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# Datasheet for the decision of 21 April 2016

**Case Number:** T 2024/11 - 3.3.02

**Application Number:** 96920051.8

**Publication Number:** 0828502

**IPC:** A61K35/78

**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

**Patent Proprietor:**
D & W Trading B.V.

**Opponents:**
ECOPHARMA HELLAS LTD.
Erber Aktiengesellschaft
bioptivet Tierarzneimittel GmbH & Co.
Frey + Lau GmbH

**Headword:**
Etheric oils/D & W TRADING

**Relevant legal provisions:**
RPBA Art. 15(3)
EPC Art. 56, 84, 113(1)

**Keyword:**
Inventive step - (no)
Amendments - undisclosed disclaimer: clarity (no)
Right to be heard - opportunity to comment (yes)

**Decisions cited:**
G 0004/92, T 0382/07, G 0009/91, T 0250/02

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**
**Boards of Appeal**
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**Case Number: T 2024/11 - 3.3.02**

# D E C I S I O N
# of Technical Board of Appeal 3.3.02
# of 21 April 2016

| | |
|---|---|
| **Appellant:**<br>(Patent Proprietor) | D & W Trading B.V.<br>Van Beekstraat 136<br>1121 NT Landsmeer (NL) |
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| **Respondent:**<br>(Opponent 1) | ECOPHARMA HELLAS LTD.<br>P.O.Box 63<br>61100 Kilkis (GR) |
| **Representative:** | Wibbelmann, Jobst<br>Wuesthoff & Wuesthoff<br>Patentanwälte PartG mbB<br>Schweigerstrasse 2<br>81541 München (DE) |
| **Respondent:**<br>(Opponent 2) | Erber Aktiengesellschaft<br>Industriestrasse 21<br>3130 Herzogenburg (AT) |
| **Representative:** | Cunow, Gerda<br>Cunow Patentanwalts KG<br>Teschnergasse 33/1/3<br>1180 Wien (AT) |
| **Respondent:**<br>(Opponent 3) | bioptivet Tierarzneimittel GmbH & Co.<br>Im Landwehrwinkel 22<br>59073 Hamm (DE) |
| **Respondent:**<br>(Opponent 4) | Frey + Lau GmbH<br>Immenhacken 12<br>24558 Henstedt-Ulzburg (DE) |

**Representative:** Stork, Ute
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**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted on 7 July 2011 revoking European patent No. 0828502 pursuant to Article 101(3)(b) EPC.**

**Composition of the Board:**

**Chairman** U. Oswald
**Members:** T. Sommerfeld
D. Prietzel-Funk

## Summary of Facts and Submissions

I. Four oppositions were filed against the granted European patent 828 502, based on application 96920051.8, which was published as international application WO 96/37210, all opponents requesting revocation of the patent in its entirety. The evoked grounds of opposition were lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC), and added subject-matter (Article 100(c) EPC).

II. A first decision of the opposition division was issued, whereby the patent was revoked. The patent proprietor lodged an appeal against this decision, and the contested decision of the opposition division was set aside by decision T 382/07 of 26 September 2008. In said decision, the technical board of appeal 3.3.4 decided that the main request fulfilled the requirements of Rule 80 EPC, Article 123(2) and (3) EPC, Article 84 EPC and Article 54 EPC, and remitted the case to the first instance for further prosecution.

III. By decision pronounced at oral proceedings, the opposition division revoked the patent on the grounds that none of the requests on file fulfilled the requirements of Article 56 EPC. Moreover the opposition division concluded that claim 1 of the first, third, fourth, fifth, sixth and seventh auxiliary requests did not comply with Articles 84 and 123(2) EPC.

IV. The patent proprietor (appellant) lodged an appeal against this decision. With the statement of the grounds of appeal, the appellant requested that the decision of the opposition division be set aside and

the patent be maintained on the basis of the main request or alternatively on the basis of one of seven auxiliary requests, all filed with the grounds of appeal.

V. By their letters of reply, both opponent 2 (hereinafter, respondent II) as well as opponent 4 (respondent IV) requested that the appeal be dismissed.

VI. A communication of the board pursuant to Rule 100(2) EPC was sent, summarising the case. The board raised objections under Articles 84 and 123(2) EPC to the pending auxiliary requests and gave a preliminary negative opinion as regards inventive step.

