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**Datasheet for the decision
of 26 September 2008**

Case Number: T 0382/07 - 3.3.04

Application Number: 96920051.8

Publication Number: 0828502

IPC: A61K 35/78

Language of the proceedings: EN

Title of invention:

Pharmaceutical compositions, based on etheric oils obtained from plants for use in the human and veterinary medical field

Patentee:

D & W Trading B.V.

Opponents:

- (01) Ecopharma Hellas Ltd.
(02) Erber Aktiengesellschaft
(03) bioptivet Tierarzneimittel GmbH & Co.
(04) Frey + Lau GmbH

Headword:

Etheric oils/D & W TRADING

Relevant legal provisions:

EPC Art. 54(3), 84, 88(4), 111(1), 123(2)(3)
PCT Art. 8
Paris Convention Art. 4, 11

Relevant legal provisions (EPC 1973):

EPC Art. 87(1)

Keyword:

"Exhibition priority (no); transfer of priority right (yes);
added matter (no) - disclaimer allowable; extension of scope
(no); clarity, support (yes); remittal (yes)"

Decisions cited:

G 0002/88, G 0011/91, G 0001/03, T 0077/87, T 0412/91,
T 1080/99, T 0062/05, T 0788/05

Headnote:

Exhibition priority: see points 8 to 8.4.



Case Number: T 0382/07 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 26 September 2008

Appellant: D & W Trading B.V.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 1 February 2007
revoking European patent No. 0828502 pursuant
to Article 102(1) EPC 1973.

Composition of the Board:

Chair: U. Kinkeldey
Members: G. Alt
R. Moufang

Summary of Facts and Submissions

I. This is an appeal by the patent proprietor against the decision of the opposition division to revoke the European patent no. 0 828 502 having the title "Pharmaceutical compositions, based on etheric oils obtained from plants for use in the human and veterinary medical field" pursuant to Article 102(1) EPC 1973. The patent claims the priority date of 26 May 1995 by referring to applications no. MK 7595 and MK 7695.

II. Claim 1 as granted read:

"1. Composition for both human and veterinary application, comprising an active agent and a pharmaceutically acceptable carrier, **characterized in that** the active agent is thymol and carvacrol, as present in the oil extracted from any of the following plants *Origanum vulgare* [sic], *Thymus vulgaris*, *Mentha piperita*, *Thymus serpyllum*, *Saturea hortensis*, *Saturea montana*, *Saturea subrotata*, *Carum carvi*, *Thymus zosterifolius*, *Ocimum basilicum*, *Morinda officinalis*, *Mosla japonica* and *Salvia officinalis*, which oil is present in an amount of 1-15% by weight, calculated on the total weight of the pharmaceutical composition."

The set of granted claims contained eight further claims relating to embodiments of the composition of claim 1.

III. The oppositions were based on Article 100(a) EPC on the grounds of lack of novelty and lack of inventive step, on Article 100(b) EPC on the ground of insufficiency of

disclosure and on Article 100(c) on the ground of added subject-matter.

IV. The opposition division decided that the amended claims 1 and 7 of the main request before it contravened the requirements of Articles 123(2) EPC due to the definition of the active agent as thymol and carvacrol and due to the term "prevention and treatment of gastro-intestinal disorders". This latter term was also regarded as broader than the respective term used in the claims as granted. Therefore, the requirements of Article 123(3) EPC were not considered to be fulfilled. The opposition division further decided that the first auxiliary request contravened the requirements of Article 123(2) EPC because the disclaimer removed less than was necessary to restore novelty over document D5 (international patent application PCT/GR96/00016 published as WO 97/01348). The second to fourth auxiliary requests were rejected as not complying with the requirements of Articles 84 and 123(2) EPC because the disclaimers in claim 1 of each of the requests contained unclear terms and because they defined an unduly large plurality of items which put an unreasonable burden on the public to find out what was protected and what not.

V. Oral proceedings before the board of appeal were held on 25 and 26 September 2008. The appellant (patent proprietor) and respondents I, II and IV (opponents 01, 02 and 04) were represented.

At the oral proceedings the appellant filed a new main request. Respondent I submitted a certified assignation deed dated 18 July 1995 concerning all the rights

derived from the Greek patent application 950100249 (the priority of which is claimed in document D5) as well as an English translation thereof.

