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Datasheet for the decision of 26 September 2022

Case Number: T 3048/19 - 3.3.04

Application Number: 11717046.4

Publication Number: 2552431

IPC: A61K31/05, A61K45/06,

A61P31/00, A61P31/04, A61P31/12

Language of the proceedings: ΕN

Title of invention:

Carvacrol/thymol composition for the treatment of salmonid rickettsial septicemia and infectious salmon anemia

Patent Proprietor:

Ewos Innovation AS

Opponent:

Nutreco IP Assets BV

Headword:

Propyl-methyl-phenol compound for treating fish/EWOS

Relevant legal provisions:

EPC Art. 54, 54(5), 56, 83, 100(a) RPBA 2020 Art. 13(2), 25 RPBA Art. 12(4)

Keyword:

Main request - non-medical use - Novelty (no)
Auxiliary requests 1 and 2 - Amendment after summons exceptional circumstances (yes)
Auxiliary requests 1 and 2 - Novelty (yes)
Auxiliary request 1 - Inventive step (no)
Auxiliary request 2 - Inventive step (yes)
Auxiliary request 2 - Sufficiency of disclosure - (yes)
Late filed experimental evidence - not admitted



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Case Number: T 3048/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 26 September 2022

Appellant: Ewos Innovation AS (Patent Proprietor) 4335 Dirdal (NO)

Representative: Sebastian STRYCH

Mitscherlich PartmbB

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 17 September 2019 concerning maintenance of the European Patent No. 2552431 in amended form.

Composition of the Board:

P. de Heij

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Summary of Facts and Submissions

- I. Appeals of both the patent proprietor and the opponent lie from the decision of the opposition division that European patent No. 2 552 431 as amended in the form of a set of claims according to auxiliary request 1 and the invention to which it relates meet the requirements of the EPC.
- II. An opposition had been filed invoking the grounds for opposition under Article 100(a), for lack of novelty (Article 54 EPC) and inventive step (Article 56 EPC), and Article 100(b) EPC.
- III. The decision under appeal dealt with sets of claims of a main request (patent as granted) and auxiliary request 1. The opposition division maintained the patent on the basis of auxiliary request 1. The opposition division held that:
 - the claimed invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art
 - the claims of the main request and auxiliary request 1 were novel
 - the subject-matter of claim 1 of the main request lacked an inventive step starting from document D10 as the closest prior art; the technical problem was the provision of a compound for the treatment of salmonid rickettsial septicaemia (SRS)
 - the subject-matter of auxiliary request 1 was not obvious starting from document D10 as the closest prior art, even when combined with the teaching in document D7 or D5; the technical problem was the provision of a specific compound for the treatment of infectious salmon anaemia (ISA)

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- IV. With the statement of grounds of appeal, the appellant-patent proprietor filed new sets of claims according to auxiliary requests 1 to 12, auxiliary request 12 being identical to the set of claims according to auxiliary request 1 in the decision upon which the patent was maintained by the opposition division.
- V. With the statement of grounds of appeal, the appellantopponent raised objections as to lack of novelty, lack of inventive step and lack of sufficiency of disclosure and filed new document D14.
- VI. In the following, the parties are addressed according to their roles in the first-instance proceedings.
- VII. The board issued a communication pursuant to Article 15(1) RPBA providing the board's preliminary appreciation of the appeal inter alia giving its analysis on claim construction especially in view of a use in a method referred to in Article 53(c) EPC and the implications on the assessment of novelty.
- VIII. The oral proceedings before the board took place as scheduled on 26 September 2022.

During the oral proceedings, the patent proprietor filed new auxiliary requests 1 and 2 and withdrew auxiliary requests 1 to 12 as filed with the statement of grounds of appeal.

At the end of the oral proceedings, the Chairwoman announced the board's decision.

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IX. The independent claims read as follows:

Main request

- "1. Propyl-methyl-phenol compound, or composition comprising a propyl-methyl-phenol compound for use in the treatment and/or prophylaxis of Salmonid rickettsial septicemia (SRS) and/or diseases caused by Piscirickettsia salmonis, and/or for the use in killing, combating or controlling Piscirickettsia salmonis.
- 2. Propyl-methyl-phenol compound, or composition comprising a propyl-methyl-phenol compound for use in the treatment and/or prophylaxis of Infectious salmon anemia (ISA) and/or diseases caused by Infectious salmon anemia virus, and/or for the use in killing, combating or controlling Infectious salmon anemia virus."
- "14. Use of a propyl-methyl-phenol compound, or composition comprising a propyl-methyl-phenol compound for the manufacturing of a pharmaceutical and/or nutraceutical composition for the treatment and/or prophylaxis of Salmonid rickettsial septicemia (SRS) and/or diseases caused by *Piscirickettsia salmonis*, and/or for the use in killing, combating or controlling *Piscirickettsia salmonis*.
- 15. Use of a propyl-methyl-phenol compound, or composition comprising a propyl-methyl-phenol compound for the manufacturing of a pharmaceutical and/or nutraceutical composition the treatment and/or prophylaxis of Infectious salmon anemia (ISA) and/or diseases caused by Infectious salmon anemia virus, and/

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or for the use in killing, combating or controlling Infectious salmon anemia virus."

New auxiliary request 1

Claims 1, 2, 14 and 15 of new auxiliary request 1 differ from those of the main request only by the deletion of the second part of these claims relating to "and/or for the use in killing, combating or controlling" *Piscirickettsia salmonis* (PS)/infectious salmon anaemia virus (ISAv).

New auxiliary request 2

The set of claims according to new auxiliary request 2 differs from the one of auxiliary request 1 by the deletion of all claims relating to SRS and PS (i.e. former claims 1 and 14), respectively. Dependent claims 8 and 10 were also deleted; the remaining claims were renumbered.

