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

Description, Pages

1-10 as published

Claims, Numbers

1-15 filed with entry into the regional phase before the EPO

Amendments (Article 123(2) EPC)

The amended claims filed with the entry into the regional phase before the EPO introduce subject-matter going beyond the disclosure of the application as originally filed, contrary to the requirements of Art. 123(2) EPC. The amendments mentioned are the following:

claim 7

There is no basis in the application as originally filed for the amount of lithium in the lithium salt being from 1.5 to 4.9 mg. The passages cited by the applicant in support of amended claim 7 do not teach such a range. Page 5, lines 21-22 discloses a range from 1.5 to 10 mg, page 10, lines 7-9 discloses a gelatin capsule comprising 4.9 mg of lithium as lithium orotate. The disclosure of a single value of lithium content in a capsule cannot be combined with a general disclosure of a range of lithium content in a formulation to form a new, originally undisclosed range. Such a combination violates the requirements of Art. 123(2) EPC.

claim 10

No basis can be found for the combination to be taken from once every other day to at least once per day. Page 7, lines 7-8 teaches that an individual may take one capsule every other day to prevent symptoms and may take one to three capsules three times a day to relieve the symptoms. Thus in fact, the amount of one capsule every other day is a separate dosage regiment rather than a lower limit of a range as presently claimed. No disclosure of one capsule very other day, being the upper limit of the dosage range presently claimed, is to be found in the cited passage at all.

claim 11

No general disclosure of the combination to be taken for more than four weeks as a preferred embodiment is to be found in the application as originally filed. Page 9, line 25 does not provide sufficient basis for this feature as firstly, it concerns a specific combination of active agents of Example 2 and secondly, the four weeks appear to be disclosed as a period during which the patient did not experienced any further gout symptoms or any adverse effect following the treatment with the combination for the first four days on regimen of Example 2 and four additional days of regimen of Example 1 (see page 9, line 19 and lines 22-24). Thus, the actual treatment disclosed in Example 2 is eight days rather than more than four weeks as presently claimed.

claim 12

The fact that the treatment with the claimed combination causes no gastrointestinal distress is disclosed in the passage cited by the applicant (page 10, lines 11-14) only for the specific therapeutic combination of Example 3. There is no general disclosure in the application as originally filed that the present combination causes no gastrointestinal distress over the whole scope claimed.

claim 13

No disclosure of the use of the therapeutic combination wherein the symptoms are relived within three days after the initiation of ingestion thereof is to be found in the application as originally filed. The disclosure at page 10, lines 10-12 cannot provide sufficient basis for this feature as firstly, it is restricted to a specific combination of active agents of the capsules of Example 3, and secondly, it teaches that a patient takes said capsules for two to four days until all gout symptoms are are ablated.

For the above reasons claims 7, 10-13 are not allowable under Art. 12382) EPC. No opinion on novelty/inventiveness of these claims will be provided in this communication.

Cited documents

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

D1 "Nuskha-e- Sang-e- Gurda",
TKDL,, 1 January 1909 (1909-01-01), XP003028851,

D2 WO 00/40258 A1 (INT CELERY DEV ALLIANCE PTY LT [AU]; BUTTERS DESLEY ETHEL [AU]; DAVIS) 13 July 2000 (2000-07-13)

D3 DATABASE WPI, Week 200869 17 November 2007 (2007-11-17) Thomson Scientific, London, GB; AN 2008-L74769 & CN 101 007 015 A (BEIJING TIANCHUAN JUNWEI MEDICINE TECH DEV CO LTD) 1 August 2007 (2007-08-01)

D4 JACOB ROBERT A ET AL: "Consumption of cherries lowers plasma urate in healthy women.", JOURNAL OF NUTRITION, vol. 133, no. 6, June 2003 (2003-06), pages 1826-1829, ISSN: 0022-3166

D5 US 2001/002407 A1 (NAIR MURALEEDHARAN G [US] ET AL) 31 May 2001 (2001-05-31)

D6 WO 2008/016823 A2 (PLEVA RAYMOND [US]) 7 February 2008 (2008-02-07)

D7 DATABASE WPI, Week 200805 23 May 2007 (2007-05-23)Thomson Scientific, London, GB; AN 2008-A59881 & CN 1 965 858 A (UNIV LANZHOU) 23 May 2007 (2007-05-23)

Unless indicated otherwise reference is made to the passages considered relevant in the search report.

Third party observations (Article 115 EPC)

The examining division notes that third party observations have been filed on 01.06.2011 with a letter of 24.05.2011.

The Examining Division has taken the translated references and the corresponding comments into consideration. However none of these exhibits discloses a composition comprising a combination of the three active ingredients as presently claimed - an extract of celery, an extract of cherry, and a lithium salt. Exhibit 9 (Mohammad Akmal Khan) discloses compositions comprising two out of the three active ingredients - celery extract and cherry extract. This document is cited herein as D1.

The other documents that disclose the use of single ingredients - celery or cherry- for the treatment of gout, renal stones, urinary calculus, etc. have been considered, they are however not cited herein as they do not add any information to the prior art documents on file.

Novelty (Article 54 EPC)

The subject-matter of independent claims 1, 9 and 14 is considered to be novel in terms of Art. 54 EPC as none of the cited documents discloses a combination of an extract of celery, an extract of cherry, and a lithium salt, as presently claimed.

Inventive step (Article 56 EPC)

The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1-6, 8, 9, 14, 15 does not involve an inventive step within the meaning of Article 56 EPC.

