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**D E C I S I O N**  
**of 28 April 2005**

**Case Number:** T 0250/02 - 3.3.4

**Application Number:** 96922166.2

**Publication Number:** 0835120

**IPC:** A61K 35/78

**Language of the proceedings:** EN

**Title of invention:**

Pharmaceutical compositions containing herbal-based active ingredients; method for preparing same and uses of same for medical and veterinary purposes

**Patentee:**

Nitsas, Fotios, A.

**Opponent:**

ROPAPHARM B.V.

**Headword:**

Pharmaceutical Compositions/NITSAS

**Relevant legal provisions:**

EPC Art. 54, 56

**Keyword:**

"Main request - inventive step (no)"

"Auxiliary request - novelty, inventive step (yes)"

**Decisions cited:**

G 0005/83, G 0002/88, G 0002/98, T 0049/89, T 0402/89,  
T 0579/01, T 0604/01

**Catchword:**

-



Case Number: T 0250/02 - 3.3.4

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.4  
of 28 April 2005

**Appellant:**  
(Opponent)

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**Decision under appeal:**

Decision of the Opposition Division of the  
European Patent Office posted 28 December 2001  
rejecting the opposition filed against European  
patent No. 0835120 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairwoman:** U. Kinkeldey  
**Members:** M. Wieser  
R. Moufang

## Summary of Facts and Submissions

I. The appeal was lodged by the Opponent (Appellant) against the decision of the Opposition Division to reject the opposition against European patent No. 0 835 120 under Article 102(2) EPC. The patent had been granted on the basis of claims 1 to 13 and claims priority from Greek application 950100249 filed on 29 June 1995. It had been opposed in its entirety under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and inventive step (Article 56 EPC).

II. Independent claim 2 as granted read:

"A pharmaceutical composition comprising a herbal essential oil containing thymol and carvacrol as its main ingredients and a pharmaceutically acceptable carrier, characterised in that

- a. the total amount of thymol and carvacrol in said essential oil is at least 55%, preferably 70% by weight of said essential oil and
- b. the ratio of carvacrol to thymol is at least 30."

Dependent claim 9 as granted read:

"A pharmaceutical composition according to any of claims 1 to 4 for use in the prevention and treatment of coccidiosis in poultry."

III. The following documents are mentioned in this decision:

- (3) The Illustrated Encyclopedia of Essential Oils, Julia Lawless (Ed.), Element Books Ltd., 1995, Reprinted 1996, page "Common Oregano".

- (5) WO 96/37210
  
- (7) Scheffer *et al.* (1986), In "Progress in Essential Oil Research", Ernst-Joachim Brunke (Ed.), Walter de Gruyter & Co., 1986, pages 151-156.
  
- (8) Römpp Chemie Lexikon, 9. erweiterte und neubearbeitete Auflage, Falbe & Regitz (Eds.), Georg Thieme Verlag, 1990, pages 260 and 2666.
  
- (9) Kirk-Othmer Encyclopedia of Chemical Technology, 4th Edition, Kirk-Othmer (Eds.), John Wiley & Sons, 1994, INDEX, p.311 & Vol. 18, p.480.
  
- (10) Hagers Handbuch der Pharmazeutischen Praxis, 5. vollständig neubearbeitete Auflage 1993, F. von Bruchhausen *et al.* (Eds.), Bd. 5, p. 960-961.

IV. With letter dated 13 November 2002 in response to the statement setting out the grounds of appeal, the Respondent (Patentee) requested that the appeal be dismissed or alternatively that the decision of the Opposition Division be set aside and the patent be maintained on the basis of a first or second auxiliary request.