Claim 1 of the appellant's sole request read:

"1. Use of a composition comprising an active agent and a pharmaceutically acceptable carrier, wherein the active agent is an oil extracted from *Origanum vulgare* [sic], which oil contains as active material thymol and carvacrol, which oil is present in an amount of 1 - 15 % by weight, calculated on the total weight of the pharmaceutical composition, provided that:

- (a) the composition is not a powder having 94 % CaCO₃, 1 % tannin and 5 % *Origanum hyrtum* oil, said composition being used for the preparation of a medicament for the treatment of Salmonellosis, Staphylococciasis, Pasteuridiosis and Colobacillosis in animals;
- (b) the composition is not a powder having 90 % CaCO₃, 5 % *Origanum hyrtum* oil and 5 % glycerine monostearate, said composition being used for the preparation of a medicament for the prevention and treatment of coccidiosis in poultry caused by the germs of the *Eimeria* group;
- (c) the composition is not a syrup having 92.5 % polyethylene glycol, 5 % *Origanum hyrtum* oil, 1 % tannin and 1.5 % glycerine monostearate, said composition being used for the preparation of a medicament for the treatment of Salmonellosis, Staphylococciasis, Pasteuridiosis and Colobacillosis in animals;
- (d) the composition is not a paste having 74 % polyethylene glycol, 5 % *Origanum hyrtum* oil, 1 %

tannin and 20 % glycerine monostearate, said composition being used for the preparation of a medicament for the treatment of Salmonellosis, Staphylococciasis, Pasteuridiosis and Colobacillosis in animals; and

- (e) the composition is not a solution having 5 % Origanum hyrtum oil, 3 % Emulgator 484, 10 % propylene glycol and 82 % distilled water, said composition being used for the preparation of a medicament for the prevention and treatment of coccidiosis in poultry caused by the germs of the Eimeria group;

for the preparation of a medicament for the prevention or treatment of gastrointestinal infections in animals."

The set of claims further contained five dependent claims.

The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the new main request filed at the oral proceedings.

Respondents I, II and IV requested that the appeal be dismissed.

At the end of the oral proceedings the board announced its decision.

VI. The following documents are referred to in the present decision:

- D5: International patent application
PCT/GR96/00016 published as WO 97/01348
- D11(2): Hagers Handbuch der Pharmazeutischen Praxis;
Band 5: Drogen E-O; 1993; pages 959-964
- D49: GR 950100249; priority document pertaining
to document D5
- D49a: Translation of document D49
- D61: Print out from "REGISTRY" file
- D64: Declaration of Dr. Dennis Murphy dated
14 July 2008
- D65: Print out of "<http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-439.pdf>" as annexed to document D64
- D66: Print out of "<http://www.chemicaland21.com/specialtychem/perchem/STEARYL%20CITRATE.htm>" as annexed to document D64

Certified assignation deed dated 18 July 1995
(including an English translation thereof)

VII. The appellant's arguments submitted in writing and at the oral proceedings, in so far as relevant to the present decision, may be summarised as follows:

Rule 80 EPC

The amendments were made to overcome objections under Articles 123(2) and 54 EPC and were therefore occasioned by grounds of opposition.

Extension of scope (Article 123(3) EPC)

Claim 1 as granted referred to a composition "comprising an active agent ... characterized in that the active agent is thymol or carvacrol ...". The non-limiting term "comprising" ruled out the interpretation that the active agent comprised only thymol and carvacrol.

Support, clarity

The claims were clear and did not lack support. In particular, as evidenced by the affidavit of Dr. Dennis Murphy, there was no ambiguity about the meaning of the term "Emulgator 484".

Amendments, entitlement to priority, novelty

The patent was formally entitled to claim the date of 26 May 1995 as priority date.

All amendments had a proper basis in the description and also the disclaimers were correctly drafted in order to exclude exactly the novelty-destroying subject-matter of document D5. Therefore, the requirements of Article 123(2) EPC were fulfilled.

In view of the disclaimers, the subject-matter of the claims were not anticipated by document D5.

Remittal

In the decision under appeal the issues of sufficiency of disclosure and inventive step had not yet been considered. Therefore, it was appropriate to remit the case to the department of first instance for further prosecution.

VIII. The respondents' arguments submitted in writing and at the oral proceedings, in so far as relevant to the present decision, may be summarised as follows:

Rule 80 EPC 2000

Neither the change in the claim category from a product according to the claims as granted into a use according to the present claims nor the change in the definition of the "active agent" was occasioned by grounds of opposition. They were therefore not allowable pursuant to Rule 80 EPC.

Extension of scope (Article 123(3) EPC)

Claim 1 as granted had to be interpreted as directed to a composition containing exclusively thymol and carvacrol as the active agent, because, due to its subordinate character, the phrase in claim 1 "as present in the oil extracted from ..." had to be understood as an illustration and not as a qualification of the active agent.