X. The decision makes reference to the following documents:

D1: O. Jintasataporn et al., Abstract (5 August 2009), http://en.engormix.com/MA-aquaculture/articles/the-effect-feeding-encapsulated-t1391/p0.htm

D5: KR20070054919 (A)

D5E: Machine-based translation of KR20070054919 (A), 12 pages

D6: C.D.V.M. Yew Yoke Ching, Feed technology update, vol. 3 (1), 2008, 8 pages

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D7: D. Baricevic *et al.*, Part 5, Chapter 8, "Oregano, The genera Origanum and Lippia", edited by Spiridon E. Kintzios, Taylor & Francis, first edn., 2002, 177-213

D8: M. Yiagnisis et al. Abstract 0-123, "Diseases of fish and shellfish", 14th EAFP International Conference, Prague, 14-19 September 2009

D9: P. Rattanachaikunsopon et al., African Journal of Microbiology Research, vol. 4(5), 2010, 420-5

D10: WO 2004/091307 A2

D11: Z.L. Zheng et al. Aquaculture, 292, 2009, 214-8

D14: Experimental report of 20 December 2019, 12 pages

XI. The patent proprietor's arguments relevant to this decision may be summarised as follows.

(a) Admittance of document D14

The opposition division had stated in its preliminary opinion that the data in Examples 1 and 2 were sufficient to render the claimed therapeutic effect plausible (see preliminary opinion, item 3.3). In reply, the opponent had neither announced that it would file any further experimental data in support of its objection nor submitted any further experimental data.

The experimental data of document D14 should, therefore, have been provided already in the first-instance proceedings.

Moreover, the list of "References" provided in document D14 would be part of the teaching and also part of the

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appeal proceedings if document D14 was admitted into the procedure. The opponent had not provided copies of these documents, thus there was no chance to double check them.

(b) Main request

Claim construction - claims 1, 2, 14 and 15

The wording "for the use in killing, combating or controlling" PS or ISAv used in the second part of claims 1, 2, 14 and 15 was clear and did not encompass an in vitro use. Claims 1 and 2 were drafted in a second medical use format, and the scope of the second part of these claims had to be understood to not go beyond this second medical use. The feature referred back to the use in treatment or prophylaxis of the bacterium/virus mentioned in the first part of the claim. The use in killing bacteria or viruses causing diseases to be treated would inevitably lead to the treatment/prophylaxis of SRS and ISA. The alleged use for wiping kitchen surfaces was not encompassed by the claims.

Novelty - claims 1, 2, 14 and 15

- First alternative - "compound for use in the treatment and/or prophylaxis"

Document D10 did not provide a direct and unambiguous disclosure of the combination of a) propyl-methyl-phenol compound for use in b) treatment and/or prophylaxis of SRS/ISA and or/diseases caused by PS/ISAv. Multiple selections would be necessary in document D10 to arrive at the subject-matter of claims 1, 2, 14 and 15.

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The claimed combination was also not directly and unambiguously disclosed in Examples 2 or 5 of document D10.

Although carvacrol and thymol were the most important polyphenols in *Origanum vulgare*, another phenol might also be responsible for the reported activity.

- Second alternative - "for the use in killing, combating or controlling"

Document D10 also failed to directly and unambiguously disclose the use of propyl-methyl-phenol compounds such as thymol or carvacrol for killing PS and ISAv. The stated use was clearly a limiting feature and was not disclosed in document D10.

(c) New auxiliary request 1

Admittance

The admittance of new auxiliary request 1 was governed by the RPBA 2007 since the date of filing of the statement of grounds of appeal was the relevant date.

The board's preliminary opinion had been issued merely a few weeks before the oral proceedings during the summer holiday period. Moreover, the board had indicated in point 23 of its communication under Article 15(1) RPBA that the parties would be heard on the issue of claim construction of the second part of claims 1, 2, 14 and 15 and had not invited the filing of further submissions.

The claim construction adopted by the board came as a complete surprise. It had not been part of the

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opposition proceedings. Given these exceptional circumstances, the submission of a new claim request was acceptable. The deletion of the second part of claims 1, 2, 14 and 15 was in direct reaction to the claim construction adopted for the first time during oral proceedings before the board, narrowed the scope of protection and was easy to understand. Furthermore, it clearly resolved the problem.

New auxiliary request 1 was filed immediately after the termination of this discussion and the board's finding that the second part of claims 1, 2, 14 and 15 as granted did not relate to a second medical use, i.e. at the earliest point in time possible.

Disclosure of the invention - claims 2 and 15 - ISA/

- Breadth of propyl-methyl-phenol compounds

During opposition proceedings, the burden of proof of insufficiency was as a general rule on the opponent. The opponent merely raised allegations why Example 2 of the patent would not be suitable for rendering the claimed therapeutic effects of the treatment/prevention of ISAv plausible.

The opponent had not shown that propyl-methyl-phenol compounds other than carvacrol would not be effective against ISAv.

There was a clear and established relationship between the results obtained in Example 2 of the patent and the therapeutic effects claimed. This had also been correctly acknowledged by the opposition division. - 9 - T 3048/19

Example 2 clearly showed that the claimed compounds were effective against ISAv and thus made the claimed effects at least plausible.

- Enablement of prophylaxis and treatment of ISAv

Example 2 of the patent rendered the prevention of ISAv infection plausible. In addition, a person skilled in the art knew that the mechanisms that made the prevention of ISA successful were the same as those that made the corresponding treatment plausible. The prevention of ISA was effective as carvacrol was shown to be effective against ISAv in Example 2. Table 2 of Example 2 clearly provided the information that even complete removal of ISAv could be achieved when carvacrol was used at 100 ppm in the current experimental set-up.

A skilled person knew that the concentration of carvacrol to achieve full removal of ISAv also depended on the ISAv concentration and the contact time and was able to put the invention into practice over the entire range claimed based on the conclusive results given in Example 2 of the patent.

The opponent had not provided clear reasoning why *in* vivo data would be required in the current case.

Inventive step

- Claims 1 and 14 - SRS/PS

Document D10 represented the closest prior art on the treatment of infectious diseases of aquatic and terrestrial animals.

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The objective technical problem was the provision of a compound or composition effective in the treatment and/ or prophylaxis of SRS.

The claimed solution to the above-mentioned objective technical problem satisfied a long-felt need in the aquatic industry. Demonstration that a compound was effective against a bacterium required laborious experimental and inventive efforts.

Document D10 comprised no pointer towards the effectiveness of propyl-methyl-phenol compounds against SRS and/or PS. There was no reason why a skilled person would not have focused on any other compound listed in document D10. To arrive at propyl-methyl-phenol (e.g. carvacrol and thymol), multiple selections among the various, chemically very different compounds listed in paragraphs [0043] to [0062] were necessary. Piscirickettsiosis as a therapeutic target had also to be selected from a long list comprising aquatic and terrestrial diseases (see paragraphs [0039] and [0040]).

