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Rechtsanwalt

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To the
European Patent Office
Directorate General 2
Erhardtstrasse 27

D-80298 Munich

Opposition EP 1 429 795 - Pelargonium

Proprietor: Schwabe GmbH & Co KG, 76227 Karlsruhe (DE)

Opponents: I. African Centre for Biosafety, Johannesburg (ZA)
II. Declaration of Bern, CH-8004 Zürich (CH)

NOTICE OF OPPOSITION

Dear Sirs,

In the name of the Opponents I and II the above-identified European Patent is herewith opposed pursuant to Art. 99 EPC. The following is requested:

1. Revocation of the patent EP 1 429 795 “Method for Manufacturing Extracts from Pelargonium etc”. in its entirety (all 8 claims granted); and

2. Oral proceedings if the Opposition Division intends to reject the opposition or to maintain the patent in amended form. .

GROUNDS OF OPPOSITION

Art. 53 (a) EPC: Ordre public

1.- There may be an infringement of ordre public or morality if there have been serious infringements of ethical norms, when the invention is made the first time (cf. Moufang GRUR Int. 1993, 439 - 450). In the case of inventions based on biological starting material from a biodiversity country, the two criteria of previous informed consent (PIC) and benefit sharing have to be examined üursuant to Art. 8-j, 15, 16 of the Convention on Biodiversity (CBD). Both the country of origin of the pelargonium roots, South Africa, and most member states of the EPO are signatory states to the CBD. Under South African law, the CBD rules on access to biological resources are self-executing, i.e. they do not require any national implementation legislation to take legal effect.

The patent applicants must prove compliance with the rules applicable in this field, if the specification of the invention contains indications of an ethically sensitive situation. This can be assumed if biological starting material from a biodiversity country is critical for the success of the teachings of the invention, i.e. essential for the technical success within the meaning of the conditional theory. For example, in its revised Patent Act of 30 June 2007, Switzerland, a member state of the EPO, has included a formal requirement for the patent applicant to submit pertinent evidence in the application procedure:

Art. 49-a PatG (new)
In the case of inventions that concern genetic resources or traditional knowledge, the patent request must contain information about the source:
a. of the genetic resources, (…)
b. of the traditional knowledge or indigenous or local communities about genetic resources, (…)

2. The foundation of the duty of a research sponsor in the field of biodiversity to specifically inform his suppliers and/or donors of biological starting material before the start of the research project and to obtain their specific consent (previous informed consent) are found in the above-mentioned Articles 15 and 16 CBD.

However, it is occasionally forgotten that prior information and consent by the suppliers/donors or biological starting material also has to include earning a commercial profit. In this respect, there are serious and substantiated doubts as to whether the patent proprietor has complied with all the above-mentioned legal requirements and met the relevant obligations.

3. In addition to previous informed consent it is to be assumed that the suppliers of biological starting material are entitled to a financial participation in the revenues of patents if this could be earned only on the basis of the starting material and/or traditional knowledge donated by them. The basis for benefit sharing of this kind can be found in Articles 1 and 15 CBD with reference to the use of biological starting material as well as Articles 8-j and 15 CBD with reference to the use of indigenous traditional knowledge.

In this case, the subject matter of the disputed patent is largely based on the favourable coincidence that sufficient quantities of pelargonium roots from South Africa and the traditional knowledge of the South African communities were available and ensured a favourable starting position for the patent proprietor's work. To exaggerate slightly, it could be said that the inventors from Schwabe and the members of the South African communities have both made equally important contributions to the end product of the patent in suit, and that the patent in suit is therefore the joint product of the inventors from Schwabe GmbH and the members of the South African communities.

4. What has been said for obtaining an invention for the first time, also applies to "use" of an invention within the meaning Article 53 a EPC, i.e. repeating the teachuings of the invention provided that the continuous supply of biological starting material from a biodiversity country is necessary and essential to this end.