The active agent according to present claim 1 was "an oil extracted from *Origanum vulgare* [sic], which oil contains as active material thymol and carvacrol". Since the active agent was an oil extract from a plant, it was inevitable that it contained active material in addition to the explicitly mentioned compounds thymol and carvacrol, for example tannins. Therefore, the meaning of the term "active agent" was broader when compared to the meaning of the same term in claim 1 as granted.

Dependent claims 2 and 3 as granted could not be taken as an indication that the term "active agent" referred to an oil because these claims had already been present in the application as filed and had not been correctly adapted to the amended claim 1 as granted.

Thus, although the present claims related to a "use", their scope was extended with regard to the claims as granted because the compositions to be used were outside the limits of the definition of the compositions in the patent.

Support, clarity

In claim 1 it was stated that the active agent, i.e. the oil, contained thymol and carvacrol as active material. This definition was ambiguous as to whether or not substances other than the two mentioned ones could contribute to the pharmaceutical effect.

As evidenced by document D61, the term "Emulgator 484" could have four possible meanings of which two were plausible to the skilled person in the context of the

patent. Therefore, the term "Emulgator 484" in disclaimer (e) was ambiguous as well as the term "polyethylene glycol" in disclaimers (c) and (d). Therefore, and also because of the high number of disclaimers, claim 1 was unclear.

Amendments, entitlement to priority, novelty

An active agent containing more than the two substances thymol and carvacrol was not disclosed in the application as filed.

The disclaimers excluded less subject-matter than necessary to restore novelty over document D5 which was entitled to its priority date of 29 June 1995. Therefore, in view of decision G 1/03, the disclaimers contravened the requirements of Article 123(2) EPC.

For the same reason the claimed subject-matter lacked novelty.

Remittal

In the decision under appeal the issues of sufficiency of disclosure and inventive step had not been considered at all. Therefore, the case should be remitted to the first instance for further prosecution.

Reasons for the Decision

Rule 80 EPC

1. The respondents argue that neither the change of the category from a claim directed to a composition to a claim directed to a use nor the reformulation of the definition for the "active agent" is occasioned by a ground of opposition.
 - 1.1 However, it is apparent from the section in the decision under appeal "Summary of facts and submissions" that the opponents (i.e. the respondents) had raised objections of lack of novelty on the basis of the argument that oil extracts from *Origanum vulgare* had already been disclosed in the prior art (points 6 to 9). Moreover, in the decision under appeal, point C, the opposition division found that the definition of the active agent as thymol and carvacrol was inconsistent with the disclosure in the application as originally filed.
 - 1.2 Thus, the board concludes that the requirements of Rule 80 EPC according to which amendments must be occasioned by grounds of opposition, are fulfilled.

Extension of scope (Article 123(3) EPC)

2. The claims as granted are directed to a "composition", whereas the claims of the main request are directed to a "use" of a composition. It is established case law that an amendment which results in this type of change of the claim category does not per se extend the scope of protection (decision G 2/88, OJ EPO 1990, 93).

2.1 The respondents argue that despite the narrowing change in the claim category the scope of present claim 1 is extended because the definition of the substance used as an "active agent" as "an oil extracted from *Origanum vulgare* [sic]" encompasses embodiments which were not encompassed by the definition of the active agent in the claims as granted.

2.2 The relevant parts of claim 1 as granted read:

"Composition ... comprising an active agent and a pharmaceutically acceptable carrier, **characterized in that** the active agent is thymol and carvacrol, as present in the oil extracted from any of the following plants *Origanum vulgare* [sic], which oil is present in an amount of 1-15% by weight, calculated on the total weight of the pharmaceutical composition".

In the board's view, the expressions "as present in the oil extracted from ..." and "which oil is present in an amount of 1-15% by weight, calculated on the total weight of the pharmaceutical composition", when considered in the context of claim 1 as granted, would have conveyed to the skilled person the meaning that the substance which is combined with the pharmaceutically acceptable carrier, i.e. the "active agent", is a plant oil extract from inter alia *Origanum vulgare* and which contains thymol and carvacrol as pharmaceutically active ingredients.

2.3 This interpretation is equivalent to the wording used in present claim 1 for the definition of the "active agent" which reads:

"Use of a composition comprising an active agent and a pharmaceutically acceptable carrier, wherein the active agent is an oil extracted from *Origanum vulgare* [sic], which oil contains as active material thymol and carvacrol ...".