Reading document D10, the skilled person did not know which compound to use for treating which disease.

Documents D6 and D7 also contained no pointer in that direction. Document D6 did not even mention SRS, nor did it disclose any individual compound listed in document D10 to be comprised in the disclosed commercial product Orego-Stim. The composition of the product was unclear. Even if it contained carvacrol and thymol, it was not clear whether the antibacterial properties of Orego-Stim were based on carvacrol and/or thymol or whether other phenols (in minor amounts) were

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responsible for the antibacterial effect. The effect could be even based on a combination of the two major phenols and other minor phenols being present in Orego-Stim.

Document D7 reported that oregano had a broad-spectrum antibacterial activity and that effects of oregano essential oils against certain bacterial species were mainly due to the presence of carvacrol and/or thymol. It was, however, also mentioned that the reported data on such effects were often questionable, in particular with regard to their accuracy. Moreover, SRS and PS were not mentioned at all. It was reported that oregano was either not effective at all or at least not particularly effective against some bacteria. It was therefore clear that, unlike with broad-spectrum antibiotics, it could not be expected that oregano, not to mention propyl-methyl-phenol compounds, would be effective against all bacteria.

None of documents D8, D9 and D11 provided any pointer to a propyl-methyl-phenol compound that might be effective against SRS either.

There was no reasonable expectation of success that a propyl-methyl-phenol compound might be effective in the treatment of SRS.

- Claims 2 and 15 - ISA/ISAv

Document D10 represented the closest prior art and related to the treatment of a long list of infectious diseases of aquatic and terrestrial animals.

The objective technical problem was the provision of a compound or composition effective in the treatment and/ or prophylaxis of ISA.

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Document D10 provided only a very general disclosure on the alleged effects. Aquatic and terrestrial diseases could not be treated the same way, and the skilled person faced with the technical problem of providing a treatment and/or prophylaxis for ISAv was faced with a long list of potential compounds to be tested (see paragraphs [0043] to [0058] of document D10). From Example 2, it was not clear what compounds were comprised in the composition. Example 5 did not provide any results and thus failed to show that the composition according to Example 2 was indeed efficient. In fact, neither Example 2 nor Example 5, which was the only one describing the treatment of fish, nor any of the other examples testing antiviral activity reported any results at all. Moreover, none of the examples related to ISAv.

Starting from document D10, a skilled person had no pointer on which compound had to be combined to treat which disease and had to carry out a research project. To arrive at propyl-methyl-phenol (e.g. carvacrol and thymol), multiple selections among the various, chemically very different compounds listed in paragraphs [0043] to [0058] were necessary.

The combination with the secondary documents D7 and D5 was of no help. Both mentioned carvacrol and thymol but not for the treatment of ISAv.

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(d) New auxiliary request 2

Admittance

The request was based on auxiliary request 12 filed with the statement of grounds of appeal and an additional amendment to claims 1 and 11, i.e. the deletion of the second half of claims 2 and 14 of the main request, which was surprisingly found not to relate to a second medical use and thus to lack novelty. This amendment was analogous to the one in auxiliary request 1, which was found admissible. The opponent could not argue that it had been taken by surprise, the scope of protection had been narrowed, and the amendments were clear and addressed all issues discussed.

Novelty, disclosure of the invention and inventive step

The reasoning put forward for the higher-ranking requests applied *mutatis mutandis* to the claimed subject-matter of auxiliary request 2.

- XII. The opponent's arguments relevant to this decision may be summarised as follows.
 - (a) Admittance of document D14

The experimental report D14 had been filed with the opponent's statement of grounds of appeal in response to the opposition division's decision that the patent disclosed the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. According to the case law of the Boards of Appeal late filing was

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justifiable if it was an appropriate and immediate reaction to developments in the previous proceedings and that an appellant who had lost the opposition proceedings should be given the opportunity to fill the gaps in its arguments by presenting further evidence in appeal.

The experiments described in document D14 were carried out by a third party and attempted to reproduce the data of Example 2 of the patent and showed that carvacrol in a concentration range from 0.2 to 100 ppm was not able to eliminate ISAv (see Table 2).

The list of "References" on pages 11 and 12 of document D14 had been provided by the independent third party that had carried out the experiments. In any case, these documents were not decisive for the data provided in document D14, and there was no intention to refer to any of the referenced documents.

(b) Main request

Claim construction - claims 1, 2, 14 and 15

The wording "for the use in killing, combating or controlling" of claims 1, 2, 14 and 15 clearly encompassed the disinfection of an aquatic locus but also the use for wiping kitchen surfaces. Since in vitro uses were not covered by Article 53(c) EPC, the claims covered compositions "suitable for" the indicated purpose.

Novelty - claims 1, 2, 14 and 15

 First alternative - "compound for use in the treatment and/or prophylaxis" - 15 - T 3048/19

Document D10 anticipated the claimed subject-matter. Paragraphs [0043] to [0046] provided a list of compounds, including thymol and carvacrol, to be used for preventing, ameliorating or curing different diseases, including the aquatic infectious diseases piscirickettsiosis and ISA (see paragraph [0040]). However, no selection from the list of paragraphs [0043] to [0046] was needed. Example 2, entitled "Formulation of an antiviral combination", disclosed a composition containing phenols, preferably from Origanum vulgare, cinnamon bark extract or lapacho extract from Tabebuia avellanedae, thus from a very short list having only three members. Example 5, entitled "Antiviral preparation against pathogenic viruses of fish", disclosed the use of the antiviral preparation described in Example 2 in the context of a disclosure listing merely 11 viral diseases of fish. Thus, as a short list (three compositions) had been combined with a long list (11 diseases), a noveltyconferring selection had not been made.

Moreover, the two lists were within the same embodiment, and the two diseases currently claimed were the commercially important ones. Under established case law, when examining novelty, different passages of one document might be combined provided that there were no reasons which would prevent a skilled person from making such a combination. In general, the technical teaching of examples might be combined with that disclosed e.g. in the description of a patent document. Different passages of a document could be combined as long they did not refer to different embodiments. This applied to paragraph [0040] and Examples 2 and 5 of document D10.

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The skilled person was aware that carvacrol and thymol were the most important phenols from *Origanum vulgare* (see documents D7, D8, D9 or D11).