Compliance with the rule of the CBD during routine repeating ("use") of the invention theory must also be proven by the patent proprietor and compliance with the applicable rules may not simply be presumed.

5. Based on these considerations, it is necessary for compliance with Articles 8-j, 15, 16 CBD be proved with certificates (or other evidence) in the application procedure and that the previous informed consent must explicitly contain permission for commercial exploitation of the donations (supplies of starting material) using patents and a corresponding benefit sharing agreement with the indigenous communities authorised to do so.

In this case, the patent holder has not yet provided any evidence of this kind. In view of this state of affairs and legal situation, the Opposition Division should seriously consider whether the (admittedly very strict) standards have been met in the instant case. If the patent proprietor should not submit good evidence of compliance with the rules of the CBD, infringement of ordre public pursuant to Article 53 (a) EPC will result.

Art. 53 (b) EPC: Plant Varieties

1.- In 2003, an Opposition Division of the EPO stated that in the case of human embryonic stem cells (University of Edinburgh) EP 0 695 351, with regard to exceptions to patentability based on ethical grounds a differentiation between process and product claims is logically incorrect. A scientific teaching is either allowed for ethical reasons or it is not; however, the ruling as to patentability cannot differentiate between product and proces (No. 2.5.4 b and c, p. 25/26 of the decision, published in Mitteilungen der Deutschen Patentanwälte 2003, 502, 508):

If the letter-bomb is clearly unacceptable how could a process for making it or even using it be acceptable?

2. This consideration can be transferred to the exception to patentability of Article 53 (b) EPC and it can be argued that the wording of Article 53 (b) covers not only plant varieties as products (and largely to biological methods for breeding plants), but also includes processes that result in an practical monopolisation of plant varieties. A formal application of the legally and politically motivated exception to patentability of Article 53(b) EPC, which makes a distinction between process and product claims, appears therefore to be logically incorrect: An exception to patentability based on grounds of legal policy such as Article 53 (b) intends to exclude the monopolisation of certain technical teachings. This intention can be achieved only if the exception covers the entire technical teaching per se and does not distinguish on the basis of the claim category in which the teaching is claimed in the patent; a purely formal evaluation, by contrast, would prevent the rule from fulfilling ist function.

3. In this context, it must be underlined out that the choice of the category of the patent claims in the field of exceptions to patentability can often result in a circumvention of the law: In this regard, T 356/93 – Plant Genetic Systems has ruled that a claim cannot be granted if granting a patent for the invention in suit with a specific claim would result in a circumvention of an exception to patentability in the EPC (No. 40.7 of the Decision).

Which would be the consequences ? Every exception to patentability could simply be circumvented by means of a clever wording of the claim, especially if a claim category was chosen (product, material, procedure, use) that does not fall under the wording of the exception. It would be too easy if the goal of these exceptions to patentability could be thwarted by a clever wording of patent claims and a comprehensive commercial monopolisation of the technical theory in question could be achieved in spite of such an exception. A procedure of this kind would constitute a classic in fraudem legis agere.

4. In this context, we must also remember the protection of the products directly obtained by a process as provided for in Article 64.2 EPC. Is a monopoly under patent law or its subject matter (technical teaching) really less acceptable in patent or legal terms, if this teaching is worded as a process claim (with the automatically resulting protection of the products directly obtained) than if the identical teaching is worded as a product claim? Or can legally motivated exceptions to patentability be circumvented with the twinkle of the connoisseur in the eyes by a smart selection of the “appropriate” category of patent claims?

Another point comes from the theory of the so-called „inevitable effect of an invention“ in T 290/86 – Blendax: According to this, a patent claim should not be granted, if

its subject matter “automatically” or “inevitably” develops effects that are contrary to an exception to patentability, in addition to other (acceptable) effects of the teaching in question.

5. Overall, the procedural claims of the patent in suit create a legal monopoly of the two plant varieties Pelargonium sidoides and Pelargonium reniforme, since they automatically or inevitably lead to an exclusive right to the two plant varieties as products, although through the intermediary of elegantly drafted process claims.