VII. Replies from the appellant and respondent II were submitted. With its reply, the appellant replaced the pending auxiliary requests by new auxiliary requests 1 to 6.

The **main request** is identical to the request considered in the previous decision T 382/07. Its claim 1 reads as follows:

"1. Use of a composition comprising an active agent and a pharmaceutically acceptable carrier, wherein the active agent is an oil extracted from Origanum vulgaris, 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 composition, provided that:

(a) the composition is not a powder having 94 % $CaCO_3$, 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 % $CaCO_3$, 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 Eimera 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."

Claim 1 of each of the auxiliary requests differs from claim 1 of the main request by amendments to the

medical use feature (last part of the claim) as follows (insertions underlined, deletions struck through):

**Auxiliary request 1**: "(...) for the preparation of a veterinary medicament for the prevention or treatment of gastrointestinal infections in animals."

**Auxiliary request 2**: "(...) for the preparation of a medicament for the prevention or treatment of gastrointestinal infections in non-human animals."

**Auxiliary request 3**: "(...) for the preparation of a medicament for the prevention ~~or treatment~~ of gastrointestinal infections in animals."

**Auxiliary request 4**: "(...) for the preparation of a veterinary medicament for the prevention ~~or treatment~~ of gastrointestinal infections in animals."

**Auxiliary request 5**: "(...) for the preparation of a medicament for the prevention ~~or treatment~~ of gastrointestinal infections in non-human animals."

**Auxiliary request 6**: "(...) for the preparation of a medicament for the prevention or treatment of ~~gastrointestinal infections in animals~~ coccidiosis in poultry."

VIII. Summons for oral proceedings before the board were issued, with no accompanying communication.

IX. The appellant and respondent IV informed in writing that they would not attend oral proceedings.

X. Oral proceedings before the board took place as scheduled, in the absence of the appellant and of the

respondents I, III and IV. At the end of the oral proceedings, the chairman announced the decision of the board.

XI. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D8 Progress in Essential Oil Research, pp.151-156 (1985)
D11 Hagers Handbuch, 5. Auflage, pp.828-835,959-964, 976-980 (1993)
D13 Kostas Bazeos, "100 Heilkräuter - 1000 Therapien" (1982): German translation of excerpts
D57 Expert opinion of Dr. Klaas D. Bos, 07.11.06

XII. The appellant's submissions, in so far as relevant for the present decision, may be summarised as follows:

*Main request and auxiliary requests 1 to 5: Inventive step*

Documents D8 and D11 did not relate to veterinary applications at all. Moreover, D8 reported results for a number of microorganisms which were not pathogenic, such as Bacillus subtilis, or which did not cause gastrointestinal pathology (page 152 fourth paragraph); D8 was thus rather a study on the antimicrobial activity of various oils obtained from several Origanum plants in general. D11 on the other hand was a handbook which taught various scientifically unproven medical uses of oil obtained from Origanum vulgare in human beings, gastrointestinal infections being just one among a list of diseases (D11, pages 960 to 961). A document directed to the same purpose as the invention was not on file, but such prior art was mentioned in

the patent at paragraph [0006]. D8 and D11 did not disclose the amount of oil of 1-15% weight, nor that it was for the preparation of a medicament for preventing or treating gastrointestinal infection in animals. The problem was the provision of alternative medicaments for the treatment of gastrointestinal infections in animals which would avoid the disadvantages of well known antibiotics used in the technical field. Examples 4 to 6 showed that the problem had been solved, and this was further confirmed by other documentary evidence on file. The claimed solution was not obvious, because none of the documents on file suggested that Origanum oils could be used to treat gastrointestinal infection in animals. D8 actually taught away from using oils from Origanum vulgare as it showed that oils from Origanum syriacum var. bevanni were more effective against the microorganisms studied than those from Origanum vulgaris var. hirtum (Table II at page 155). At the priority date, it was commonly known that antibiotics were mostly used in sub-therapeutic amounts to promote growth of the animals, to increase food conversion and to prevent diseases, but hardly for the treatment of sick animals. Hence, the skilled person could have investigated oregano oil as an additive for promoting growth and increasing food conversion, but he would not do so for solving the technical problem of prevention or treatment of gastrointestinal infections in animals.