The skilled person was also aware of the commercial importance of PS and ISAv and, thus, would have combined the phenols from *Origanum vulgare* with the commercially relevant fish pathogens PS and ISAv.

- Second alternative - "for the use in killing, combating or controlling"

Document D10 clearly disclosed thymol and carvacrol and, more generally, phenols from *Origanum vulgare* for killing, combating or controlling PS and ISAv. These actives disrupted the cell membrane and were thus suitable for use in any environment.

Thus, the subject-matter of claims 1, 2, 14 and 15

lacked novelty.

(c) New auxiliary request 1

Admittance

New auxiliary request 1 was not to be admitted.

The issue of claim construction with regard to a non-medical use had been casually mentioned in the opponent's letter dated 11 May 2020. However, it was specifically addressed in the board's communication pursuant to Article 15(1) RPBA issued six weeks before the oral hearing. Thus, the patent proprietor should have provided this new set of claims immediately after having received the board's communication and not have awaited the oral hearing to submit them.

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The new auxiliary request 1 was not convergent with the other auxiliary requests presented before, was late filed and represented an amendment to the appeal case, for which no exceptional circumstances within the meaning of Article 13(2) RPBA 2020 could be identified.

Disclosure of the invention - claims 2 and 15 - ISA/

- Breadth of propyl-methyl-phenol compounds

Example 2 of the patent tested a single compound, carvacrol, only, against ISAv. The patent did not provide evidence that thymol or any propyl-methyl-phenol compound other than carvacrol was effective against ISAv. Carvacrol was an isopropyl compound and contained alkyl substituents at the 2 and 5 positions of the phenol ring. The claims also covered linear propyl groups and alkyl substituents at any position (2, 3, 4, 5 or 6). The technical effect of efficacy against ISAv was stated in the claim. However, it was not plausible that all such compounds would be effective.

The burden of proof was on the patent proprietor to show that all compounds under a broad product claim had the same pharmaceutical activity as the ones tested.

- Enablement of prophylaxis and treatment of ISAv

The relevant standard under the case law was that a claimed therapeutic effect might be proven by any kind of data as long as they clearly and unambiguously reflected the therapeutic effect. *In vitro* tests should

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be carefully selected and correspond as closely as possible to *in vivo* conditions.

Example 2 of the patent did not clearly and unambiguously reflect a therapeutic effect.

Example 2 clearly demonstrated that doses of carvacrol below 100 ppm and less than 60 minutes pre-incubation with the ISA virus did not reproducibly reduce infectivity of the virus. The finding that at least 100 ppm carvacrol should be pre-incubated for at least 60 minutes with ISAv to prevent it from infecting kidney cells was of no relevance to the *in vivo* situation where salmonids were cultured in open water and where carvacrol and ISAv could not be pre-incubated.

There was no evidence that carvacrol could travel through the fish digestive system and immune system to encounter ISAv where it occurred intracellularly in the spleen, kidney, liver and heart of the fish.

No in vivo data at all were provided regarding on ISAv, not even post-published in vivo data. This implied that the patent proprietor had not been successful in using carvacrol in prophylaxis or treatment of ISAv in fish. The patent did no more than put forward a hypothesis that carvacrol might be useful for this purpose.

Inventive step

- Claims 1 and 14 - SRS/PS

Document D10 represented the closest prior art.

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The subject-matter of current claim 1 differed from the teaching in document D10 in that a propyl-methyl-phenol-compound, such as carvacrol, was specifically used for the treatment of SRS.

The underlying problem was the provision of a specific compound for the treatment or prophylaxis of SRS.

The claimed subject-matter lacked an inventive step over document D10 alone or in combination with documents D6 to D9 or D11.

The patent itself acknowledged that SRS was known to be a fatal disease in salmonids with a significant economic impact.

Confronted with the underlying technical problem of identifying a compound among the compounds listed in document D10 for the treatment of SRS, the skilled person would search for further information on the compounds listed in the closest prior-art document D10.

It was known from documents D6, D7, D8, D9 and D11 that oregano, carvacrol and thymol had a broad antibacterial effect, including on gram-negative bacteria, by acting on the bacterial membrane. Also, documents D1, D8 and D12 reported effects against many bacteria.

Based on the broad antibacterial activity reported for carvacrol and thymol, the person skilled in the art would have tested carvacrol against SRS with a high expectation of success.

- Claims 2 and 15 - ISA/ISAv

Document 10 represented the closest prior art and listed 11 viral diseases of fish, including ISAv (see

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paragraph [0040]). Example 2 disclosed the composition used in Example 5 for treating various viral diseases caused by infectious pancreatic necrosis virus and haematopoietic necrosis virus in fish.

The skilled person would have been aware from their common general knowledge that dealing with ISAv was a pressing commercial problem in the aquaculture industry, as disclosed in the closest prior-art document D10. The skilled person was taught by document D10, Examples 2 and 5, that Origanum vulgare was one of the three preferred compositions for treating fish viruses and was therefore obvious. They would have had a high expectation of success for this treatment.

The antiviral activity was further confirmed by document D7, which reported a broad antiviral activity of *Origanum vulgare* extracts, e.g. against ECHO₉ Hill virus and human immunodeficiency virus (HIV) (see page 196, first full paragraph).

Document D5 also reported the use of oregano extracts for treating influenza virus (see claim 1). The patent itself stated that ISAv appeared to be most like influenza viruses (see paragraph [0007]).

(d) New auxiliary request 2

Admittance

Filing a new claim request towards the end of oral proceedings required another reassessment. The patent proprietor already had one chance by filing auxiliary request 1. The claims of auxiliary request 2 introduced an additional problem, lack of sufficiency of

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disclosure, because claim 5 now referred to claim 1 and no longer to claims 1 and 2 as in auxiliary request 1. Auxiliary request 12 as filed with the statement of grounds of appeal, on which this new auxiliary request 2 was based, was also inadmissible.

Novelty, disclosure of the invention and inventive step

There were no additional objections to the new auxiliary request 2 beyond those raised against the higher-ranking requests.