There is no doubt that the production and the entire trade with the roots of the two pelargonium varieties could be controlled and monopolised with the help of the patent in suit, since the roots as a product would constitute preparatory actions for an infringement of the process claims 1 to 8 and, as such, would already fall under the scope of protection of these process claims.

Similarly, the production and the entire trade with extracts of the two pelargonium varieties could be controlled and monopolised with the help of the patent in suit, since all extracts, tinctures, etc. of this kind from components of the two pelargonium varieties would fall under the scope of protection of process claims 1 – 8 as products directly obtained by the process according to Article 64 (2) EPC.

Therefore, the process claims of Claims 1 – 8 would confer on the patent proprietor a complete monopoly of the two plant varieties Pelargonium sidoides and P. reniforme and therefore constitute a clever circumvention of the exception to patentability of Article 53 (b) EPÜ within the ruling of T 356/93.

Article 83 EPC: Sufficient Disclosure / Clarity Article 84 EPC

1. The patent claims contain many alternatives, including one that are not explained or have been repealed.

PA 1 Actually, two different inventions: Percolation or two-stage maceration
PA 1 maybe slightly pressed, maybe filtered

These alternatives make it more difficult to understand and cause uncertainty with regard to the reproducibility of the technical teaching.

2. The patent claims contain a number of unclear expressions:

PA 1 Starting material: Roots from … : dried or moist? Greased or not?*
PA 1 slightly pressed
PA 1 after a solid/liquid separation
PA 2 Is dried
PA 4 Variously concentrated aqueous ethanol
Where is the threshold of the (still tolerable) concentrations beyond which the it appears no longer possible to implement the technical theory of the disputed patent?
PA 7 Weighted average concentration

3. A number of detailsnecessary for a precise definition of the subject matter of the patent are missing in the patent claims. For example, in sections [0018] ff adequate information on the following details is missing:

PA 1 Geographical origin of the roots and donors
PA 1 Duration and temperature of the individual procedural stages; relationship between weight of the starting material and volume of the solvent;
PA 2 Duration and temperature and further details of drying

Article 54 EPC: Novelty

1.- The analysis of the features provides the structure of patent claim 1 of the patent in suit shown in the diagram below, the letters of which are used for the individual features of the diagram below.

[Diagram:
EP 1 429 795: Analysis of Features Claim 1

(a) Manufacturing an extract

(b1) from Pelargonium sidoides AND/OR from Pelargonium reniforme (b2)

either – or

(c1) PERCOLATION MACERATION (d1)

(c2) aqueous-ethanol solvent aqueous-ethanol solvent

“possibly” two-stage (d3)

(c3) lightly press drug residue filter extract solution after 1st maceration (d4)

(c4) filter raw extract macerate drug residue 2nd time (d5)

blend extract solvent (after solid/liquid separation) (d6)

2.- D1 and D2 disclose the pelargonium extracts in the form of a product-by-process claim.

D 1, p. 141: The parent plant of the umckaloabo drug is today mainly considered to be the previously inadequately described medicinal plant Pelargonium sidoides DC. Today, the modern herbal medicine umckaloabo is used as an ethanol fluid extract. The made-up medicine is indicated for acute and chronic infections of the respiratory tract and the area.

p. 144: In the traditional medicine of South Africa, the use of these root pieces is documented for diarrhoea, gastro-intestinal complaints, dymenorrhoea, polymenorrhoea and liver complaints. Today, the modern herbal medicine umckaloabo is used as an ethanol fluid extract.

D 2, p. 300: Umckaloabo is an alcohol extract from the roots of Pelargonium reniforme and/or P. sidoides DC. and has been successfully used to treat respiratory tract and infections for many years because of its anti-infectious effect.
p. 303: Umckaloabo (composition: 100 g drops contain: 80 g alcohol extract 11.2 % m/m from the roots of Pelargonium reniforme Curt. / Pelargonium sidoides DC. Drug extract relationship 1 + 10; 20 g glycerine) is a made-up medicine in drop form for oral application. It contains the root extract of the two pelargonium species native to eastern South Africa from the Geraniaceae family. To this day, the root drug (....) is used in African traditional medicine to treat respiratory diseases, including tuberculosis.

