

STATUS AND APPLICATIONS

I. Patent EP 1 429 795 was granted following the European patent application no. 02 777 223.5, filed on 26.09.2002, claiming priority DE 10147644 of 27.09.2001. The granting of the patent was published on 13.06.2007 in Patent Bulletin 2007/24. Dr Willmar Schwabe GmbH & Co. KG is the proprietor of the patent.

II. Notices of opposition against the patent were filed by the following Opponents:

1. Frutarom Schweiz AG, on 10.03.2008 (hereinafter referred to as OI);
2. African Centre for Biosafety and Bern declaration, on 12.03.2008 (hereinafter referred to as OII);
3. Alpinamed AG, on 11.03.2008 (hereinafter referred to as OIII);
4. Finzelberg GmbH & Co. KG, on 13.03.2008 (hereinafter referred to as OIV).

All the notices of opposition were against the granted patent in its entirety. All the Opponents alternatively applied for a hearing.

- III. OI invoked lack of novelty and Inventive step (Art. 100a & 54 and 56 EPC) and lack of disclosure (Art. 100b & 83 EPC) against the contested patent. This was accompanied by the filed evidentiary documents D1-D7 (see Annexure 1).
- IV. OII based his objection on non-patentability of the subject matter, with reference to Art. 54, 53a, 53b, 84 and 83 EPC. OII submitted D8-14 (see Annexure 1) as evidence.
- V. OIII invoked lack of novelty and Inventive step (Art. 100a & 54 and 56 EPC) against the contested patent. OIII submitted documents D15-D24 (see Annexure 1) as evidence.
- VI. OIV argued that the subject matter of the patent in-suit was not new (Art. 100a & 54 EPC) and that it is obvious to the skilled person (Art. 100a & 56 EPC). Documents D24-D31 (see Annexure 1) were submitted as evidence.

VII. In his submission dated 18.12.2008, the proprietor of the patent applied for rejection of the notices of opposition and to maintain the patent in the form of a new main application. He submitted the documents D32 and D33. A hearing was alternatively requested.

Claim 1 of the main application reads (changes to the granted claim are printed in **bold**):

Process for the production of a *Pelargonium sidoides* and/or *Pelargonium reniforme* extract, characterised by the *Pelargonium sidoides* and/or *reniforme* roots either being subjected to

a) percolation with an aqueous ethanolic solvent, the drug residue optionally being slightly squeezed and the raw extract optionally filtered,

whereby, during percolation, the substance is mashed with an aqueous ethanolic solvent before the actual percolation, and

mashing and percolation is performed with different concentrations of aqueous ethanol,

whereby the weighted average concentration of the aqueous ethanol used in mashing and percolation is in the range of 10-92 % by weight, or

b) a two-step maceration with an aqueous ethanolic solvent, wherein the extract solution is filtered out after the first maceration and the drug residue is macerated a second time and the extract solutions are combined after the solid/liquid separation,

wherein the aqueous ethanolic solvent is 10-92 % ethanol by weight.

PRELIMINARY OPINION OF THE OPPOSITION DIVISION

1. Admissibility of the notices of opposition

All the notices of opposition are admissible, since they comply with the requirements of Articles 99(1) and 100 EPC and with rules 1(1) and 76 EPC.

The opposition document of OII did not state the grounds (R. 76(2)c EPC) on 10.03.2008. This was later submitted in time on 12.03.2008. OII submitted a joint notice of opposition in the name of "the African Centre for Biosafety" and the "Bern declaration". Documents were submitted on 21.05.2008 as evidence of the legal form and the authorised signatories for this Opponent.

2. Admissibility of the new main application

Claim 1 is based on a combination of the granted claims 1, 3, 4, 5 and 7 (corresponding to claims 1, 3, 4, 5 and 7 of the originally filed version). The opposition division is therefore provisionally of the opinion that the requirements of Art. 123(2) and (3) EPC have been complied with. The opposition division is furthermore of the opinion that these changes were precipitated by a ground for opposition based on Art. 100 EPC (R. 80 EPC).

3. Exceptions to patentability

OII has questioned the patentability of the patent in-suit under the conditions of Art. 53 EPC. It should therefore be examined whether one of the claimed subject matters is excluded from patentability under Art. 53 (a) or under Art. 53(b) EPC. The opposition division is of the opinion that the exceptions to patentability should be interpreted strictly (see ins. T 356/93, Grounds for decisions 8, AB11995, 545).

3.1. Art. 53 (a) EPC : "ordre public" and morality

Art. 53 (a) EPC prohibits patenting of "inventions, the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states".

The concept of “ordre public” also includes the protection of the environment. Under Article 53 (a) EPC, inventions that are likely to seriously jeopardise the environment if implemented, would therefore be excluded from patenting on the grounds of violating “ordre public”.