- XIII. The parties' requests relevant to the decision were as follows.
 - (a) The patent proprietor requested that:
 - the decision under appeal be set aside and that the opposition be rejected, i.e. that the patent be maintained as granted or, alternatively, that the patent be maintained in amended form on the basis of the sets of claims of new auxiliary request 1 or 2, as filed during the oral proceedings
 - new auxiliary requests 1 and 2 be admitted into the appeal proceedings
 - documents D13 to D16 not be admitted into the appeal proceedings
 - (b) The opponent requested that:
 - the decision under appeal be set aside and that the patent be revoked
 - new auxiliary requests 1 and 2 not be admitted into the appeal proceedings (Article 13(2) RPBA)
 - documents D13 to D16 be admitted

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Reasons for the Decision

- 1. Admittance of the experimental report D14
- 1.1 Article 12(4) RPBA 2007, which applies to the opponent's statement of grounds of appeal, filed before 1 January 2020 (see Article 25(2) RPBA 2020), gives the board the power to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings.
- 1.2 The opponent did not dispute that the objections addressing the disclosure of the invention under Article 83 EPC had already been raised in the first-instance proceedings (see e.g. page 11, paragraph 1 of the notice of opposition filed in March 2018).

 Thus, the opponent could and should have submitted the experimental evidence of document D14 already with its notice of opposition.
- 1.3 In view of the primary object of the appeal proceedings to review the decision under appeal in a judicial manner, the board exercised its discretion to not admit document D14 into the appeal proceedings (Article 12(4) RPBA 2007).
- 2. Main request
- 2.1 Claim construction claims 1, 2, 14 and 15
- 2.1.1 The first alternative in claims 1 and 2 is directed to a propyl-methyl-phenol compound, or composition comprising a propyl-methyl-phenol compound <u>for use in the treatment and/or prophylaxis</u> of SRS/ISA and/or diseases caused by PS/ISAv and thus is formulated in

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the form of a second medical use under Article 54(5) EPC.

- 2.1.2 The first alternative in claims 14 and 15 is formulated in the form of a so-called Swiss-type second medical use claim, i.e. a <u>use of</u> a propyl-methyl-phenol compound, or composition comprising a propyl-methyl-phenol compound <u>for the manufacturing of a pharmaceutical and/or nutraceutical composition for the treatment and/or prophylaxis</u> of SRS and/or diseases caused by PS.
- 2.1.3 The second alternative in claims 1, 2, 14 and 15 is connected to the respective first alternative by an and/or connector and continues by stating for the use in killing, combating or controlling PS/ISAv.

Due to the "or" option, the first and the second parts of these claims are true alternatives.

Purpose limited product claims, formulated in accordance with Article 54(5) EPC, are limited by their reference to methods of Article 53(c) EPC. However, "killing, combating or controlling" is not restricted to methods for treatment of the animal (including human) body by therapy and includes disinfection of water, as also indicated in the description of the patent which states "said propyl-methyl-phenol compound is applied to a locus to be protected from said bacteria or virus" (see paragraph [0020] of the patent in suit). In this case, the killing, combating or controlling of PS/SRS or ISA/ISAv may occur outside the fish.

Consequently, the compounds and compositions comprising the compounds of the second alternative defined in

claims 1 and 2 ("for the use in killing, combating or controlling") do not profit from the purpose limitation under Article 54(5) EPC but are to be construed as compounds and compositions merely "suitable for" the intended use (see Case Law of the Boards of Appeal, 10th edn., 2022, I.C.8.1.5.). Claims 14 and 15, formulated as so-called "Swiss-type" claims, are construed as relating to uses for the manufacture of a composition suitable for the intended use.

2.2 Novelty - claims 1, 2, 14 and 15

2.2.1 Document D10 discloses compositions of plant-derived bioactive feed additives and a method of use of these additives for the protection or prevention of diseases in terrestrial and aquatic animals by adding these additives to their feed (see paragraph [0019]).

Paragraphs [0039] and [0040] provide a list of infectious microorganisms-based pathogenic conditions of terrestrial and aquatic animals, including ISA and piscirickettsiosis (see page 8, lines 3 to 4).

Paragraphs [0043] to [0062] list a number of non-volatile or volatile bioactive compounds. Among the non-volatile compounds, phenols, including propylmethyl-phenols such as thymol or carvacrol, are an option (see paragraph [0044]).

Example 2 of document D10 discloses the formulation of an antiviral combination which comprises a primary composition containing polyphenols, preferably from Olea europaea leaf extract standardised to 15% oleuropein. Further comprised is a secondary composition containing phenols from Origanum vulgare or cinnamon bark extract, standardised to 25% (w/w); or lapacho extract from Tabebuia avellanedae.

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Example 5 provides a protocol using the antiviral preparation described in Example 2 against the fish pathogenic viruses infectious pancreatic necrosis virus and haematopoietic necrosis virus.

2.2.2 First alternative - "compound for use in the treatment and/or prophylaxis"

The board agrees with the patent proprietor that to arrive at the subject-matter of claim 1, multiple selections from lists of alternatives provided in document D10 are necessary.

(a) Compound:

Propyl-methyl-phenol compounds or compositions comprising a propyl-methyl-phenol compound have to be selected from a long list of possible actives described by various characteristics, including physical, chemical and origin-related characteristics (see paragraphs [0043] to [0062]).

(b) Type of disease:

The disease to be treated needs to be selected from an infectious terrestrial animal disease (see [0039]) and an infectious aquatic disease (see paragraph [0040]). The aquatic infectious disease might be any in the long list in paragraph [0040], requiring the selection of piscirickettsiosis and ISA (see page 8, lines 3 and 4).

The opponent argued that Example 2 of document D10 provided a short list of only three alternatives.

The board, however, considers, that neither Example 2 nor Example 5 (see point 1 above) discloses the claimed combination of disease/pathogen and therapeutic compound(s). Example 2 provides formulations of

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antiviral combinations comprising a primary composition containing polyphenols, preferably from Olea europaea leaf extract and a secondary composition containing phenols, preferably from Origanum vulgare, cinnamon bark extract or lapacho from Tabebuia avellanedae.

However, propyl-methyl-phenol compounds are not mentioned. Moreover, Example 5 does not clarify which polyphenol-phenol combination of Example 2 is to be used and does not disclose SRS and/or diseases caused by PS nor ISA and/or diseases caused by ISAv.

Thus, the subject-matter of claims 1, 2, 14 and 15 relating to the "second medical use" of propyl-methyl-phenol compounds is considered novel within the meaning of Article 54 EPC.