The following documents also provide a precise product-by-process representation:

Adrien Sechehaye, The treatment of pulmonary and surgical tuberculosis with Umckaloabo, London 1930:

p. 38/39: Chemical Composition: Alcohol 11.23 %, Glycerine 6.84 %, ... Water 77.93 %

Sabine Bladt, Hildebert Wagner, (1988), Cumarindrogen, 1. Mitteilung: Qualitätsprüfung der Umcka-Droge und ihrer Zubereitungen, Deutsche Apotheker-Zeitung 128 (1988), 292- 296.
p. 292 The root drug used in African traditional medicine against tuberculosis has been used in Europe for around 50 years in the form of the so-called Umckaloabo-Stevens cure to support tuberculosis treatment. (....)
The DC separation of the alcohol total extract of the drug over DC gravel gel 60 F 254 ready-made plate in the mobile liquid system I (....) shows ....
p. 294 80 g percolate made of 8 g drug are processed in 100 ml umckaloabo Stevens cure. In an exhaustive extraction, around 3.6 mg free umckaline per 100 ml umckaloabo Stevens cure are to be expected. (....)

3. A document of prior art worded as product-by-process information automatically or by definition discloses the process for manufacturing the product.

The person skilled in the art of phytochemistry and phytomedicine is aware that extraction refers to the two variants of percolation (continuous cold extraction) and maceration (discontinuous cold extraction, batch method). Bladt/Wagner (1988) also explicitly refer to the method of percolation.

Consequently, the documents disclose the features a, b1, b2, c1, c2 as well as d1 and d2 in a way excluding novelty.

4. The person skilled in the art of phytochemistry and phytomedicine is also aware that in a discontinuous method of maceration (batch process) the yields of extracted material can be improved by removing the supernatant after a first run (e.g. by filtration or decanting) and the solid being extracted with the solvent a second (and maybe more) time(s).

The cited documents therefore also disclose the feature d3 (two-stage) in a way excluding novelty.

5. Whether the remaining features c3 and c4 (percolation) and d4, d5 and d6 (maceration) still involve an adequate inventive step to grant claim 1 (and all subsidiary claims), appears doubtful for the following reasons:

It must be remembered that the features c3 (lightly press residue) and c4 (filter extract) are called optional by the patentee himself. It must also be underlined that the items d4 (filter out extract), d5 (macerate the residue for the 2nd time) and d6 (blend extracts) appear to be redundant since they only verbally represent what happens automatically in a two-stage (d3) maceration process (d1).

6.- The patentee wrongly refers to G 2/88 : This decision concerned the issue of novelty of a second use of a known substance (growth control – fungcidal effec). It ruled that achieving the (second) technical effect should be viewed as a functional technical feature of the patent claim. If this technical feature had not previously been accessible to the public by the means named in Article 54 (2) EPC, the claimed invention is new, even if this technical effect may have occurred inherently in the execution of something that had previously been made accessible to the public. Or, put more simply: By revealing a substance and a first effect, a second effect is not automatically revealed.

The extent to which this decision G 2/88 has a bearing on this case cannot be understood. It treats information contained in a document that discloses a substance, or composition of matter in the nature of a product-by-process claim, not the disclosure of second effects of substances.

Moreover, G 2/88 also points out (No. 10, S. 111) that in the event of a “written description”, the information contained in this written description should be made accessible to the public. Furthermore, the theory contained in the written description, e.g. about the implementation of a method, further information can be made accessible as an inherent result of the implementation of this doctrine (with references to T 12/81 - Diastereomers, T 124/87 - Copolymers, T 303/86 - Flavour concentrates). In a simplified way, the information contained in a printed document is not limited to its wording, but also comprises inherent results of theteaching in question that the reader skilled in the art can deduce from the description.