The concept of morality is linked to the conviction that a certain behaviour is correct and justifiable, but another is wrong, whereby this conviction is based on the totality of the accepted norms, deeply rooted in a certain culture. Article 53 (a) EPC therefore excludes patenting of inventions, the implementation of which would be in conflict with the accepted codes of conduct of such a culture, based on the violation of morality.

The second half of the Article 53 (a) EPC sentence qualifies that “such exploitation ... shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states”. This qualification explains that the question whether a subject matter violates “ordre public” or morality must be judged independent of possible national legal stipulations. Vice versa, a certain subject matter cannot, for the same reason, be judged compliant with the requirements of Article 53 (a) EPC, merely because its implementation is allowed in certain or all of the contracting states. Approval or prohibition of the implementation under national laws or regulations is therefore not a sufficient criterion for examination for compliance with Article 53 (a) EPC.

The question whether a claimed invention falls under the exception to patentability in accordance with Article 53 (a) EPC must therefore be answered based on the facts of each individual case, based on the abovementioned definition of the concepts of “ordre public” and “morality”. In this respect, the concrete facts of the particular case must be analysed and it must then be examined whether the patent applied for can be granted in view of these facts. As proof of validity of objections under Article 53 a) EPC against the claimed subject matter of the patent in-suit, OII cites the Convention on Biological Diversity (CBD), where it is stipulated that for inventions based on biological source materials originating from a biodiversity country, the two criteria of “previous informed consent” and “benefit sharing” should be examined (Art. 8 0), 15 and 16 CBD), with the comment that most of the EPC member states and also the country of origin of the original material (South Africa) are signatories of the CBD. OII furthermore refers to Article 49a PatG [*Patent Act*], Switzerland, in terms of which the patent should state the source of traditional knowledge of indigenous or local communities.

Since the proprietor of the patent has not yet provided proof of CBD compliance, OII argues that the patent in-suit violates Art. 53 (a) EPC.

The proprietor of the patent referred to §34a PatG of the German patent law, which states that the geographic place of origin of the biological subject material of the invention shall be named, but that the validity of the rights under granted patents shall remain unaffected hereby. The proprietor of the patent also remarked that the patent in-suit states in Paragraph [0002], line 5, that “*Pelargonium sidoides* is a plant that has traditionally been used as a medicine in southern Africa for a long time”, whereby at least the criteria of the German patent law have been complied with.

In the case at hand, it must be decided whether the use of any of the subject matter claimed in the patent in-suit is likely to seriously harm the environment or contravenes the generally accepted codes of conduct, at least in the European cultural environment. OII has not provided any conclusive evidence either of a threat to the environment or of the aforementioned contradiction. The CBD stipulations presuppose legal arrangements in the country of origin to create the necessary legal base, especially for Articles 8, 15 and 16. OII has not, however, submitted or even mentioned information on South African law, particularly to a law applicable on the priority date, if there was any. Statements on Swiss or German law may serve as orientation and to emphasize the relevancy and importance of the CBD in the European cultural environment, but cannot be considered decisive. In addition, it bears mentioning that the proprietor of the patent has not only met the criteria of the German patent law by disclosing the geographical place of origin of the biological subject material of the invention, but also asserts that he has obtained the required official collection and export licenses, that the sustainability of his actions is monitored and that various “benefit sharing” measures have been taken, even though the relevant law has only been enacted in April 2008. On the other hand, neither has the proprietor of the patent submitted any proof of his claimed actions.

In view of these facts, the opposition division is still of the provisional opinion that no violation of Art. 53 (a) EPC is in evidence, for the time being. The proprietor of the patent is, however, requested to provide evidence of his abovementioned assertions in the form of copies of the sustainability reports or relevant licenses, for instance, before the date for submissions set in the summons, in preparation for the hearing.

3.2. Art. 53 (b) EPC : Plant species

OII asserted that the process claims of the patent in-suit enable a legal monopoly under Art. 64 (2) EPC of the two plant species *Perlargonium sidoides* and *Perlargonium reniforme* and that the process claims constitute a circumvention of the exceptions to patentability under Art. 53b EPC, T 356/93.

The proprietor of the patent argued that the process claims protect solely the procedure for the production of an extract as specifically described in the claims.

The opposition division is of the provisional opinion that the subject matter of the process claims has reference to the production of an extract and not to the plant species as such. The claimed subject matter therefore does not appear to violate Art. 53b EPC.

4. Art. 83 EPC : Sufficient disclosure

OI was of the opinion that the description “in a 2:8 ratio” in the granted Claim 8 (corresponds to Claim 5 of the new main application) is unclear, since it could be referring to either the mashing or the percolation.