Claim 1 of the second auxiliary request read:

"A pharmaceutical composition comprising a herbal essential oil containing thymol and carvacrol as its main ingredients and a pharmaceutically acceptable carrier, characterized in that

- a. the total amount of thymol and carvacrol in said essential oil is at least 55%, preferably 70% by weight of said essential oil and
  - b. the ratio of carvacrol to thymol is between 40 and 110."
- V. When summoning to oral proceedings, the Board sent a communication pursuant to Article 12(1) RPBA dated 3 December 2004. In point 10.8 of this communication, the Board noted in relation to claim 1 of the second auxiliary request, that all examples in the patent in suit were carried out with an essential oil having a carvacrol to thymol ratio of 75,7 and no beneficial effect was substantiated by experimental data in the form of comparative tests for pharmaceutical compositions wherein the ratio of carvacrol to thymol was between 40 and 110.
- VI. In response to this communication the Respondent filed, with letter of 4 February 2005, four new claim requests as well as an experimental report authored by Dr Tsinas in support of his case in favour of inventive step of the claimed invention. Claim 1 of the new first auxiliary request was identical to claim 1 of the second auxiliary request filed with letter dated 13 November 2002 (see section IV above), but for the adapted wording of feature b. which reads "b. the ratio of carvacrol to thymol is between 40:1 and 110:1."
- VII. With letter dated 28 February 2005 the Appellant introduced four further documents into the proceedings, including document (10).

VIII. Oral proceedings were held on 28 April 2005. During these oral proceedings the parties maintained the following requests:

The Appellant (Opponent) requested that the decision be set aside and the patent revoked.

Furthermore, the Appellant requested to disregard, pursuant to Article 114(2) EPC, the experimental report authored by Dr Tsinas and filed by Respondent with letter of 4 February 2005.

The Respondent (Patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of a new main request or, alternatively, on the bases of the sole claim of a new auxiliary request and pages 2 to 7 of the amended description, all filed during the oral proceedings.

The Respondent furthermore requested not to allow into the proceedings the documents submitted by the Appellant with letter of 28 February 2005.

Claim 1 of the Respondent's new main request was identical to claim 1 of the first auxiliary request filed on 4 February 2005 (see section VI above) and corresponded hence to claim 1 of the second auxiliary request filed on 13 November 2002 (see section IV above).

The sole claim of the new auxiliary request read:

"A use of a composition comprising a herbal essential oil containing thymol and carvacrol as its main ingredients, wherein

- a. the total amount of thymol and carvacrol in said essential oil is at least 55%, preferably 70% by weight of said essential oil and
- b. the ratio of carvacrol to thymol is at least 30; in the preparation of a pharmaceutical composition wherein said essential oil is mixed with a pharmaceutically acceptable carrier for the prevention or treatment of coccidiosis in poultry."

IX. The Appellant's arguments as far as they are relevant for the present decision may be summarised as follows:

*Admissibility into the procedure of document (10)*

- Document (10) should be allowed into the proceedings as it was filed in response to an unexpected change of the legal and factual framework of the appeal proceedings seeing that the Respondent had filed an experimental report by Dr Tsinas and new claim requests.

*Admissibility into the procedure of the experimental report by Dr Tsinas*

- This late filed evidence could have been filed much earlier in the proceedings and the Respondent had not indicated any reasons for the late filing. It had been established case law of the Boards of Appeal not to admit experimental evidence at such a late stage in the proceedings. Allowing the evidence in the proceedings deprived the Appellant from doing

counter experiments. The report should therefore be disregarded pursuant to Article 114(2) EPC.

*Main request*

*Novelty*

- Document (5) stated on page 7, lines 34 to 37, that "*On the basis of the existing types of Origanum vulgare it has been possible to obtain seeds of Origanum vulgare plants having about 91% active material: 86-88% carvacrol and 3-5% thymol.*". It was therefore common general knowledge of the skilled person that other types of *Origanum vulgare* contain carvacrol and thymol within the range of ratios as specified in claim 1. Such plants were indeed known to the skilled person from document (10), which was representative for the skilled person's common general knowledge. Claim 1 therefore lacked novelty under Article 54(3), (4) EPC over document (5) and the common general knowledge.

*Inventive step*

- The data disclosed in table II of document (7), which Appellant considered to represent the closest prior art, showed that the higher the ratio of carvacrol to thymol in an herbal essential oil was, the more effective the growth of certain micro-organisms was inhibited by such oil. Consequently, for a person skilled in the art desiring to optimise the activity of the pharmaceutical compositions as disclosed in document (7), it was obvious to try with a reasonable expectation of success to



experiment with the *Origanum* oil as disclosed in document (10), an oil having features which overlap with features a. and b. of claim 1 and hence, he would inevitably arrive at the subject matter of claim 1.