In this case, this must also be extended to the information contained in a product-by-process information: If a product (substance, composition of matter) is disclosed by a product-by-process wording, the information contained in this description automatically comprises the method to manufacture the product, as described above at No. 3.

7. The patentee holder wrongly refers to G 1/92: This decision treats the problem of the extent to which a product (accessible to the public) discloses its chemical composition and thus constitutes state of the art. It ruled that the chemical composition of a product is state of the art if the product itself is accessible to the public and can be analysed and reproduced by an expert, irrespective of whether there are particular reasons for analysing the composition.

The extent to which this decision G 1/92 has a bearing on this case cannot be seen: This case is about the information or disclosure contained in a printed document that contains a product-by-process information, whereas G 1/92 is about the information contained in a product accessible to the public.

Article 56 EPC: Inventive Step

Even if we reached the conclusion that D1, D2 and Bladt/Wagner (1988) do not anticipate the subject matter of patent claim 1 in a excluding novelty, these documents show that the subject matter of claim 1 lacks inventive step (Article 56 EPC).

1. Counting of intellectual steps: One important criterion in assessing inventive step consists in counting the intellectual steps that are needed for the transition from the state of the art to the subject matter of the patent. This method, also known as the multi-stage method, has been particularly recommended for the Examination in the EPO by Van Benthem/Wallace (GRUR Int. 1978, 219, 222).

In the instant case, there is only one single intellectual step, namely a specification of the term “extract” in D1, D2 and Bladt/Wagner (1988) by common textbook knowledge of a person skilled in the art of phytomedicine is required to arrive at the subject matter of patent claim 1:

Hagers Handbuch der pharmazeutischen Praxis, Bd. 2 Methoden, 5. A. Berlin 1991, p. 407 - 409: Article Fest-flüssig-Extraktion, Perkolation (p. 408/9), Mazeration (p. 408);

European Pharmacopoeia, Third Edition, Strasbourg, published June 1996, p. 837, Abschnitt Extracts - Production by percolation - production by maceration;

European Pharmacopoeia, Fourth Edition, Strasbourg, published 20th September 2001, p. 508/509, Abschnitt Extracts - Production by percolation - production by maceration;

Affidavit Dr. Stafford, Sections maceration and percolation

2. If the subject matter of the patent in suit is conceived as an application of common textbook knowledge of the person skilled in the art to a certain starting material (pelargonium roots), once again, only one single intellectual step was needed to move from the state of the art to the subject matter of the patent: Only the term of the extraction material/starting material had to be specified with the pelargonium roots in the textbooks.

Starting with the Rwexu affidavit (cold water, percolate for 12 hours, room temperature), only one single intellectual step was required to move from the state of the art to the subject matter of the patent (PA 1 in the variant c1 - percolation) Then, only ethanol had to be added to the cold water to realise the feature (c2) of patent claim 1.

Affidavit Milile Rwexu, Section No. 5 preparation process

3. The two-stage method of maceration (features d3 and d5) also constitutes textbook knowledge and is based on the simple knowledge that no complete or satisfactory yield can be achieved regularly with one-stage maceration:

Hagers Handbuch, p. 408, Section Mazeration: Remazeration, Stufenmazeration;

And the next stages, where after first maceration the residue is “decanted, filtered and pressed” (feature d4) can explicitly be classified as standard textbook knowledge for the skilled person.

4. The patentee wrongly refers to the therapeutic effect of the products directly obtained by the process: As has already been noted in the test method, the therapeutic effect of umckaloabo in bronchitis etc. is not novel, but has been known and used for decades worldwide. It can consequently not contribute to the inventive step of a process of manufacture; consequentely the patent claims 9 – 13 based on therapeutic use had to be eliminated.