Thus, although defined by different words, the "active agent" is, in the board's view, the same according to claim 1 as granted and according to present claim 1.

Consequently, the respondents' argument that present claim 1 encompasses the use of a substance which was not an embodiment of claim 1 as granted does not convince the board.

2.4 Since this conclusion is reached on the basis of the interpretation of claim 1 as granted alone, the respondents' argument that claims 2 and 3 should not be considered for the interpretation of claim 1 since their formulation had not been properly adapted to the amendment of claim 1 during prosecution need not be dealt with.

2.5 Finally, the board notes that claim 1 of the main request is also restricted with regard to the plant from which the oil is extracted, i.e. according to present claim 1 only oils extracted from *Origanum vulgare* are used in the composition.

2.6 Since claim 1 as granted and present claim 1 are the claims with the broadest scope within the respective sets of claims, it follows from the above reasoning that the protection conferred by the patent as granted

is not extended by the amendment in present claim 1.
The requirements of Article 123(3) EPC are fulfilled.

Support, clarity

3. The respondents submit that the definition in claim 1 of the main request that the active agent "contains as active material thymol and carvacrol" is ambiguous as to whether or not substances other than thymol and carvacrol could contribute to the pharmaceutical effect.
- 3.1 However, the active agent is defined in claim 1 as "an oil extracted from *Origanum vulgare* [sic]". According to document D11(2), a pharmaceutical handbook, oil extracted from *Origanum* plants contains a plurality of compounds besides carvacrol and thymol, for example gamma-terpinen, p-cymen, alpha-pinen, etc. (page 960, first column, fourth paragraph and second column, section "Inhaltsstoffe"; page 962, section "Inhaltsstoffe"). Thus, in the board's view, the skilled person would rule out the possibility that the expression "an oil extracted from *Origanum vulgare* [sic]" refers to an oil extract that solely contains the two substances explicitly recited in the claim. This understanding is, in the board's view, also supported by the non-limiting term "containing" in claim 1, as well as by the description of the patent which does not disclose a high-degree purification process and where the presence of further compounds in the extracted oil is reported (see page 6, first paragraph). Thus, in the board's view, there is neither a lack of clarity nor of support in this respect.

4. The respondents maintain that claim 1 is unclear because the terms "polyethylene glycol" present in disclaimers (c) and (d) and the term "Emulgator 484" present in disclaimer (e) are ambiguous and, further, because the number of disclaimers is too high.
- 4.1 It is true that polyethylene glycol is a substance available over a wide range of molecular weights (from 300 g/mol to 10,000,000 g/mol). However, the board is convinced that the skilled person who, in the present case, is familiar with the formulation of medicaments, knows which molecular weight forms of polyethylene glycol are suitable for the preparation of the composition referred to in the disclaimer and would therefore interpret the term "polyethylene glycol" without difficulty.
- 4.2 As to the term "Emulgator 484", the respondents argue that in the context of the present patent the skilled person would consider plausible two of the four possible meanings disclosed for it in document D61, i.e. the term could stand for "glycerol polyethylene glycol ricinoleate" or for "stearyl citrate".

The ingredients of the composition referred to in disclaimer (e) are 5% Origanum hyrtum oil, 3% Emulgator 484, 10% propylene glycol and 82% distilled water. Due to the predominant amount of water in that composition, the board is convinced by Dr. Murphy's submission in point 6 of his declaration (document D64) that the obvious reason for including Emulgator 484 in that composition is to create an oregano oil-in-water emulsion.

However, as indicated in the declaration of Dr. Murphy, point 6 with reference to documents D65 and D66, stearyl citrate is insoluble in water (document D65), but soluble in oil (document D66). Hence, the compound is able to emulsify water in oil, but not oil in water. Consequently, the board comes to the conclusion that in the context of the present patent the skilled person would rule out the meaning "stearyl citrate" for the term "Emulgator 484". Therefore, the respondents' argument that in the context of the present patent the skilled person would consider plausible two possible meanings for the term "Emulgator 484", and that therefore the meaning of disclaimer (e) was ambiguous, does not convince the board.

4.3 If the meaning of each of a plurality of disclaimers is clear, the number of disclaimers in a claim does not necessarily lead to a lack of clarity of this claim. Since here the meaning of the disclaimers is clear (see points 4 to 4.2 above), the number of five disclaimers is not too high to enable the skilled person to understand what is protected and what is not. Hence, the number of disclaimers is also not a reason for lack of clarity in the present case.