*First auxiliary request*

*Novelty*

- The treatment of coccidiosis in poultry was described in document (5) at page 6, lines 1 to 2. The claimed ratio of carvacrol to thymol to be at least 30, i.e. only just above the highest ratio explicitly disclosed in document (5) being 29, did not justify novelty of the claimed subject matter. Moreover, the same argument as developed against claim 1 of the main request based on document (5) combined with the common general knowledge of the skilled person applied to claim 1 of the auxiliary request.

*Inventive step*

- Coccidiosis was caused by germs of the *Eimeria* group of parasites. It was commonly known that antibiotics were used to treat coccidiosis. Since the compositions as claimed have antibiotic activity, e.g. as can be taken from document (7), it was at least obvious for a person skilled in the art to try with a reasonable expectation of success to employ these compositions for this disease. Moreover, document (3) disclosed that oregano oil had been

used as parasiticide. Accordingly, claim 1 of the auxiliary request lacked inventive step.

- X. The Respondent's arguments as far as they are relevant for the present decision may be summarised as follows:

*Admissibility into the procedure of document (10)*

- Document (10), filed by the Appellant, merely reflected common general knowledge of the relevant skilled person which was not more relevant than any of the documents which had been in the proceedings prior to its submission.

*Admissibility into the procedure of the experimental report by Dr Tsinas*

- The experimental report authored by Dr Tsinas had been filed in direct response to the Board's communication pursuant to Article 12(1) RPBA dated 3 December 2004 questioning the substantiation of a beneficial effect for the claimed subject-matter.

*Main request*

*Novelty*

- For the purpose of examining the novelty of claimed subject-matter, the common general knowledge of the relevant skilled person could not be used to fill in gaps in the disclosure of a prior art document in order to come to a finding of lack of novelty. Accordingly, despite the knowledge of the skilled person of other *Origanum* variants as the ones

disclosed in document (5), e.g. the plants disclosed in document (10), document (5) was not novelty destroying under Article 54(3), (4) EPC for the subject-matter of claim 1 of the main request.

*Inventive step*

- Document (7) did not, neither explicitly nor implicitly, elaborated on the importance of the ratio of carvacrol to thymol in the herbal essential oils disclosed for their activity. The first sentence of the section "Results and discussion" at page 152 merely characterised a feature of the tested essential oils without pointing to any consequences of this fact for their activity.
- Furthermore, the data in table II of document (7) was not of such nature that a skilled person would draw a general conclusion that the higher the ratio carvacrol to thymol was in the essential oil, the higher the anti-microbial activity was. In addition, document (7) emphasised that the data reported in table II had no direct correlation with the antimicrobial activity expressed as minimum inhibitory concentration values.
- Document (10) was not suitable to represent the closest prior art as the document itself questioned the pharmaceutical efficacy of the essential oils disclosed. At page 960, in the section describing the activities of the essential oils, document (10) stated that since high concentrations of the oils were used in the reported micro-organism inhibition studies, such results were of little relevance for a

possible pharmaceutical application. Furthermore, at page 961, in the section describing the traditional uses of the essential oils, document (10) qualified these uses with the remark that the efficacy of the oil in these uses had not been proven by scientific experimentation.

- As reiterated in paragraph [0021] of the specification of the patent the best antimicrobial activities of the essential oils were observed in the range of 40 to 110. This was confirmed by the comparative data provided with the experimental report of Dr Tsinas. The compositions of claim 1 were therefore particularly well suited as substitutions of conventional antibiotics.

*Auxiliary request*

*Novelty*

- For the same reasons as for the main request, the subject matter of claim 1 of the auxiliary request was novel.

*Inventive step*

- Neither document (7) taken alone, nor read in conjunction with document (3) rendered the subject-matter of claim 1 obvious. In fact, the applicability of the herbal essential oils of claim 1 in the treatment or prevention of coccidiosis in poultry was not disclosed in any of the cited prior art documents pursuant to Article 54(2) EPC.