2.2.3 Second alternative - "for the use in killing, combating or controlling"

Based on the claim construction above (see point 2.1), any prior-art compound "suitable for" killing, combating or controlling PS/ISAv, i.e. inherently possessing the claimed physiological properties, will take away novelty of the claimed composition.

Document D10 discloses a composition comprising thymol or carvacrol (see paragraph [0044]), i.e. propylmethyl-phenol compounds, suitable for killing, combating or controlling PS and ISAv. It is inherent that the composition has been manufactured.

Thus, the second alternative "for the use in killing, combating or controlling" of claims 1, 2, 14 and 15 is anticipated by the disclosure of document D10 within the meaning of Article 54 EPC. The main request is not allowable.

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3. New auxiliary request 1

3.1 Admittance - Article 13(2) RPBA

The appeals were filed before 1 January 2020. The transitional provisions laid down in Article 25 (1) and (3) RPBA 2020 specify that the revised version applies to any appeal pending on, or filed after, 1 January 2020. Where the summons to oral proceedings (or a communication of the board under Rule 100(2) EPC) has been notified before the date of the entry into force, Article 13(2) RPBA 2020 shall not apply. However, in the case at hand, the board's summonses were issued on 8 December 2021, i.e. after 1 January 2020.

Thus, in the current case, Article 13(2) RPBA 2020 applies to any amendment to a party's appeal case filed after notification of a summons to oral proceedings.

Although foreshadowed in the opponent's reply to the patent proprietor's statement of grounds of appeal dated 11 May 2020, the issue of claim construction of claims 1, 2, 14 and 15 of the main request was first clearly highlighted in the board's communication under Article 15(1) RPBA, which was issued during the summer period six weeks before the oral proceedings.

The board considers that these circumstances represent exceptional circumstances which justify the late reaction to the board's objection.

The amendments effected in the set of claims of the auxiliary request 1 are limited to the deletion of the second alternative from claims 1, 2, 14 and 15 and as such are convergent, leaving aside whether this is even a relevant requirement in the current circumstances.

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Consequently, the board admitted auxiliary request 1 into the proceedings.

3.2 Disclosure of the invention - Article 83 EPC

Claims 1 and 14 - SRS/PS

3.2.1 Given that the subject-matter of claims 1 and 14 was found to lack an inventive step (see points 3.3.1 to 3.3.13 below), it is not necessary to discuss sufficiency of disclosure for the subject-matter of these claims, which relate to SRS and PS.

Claims 2 and 15 - ISA/ISAv

- 3.2.2 Claim 2 is drafted in the form of a purpose-limited product claim in accordance with Article 54(5) EPC, and claim 15 is drafted in the form of a Swiss-type claim. Both claims thus define second medical uses.
- 3.2.3 The requirement of sufficiency of disclosure is generally considered to be fulfilled for a claim to a second medical use if having regard to the disclosure of the patent and the common general knowledge, the skilled person would have considered that the compounds referred to in the claims are suitable for achieving the therapeutic effect.

Enablement of prophylaxis and treatment of ISAv

3.2.4 Example 2 of the patent shows that in vitro preincubation of ISAv with 100 ppm of the propyl-methylphenol compound carvacrol for 60 minutes or longer
inhibits ISAv replication in a monolayer of Atlantic
salmon kidney-1 cells over a period of ten days in
vitro (see paragraphs [0037] and [0038] and Table 2).

3.2.5 The data in Example 2 of the patent provide an initial indication showing that the virulence/infectivity of ISAv on salmon kidney cells is affected by carvacrol. The outbreak and the pathogenesis of a virus-mediated disease can be influenced by reducing the virulence/infectivity of the virus. Thus, the claimed therapeutic and prophylactic effect of carvacrol against ISAv is rendered plausible by the evidence provided in the patent. In vivo data are not required for this assessment. Once the effect is known, an adequate amount of carvacrol, be it less or more than 100 ppm, can be routinely determined.

The opponent argued that in vitro tests were not relevant for the in vivo situation in aquaculture where salmonids were cultured in open water and where carvacrol and ISAv could not be pre-incubated.

However, whether the patent can be practically used in such a situation is not relevant to the current assessment of sufficiency as long as the compounds can be used to achieve the therapeutic effect.

The opponent has furthermore suggested that carvacrol could not travel through the fish's digestive and immune system to encounter ISAv where it occurred intracellularly in the fish's spleen, kidney, liver and heart. However, there is not the slightest evidence in the proceedings to support this allegation.

Breadth of propyl-methyl-phenol compounds

The claim relates to propyl-methyl-phenol compounds, i.e. compounds with distinct structures and substituents of which at least the phenols are generally known to have biocidal activity. There is no

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substantiated evidence from the opponents that goes beyond simple assertions that not all the compounds are biocidal.

- 3.2.6 The board concludes that the patent discloses the subject-matter of claims 2 and 15 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- 3.3 Inventive step Article 56 EPC

Claims 1 and 14 - SRS/PS

Closest prior art

3.3.1 It is common ground that document D10 represents a suitable closest prior art for assessing inventive step. The document is summarised in point 2.2.1 above.

Difference and objective technical problem

3.3.2 The difference between the subject-matter of claims 1 and 14 and the teaching in document D10 is that SRS and/or diseases caused by PS are treated or prevented using a propyl-methyl-phenol compound.

The objective technical problem is the provision of a compound or a composition for the treatment and prevention of any disease caused by PS.

Obviousness

3.3.3 The board considers that faced with the problem of treating and/or preventing PS infection, the skilled person, starting from document D10 as the closest prior art, would have considered any therapeutic agent in the

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list provided in document D10 having well established antibacterial activity, in particular in the context of aquaculture. It is of no relevance that D10 also mentions compounds other than thymol and carvacrol which are propyl-methyl-phenol compounds according to current claim 1.

The skilled person starting from document D10 would have checked the activities and specificities of the therapeutic agents disclosed in this document, including carvacrol and thymol. Documents D1/D12, D6 to D9 and D11 have been cited in this context. The content of these documents is briefly summarised in the following paragraphs.