5. The board concludes that claim 1 of the main request fulfils the requirements of Article 84 EPC.

Amendments in the light of Article 123(2) EPC

6. The basis for the amendment in claim 1 "wherein the active agent is an oil extracted from *Origanum vulgare* [sic], which oil contains as active material thymol and carvacrol" and the restriction to oils from *Origanum*

vulgare is present in claim 3 as originally filed reading: "...the active agent is at least an oil extracted from *Origanum vulgare* [sic] and optionally *Thymus vulgaris*."

The presence of thymol and carvacrol as pharmaceutically active material in the oil is, in the board's view, derivable from page 7, lines 24 to 25 of the application document as originally filed (published version) because thymol and carvacrol are the only substances which are explicitly mentioned as ingredients of the oil extract, and also from page 8, lines 34 and 35 where thymol and carvacrol are denoted as important substances of the extracted oil and - implicitly - as substances present in high quantity: "The remnants are the important substances: carvacrol 86-88%; thymol 3-5% and in minor quantities: pinene, borneol, linalol etc." In view of this passage the respondents' argument that the application as filed does not disclose oils containing material other than thymol and carvacrol is not well-founded.

The use of the composition for gastro-intestinal infections in animals is disclosed on page 5, lines 40-43 of the application document as originally filed (published version): "In view of the above, the pharmaceutical compositions are particularly used for prevention and treatment of gastro-intestinal infections in humans and particularly in animals....".

Disclaimers

7. Claim 1 recites five disclaimers which are not disclosed in the application as originally filed. They

were added in order to restore novelty over document D5 which was introduced as prior art only under Article 54(3) EPC since it was published on 16 January 1997, i.e. after the filing date of the application from which the patent in suit is derived.

- 7.1 One of the requirements for the allowability of an undisclosed disclaimer introduced to exclude an anticipation under Article 54(3) EPC is that it removes what is necessary to restore novelty and not more (see decision G 1/03, OJ EPO 2004, 413; point 3 of the reasons). The board therefore has to examine whether and, if so, to what extent the disclosure of document D5 is comprised in the state of the art under Article 54(3) EPC with respect to the subject-matter of the patent in suit. In this context it is necessary to consider the respective priority claims of the patent in suit, on the one hand, and of document D5, on the other.

Entitlement to priority of the patent in suit

8. The patent in suit claims priority from two applications, MK 7595 (= document D3, application number 950075) and MK 7695 (= document D1, application number 950076), filed with the industrial property protection office of the former Yugoslav Republic of Macedonia which became party to the Paris Convention for the Protection of Industrial Property ("Paris Convention") on 8 September 1991. The patent indicates the 26 May 1995 as the priority date of each of these prior applications. It is undisputed between the parties and follows from an inspection of these applications and their translations that they were

filed only on 25 August 1995 but that they claimed an exhibition priority of 26 May 1995 in view of a disclosure at the international fair MEDICINE 95 held in Skopje from 25 to 29 May 1995.

8.1 The possibility of recognising exhibition priorities internationally follows from Article 11 Paris Convention. According to its paragraph (1), the countries of the Paris Union shall, in conformity with their domestic legislation, grant temporary protection to, inter alia, patentable inventions in respect of goods exhibited at official or officially recognised international exhibitions held in the territory of any of them. According to paragraph (2) of the provision, such temporary protection shall not extend the periods of priority provided by Article 4 Paris Convention. If later the right of priority is invoked, the authorities of any country may provide that the period shall start from the date of introduction of the goods into the exhibition.

8.2 It follows from Article 11 Paris Convention that the Paris Union member countries are allowed to recognise exhibition priorities in their domestic law under certain conditions but that they are not obliged to do so. The temporary protection required by Article 11(1) Paris Convention can be achieved also by other legislative means such as a grace period exempting the public display of the invention by the applicant or his predecessor at certain exhibitions (see Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967, Geneva 1968, p. 150). This is the route the European legislator elected when drafting the

European Patent Convention, which does not provide for exhibition priorities but contains a specific and narrowly limited rule on non-prejudicial disclosures made at exhibitions in its Article 55(1)(b) (see Loth, Europäisches Patentübereinkommen - Münchner Gemeinschaftskommentar, Art. 55 marginal no. 9, 29 and 99).

8.3 Whether or not an applicant is entitled to claim an exhibition priority is thus a matter to be decided on the basis of the respective national law of the country where protection and priority are claimed - i.e. in the case of a European application or patent on the basis of the EPC - and does not depend on the law of the country where the exhibition takes place or where a first application claiming the exhibition priority is filed. Since the EPC does not recognise exhibition priorities, any priority claim based on an invention disclosure at an exhibition must fail in the present case, independently of whether the law of the former Yugoslav Republic of Macedonia recognises or recognised exhibition priorities.

