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Date 20.05.2014  
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Sheet 1  
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Anmelde-Nr:  
Application No: 09 828 425.0  
Demande n°:

EP 2512444

The examination is being carried out on the **following application documents**

**Description, Pages**

1-26 as originally filed

**Claims, Numbers**

1-15 received on 11-10-2011 with letter of 06-10-2011

1 This is in reply to you letters of 06-10-2011 and 05.12.2013.

**2 Amendments (Article 123(2) EPC)**

2.1 The amendments filed with the letter dated 06-10-2011 introduce subject-matter which extends beyond the content of the application as originally filed, contrary to Article 123(2) EPC. The amendments/features concerned are the following:

2.2 In claims 4-11 and 13, there is a separate second sentence present. This is not in accordance with Article EPC (see point 3.1 below). Furthermore, the features present in these sentences are not disclosed in the application as originally filed. Consequently, the subject-matter of the amended claims 4-11, 13 does not meet the requirements according to Article 123(2) EPC.

2.3 The subject-matter of claim 13 does not fulfil the requirements of Article 123(2) EPC, because there is no basis in the application as originally filed for vaginal, oral and nose suppositories, and for "glyceride-type fatty, fatty vehicles, adeps solidus, macrogol". This claim should be deleted.

2.4 When amending, the Applicant is requested to identify those passages in the specification as originally filed on which the amendments are based (Guidelines H-III, 2.2).

**3 Clarity (Article 84 EPC)**

The application does not meet the requirements of Article 84 EPC, because the subject-matter of claims 1-13 is not clear.

- 3.1 Claims 4-11 and 13 do not comply with Rule 43(1) EPC, since they contain several sentences and are not in the two-part form, with those features known in combination from the prior art being placed in the preamble (Rule 43(1)(a) EPC) and the remaining features being included in the characterising part (Rule 43(1)(b) EPC). As a result the subject-matter of said claims is unclear (Article 84 EPC).
- 3.2 In claims 1, 2, 4-11 brackets are used. The applicant is requested to remove these brackets, which are generally not permissible since lack of clarity may arise (cf. Guidelines, F-IV, 4.19).
- 3.3 The term "similar" used in claims 3 and 12 is unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claims unclear (Article 84 EPC). Because the description does not provide further information on what is "similar" this term should be deleted.

4 **Rule 45(3) EPC**

The fees for claims 16-38 were not paid, and therefore are considered to be abandoned according to Rule 45(3) EPC. Said claims will not be examined and should therefore be deleted.

5 **Prior Art**

- 5.1 Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure:

D1 DATABASE WPI, Week 200143, Thomson Scientific, London, GB;  
AN 2001-399065, XP002618347,  
& CN 1 290 538 A (WAN D) 11 April 2001

D2 "Suppositorien, Vaginalzubereitungen, Stifte"; "Chapter 13"  
In: Bauer, Frömming, Führer (Eds): "Pharmazeutische  
Technologie", 1993, Georg Thieme Verlag, Stuttgart,  
XP002618348, ISBN: 3-13-692504-1, vol. 4, pages 272-277



D3 "Homöopathische Zubereitungen und Darreichungsformen";  
"Chapter 19"  
In: Bauer, Frömming, Führer (Eds): "Pharmazeutische  
Technologie", 1993, Georg Thieme Verlag, Stuttgart,  
XP002618349, ISBN: 3-13-692504-1, vol. 4, pages 382-388

D4 J. Tukker: "Rectal and vaginal drug delivery"; "Chapter 34"  
In: M.E. Aulton (Ed): "Pharmaceutics. The science of dosage form  
design", 2002, Churchill Livingstone, Edinburgh, XP002618350,  
ISBN: 0443055173, vol. 2, pages 534-543

5.2 The following documents are cited by the Examiner. A copy of the documents  
is annexed to the communication and the numbering will be adhered to in the  
rest of the procedure.