5. The patentee wrongly refers to an alleged surprise/surprising effect of his process:

5.1 The fact that the dry extract yield in percolation in line with the patent and two-stage maceration would be higher than that of one-stage maceration according to DAB 10 was completely foreseeable. It corresponds to the simple statement in Hagers Handbuch, ibid p. 408, Article Maceration, that complete extraction of the active agent cannot be achieved with simple maceration.

And even with the continuous method of percolation it is textbook knowledge that the yield depends on the extraction time and the quantity of the material to be extracted (Hagers Handbuch, ibid p. 408): Therefore, if the correlation between extracted material and solvent is increased in favour of the solvent, it is entirely foreseeable that the dry extract yield will increase.
Hagers Handbuch der pharmazeutischen Praxis, Bd. 2 Methoden, 5. A. Berlin 1991, Perkolation (p. 408/9), Mazeration (p. 408).

5.2 The finding that the content of overall phenole groups in the extract is increased if the ethanol content of the solvent is increased and does not reach a maximum value at medium ethanol concentrations (?) does not appear surprising either. Phenols contain nonpolar groups and it is therefore not surprising that as the content of nonpolar groups is increased in the solvent (EtOH), the extraction of phenols is equally increased (according to

the popular mediaeval sentence: similia similibus solvuntur). A simple look in the popular Handbook of Chemistry and Physics shows the following solubilities of individual phenol compunds:

Solubility in grams per 100 ml of

Phenol	Water:	6.7	Alcohol:	unlimited
Pyrogallol		62.5		100
2-Naphthol		0.074		12..5
etc. etc.				

5.3 The finding that, in parallel to the overall phenol concentrations [0024], the antioxidative potential of the extracts [0026] rises appears equally not surprising. Since it is known that the antioxidative effect of phytomedical preparations is largely due to their polyphenol content, the analysis methods outlined in sections [0024] and [0026] appear merely to offer two alternative indicators for the identical phenomenon, namely measuring the concentration of polyphenols.

6. Neither do the dependent patent claims disclose any inventive step above and beyond the subject matter of PA 1. In this connection it must be emphasized that so-called parameter inventions where a certain area of one (or more) process parameters is selected, regularly lack the level of invention because they constitute routine measures (Guidelines C.IV Annex 3.1 ii and 3.2 I, T 253/93 – Permanent Magnet Alloys, T 36/82 – Parabolic Antenna, T 410/87 – Reproduction Device).

In the instant case, the parameter areas claimed in the dependent claims are obvious parameter inventions that do not exceed the level of simplest routine measures and mere trial and error. In particular, no discontinuities whatsoever of the correlations (e.g. of the solubility curves) have been found and reported (or even less: systematically exploited).

Yours sincerely

Prof. Dr. F. Dolder
Rechtsanwalt - Attorney-at-Law

Enclosures

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LIST OF ENCLOSURES

1) Adrien Sechehaye, The treatment of pulmonary and surgical tuberculosis with Umckaloabo, London 1930.

2) Sabine Bladt, Hildebert Wagner, (1988), Cumarindrogen, 1. Mitteilung: Qualitätsprüfung der Umcka-Droge und ihrer Zubereitungen, Deutsche Apotheker-Zeitung 128 (1988), 292- 296

3) Hagers Handbuch der pharmazeutischen Praxis, Bd. 2 Methoden, 5. A. Berlin 1991, p. 407 - 409: Article Fest-flüssig-Extraktion, Perkolation (p. 408/9), Mazeration (p. 408);

4) European Pharmacopoeia, Third Edition, Strasbourg, published June 1996, p. 837, Abschnitt Extracts - Production by percolation - production by maceration;

5) European Pharmacopoeia, Fourth Edition, Strasbourg, published 20th September 2001, p. 508/509, Abschnitt Extracts - Production by percolation - production by maceration;

6) Affidavit Dr. Stafford, Sections maceration and percolation

7) Affidavit Milile Rwexu, Section No. 5 preparation procedure

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