8.4 The above finding is not altered by the fact that the patent in suit originated from an international application filed under the PCT, and that, according to Article 8(2)(a) PCT, the conditions for, and the effect of, any priority claim declared in an international application shall generally be as provided in Article 4 Paris Convention (Stockholm Act). This latter provision only provides a basis for claiming the filing date of a prior application, i.e. not the date of a prior disclosure at an exhibition, as the priority date. The board notes that Article 8 PCT does not refer to

Article 11 Paris Convention. Furthermore, even if Article 11(2) Paris Convention were to apply, the option given by this provision to modify the start of the priority period under Article 4 Paris Convention by taking into account the date of a relevant exhibition is an option for the country of the successive filing (see Bodenhausen, *ibidem*, page 152), not for the country of the first filing. Since the EPC does not recognise exhibition priorities (see above, point 8.3), the priority date of 26 May 1995 cannot be validly claimed for the European patent in suit. Whether the appellant is entitled to claim the actual filing date of the prior applications MK 7595 and MK 7695 (25 August 1995) is not relevant for the outcome of the present proceedings and does not need to be decided.

Document D5: Formal entitlement to priority

9. Document D5 is an international patent application filed on 27 June 1996 under the PCT and published on 16 January 1997. It has entered the regional phase before the European Patent Office resulting in European application No. 96922166.2 and claims priority from the Greek patent application No. 950100249 filed on 29 June 1995, i.e. a date which is earlier than the filing date of the patent in suit (24 May 1996) and also earlier than the filing date of the prior applications MK 7595 and MK 7695 (25 August 1995; see point 8 above). This Greek application and its certified translation are referred to as documents D49 and D49a, respectively, in the present decision.

- 9.1 Document D49 indicates four natural persons as applicants whereas only one of them is the sole

applicant of document D5. Thus the formal entitlement to the priority claim made in document D5 presupposes that the three other co-applicants of document D49 transferred the joint priority right to the sole applicant of document D5 before its filing date (see Article 87(1) EPC and Article 8(2)(a) PCT in connection with Article 4 A(1) Paris Convention; T 62/05 of 14 November 2006, point 3 of the reasons; T 788/05 of 8 May 2007, point 2 of the reasons; Guidelines for Examination in the EPO, A-III 6.1). When this issue arose for the first time in the course of the oral proceedings before the board, respondent I submitted a certified assignation deed dated 18 July 1995 together with its translation into English. In the light of this document, the board is satisfied that the required transfer of the priority right to the sole applicant of document D5 did in fact occur before the relevant point of time.

Document D5: Disclosure content and substantive entitlement to priority

10. Since the filing date of document D5 (27 June 1996) is later than the filing date of the application on which the patent in suit is based (24 May 1996), the information disclosed in document D5 is comprised in the prior art pursuant to Articles 54(3) and 89 EPC only to the extent that corresponding information is also present in priority document D49a (see Article 88(3) and (4) EPC and Article 4 H Paris Convention). The board therefore has to analyse and compare the relevant disclosures of both documents having regard to the subject-matter of the claims of the appellant's main request.

10.1 Document D5 discloses on page 2 in the section "Background of the invention" that the described invention "refers to compositions containing essential oils that are as effective against inflammations, infections and diarrhoea as antibiotics and sulphamides", and that the substances that constitute the essential ingredients of these pharmaceutical compositions can be obtained from herbs of the plant family Labiatae which are known to contain high amounts of thymol and carvacrol. Several plant species are mentioned as examples.

Then, at the bottom of page 2, it is stated that it was found that essential oils containing thymol in amounts corresponding to a carvacrol : thymol ratio of lower than 5 : 1 do not have satisfactory antimicrobial activity. In line with this finding, it is said on page 3 in the section "Summary of the invention" that the herbal essential oil contained in the pharmaceutical composition of the invention is characterised inter alia in that the ratio of carvacrol to thymol is at least 10 and that this ratio is found to provide for surprising antimicrobial properties.

Apart from the general description of the invention document D5 comprises nine examples, examples 1 and 2 of which disclose subject-matter relevant in the present context because they relate, inter alia, to compositions for veterinary use. In toto, Examples 1 and 2 disclose five different compositions for veterinary use.

The relevant parts of Examples 1 and 2 read as follows:

"Examples 1 to 9

Examples 1 to 9 concern the preparation of pharmaceutical compositions comprising the essential oil of *origanum hyrtum* [...] .