XIII. The arguments of respondents II and IV, in so far as relevant for the present decision, may be summarised as follows:

*Main request and auxiliary requests 1 to 5:*
*Inventive step*

Respondent II argued that D8 and D11 were directed to a similar purpose as the invention and constituted the prior art which required the smallest number of structural modifications in order to arrive at the invention. The only differences to the claimed subject-matter was that they did not mention *expressis verbis* the use of origanum oil in animals nor the amount of active agent as being 1-15% of oregano oil. Document D8 was not explicitly directed to human therapeutical applications, and the patent application itself did not originally make any distinction between use for humans or for other animals, nor did it report any unexpected effects for the use in animals in comparison to the use in humans. Other documents on file also showed that etheric oils (also from Origanum) could be used in different clinical situations in both humans and animals. There was no prejudice in the prior art against using in animals the etheric oils which had been already used in humans. In the patent there was no disclosure of such a composition wherein only oregano oil derived from Origanum vulgare as active agent was present: example 2 disclosed a composition comprising not only 3-5% of oregano oil but also thymus vulgaris oil, Mentha piperita oil and tannin. Only in example 6 was oregano oil used as sole active agent, but here it was not disclosed in which percentage. Thus the selection of 1-15% oregano oil appeared to be an arbitrary selection.

Respondent IV considered D11 or D13 as the closest prior art and formulated the technical problem as the provision of a new patient group and the appropriate dosage therefor. As was apparent from the patent application itself, the idea of using the same composition for both humans and animals was plausible. Indeed, many of the pharmaceuticals which were used for

veterinary applications had been first used for medical (human) applications. On the other hand, before being used in humans, medicaments had to be tested for toxicity and efficacy in animals. In view of the problems of the industrialized animal raising there was a need to have alternatives to antibiotic use in animals. As to the further difference relative to the dosage, this was just a usual dosage range which would be defined by routine trials and there was no evidence that it was especially advantageous or unusual.

*Auxiliary request 6*

Respondent II argued that the disclaimers rendered the claim unclear and did not fulfil Article 123(2) EPC. The indication for "prevention or treatment" also added subject-matter, because in the original filed application only "prevention and treatment" could be found.

XIV. Respondents I and III have not made any submissions during the whole appeal proceedings.

XV. The appellant requested (in writing) that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed with the grounds of appeal, or alternatively on the basis of one of auxiliary requests 1 to 6, all filed with letter of 16 October 2015.

Respondents II and IV (the latter in writing) requested that the appeal be dismissed.

## Reasons for the Decision

1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of the appellant and of respondents I, III and IV who had been duly summoned but decided not to attend.

The present decision is based on facts and evidence put forward during the written proceedings and on which all parties have had an opportunity to comment.

Therefore the conditions set forth in Enlarged Board of Appeal opinion G 4/92, OJ EPO 1994, 149, are met.

Moreover, as stipulated by Article 15(3) RPBA the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

3. T 382/07: Res judicata

3.1 The claims of the main request have already been the subject of the decision T 382/07, which concluded that they fulfilled the requirements of Rule 80 EPC, Article 123(2)(3) EPC, Article 84 EPC and Article 54 EPC. These issues are thus not open for discussion as regards the main request.

3.2 Furthermore, for the auxiliary requests, the present board of appeal is bound by the ratio decidendi of the previous decision T 382/07, but only in so far as the facts are the same. As regards amendments, these have to be fully examined as to their compliance with all requirements of the EPC, in accordance with G9/91, OJ 1993, 408 (point 19 of the Reasons).

4. Main request

4.1 Article 56 EPC

4.1.1 The present patent discloses the use of pharmaceutical compositions comprising etheric oils extracted from specific plants for the prevention and treatment of gastrointestinal disorders in the human and veterinary medical field (paragraph [0001]). Paragraphs [0002] and [0003] further disclose the technical problem "that is solved with this invention" as being "the obtainment of various types of human medicaments on the basis of active natural components that successfully replace prior art medicaments based on sulfonamids, antibiotics, cortisones etc." (paragraph [0002], emphasis added by the board) and as being "the obtainment of various types of veterinary medicaments on the basis of natural components, that successfully replace prior art products based on sulfonamids, antibiotics etc.. " (paragraph [0003], emphasis added by the board). The therapies proposed by the patent would overcome the shortcomings associated with conventional antibiotic treatment, namely the presence of bioresidues ("biorecidives" [sic]), either in the human body or in the meat or milk of animals, and of generation of microorganism resistance against antibiotics (paragraphs [0002] and [0003]). It is thus apparent that the aim of the patent is to provide "ecologically healthy" alternatives to medicaments such as antibiotics in the treatment of gastrointestinal infections both in humans and in other animals (paragraphs [0004] to [0007]).