OII argued that the patent claims included two different inventions (percolation or two-step maceration) and that these claims contained many ambiguous individual concepts). Apart from that, he said, Section [0018] did not contain information on the geographical origin of the roots and donors, the duration and temperature of the individual processing steps and the duration and temperature of drying.

In reply, the proprietor of the patent referred to Example 1 of the patent in-suit.

The opposition division reminds the parties that objections pursuant to Art. 82 and 84 EPC are not considered reasons for opposition under Art. 100 EPC. The opposition division furthermore asserts that the patent in-suit discloses various examples of implementation. In accordance with the established case law of the EPO, the objection of insufficient disclosure can only be raised in case of serious doubts, supported by verifiable facts (T 19/90). The burden of proof is on the Opponents and has not been produced thus far.

The opposition division is provisionally of the opinion that the patent in-suit complies with the requirements of Art. 83 EPC.

5. Prior art

The parties submitted documents D1-D33 (see Annexure 1) as evidence. Regarding the relevancy of this evidence to the examination for novelty and inventive step, the opposition division is of the following provisional opinion.

The Umckaloabo® and Umckaloabo Stevenskur® commercial products and their use have been disclosed in D3-D5, D8, D9, D24 and D25. D25 discloses that Umckaloabo Stevenskur® is a 1:10 percolate of Radix Umckaloaboa (Geraniaceae).

D8 discloses the use of a medical drug (the so-called Stevenskur, see Page 2, lines 5-8 of the patent in-suit) based on the "Umckaloabo plant".

D11 (affidavit Milile Rwexu) discloses the use of **aqueous** extracts from *P. reniforme* and/or *P. sidoides* by Igqirhakazi (= "Xhosa Diviners" or traditional healers).

D13 (affidavit, Dr Stafford), discloses the general specialised knowledge with respect to maceration and percolation procedures using an aqueous ethanolic solvent.

D15 discloses the production of extracts from *P. reniforme* in accordance with production instructions 4a of the HAB 1 (homeopathic medicines book, submitted as D16). D16 refers to D17 (DAB 10, German Pharmacopoeia 10th edition), which generally discloses that tinctures can be produced both through maceration and through percolation.

6. Article 54, EPC : Novelty

All the Opponents were of the opinion that the subject matter of the granted claims was not new.

OI, OII and OIV were of the opinion that the Umckaloabo® (see D3-D5, D8, D9, D24) and Umckaloabo Stevenskur® (D25) commercial products were an alcoholic extraction from *P. reniforme* or *P. sidoides* DC roots and precluded novelty of the granted Claim 1.

OIII was of the opinion that D15+D16 precluded novelty of both process variants (percolation and maceration).

The opposition division is of the provisional opinion that no cited Prior art **directly** and **obviously** discloses **all** the characteristics of the claimed new process.

D15, but only in combination with D16 **and** D17 (DAB 10, German Pharmacopoeia, 10th edition) disclose most of the relevant process characteristics in context. These documents, however, do not discuss the process steps for mashing for the percolation variant and do not explicitly disclose a **two-step** maceration procedure.

7. Art. 56 EPC : Inventive step

In the interest of an objective and traceable assessment of the inventive step, the opposition division uses the so-called “problem-and-solution approach” (guidelines C-IV 11.7). The parties are requested to adapt their written and verbal inputs and arguments to comply with this method. Since Claim 1 clearly includes two variants (a percolation and a two-step maceration), it appears necessary in the opinion of the opposition division to (at least partially) make two assessments of the inventive step.

7.1. Determining the closest Prior art

All the Opponents refer to the Umckaloabo® commercial product (see D3-D5, D8, D9, D24) as the closest Prior art. Paragraph [0006] of the patent in-suit refers to D9, D3 and D25 in addition. The two variants of Claim 1 appear to differ in their closest Prior art, with respect to the type of solvent (aqueous ethanolic solvent with 10-92 % by weight).

7.2. Determination of the technical problem to be solved

According to [0008] of the patent in-suit, the problem to be solved is defined as the provision of an **improved** gentle method for the production of extracts from *P. sidoides* and *P. reniforme*. The patent in-suit discloses examples showing the effect of different solvents on the yield, the active ingredient and the pharmacological effect of extracts.

Since these were not necessarily assays to compare the subject matter of the patent in-suit with the closest Prior art, the technical problem to be solved should rather be seen as the provision of an **alternative** process.

7.3.1 Percolation variant

In the course of the hearing, it must be examined whether the skilled person would change the closest Prior art, in the hope of thereby solving the objective technical problem.

7.3.2 Two-step maceration variant

Based on the Prior art as referred to in Paragraph [0006] of the patent in-suit, it must be examined whether the skilled person would have reason to change both the solvent and also to add an additional maceration step to the process.