Example 1

There is provided a pharmaceutical composition for medical and veterinary uses for the treatment of Salmonellosis, Staphylococciasis, Pasteuridiosis and Colobacillosis (caused by *E. coli*) that attack the abdominal region (stomach and intestines) of humans and animals.

The composition is prepared in powder form, in syrup form or in paste form.

a) Powder form

The amounts of the essential ingredients used to prepare the powder form are given below:

<u>Ingredient</u>	<u>Veterinary use</u>	<u>[...]</u>
CaCO ₃	94%	[...]
Lactose	-	[...]
Tannin	1%	[...]
Origanum hyrtum oil	5%	[...]

[...]

b) Syrup form

As mentioned above, the pharmaceutical composition for the treatment of Salmonellosis, Staphylococciasis, Pasteuridiosis and Colobacillosis (caused by *E. coli*) can also be in syrup form. [...]

<u>Ingredient</u>	<u>Veterinary use [...]</u>	
Polyethylene glycol	92,5%	[...]
Origanum hyrtum oil	5%	[...]
Tannin	1%	[...]
Glycerine monostearate	1,5%	[...]

[...]

c) Paste form

According to the same method, but with slight variation of the levels of the various ingredients, a paste form is produced, intended for veterinary use only.

Ingredients

Polyethylene glycol	74%
Origanum hyrtum oil	5%
Tannin	1%
Glycerine monostearate	20%

[...]

Example 2

One additional form of powder is that intended for the prevention and treatment of coccidiosis in poultry, caused by the germs of the Eimeria group (E. tenella, E. acervulina, E. colhici, E. duodenalis, E. mitri, E. fasiani and the like. [...])

<u>Ingredient</u>	<u>Veterinary use (poultry)</u>	
CaCO ₃	90%	
Origanum hyrtum oil	5%	
Glycerine monostearate	1%	

[...]

For the prevention and treatment of coccidiosis, a solution form can also be prepared, with the following essential ingredients in the corresponding levels:

Ingredients

Origanum hyrtum oil	5%
Emulgator 484	3%
Propylene glycol	10%
Distilled water	82%

[...]".

- 10.2 Turning to document D49a, it is apparent from the section "Detailed description of the invention" on page 1 that the described invention relates to anti-inflammatory compositions containing essences of herbal origin that are as effective against inflammations, infections and diarrhoea as antibiotics and sulphamides. It is further stated on page 2 that the essential ingredient of the said anti-inflammatory compositions "... are herbal essences with high contents in thymol, carvacrol and tannin ...". In contrast to document D5, there is no information in neither the description nor the claims of document D49a which characterises the described invention by a certain ratio of carvacrol to thymol.

In addition to the general description, document D49a comprises eight examples. Example I of document D49a literally recites, albeit in a different order, the five compositions for veterinary use of examples 1 and

2 of document D5, with the exception that in the composition corresponding to the first composition of Example 2 of document D5 the content of glycerine monostearate is 5% according to document D49a, whereas it is 1% according to document D5 (see point 10.1 above). With respect to this difference, in the board's view the skilled person studying document D5 would recognise that, in contrast to the summed percentages for all the other relevant compositions, the sum of percentages for this one does not amount to 100 and that therefore the composition cannot be meant to read as such.

The board considers that for establishing the intended percentages of ingredients and in the absence of indications in the patent document itself, the skilled person would compare the disclosure of the erroneous composition to the disclosure of the corresponding composition in the priority document, because the disclosure of a specific example, if there is a corresponding one, is highly unlikely to change between the priority and the later application. He/she would therefore conclude that the value of 1% should in fact read 5% (see above).

The present board is aware of decision G 11/91 (OJ EPO, 1993, 125) regarding the correction of errors in the disclosure of a patent application pursuant to Rule 88 EPC 1973. The Enlarged Board held in point 7 of the reasons that priority documents may not be used to establish what a skilled person would actually derive, on the date of filing, from the parts of a European patent application relating to the disclosure.

However, in the present board's view, this decision is not applicable to the present case which is not related to the question of whether or not the correction of an error complies with the requirements of Article 123(2) EPC but rather is concerned with establishing the true disclosure content of a patent application in the case of an obvious error for the purposes of Article 54(3) EPC and for determining the validity of the claimed priority.