## Reasons for the Decision

### *Admissibility into the proceedings of document (10)*

1. Document (10), an excerpt of "Hagers Handbuch der Pharmazeutischen Praxis" and prior art in accordance with Article 54(2) EPC, was submitted by the Appellant with letter of 28 February 2005, in response to claim requests filed by the Respondent in direct reaction to the Appellant's appeal and the communication of the Board pursuant to Article 12(1) of the RPBA, dated 3 December 2004. These claim requests included for the first time during the opposition and subsequent appeal proceedings certain exemplified ranges of ratios of carvacrol to thymol. They therefore caused, in the Board's judgement, a new factual situation for the Appellant which could allow for the submission of new documents.
  
2. Document (10) describes essential *Origanum* oils containing carvacrol and thymol in amounts and having specific ranges of ratios of carvacrol to thymol which overlap with those as now specified in claim 1 of the new main request. A *prima facie* relevance of document (10) for coming to the present decision is therefore established. It is worth noting here that the relevance of document (10) is confirmed by the reasons for the present decision dealing with novelty and inventive step of the new main and auxiliary request. Consequently, the Board admits document (10) into the proceedings in exercising its discretion provided under Article 114(2) EPC.

*Admissibility into the procedure of the experimental report by Dr Tsinas*

3. The experimental report authored by Dr Tsinas was filed by the Respondent in direct response to a remark in point 10.8 of the Board's communication pursuant to Article 12(1) RPBA questioning the substantiation of a beneficial effect by experimental data in the form of comparative tests for the claimed subject-matter in the patent. The data in the experimental report was therefore *prima facie* relevant for the decision to be taken, and hence, independently of their late filing, to be admitted in the proceedings.

*Validity of the priority for the subject-matter of claim 1 of both requests*

4. The patent in suit claims priority from Greek application 950100249 filed on 29 June 1995. The priority document does not disclose a herbal essential oil wherein the total amount of carvacrol and thymol is at least 55%, preferably 70% by weight of said essential oil, as required by claim 1 of both requests. As follows from page 2, lines 15 to 17, of its English translation, the priority document discloses *Origanum hyrtum* containing "thymol and carvacrol in levels of 55% to 65%". Moreover, the priority document does not disclose the exact ratios of carvacrol to thymol as contained in claim 1 of the requests. In accordance with decision G 2/98 of the Enlarged Board of Appeal (OJ EPO 2001, 413), the requirement for claiming priority of "the same invention" referred to in Article 87(1) EPC means that priority of a previous

application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject matter of a claim directly and unambiguously from the previous application as a whole. In view of the above, claim 1 of the main request and auxiliary request are not entitled to the claimed priority date, with the consequence that their relevant date is the International filing date 27 June 1996. Both parties agreed to this finding during the oral proceedings.

*Main request*

*Articles 123(2), (3) and 84 EPC*

5. The Appellant has not forwarded any objections to claim 1 of the main request on the basis of Articles 123(2), (3) and 84 EPC. Since the main request is not allowable for other reasons, it is not necessary for the purpose of this decision that the Board decides on the compliance of the main request with these requirements.

*Novelty*

6. Following from the above finding on the validity of the priority for claim 1, document (5) which was filed on 24 May 1996 and published on 28 November 1996, is contained in the prior art pursuant to Article 54(3), (4) EPC, independently of the entitlement to the priority claimed in that patent application. The document is concerned with pharmaceutical compositions based on herbal essential oils, i.e. it describes at page 7, lines 23 to 25, etheric oils extracted from a variety of plants which in general contain a certain percentage

of thymol and carvacrol, i.e. approximately 60-70% carvacrol and 3% thymol. The ratio of carvacrol to thymol therefore varies in these oils from about 20:1 to 23:1. Furthermore, at page 8 lines 32 to 36 document (5) describes an oil derived from *Origanum vulgare* applied in the pharmaceutical compositions. The oil contains carvacrol in an amount of 86-88% and thymol in an amount of 3-5%. The ratio of carvacrol to thymol therefore varies in this oil from about 1:17 to 1:29.