- 3.3.4 Documents D1 and D12 determine the effect of an encapsulated combination of 1:1 thymol:carvacrol as a performance enhancer fed into a low-protein diet of hybrid catfish larvae (Clarias gariepinus x Clarias macrocephalus) grown under normal and challenge conditions. Upon disease challenge with virulent Aeromonas hydrophila, channel catfish larvae fed with different doses of the 1:1 thymol:carvacrol mixture showed significantly lower mortality rates compared to controls. However, neither D1 nor D12 reports a direct antimicrobial effect for the thymol-carvacrol mixture used.
- 3.3.5 Document D6 reports on the effects of the oregano-based commercial product Orego-Stim in livestock and aquatic animals. The phenolic compounds effectively killed gram-negative and gram-positive bacteria (see third page, last three paragraphs).
- 3.3.6 Textbook chapter D7, which can be considered to represent common general knowledge of the skilled

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person, reviews the biological/pharmacological activity of the Origanum genus and discloses on page 177, first paragraph that "Essential oil 'rich' taxa with an essential oil content of more than 2 per cent (most commercially known oregano plants), is mainly characterised either by the dominant occurrence of carvacrol and/or thymol [...] or by linalool, terpinene-4-ol and sabinene hydrate as main components...". Pages 185 to 195 comprise the chapter on "ANTIBACTERIAL ACTIVITY", which teaches that "[b] ased on a broad spectra of antibacterial activity, oregano seems to be one of the most inhibitory spices tested. However, when considering the reported data, questions on the accuracy of the interpreted information often arise". Origanum vulgare essential oil is described to be characterised by high thymol and carvacrol content and to show a strong inhibitory effect against a broad spectrum of gram-positive and gram-negative bacteria (see page 186, paragraph 2). On page 187, third full paragraph, it is stated that the antibacterial effects of oregano essential oils were mainly due to the presence of phenolic constituents (carvacrol and/or thymol).

- 3.3.7 Document D8 reports that dietary supplementation with essential oils from Origanum vulgare has important antiparasitic/antibacterial effects in European bass. The oregano essential oil was in the form of a liquid commercially known as Orego-Stim (Ecopharm Hellas, SA, Greece) containing 5% oregano essential oil. Carvacrol and thymol, the two major phenols that constitute about 78 to 82% of the essential oil, were principally responsible for this activity.
- 3.3.8 Document D9 assesses the synergistic efficacy of carvacrol and cymene against *Edwardsiella tarda in*

vitro and in tilapia (Oreochromis niloticus). Page 421, left-hand column, paragraph 1 reports that carvacrol is a major component of oregano and thyme essential oils and that it has been shown to inhibit many strains of food-borne pathogenic bacteria. Page 423, right-hand column, last paragraph to page 424, left-hand column discloses that carvacrol is present in plants such as oregano (Origanum vulgare), thyme (Thymus vulgaris) and savory (Satureja hortensis) and that it has a wellknown broad-spectrum of antimicrobial activity against both gram-positive and gram-negative bacteria. Carvacrol was shown in this study to inhibit Edwardsiella tarda in vitro, and it is disclosed that a fish diet supplemented with 200 ppm of carvacrol was able to reduce the mortality of Edwardsiella tardainfected tilapia when it was used together with cymene. It is speculated that cymene is able to enhance the inhibitory effect of carvacrol against Edwardsiella tarda.

3.3.9 Document D11 evaluates oregano essential oil (Origanum heracleoticum L.) on growth, antioxidant effect and resistance against Aeromonas hydrophila in channel catfish (Ictalurus punctatus). Accordingly, carvacrol and thymol were the two main active components of oregano essential oil. The bacteriostatic effects found in oregano were due to its high content of phenolic compounds, particularly carvacrol. Recent studies had shown that oregano essential oils had great antimicrobial properties (see abstract and first paragraph of the introduction). The fish were challenged with Aeromonas hydrophila and cumulative mortality was recorded for six days. A diet including carvacrol extract reduced mortality by 12%. A diet including carvacrol extract and thymol extract reduced mortality by 21%.

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- 3.3.10 The disclosure in documents D7 to D9 and D11, summarised above, shows that the antibacterial effects of carvacrol and thymol were known in the state of the art and that these two propyl-methyl-phenols are the two major phenols of oregano essential oils.
- 3.3.11 The patent proprietor has challenged this finding pointing to certain paragraphs in documents D7 and D11.

Textbook chapter D7 teaches that some bacteria, such as *Pseudomonas aeruginosa*, may be less susceptible to the action of *Origanum* extracts. Page 185, last paragraph, line 7 and page 186, first paragraph, line 13 report resistance of *Pseudomonas aeruginosa* to *Origanum* essential oils.

However, the general teaching of document D7 supports the antimicrobial activity of propyl-methyl-phenols derived from essential oils of Origanum extracts. Page 187, first full paragraph reports inhibition of Pseudomonas aeruginosa to essential oil from Oryza officinalis. The second paragraph on the same page reports that essential oil from Origanum majorana showed a remarkable effect against Pseudomonas aeruginosa. Finally, page 187, third full paragraph mentions that "P. aeruginosa exhibited resistance to all three tested essential oils as well as towards the compounds tested (carvacrol, thymol, y-terpinene, p-cymene), although later findings of Dorman and Deans (2000) confirmed good inhibitory effects of O. vulgare essential oils and of carvacrol against this G(-)bacteria".

Document D11 discloses that carvacrol alone or a combination of carvacrol and thymol have a certain

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antibacterial activity against Aeromonas hydrophila while a mixture comprising carvacrol, thymol and the more than 30 different other active constituents of Orego-Stim shows the highest antibacterial activity (see Figure 1).

- 3.3.12 In sum, the general teaching of the above-cited documents, in particular documents D7 to D9 and D11, is that oregano essential oils and the comprised carvacrol and/or thymol are effective against a wide range of bacteria, including bacteria relevant to pisciculture.
- 3.3.13 The skilled person faced with the problem of providing a composition for the treatment and prevention of diseases caused by PS would have considered the known broad antibacterial activity reported for the propylmethyl-phenol compounds carvacrol and/or thymol and would have used them with a reasonable expectation of success.

Starting from the closest prior-art document D10 and the knowledge of the broad antibacterial activity of carvacrol and/or thymol reviewed in particular in document D7 but also reported in documents D8, D9 and D11, the skilled person would have arrived at the claimed subject-matter in an obvious way.

Thus, the subject-matter of claims 1 and 14 does not involve an inventive step within the meaning of Article 56 EPC.

