dosage units are administered for 2 or 3 times 28 consecutive days.

43. The method according to any one of claims 25 to 42, wherein drospirenone is sprayed from a solution onto particles of an inert carrier.

44. The method according to any one of claims 25 to 39, wherein the female mammal is a female human.

45. A pharmaceutical composition comprising as a first active agent drospirenone and as a second active agent ethinylestradiol substantially as hereinbefore described with reference to Example 1.