- 6.1 Since the ratio of carvacrol to thymol of the oil applied in the pharmaceutical composition of claim 1 of the main request varies between 40:1 and 110:1, which is distinct from the ratios disclosed in document (5), the Board judges that the subject matter of claim 1 of the main request is novel over the disclosure in this document.
- 6.2 The Respondent has argued that in view of the fact that document (5) on page 7, lines 34 to 37 discloses that "On the basis of the existing types of *Origanum vulgare* it has been possible to obtain seeds of *Origanum vulgare* plants having about 91% active material: 86-88% carvacrol and 3-5% thymol.", it was common general knowledge of the skilled person that other types of *Origanum vulgare* contain carvacrol and thymol within the range of ratios as specified in claim 1. That indeed such plants existed was evidenced by document (10) which was representative for the skilled person's common general knowledge. Document (5) read in the light of the common general knowledge of the skilled person was therefore prejudicial for the novelty of claim 1.



- 6.3 The consistent view in the case law of the Boards of Appeal is that for subject-matter of a claim to lack novelty it must be clearly and directly derivable from a piece of the prior art. The disclosure is determined by what knowledge and understanding can and may be expected of the skilled person in the technical field in question. Furthermore, it is a general legal rule for the interpretation of any document, in order to determine its content and disclosure, that no part of that document should be construed in isolation from the remainder of that document, i.e. each part of such a document should be read in the context of the contents of the document as a whole.
- 6.4 In the present case, as established above, document (5) discloses pharmaceutical compositions comprising a herbal essential oil containing carvacrol and thymol as its main ingredients and a pharmaceutical carrier. The passage at page 7 of document (5), referred to by the Respondent, frames in that part of the document dealing with the procedure for obtaining the etheric oils from *Origanum vulgare* plants for use in the pharmaceutical compositions. The procedure, as described on pages 7 and 8, consists of four phases. The first phase concerns the selection of the plants which have to be grown (phase 2) and used to produce the etheric oil from (phases 3 and 4). The referred to passage details that in phase 1 seeds are used from plants that have a particular amount of active material, i.e. 86-88% carvacrol and 3-5% thymol.
- 6.5 It may be true, as argued by the Respondent, that the person skilled in the art, at the relevant date, was aware of the fact that *Origanum vulgare* plant types

existed which have another composition of the active material in their isolated etheric oil than the plants as selected in document (5), as is indeed evidenced by the disclosure in document (10). However, the described selection of seeds to grow the plants from in the procedure for obtaining the etheric oils from *Origanum vulgare* plants as disclosed in document (5) is an essential and specific teaching for working the invention disclosed therein. Any interpretation of that passage as to directly and clearly disclose any other *Origanum vulgare* etheric oils than those specified would be contrary to the principles established in the case law of the Boards of Appeal in determining the content of prior art disclosures.

- 6.6 For the above reasons, and even when read in the light of the common general knowledge of the person skilled in the art, document (5) does not prejudice the novelty of claim 1.
7. Document (10) discloses at page 960 under the heading "Inhaltsstoffe", a herbal essential oil derived from *Origanum* that "*neben einem hohen Gehalt an Carvacrol (40 bis 70%), ... Thymol (1 bis 4%) enthält*" (besides a high content of carvacrol (40 to 70%), contains ... thymol (1 to 4%)). The total amount of carvacrol and thymol in this oil therefore ranges between 41 and 74%, whereas the ratio of carvacrol to thymol ranges from 10:1 (40/4) to 70:1 (70/1). The total amount of carvacrol and thymol in these oils therefore overlap with the amount as defined in feature a. in claim 1 of the main request. Similarly, the range of the ratio of carvacrol to thymol overlaps in the ratio range 40:1 to 70:1 with features b. in this claim. Document (10)

describes furthermore on page 961, under the heading "Volkstümliche Anwendungen und andere Anwendungsgebiete", a variety of diseases treated by the oils, including *inter alia* colds and wounds. Document (10) furthermore discloses at page 961, top paragraphs of the right hand column, mixtures of vaselinium with the *Origanum* essential oil as disclosed used to study side effects and immunotoxicity. These compositions thus comprise the herbal essential oil and a pharmaceutically acceptable carrier.

