EP 2448577

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

Description, Pages

1-11 as published

Claims, Numbers

1-4 received on 10-06-2013 with letter of 10-06-2013

Drawings, Sheets

1/2, 2/2 as published

Reference is made to the following documents cited in the supplementary European search report;

D1 DE 20 2010 004750 U1 (BIOFRONTERA BIOSCIENCE GMBH [DE]) 11 October 2011 (2011-10-11)

D2 US 2006/286054 A1 (GOMEZ HECTOR J [US]) 21 December 2006 (2006-12-21)

D3 CN 1 085 600 A (DISHENG NEW TECHNOLOGY INST NA [CN]) 20 April 1994 (1994-04-20)

D4 US 6 440 465 B1 (MEISNER LORRAINE FAXON [US]) 27 August 2002 (2002-08-27)

D5 US 6 482 839 B1 (THORNFELDT CARL R [US]) 19 November 2002 (2002-11-19)

The following document is cited by the applicant; the numbering will be adhered to in the rest of the procedure.

D6 REUTER JULIANE ET AL: "Botanicals in dermatology: an evidence-based review.",
AMERICAN JOURNAL OF CLINICAL DERMATOLOGY 2010,
vol. 11, no. 4, 2010, pages 247-267,
ISSN: 1175-0561

Reference is also made to exhibits 01-07 submitted by third-parties and sent to the applicant on 18.07.2014.

Rule 164(2) EPC

Present claims 1-4 do not comply with the requirements of Rule 164(2) EPC for the following reasons;

In respect of the present application, an objection of lack of unity of invention was raised in the supplementary European search report. The Examining Division agrees with the finding of lack of unity of invention for the reasons indicated in the opinion accompanying the supplementary European search report (ESOP).

The applicant is reminded that a search has been performed only for invention 1 as defined in the ESOP. **Only this invention can therefore be elected (Rule 164(2) EPC).** The Applicant is asked to limit the application accordingly. Other inventions are to be excised from the claims, description and drawings.

For the sake of completeness, the searched invention is repeated below.

Invention 1:

A topical pharmaceutical composition for use in preventing or treating red face related skin disorders, comprising at least 0.02% w/w of berberine or a biologically equivalent analogue of berberine or pharmaceutically acceptable salts thereof, wherein the red face related skin disorder is ***rosacea****.*

The subject-matter to be excised may be made the subject of one or more divisional applications. The divisional applications must be filed with the European Patent Office in Munich, The Hague or Berlin and shall be filed in the language of the proceedings relating to the present application (cf. Article 76(1) and Rule 36(2) EPC).

In the letter of 10.06.2013, the applicant argued that the single general inventive concept linking the inventions as defined in the ESOP is "a pharmaceutical composition comprising berberine or the biologically equivalent thereof as the only pharmaceutically active component".

The Examining Division respectfully disagrees with such statement. The wording of the claims as submitted for entry into the European regional phase, as well as the wording of present claims, does not exclude the presence of other additional components including active agents in the composition. In particular, the term "comprising" is to be construed as "including", comprehending", "containing" (Guidelines F-IV,4.21). It is to be noted that the link between the

inventions required by Article 82 EPC must be a technical relationship which finds expression in the claims in terms of the same or corresponding special technical features (Guidelines F-V-2). Therefore, the single general inventive concept linking inventions 1-7 (and present claims), is the use of a topical pharmaceutical composition comprising at least 0.02% w/w berberine in the treatment of red face skin disorders. Said common concept is already known from D1 and D3 (see ESOP).

Moreover, the common concept identified by the applicant can not, in any case, fulfill the role of "single general inventive concept", particularly in view of D1, from which it results that the antipsoriatic effects of the compositions of D1 are to be attributed to berberine (paragraphs [0018] and [0053]). Thus, "the use of berberine as the only pharmaceutically active agent for the treatment of red face related disorders", would in any case lack inventive step over said document.

Third-party observations

Third-party observations were submitted on 02.07.2014. However, in view of the objections under Rule 164(2) EPC, the assessment of the relevancy of these documents is postponed to a further stage of the procedure.

Remarks

The applicant is invited to file a new (independent) claim which takes account of the above comments.

Should the objections raised not be overcome by suitable amendments, the next step envisaged by the Examining Division is a summons to oral proceedings as requested by the applicant in order to discuss the outstanding subject-matter and if possible reach a final decision on patentability.