4.1.2 It is established practice in proceedings before the EPO that inventive step is assessed according to the

problem-solution-approach, which involves the determination of the closest prior art document, the formulation of the problem to be solved in view of the closest prior art document and its solution. According to established case law, the closest prior art document is a disclosure providing the most promising springboard towards the claimed invention; this is normally a document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention.

4.1.3 Present claim 1 is in the form of a Swiss-type medical use claim, wherein the therapeutical indication is "prevention or treatment of gastrointestinal infections in animals". This is thus the purpose of the claimed subject-matter, and as such the closest prior art should accordingly also be a disclosure directed to the prevention or treatment of gastrointestinal infections in animals, as correctly argued by the appellant.

4.1.4 None of the prior art documents on file which are citable under Article 54(2) EPC serves this purpose or objective. However, it has not been disputed that the conventional treatment of infections (including gastrointestinal infections) in animals in the prior art was by administration of antibiotics, sulfonamids or adrenocortical hormones (see also patent, paragraphs [0004] and [0006], the latter having been cited by the appellant as representing the closest prior art). This was also confirmed in the expert declaration D57, at paragraph 3.4. In the present circumstances and following the approach of the decision T 250/02 of 28 April 2005 (see reasons 19.2), the board thus comes to the conclusion that this conventional treatment of gastrointestinal infections in animals is to represent the closest prior art.

4.1.5 The technical problem is thus to provide an alternative prevention or treatment of gastrointestinal infections in animals. The solution according to claim 1 is to use a composition as claimed. In view of the data provided in Table A of the patent, displaying an "antibiogram" of origanum oil, the board is satisfied that the technical problem as formulated has been plausibly solved in the patent by the claimed subject-matter.

4.1.6 However, the board notes that it was already known from the prior art that origanum oil possessed antimicrobial activity against a number of pathogens, including at least some that are known to cause gastrointestinal infections in animals (e.g. Escherichia coli, Salmonella spp., Clostridium spp.: see paragraph [0020] of the patent): document D8 (Table II) and D11 (page 961, left column, lines 15 to 22, 41 to 42 and penultimate paragraph). Thus, the skilled person, motivated to provide alternative treatment possibilities for gastrointestinal infections in animals, in particular such treatments that do not have the shortcomings of the conventional antibiotic treatment, would be prompted by D8 and D11 to use origanum oil-based compositions for this purpose. In view of the already available functional in vitro data mentioned above (D8, D11), the expectation of success would be reasonable. In fact, the conclusions of the patent are also based on in vitro tests of the oil's antimicrobicidal activity ("antibiograms"), see paragraphs [0018] to [0020], with the only exception of the treatment of coccidiosis (Eumeria sp.) in poultry, which was also tested in vivo (Examples 4 and 5).

4.1.7 As regards the feature of the amount of oil used as being 1 to 15% weight, while this is indeed not

disclosed in the prior art, there is also no specific effect disclosed in the patent in connection with this specific amount. In fact, the patent states in paragraph [0015] that "the content of active agent in the pharmaceutical compositions according to the invention, which in fact does also depend on its pharmaceutical use, may vary between wide limits". No amounts are indicated for the antibiogram data of Table A. In the examples 2 and 3, formulations for veterinary pharmaceutical medicaments are disclosed which comprise 3 to 5% of origanum vulgaris oil, among other active ingredients; there is however no disclosure of the use of these formulations for treatment. For the specific use of treatment and prevention of coccidiosis in poultry (examples 4 and 5), a composition is used which comprises 5% origanum vulgaris oil and 95% $CaCO_3$, and a therapeutic effect is demonstrated. However, nowhere in the application is it apparent that a therapeutic effect or any further effect are specifically connected to the claimed amount.

4.1.8 Accordingly, the board comes to the conclusion that the skilled person would be prompted by the prior art (D8, D11) to use oils from Origanum vulgare as alternative to the conventional antibiotic treatment for gastrointestinal infections in animals, and would merely need routine measures to determine the appropriate amount to be used. Claim 1 is thus considered to lack inventive step.