7.1 The Board considers these mixtures however not to be detrimental for the novelty of the subject-matter of claim 1 of the main request, for the reason that document (10) not explicitly specifies the composition of carvacrol and thymol in the *Origanum* oil applied in these particular compositions. Although document (10) discloses *Origanum* oils having composition ranges overlapping with those defined in claim 1, these composition ranges cannot automatically be combined with the pharmaceutically acceptable carrier disclosed for studying side effects and immunotoxicity. In fact, the side effects and immunotoxicity of the oils could therefore have been studied with oil which do not fall within the definition of the herbal essential oils in claim 1. Therefore, document (10) does not disclose the subject matter of claim 1 in a clear and unambiguous manner. Accordingly, document (10) is not prejudicial for the novelty of claim 1 of the main request.

8. No further objections as to lack of novelty were formulated by the Appellant. The Board is therefore satisfied that the subject-matter of claim 1 of the main request is novel.

*Inventive step*

9. In the light of the disclosure in document (10), which the Board considers to represent the closest prior art, the problem to be solved is seen in the provision of a pharmaceutical composition comprising as active ingredient essential oils from *Origanum*, including those as disclosed in document (10) in the overlapping total amount of carvacrol and thymol (feature a.) and the overlapping range of the ratio of carvacrol to thymol (feature b).
- 9.1 The solution proposed in claim 1 of the main request is to admix the essential oils with a pharmaceutically acceptable carrier. The Board is satisfied that the subject-matter of claim 1 solves this problem.
- 9.2 The Board considers, however, that it belongs to the common general knowledge of a skilled person in the art of pharmacology, to admix a pharmaceutically active substance with a pharmaceutically acceptable carrier, e.g. vaselinum, with a view to produce a pharmaceutical composition suitable for administration. This consideration is confirmed by the disclosure in two handbooks, excerpts of which were filed as documents (8), see page 260, right hand column lines 47 to 54 and document (9), see page 480, first paragraph. Accordingly, the formulation of such pharmaceutical compositions including as active ingredient the essential oils as disclosed in document (10), does not go beyond mere routine formulation of such pharmaceutical compositions with a view to conveniently administer the active ingredient.

10. The Respondent has argued that, as reiterated in paragraph [0021] of the specification of the patent and confirmed by the comparative data provided with the experimental report of Dr Tsinas, the best antimicrobial activities of the essential oils disclosed were observed in the range of ratios of carvacrol to thymol of 40 to 110. The compositions of claim 1 therefore exhibited beneficial effects which made them particularly well suited as substituent of conventional antibiotics. Inventive step should therefore be acknowledged on this advantageous effect.
- 10.1 It is established case law of the Boards of Appeal (see Case Law of the Boards of Appeal of the European Patent Office, 4th Edition, 2001, point I.D.7.7) that if, having regard to the state of the art, it had been obvious for a skilled person to arrive at something falling within the terms of a claim, additional or extra effects inevitably achieved by the obvious measures would constitute a "bonus effect" which cannot support inventive step.
- 10.2 The primary question to be answered in relation to the Respondent's argument is - independently of any judgement of the Board whether or not, in the present case, the experimental results indeed show the alleged beneficial superior antimicrobial activity - whether or not beneficial effects in the form of such superior activities of the essential oils as now claimed and reported on in the experimental report of Dr Tsinas can justify acknowledgement of inventive step of the claimed subject-matter, in a situation where such an effect was inevitably achieved by the pharmaceutical