The problem to be solved by the present application is the provision of an agent for relieving or preventing symptoms associated with uric acid crystals. The solution as claimed is a therapeutic combination of three active ingredients: an extract of celery, an extract of cherry, and a lithium salt. The use of the single components of the claimed combination for the same purpose is known from the prior art - see D2, D3 for celery extracts, D4-D6 for cherry extracts and D7 for lithium salts. Use of a combination of known agents for a known therapeutic application can be considered inventive only if such a combined use provides for an unexpected beneficial technical effect superior to the sum of the effects of the components when used alone (i.e. synergism). However, no such superior effect of the presently claimed combination is shown by the application. In the absence of an superior technical effect, the claimed composition represents a mere juxtaposition of known components using their known properties, which cannot be considered inventive. Thus, independent claims 1, 9 are considered to lack an inventive step in terms of Art. 56 EPC.

Furthermore, D1 solves the same technical problem as the present application - treatment of nephrolit/ renal stone, and cystolith, which are conditions falling within the scope of symptoms associated with uric acid crystals, by a formulation comprising *inter alia* extract of celery seeds and extract from sour cherry stones. Taking D1 as the closest prior art, the presently claimed subject-matter differs over the solution of D1 in that a lithium salt is added to the composition. However, it is known from the prior art that lithium carbonate is effective in the prevention and treatment or renal calculus (D7), therefore, it would have been obvious to a person skilled in the art to combine the teachings of D1 and D7 and the claimed solution cannot be considered inventive. Moreover, the addition of (a) lithium salt to the composition of D1 is not shown to provide any technical effect which would not have been already provided by the composition of D1. As the feature distinguishing the claimed subject-matter over the closest prior art does not bring any technical effect, no inventiveness can be acknowledged for the subject-matter of independent claims 1 and 9.

The subject-matter of independent claim 14 cannot be considered inventive in terms of Art. 56 as mixing together three known active ingredients and forming the mixture into a medicament is a common technique within ordinary skills of a person skilled in the art.

None of the features of dependent claims 2-6, 8 and 15 can be considered to convey inventiveness to the subject-matter claimed. The claimed contents of ingredients (claims 2-5) are arbitrary choices with no shown technical effects. The choice of sweet cherries (claim 3) would be obvious in view of D4 or D5, the choice of lithium carbonate as a preferred lithium salt (claim 6) would be obvious from D7. The use of celery seed extract and (claim 15) is disclosed in D1-D3, cherry fruit extract (claim 15) is disclosed in D5, D6. The choice of Prunus maackii as the preferred cherry (claim 8) is not shown to provide for any technical effect.

Concluding remarks

It is not at present apparent which part of the application could serve as a basis for a new, allowable claim. Should the applicant nevertheless regard some particular matter as patentable, an independent claim should be filed taking account of Rule 43(1) EPC. The applicant should also indicate how the subject-matter of the new claim differs from the state of the art and the significance thereof.

In order to comply with the requirements of Rule 137(4) EPC, the applicant should clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (see Guidelines H III, 2.1).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

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SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 09 84 4722

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
Y	"Nuskha-e- Sang-e- Gurda", TKDL,, 1 January 1909 (1909-01-01), XP003028851, * the whole document *	1-15	INV. A61K36/736 A61P13/04 A61P19/06 A61K33/00
Y	WO 00/40258 A1 (INT CELERY DEV ALLIANCE PTY LT [AU]; BUTTERS DESLEY ETHEL [AU]; DAVIS) 13 July 2000 (2000-07-13) * page 4, line 16 - line 23 * * page 2, line 22 - line 30 * * page 14, line 4 - line 11 * * page 19, line 10 - line 17 * * page 15, line 13 - line 30 *	1-15	A61K36/23
Y	DATABASE WPI Week 200869 17 November 2007 (2007-11-17) Thomson Scientific, London, GB; AN 2008-L74769 XP002690497, & CN 101 007 015 A (BEIJING TIANCHUAN JUNWEI MEDICINE TECH DEV CO LTD) 1 August 2007 (2007-08-01) * abstract *	1-15	TECHNICAL FIELDS SEARCHED (IPC) A61K A61P
Y	JACOB ROBERT A ET AL: "Consumption of cherries lowers plasma urate in healthy women.", JOURNAL OF NUTRITION, vol. 133, no. 6, June 2003 (2003-06), pages 1826-1829, XP002690498, ISSN: 0022-3166 * abstract *	1-15	
Y	US 2001/002407 A1 (NAIR MURALEEDHARAN G [US] ET AL) 31 May 2001 (2001-05-31) * paragraphs [0007], [0034] - [0039], [0075] *	1-15	

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The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
Munich	18 January 2013	Böhmerova, Eva

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 09 84 4722

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
Y	WO 2008/016823 A2 (PLEVA RAYMOND [US]) 7 February 2008 (2008-02-07) * paragraphs [0013], [0014], [0029], [0030] * -----	1-15	
Y	DATABASE WPI Week 200805 23 May 2007 (2007-05-23) Thomson Scientific, London, GB; AN 2008-A59881 XP002690499, & CN 1 965 858 A (UNIV LANZHOU) 23 May 2007 (2007-05-23) * abstract * -----	1-15	
Y	EP 0 068 854 A1 (HORROBIN DAVID F [CA]; LIEB JULIAN [US]) 5 January 1983 (1983-01-05) * page 3, last paragraph - page 4, line 2 * * page 2, paragraph 3 - paragraph 4 * * page 5, last paragraph - page 6, paragraph 1 * -----	1-15	TECHNICAL FIELDS SEARCHED (IPC)

The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
Munich	18 January 2013	Böhmerova, Eva

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 09 84 4722

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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18-01-2013

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