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Claims 2 and 15 - ISA/ISAv

Closest prior art

3.3.14 It was common ground that document D10 represents a suitable closest prior art for assessing inventive step. Its teaching is summarised in point 2.2.1 above.

Difference and objective technical problem

- 3.3.15 The difference between the subject-matter of claims 2 and 15 and the teaching in document D10 is that ISA and/or diseases caused by ISAv are treated or prevented using a propyl-methyl-phenol compound. The technical effect is that prevention and treatment of ISA and/or diseases caused by ISAv is provided.
- 3.3.16 The objective technical problem is the provision of a compound or a composition for the treatment and prevention of any disease caused by ISAv.

Obviousness

- 3.3.17 The board considers that faced with the problem of treating and/or preventing ISAv infection, the skilled person starting from document D10 as the closest prior art would have to select a suitable therapeutic agent from the list provided in document D10 having well-established antiviral activity in particular in aquaculture.
- 3.3.18 Example 2 of document D10 discloses three more specifically defined formulations, only one of which comprises phenols from *Origanum vulgare* (as secondary composition). Example 5 concerns the use of any preparation as described in Example 2 for treating

infectious pancreatic necrosis virus or haematopoietic necrosis virus in fish. However, the specific composition of the preparation is not disclosed, and no data concerning the efficacy of the tested compounds are provided. Also, the preparation is not used to combat ISAv. Consequently, the skilled person cannot evaluate the possible efficacy of propyl-methyl-phenol compounds on the viruses used in Example 5, let alone on ISAv.

3.3.19 Document D5E (machine translation provided of document D5) defines, as far as can be understood from this machine translation, the use of a mixture of Banaba (Lagerstroemia speciosa) (see fifth page) and Origanum vulgare water and alcohol extracts (see sixth page) for treating influenza viruses (see claims 1 to 5).

Example 1 discloses that a water-soluble plant extract from oregano leaves (see reference Example 1 on the ninth page) inhibited type A influenza (see eleventh page, paragraphs 3 and 4).

The opponent argued that the patent itself stated in paragraph [0007] that "[i]nfectious salmon anemia appears to be most like influenza viruses". However, apart from this general statement, no further information has been provided in this context in appeal. No prior art has been invoked shedding light on the understanding of the skilled person. The relevance of a virus known in the context of infectious viruses acting on endotherms, in particular, humans, for viruses affecting (cold-blooded) fish has thus not been established.

3.3.20 Furthermore and of utmost importance, it is not specified in document D5E how the various water/alcohol plant extracts were prepared and whether and to what

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extent they even contain propyl-methyl-phenols. Propyl-methyl-phenolic compounds are not identified as an active antiviral principle of the oregano extracts used.

3.3.21 Textbook chapter D7 discloses on page 196, chapter "IMMUNOSTIMULANT, ANTIMUTAGENIC AND ANTICANCER ACTIVITY" that oregano extracts or herbal mixtures comprising Origanum spp. possess in vitro antiviral activity or had immunostimulating effects both in vitro and in vivo. Inhibition of the intracellular propagation of ECHO₉ Hill virus and human HIV infection and HIV-1 induced cytopathogenicity are reported.

The flavonoid luteolin, a constituent of *Origani herba*, is identified as being responsible for the induction of an interferon-like substance in the context of Hill virus. Thus, this antiviral effect is not based on propyl-methyl-phenols.

Carnosol, carnosic acid, carvacrol and thymol are mentioned as possible active compounds for inhibiting HIV infection. The relevance of this, HIV being a retrovirus, for infections by ISAv has not been established by the opponent.

3.3.22 Thus, in contrast to the situation with PS, the priorart literature only mentions carvacrol and thymol as potential active principles in the treatment of HIV, i.e. a very particular viral setting. A broad antiviral activity of propyl-methyl-phenol compounds cannot be deduced from this. Consequently, the skilled person had no expectation that propyl-methyl-phenol compounds, such as carvacrol and thymol mentioned in document D10, could successfully be used to combat ISAv.

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- 3.3.23 Based on the scarce information provided in the cited prior art on the antiviral activity of propyl-methyl-phenol compounds, the board considers that the claimed subject-matter of claims 2 and 15 was not obvious starting from the closest prior-art document D10 alone or in combination with document D7 and/or D5/D5E.

 Consequently, the subject-matter of claims 2 and 15 of new auxiliary request 1 involves an inventive step within the meaning of Article 56 EPC.
- 4. New auxiliary request 2
- 4.1 Admittance Article 13(2) RPBA

New auxiliary request 2 is based on the set of claims on which the patent was maintained by the opposition division. It was refiled as auxiliary request 12 with the statement of grounds of appeal.

New auxiliary request 2 differs from auxiliary request 12 as filed with the patent proprietor's statement of grounds of appeal only in that the second alternative of independent claims 1 and 11, which was found to lack novelty due to its wording (see above), has been deleted. This amendment is analogous to that in new auxiliary request 1, which the board admitted into the proceedings (see point 3.1 above). For the same reasons that justified admittance of new auxiliary request 1, the board admitted auxiliary request 2 into the proceedings.

4.2 Novelty - Article 54 EPC - claims 1 and 11

The subject-matter of claims 1 and 11 is considered to be novel for the same reasons as provided for the

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second medical use alternative of claims 2 and 15 of the main request (see point 2.2.2 above).

4.3 Inventive step - Article 56 EPC - claims 1 and 11

The subject-matter of claims 1 and 11 is considered to involve an inventive for the same reasons as provided for the subject-matter of claims 2 and 15 of new auxiliary request 1 (see points 3.3.14 to 3.3.23 above).

4.4 Disclosure of the invention - Article 83 EPC - claims 1 and 11

The patent discloses the subject-matter of claims 1 and 11 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art for the same reasons as provided for the subject-matter of claims 2 and 15 of new auxiliary request 1 (see points 3.2.2 to 3.2.6 above).

5. The board did not decide on other requests of the parties since they were not relevant for the decision.

Order

For these reasons it is decided that:

- The decision under appeal is set aside. The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

claims 1 to 11, filed as New auxiliary request 2 during the oral proceedings of 26 September 2022

The Registrar:

The Chairwoman:



I. Aperribay

M. Pregetter

Decision electronically authenticated