- compositions implementing features which were obvious to a skilled person.
- 10.3 Indeed, as can be taken from point 9.2 above, it is the Board's judgement, that document (10) read in the light of the common general knowledge of the skilled person, renders obvious the routine formulation of pharmaceutical compositions comprising herbal essential oils which to a large extent overlap in their composition in respect of the total amount of carvacrol and thymol and the ratio of carvacrol to thymol. The results reported on in the experimental report of Dr Tsinas confirm the applicability of the essential oils as disclosed in document (10) in pharmaceutical compositions and their activity as foreshadowed in this document.
- 10.4 The Board considers that any allegedly further effects revealed by Respondent's experimental evidence merely consist of inherent features of the compositions that the skilled person would formulate in order to solve the objective technical problem underlying the invention of claim 1 having knowledge of the closest prior art. Such further effects could possibly justify the allowability of subject-matter formulated in certain claim formats, however, it cannot justify inventive step of subject-matter of product claims which, as in this case, the skilled person would routinely formulate.
- 10.5 In addition the Board notes that in line with the case law of the Boards of Appeal that additional or extra effects inevitably achieved by obvious measures, constitute a "bonus effect" which cannot support

inventive step, this should all the more be true for cases where the "additional or extra effect" merely consists of the very foreseen technical effect, albeit more efficient.

11. The Respondent has furthermore argued that document (10) was not suitable to represent the closest prior art as the document itself taught away from using *Origanum* essential oils by questioning their pharmaceutical efficacy. The Board cannot concur with this view for the following reasons.

11.1 As reiterated in point 7 above, document (10) describes on page 961, under the heading "Volkstümliche Anwendungen und andere Anwendungsgebiete", a variety of diseases traditionally treated by the oils. In view of the fact that this traditional application is mentioned in a handbook of *pharmaceutical practice* published shortly before the relevant date of the patent in suit, i.e. document (10) published in 1993, the Board is satisfied that the skilled person at least can be taken to accept the credibility of the efficacy of treatments based on the mentioned established traditional and empirical practice. The remark in the document that the efficacy of the oil for the uses indicated had not been proven by scientific experimentation is rather to be interpreted as reflecting the cautious approach of the authors of document (10) to compose a comprehensive collection of data relevant to the skilled person seeking guidance in its pharmaceutical practice, than articulating a true prejudice against the pharmaceutical applicability of the disclosed herbal essential oils.

- 11.2 As to the fact that document (10) states on page 960 that the reported micro-organism inhibitory test results are pharmaceutically of little relevance, the Board notes that claim 1 of the main request does not specify any particular mode of action of the pharmaceutical composition claimed, let alone an antibiotic activity. Accordingly, the quoted passage in document (10) is not of relevance in the assessment of an inventive step of the subject-matter of claim 1.
12. In view of the foregoing the Board considers the subject-matter of claim 1 not to involve an inventive step (Article 56 EPC).

*Auxiliary request*

*Articles 123(2), (3) and 84 EPC*

13. The sole claim 1 of the new auxiliary request had not been objected to by the Respondent under these requirements of the EPC. The Board has equally no objections to this claim under Article 84 EPC.
14. Claim 1 of the auxiliary request is drafted in the "second/further medical use" format (see decision G 5/83, OJ EPO 1985, 64), i.e. the composition comprising a herbal essential oil as defined is to be used in the preparation of a pharmaceutical composition for the prevention or treatment of coccidiosis in poultry. The claim finds its basis in claim 1 of the application as originally filed describing a pharmaceutical composition identical to that of claim 2 as granted but for feature b. in which the ratio of carvacrol to thymol was at least 10. Basis for the new



- lower limit of the ratio of carvacrol to thymol being at least 30 can be found in claim 2 of the application as filed exemplifying the ratio of carvacrol to thymol to be within the range of 30 to 150. Furthermore the second/further medical use, i.e. for the prevention or treatment of coccidiosis in poultry, finds basis in claim 8 of the application as filed. The requirements of Article 123(2) EPC are therefore fulfilled.
15. Article 123(3) EPC provides that during opposition proceedings the claims of the European patent may not be amended in such a way as to extend the protection conferred upon grant. In accordance with the established case law of the Boards of Appeal (e.g. cf. T 49/89 of 10 July 1990, reasons point 3.2.2; T 402/89 of 12 August 1991, reasons point 2, T 604/01 of 12 August 2004, reasons point 2.3), the Board holds that the legal notion "*protection conferred*" in Article 123(3) EPC refers to the totality of protection established by the claims as granted and not necessarily to the scope of protection within the wording of each single claim as granted. Thus, in order to assess any amendment under Article 123(3) EPC after grant, it is necessary to examine whether or not the totality of the claims before amendment in comparison with the totality of the claims after amendment extends the protection conferred (see also T 579/01 of 30 June 2004, reasons point 9).
16. Independent claim 2 of the patent as granted (see section II above), is a product claim. The change of category from product claims to use claims does not broaden the scope of the claims (see decision G 2/88, OJ EPO 1990, 93, Headnote II). In fact, the change of

category of a product to a use claims, i.e. from a claim directed to a pharmaceutical composition per se to a claim in the form typically intended to claim a second medical indication, represents a limitation of the scope and is not per se contrary to Article 123(3) EPC.

*Novelty*

17. Document (5), prior art pursuant to Article 54(3), (4) EPC, discloses at page 6, lines 1 to 2, the application of pharmaceutical compositions containing *Origanum* essential oils with high levels of carvacrol and thymol for the prevention and treatment of coccidiosis in poultry. However, as reiterated in point 6. above, the ratio of carvacrol to thymol in the essential oils disclosed in document (5) varies from 1:17 to 1:29 and hence, does not overlap with the ratio of at least 30 in claim 1 of the auxiliary request.
  
18. None of the other documents cited by the parties describe the use of *Origanum* essential oils for the prevention or treatment of coccidiosis in poultry. The Board therefore concludes that the subject matter of claim 1 of the auxiliary request is novel.

*Inventive step*

19. In accordance with established case law of the Boards of appeal concerning the closest prior art in the context of the problem and solution approach, such prior art should disclose subject-matter conceived for the same purpose or aiming at the same objective as the

claimed invention and having the most relevant technical features in common.

- 19.1 The invention according to claim 1 serves the purpose to provide a pharmaceutical composition for the prevention or treatment of coccidiosis in poultry. In the light of the criteria elaborated by the Boards of Appeal the most appropriate starting point for assessing inventive step of the subject-matter of the sole claim 1 of the auxiliary request is in the present case considered to be a document dealing with the treatment or prevention of coccidiosis.
- 19.2 None of the prior art documents on file and relevant under Article 54(2) EPC, serves this purpose or objective. However, it has been undisputed among the parties that the conventional treatment of coccidiosis in the prior art was by administration of antibiotics. The Board, in the present circumstances, comes to the conclusion that this conventional treatment of coccidiosis is to constitute the most appropriate starting point and to represent the closest prior art for assessing the claimed invention in the light of the problem and solution approach.
- 19.3 Starting from this closest prior art, the technical problem to be solved by the invention defined in claim 1 of the auxiliary request is to provide for an alternative treatment or prevention of coccidiosis to the conventional treatment of the disease by antibiotic administration.
- 19.4 Throughout the opposition and appeal procedure, the Appellant has not, neither explicitly nor implicitly,

questioned the functionality of the subject-matter as now claimed in claim 1. Therefore, the Board is satisfied that the patent in suit plausibly solves the above formulated problem for coccidiosis in poultry as claimed.

19.5 Coccidiosis is caused by the *Eimeria* group of eukaryotic parasites. Although document (3) discloses a general "parasiticide" action for *Origanum* essential oils, this does not constitute a sufficient pointer to a skilled person to formulate a pharmaceutical composition based on the *Origano* herbal essential oil disclosed in the said document for a functional treatment of coccidiosis with reasonable expectation of succes. Furthermore, and in addition, none of the cited prior art documents pursuant to Article 54(2) EPC suggest the skilled person the use of herbal essential oils having a high carvacrol and thymol content, including the oil as defined in claim 1, in treatment or prevention of coccidiosis. Accordingly, the subject-matter of claim 1 involves an inventive step.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
  
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the sole claim of the Auxiliary Request and pages 2 to 7 of the amended description filed during oral proceedings.

The Registrar:

The Chairwoman:

P. Cremona

U. Kinkeldey