D5a CN 1 739 645 A (GUIZHOU YIBAI PHARMACEUTICAL) 1 March  
D5b 2006

machine translation CN 1 739 645 A

D6 SCHELLERER S: "DEM SCHNUPFEN EIN SCHNIPPCHEN  
SCHLAGEN",  
PHARMAZEUTISCHE ZEITUNG, vol. 148, no. 37, 11 September  
2003, pages 16-25, XP001247323, ISSN: 0031-7136

D7 US 6 541 045 B1 (CHARTERS ET AL) 1 April 2003

5.3 **The third-party observation filed with the letter of 05.08.2013 has been taken  
into account.**

## 6 **Inventive step (Article 56 EPC)**

The present application does not meet the requirements of Article 52(1) EPC,  
because the subject-matter of claims 1-15 does not involve an inventive step  
in the sense of Article 56 EPC.

6.1 Document D5 can be considered to represent the most relevant state of the  
art to the subject matter of claim 1, discloses a medicinal preparation  
comprising seven herbal medicinal materials among which Ephedrae and  
armeniacaе amara for use in treating cough. The preparation can be in the  
form of a tablet, capsule, oral liquid, syrup, granular formulation, pill, powder,  
injection, suppository, emulsion, patch, etc.

The subject-matter of independent claim 1 differs from the disclosure of D5 in that it contains additionally the spagyric plants *Drosera rotundifolia*, *Hydrastis canadensis*, *Thymus vulgaris*, Propolis, *Catharanthus roseus*, *Bryonia alba*, *Sambucus nigra*, *Mandragora officinalis*.

The technical effect brought by these differences is neither shown, nor substantiated in the description.

In the description, only the preparation of the suppositories is described.

With the letter of 6-10-2011 experimental data was provided that the claimed suppositories resulted in a decrease of the symptoms of dry cough. These data were again presented in the letter of 05.12.2013.

However, no data were presented in which the claimed spagyric suppositories present unexpected effects or properties in comparison with known suppositories.

The underlying technical problem to be solved by the present application may be regarded as how to provide an alternative pharmaceutical composition.

Like *ephedrae* and *armeniaca* amara, the plants *Drosera rotundifolia*, *Hydrastis canadensis*, *Thymus vulgaris*, Propolis, *Catharanthus roseus*, *Bryonia alba*, *Sambucus nigra*, *Mandragora officinalis* have been used in cough medication as well. See e.g. D6 (page 18, lines 24-29; page 21, left-hand column, lines 32-39), D7 (claims 10-26).

The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein all plants are previously known for treating the same disorder is considered to be an obvious combination.

Furthermore, the preparation of spagyric mixtures and suppositories according to homeopathic methods is common knowledge (see document D3).

The skilled person would therefore regard it as a normal option to include more spagyric plants in the preparation described in D5 in order to solve the problem posed.

Consequently, the solution proposed in claim 1 of the present application cannot be considered to involve an inventive step (Article 56 EPC).

## 6.2 DEPENDENT CLAIMS 2-15

Dependent claims 2-15 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements with respect of inventive step. The features claimed in these dependent claims are

either derivable from D5 in combination with D6/D7 (e.g. the presence of additional plants in claims 4-11), or from D5 with D3 (e.g. the process feature in claims 2, 12), or they concern minor modifications and routine experimentation which lie in the normal practice of the skilled person (e.g. the use of certain excipients for the suppositories in claims 13-15).

7 **Further remarks**

- 7.1 To meet the requirements of Rule 42(1)(b) EPC, the documents D1-D7 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.
- 7.2 Although the language of the proceedings application is English, parts of the description are in German, and part of claim 6 is in Italian. This is not in accordance with Article 14(1) and (2) EPC which state that a European patent application shall be filed in **one** of the **official** languages English, French and German..
- 7.3 In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see Guidelines H-III, 2.1).
- 7.4 Finally it is noted that, having regard to Rule 137(3) EPC, amendments going in all kind of different directions (which may be considered in view of the very different nature of the dependent claims) will be objected to.