As far as the determination of the disclosure content of a prior art document is concerned it has been held by the boards of appeal in several decisions that for the correction of an obvious error in such a document the skilled person may resort to readily accessible relevant external documents, for example to a corresponding US patent application in the case of an obvious error in a British patent application (decision T 412/91 of 27 February 1996, see in particular point 3.5 of the reasons) or to the original document in the case of an obvious error in an abstract of that document (decisions T 77/87, OJ EPO 1990, 280, point 4.1.4 of the reasons and T 1080/99, OJ EPO 2002, 568, points 4.5 and 4.6 of the reasons).

Therefore, the board concludes that, in effect, the relevant examples in document D5 and document D49a are identical. This was also the view of the parties.

10.3 It follows from the above that, as a general disclosure, document D5 teaches that pharmaceutical compositions comprising essential oils having a ratio of carvacrol to thymol of at least 10 have a surprising antimicrobial activity, whereas document D49a discloses

that pharmaceutical compositions comprising herbal essences with high contents in thymol, carvacrol and tannin may be used in antimicrobial agents. Since the general disclosure of document D5 differs from that of document D49a, it is not entitled to the claimed priority and can therefore not be detrimental to the novelty of the subject-matter of claim 1 or of any other claim.

10.4 In addition, the board notes that claim 1 recites the feature that the "oil is present in an amount of 1 - 15% by weight, calculated on the total weight of the pharmaceutical composition". While the board accepts that this feature is not disclosed, as part of the general disclosure, in either of documents D5 and D49a, there are nevertheless doubts whether, in the light of case law regarding the novelty of selection inventions (see Case Law of the Boards of Appeal of the European Patent Office, 5th edition 2006, I.C.4.2), this fact would suffice to establish novelty. However, in view of the conclusions in points 10 to 10.3 above, a decision on this question is not needed.

10.5 The respondents' main argument turns on the question of the information content of the specific examples when read in the light of the general teaching. The respondents argue that the disclaimers in claim 1 should contain more than exactly the five relevant compositions disclosed in the examples of document D5 because account had also to be taken of the general disclosure in that document. The disclaimers according to the appellant's main request were not sufficient to restore novelty over the prior art under Article 54(3) EPC and therefore contravened the requirements of

Article 123(2) EPC as interpreted by the Enlarged Board of Appeal in its decision G 1/03 (supra).

However, as already set out in point 10.3 above, the general disclosure in documents D5 and D49a differs. Therefore, in the absence of necessary congruence, the teaching in the examples is not open for generalisation on the basis of the general disclosure.

10.6 Moreover, in the board's view, although they are present in both documents D5 and D49a, the five example compositions as such also do not offer the potential for generalisation. The board considers that each composition is characteristic in the sense that the type and the amount of the ingredients are specifically adapted to the type of formulation and to the disease to be treated. For example, for the treatment of salmonellosis, staphylococciasis, pasteuridiosis and colobacillosis the origanum oil is applied as a powder, syrup or paste, whereas it is applied as a powder or a solution for the treatment of coccidiosis. Concerning the ingredients, the powder for the treatment of salmonellosis, staphylococciasis, pasteuridiosis and colobacillosis consists of 94% CaCO₃, 1% tannin and 5% Origanum hyrtum oil, whereas the powder used for the treatment of coccidiosis is composed of 90% CaCO₃, 5% glycerine monostearate and 5% Origanum hyrtum oil (point 10.1 above).

10.7 The board thus concludes that the novelty-destroying disclosure in document D5 is restricted to the five specific compositions and their use for the indicated disease.

These are the features recited in disclaimers (a) to (e) in claim 1. Therefore, the disclaimers exclude what is necessary to restore novelty over the disclosure in document D5 and are therefore in agreement with the requirement established by the Enlarged Board of Appeal in decision G 1/03 (see point 7.1 above).

11. Claim 1 and dependent claims 2 to 6 fulfil the requirements of Article 123(2) EPC.

Novelty

12. In view of the observations in points 10 to 10.6 above, the board concludes that document D5 does not take away the novelty of the subject-matter of claim 1 and of dependent claims 2 to 6.

At the oral proceedings the respondents did not rely on objections of lack of novelty on the basis of other documents on file and the board also sees no reason to raise such objections.

Therefore, the board concludes that the requirements of Article 54 EPC are fulfilled.

Remittal

13. The grounds of opposition under Article 100(a) EPC that the patent does not involve an inventive step and under Article 100(b) EPC that the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art have not been addressed in the decision under appeal. The respondents have expressly asked for

remittal and the appellant has not objected to it.
Given these circumstances, the board decides to
exercise its discretion under Article 111(1) EPC in
favour of remittal.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the new main request filed at the oral proceedings.

The Registrar:

The Chair:

P. Cremona

U. Kinkeldey