4.1.9 The appellant essentially argued that documents D8 and D11 were not concerned with treatment of gastrointestinal infections in animals (as opposed to humans), and D8 in fact would teach away from using oils from Origanum vulgare since it showed that oils from Origanum syriacum var. bevanni were more effective

than those from Origanum vulgaris var. hirtum against the microorganisms studied. Moreover, antibiotics were mostly used in animals for promoting growth and increasing food conversion, rather than for treating gastrointestinal infections. Hence, the skilled person would consider questionable that oregano oil could be an effective alternative to antibiotics for promoting growth and increasing food conversion. The skilled person could have investigated oregano oil as an additive for promoting growth and increasing food conversion, but he would not do so in an attempt to solve the technical problem of prevention or treatment of gastrointestinal infections in animals.

4.1.10 The board does not agree with these arguments. Since at least some of the microorganisms tested in D8 and D11 were known to cause gastrointestinal infection (see above, section 4.1.6), this would be an obvious therapeutical indication, both for human and for other animals. Just like the patent, the prior art shows antimicrobial effects of the oregano oil and this justifies the therapeutic indication. Document D8 shows an antimicrobial effect for oils derived from Oreganum vulgare, and the board fails to see a significant difference in relation to oils from other Oreganum species. Finally, the issue of using oregano oil as an alternative to antibiotics for promoting growth and increasing food conversion is outside the scope of the claim, which is directed at therapies for gastrointestinal infections in animals. Independently of other possible uses of antibiotics in animals, the problem addressed by the patent concerns their use for treatment of gastrointestinal infections, and the patent itself states (and is further confirmed by D57) that antibiotics constituted the standard therapy for gastrointestinal infections in animals.

5. Auxiliary requests 1 to 5

5.1 Article 56 EPC

5.1.1 Claim 1 of these requests merely differs from claim 1 of the main request by restriction to a veterinary medicament (auxiliary requests 1 and 4), or to the use in non-human animals (auxiliary requests 2 and 5), or to the use being solely for prevention (auxiliary requests 3, 4 and 5). The board notes that the above considerations concerning the main request already apply to veterinary medicaments and to the use in non-human animals. Moreover, the board fails to see how the restriction to preventive treatment is to contribute to inventive step and notes that use in prevention has only been demonstrated in the patent in the context of coccidiosis in poultry.

5.1.2 Hence, auxiliary requests 1 to 5 are also considered to lack an inventive step.

6. Auxiliary request 6

6.1 Article 84 EPC

6.1.1 Claim 1 is directed to the use of the composition (defined as in claim 1 of the main request) for the preparation of a medicament for the prevention or treatment of coccidiosis in poultry. This claim comprises the same five undisclosed disclaimers that are also present in claim 1 of the main request. While these disclaimers were found allowable under Article 84 EPC and Article 123(2) EPC in decision T 382/07, they have to be re-examined in the context of the present

auxiliary request, wherein claim 1 is restricted to prevention or treatment of coccidiosis in poultry.

6.1.2 Disclaimers (a), (c) and (d) are not related to coccidiosis in poultry but rather to Salmonellosis, Staphylococciasis, Pasteurodiosis and Colobacillosis in animals. Since the claim is restricted to coccidiosis in poultry as sole therapeutical indication, the presence of these disclaimers, related to other therapeutic indications, is unnecessary and thus redundant, and raises doubts as to what subject-matter is in fact encompassed by the claim.

6.1.3 Auxiliary request 6 therefore contravenes the requirements of Article 84 EPC.

7. Right to be heard

7.1 The auxiliary requests were only submitted in reply to a communication from the board. No further communications from the board ensued, nor was there any reply from the respondents addressing these new requests. As such, the objection for lack of clarity directed against auxiliary request 6 was only put forward at the oral proceedings, in which the appellant was not present.

7.2 The principle of the right to be heard pursuant to Article 113(1) EPC is nevertheless observed since that Article only affords the opportunity to be heard and, by absenting itself from the oral proceedings, a party gives up that opportunity.

7.3 In fact, when submitting amended claims, a patent proprietor has to count on the possibility of new objections, in particular under Articles 84 and 123(2)

(3) EPC, being raised against them. In the present case, a similar objection, albeit in the context of different claims, had already been raised even by the opposition division in its decision: on pages 9 and 10, sections D) and E) of the decision, the opposition division concluded that Articles 84 EPC and 123(2) EPC were not fulfilled for almost all of the then valid auxiliary requests, in view of a discrepancy between the subject-matter covered by the claim and the disclaimed subject-matter.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated