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**Datasheet for the decision
of 9 November 2022**

Case Number: T 1571/19 - 3.3.09

Application Number: 13803287.5

Publication Number: 2914124

IPC: A23K50/80, A23K20/00

Language of the proceedings: EN

Title of invention:
FEED COMPOSITION FOR FISH

Patent Proprietor:
Ewos Innovation AS

Opponent:
Nutreco IP Assets BV

Headword:
Feed composition for fish/EWOS

Relevant legal provisions:
EPC Art. 54(2), 54(5), 56, 83
RPBA Art. 12(4), 15(1)

Keyword:

Sufficiency (yes): therapeutic effect rendered plausible by the tests shown in the patent; no counter-evidence that the effect cannot be attained

Novelty (yes): no convincing evidence that the invention was made available to the public by public prior use or oral disclosure

Inventive step (yes): claimed therapeutic use not obvious over the cited prior art

Decisions cited:

T 1028/05, T 1685/10

Catchword:

Most promising springboard toward the claimed invention too short to allow the skilled person to reach out to cited secondary document and to overcome the considerable gap separating the closest prior art from the claimed subject-matter (reasons 3.35 to 3.39)



Beschwerdekammern

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Case Number: T 1571/19 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 9 November 2022

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 28 March 2019 rejecting the opposition filed against European patent No. 2914124 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman A. Haderlein
Members: A. Veronese
E. Kossonakou

Summary of Facts and Submissions

- I. The appeal was filed by the opponent (appellant) against the decision of the opposition division rejecting the opposition filed against the European patent.
- II. With its notice of opposition, the opponent had requested the revocation of the patent in its entirety on the grounds of Article 100(a) (lack of novelty and lack of inventive step) and 100(b) EPC.
- III. The documents submitted during the opposition proceedings included the following:
- D1: Abstract of thesis of Ms Martinez-Rubio, retrieved from the University of Stirling Online Research Repository (STORRE)
 - D1a: Display of the full version of the abstract D1
 - D1b: Extract from STORRE
 - D2: Thesis of Ms Martinez-Rubio, retrieved from STORRE
 - D3: WO2011/031166 A2
 - D5: Thesis of Mr Gerrit Timmerhaus, available in printed form from 13 March 2012
 - D9: B.B. Jensen et al., "Diseases of aquatic organisms", 2013, vol. 107, pp. 141-150
 - D14: Programme of MonAqua's "*Optimalisering*" conference, held in Kristiansund in November 2005
 - D14a: English translation of D14
 - D15: Email of 16 May 2018 from Beate Fonhun, from the library of the Norwegian University of Life Sciences (NMBU University), indicating the date on which the D5 was made available to the public

D16: Declaration by Ms Vikene, dated 10 December 2018

D16a: English translation of invoices annexed to D16

D17: Declaration by Mr Marthinussen, dated
10 December 2018

D18: Declaration by Ms Karlsen, dated 15 November 2018

IV. Claim 1 of the granted patent reads as follows:

"1. A feed composition for fish for use in the prevention and/or treatment of diseases caused by the Piscine Myocarditis Virus (PMCV), including Cardiomyopathy syndrome (CMS) and liver steatosis caused by PMCV, comprising conventional feed ingredients such as proteins, lipids, vitamins, carbohydrates and minerals, characterized in that the feed comprises fatty acids and that more than 20 % of the total fatty acids are n-3 fatty acids."

V. In its decision, the opposition division found, *inter alia*, that:

- the claimed invention was sufficiently disclosed; the patent made it credible that compositions comprising n-3 fatty acids induced beneficial effects in fish affected by PMCV and provided sufficient information to carry out the invention
- claim 1 was drafted according to Article 54(5) EPC; the claimed subject-matter was novel over the alleged prior use and the oral disclosure described in D14, D14a, D16, D16a, D17 and D18
- D2 was not part of the state of the art and D1 was made available to the public after the priority date

- the claimed subject-matter involved an inventive step over the teaching of D5 in combination with that of D3 and, as far as it did not enjoy priority right, it also involved an inventive step over D1

VI. With its statement setting out the grounds of appeal, the appellant filed the following documents:

D19: Extract from the Internet DSPACE HELP page from STORRE

D20: Extract from a web page of the University of Stirling

D21: Fisk. Dir. Skr. Ernæring, 1991, vol. IV(1), pp. 51-63

VII. The arguments from the **appellant** which are relevant for the decision can be summarised as follows:

- the claimed invention was not sufficiently disclosed; there was no evidence that the claimed n-3 fatty acid compositions were therapeutically effective, let alone for treating all of the diseases claimed; on the contrary, there was evidence that the compositions were not therapeutically effective at all
- the claimed subject-matter lacked novelty over the oral disclosure of Mr Marthinussen, as evidenced by D14/D14a, D16/D16a, D17 and D18, and over the public prior use substantiated by D16 to D18
- D1 and D2 were part of the state of the art; the publication embargo mentioned in D1a applied to the electronic version of D2, not to the abstract D1; D19 showed that the "issue date" of D1 was its publication date and D20 showed that D2 was made

available to the public in printed form before the filing date; D1 and D2 were to be taken into account for assessing inventive step

- the claimed subject-matter did not involve an inventive step over the teaching of D5 in combination with that of D3; starting from D5, which did not disclose compositions comprising n-3 fatty acids, the problem was the provision of a composition reducing inflammation in the atrium and ventricle of fish hearts; the claimed solution was obvious in view of D3, which disclosed the claimed composition to treat HSMI, a fish disease relating to CMS having similar symptoms and gene expression; in view of the similarity of the diseases the skilled person would have expected the compositions described in D3 to also be effective in the treatment of CMS; the claimed subject-matter was also obvious starting from D1 as closest prior art.

VIII. The arguments from the patent proprietor (**respondent**) which were relevant for the decision can be summarised as follows:

- D19 to D21 should not be admitted
- the claimed invention was sufficiently disclosed; the tests in the patent showed that the claimed composition comprising n-3 fatty acids induced beneficial effects on the heart and liver of fish infected by the PMCV virus; even a temporary benefit in the atrium qualified as treatment; the appellant's objections were not substantiated; there was no evidence that n-3 fatty acids were ineffective

- the claimed subject-matter was novel over the alleged oral disclosure and the public prior use because the evidence provided did not show that the claimed invention was effectively already disclosed

- D1 and D2 were not part of the state of the art because the publication thereof was subjected to an embargo until 15 December 2013; there was no evidence that the "issue date" of D1 was a publication date

- the claimed subject-matter involved an inventive step over D5, the closest prior art; D5 did not disclose feed compositions, let alone feed compositions comprising fatty acids for treating the claimed diseases; the underlying problem was the provision of a treatment for the claimed diseases; D5 did not contain any hint at the claimed solution; the teaching of D3 was limited to the treatment of HSMI; starting from D5 the skilled person could not have expected the compositions of D3 to be effective in the treatment of CMS and liver steatosis caused by PMCV.

Reasons for the Decision

Main request

1. *Sufficiency of disclosure*

- 1.1 Claim 1 of the opposed patent is drafted according to Article 54(5) EPC and relates to a feed composition for fish, comprising n-3 fatty acids, for use in the treatment and prevention of diseases caused by the piscine myocarditis virus (PMCV), in particular cardiomyopathy syndrome (CMS) and liver steatosis

caused by PMCV. According to paragraphs [0009], [0010], [0011] and [0061] of the patent, the claimed composition increases the levels of n-3 fatty acids in the hearts and livers of fish and this results in the claimed beneficial therapeutic effects.

- 1.2 Attaining the claimed therapeutic effects is a functional technical feature characterising claim 1. Thus, in order to meet the requirement of sufficiency of disclosure, the patent must render it plausible that the claimed feed composition is suitable for treating the diseases indicated in the claim (see the Case Law of the Boards of Appeal of the European Patent Office, 10th edition, Section II.C.7.2.1).
- 1.3 The patent discloses the results of a trial in which two compositions, "CMS 1" and "CMS 2", comprising n-3 fatty acids in the claimed amounts, and a reference composition comprising them in a lower amount, were administered to fish.
- 1.4 According to the appellant, the claimed invention was not sufficiently disclosed because the results were unsuitable for showing that feed compositions including the required amounts of n-3 fatty acids induced therapeutic benefits on CMS and liver steatosis caused by PMCV. The appellant argued in particular that:
 - Figures 3 and 4 and paragraph [0063] of the patent did not show that the tested CMS compositions induced beneficial effects on the heart; an effect on the atrium was observed during weeks 6 and 8, but faded during weeks 10 to 14; the effect on the ventricle after 14 weeks was not significant either

- Figure 5 showed that the CMS compositions comprising n-3 fatty acids did not prevent liver steatosis; an increase in the histology score was in fact observed during weeks 6, 8 and 10
- there was no evidence of a direct effect of n-3 fatty acids on the metabolic mechanism involved in CMS and that n-3 fatty acids induced the observed effects; there was no correlation between the amount of n-3 fatty acids in the diet, the amount in the target tissues and the effects on the heart; furthermore, the tested CMS compositions differed from the control not only in their n-3 fatty acid content but also in other features, e.g. in the total amount of lipids and in the ratio between n-3 to n-6 fatty acids; these could also have triggered the observed effects
- D2 taught that the observed effects were induced by the reduced content of lipids in the CMS compositions, rather than by the increase in the amount of n-3 fatty acids
- since the inoculation of the virus was "controlled" in the tests, it was not credible that the effects could be reproduced in an uncontrolled setting
- eicosapentaenoic acid (EPA) was the preponderant ingredient in the tested compositions; it was not credible that any composition comprising other n-3 fatty acids afforded the same results
- claim 1 defined the minimum proportion of n-3 fatty acids over the total amount of fatty acids, not the minimum amounts thereof in the composition; thus, it encompassed compositions comprising negligible

amounts of n-3 fatty acids and any fatty acid profile; these could be not be effective either.

- 1.5 These arguments are not convincing.
- 1.6 Figure 3 shows that the tested CMS compositions, enriched with n-3 fatty acids, induce beneficial effects over the entire sampling period in the ventricle of fish affected by CMS induced by PMCV; positive effects are also observed in the atrium during weeks 6, 8 and 14. Although the results at week 14 do not achieve statistical significance, the overall picture makes it credible that the tested compositions are suitable for treating CMS induced by PMCV.
- 1.7 The appellant selectively focused on some of the results shown in the patent, ignoring the overall picture. It is noted that the positive effects on the ventricle alone make it plausible that the treatment is beneficial against CMS: the ventricle is in fact the strongest part of the heart which pumps blood to the gills, where the blood is re-oxygenated, and then out to the entire body. Moreover, as argued by the respondent, even a temporary effect on the atrium is beneficial and qualifies, as such, as a treatment. Similar conclusions can be drawn in relation to liver steatosis induced by PMCV. In fact, as shown in Figure 5, the markers of steatosis remain lower in the treatment group for the duration of the treatment.
- 1.8 Moreover, Figure 2 of the patent shows that feeding fish with compositions enriched with n-3 fatty acids causes the accumulation of these compounds, EPA in particular, in the heart tissue. With the exception of one value, which relates to composition CMS 2 at week 12, this accumulation correlates with the effects in

the ventricle shown in Figure 3. This makes it plausible that compositions comprising higher amounts of n-3 fatty acids are beneficial in fish infected with PMCV.

- 1.9 The divergency observed in the data relating to the atrium in weeks 10 and 12 is not sufficient to undermine the relevance of the results and to conclude that the tested compositions are not effective. Since the overall picture makes it credible that there was a positive effect over the entire treatment period, it is also irrelevant that the induction of the infection was "controlled" during the trial.

- 1.10 The appellant noted that the tested CMS compositions differed from the control not only in the content of EPA and total n-3 fatty acids but also in other features, in particular in the total amount of lipids and in the n-3 vs n-6 fatty acid ratio. In its opinion, this cast serious doubts on the observed effects having been induced by n-3 fatty acids. In this context, the appellant referred to D2, a thesis discussing the results of the same trial described in the opposed patent. In the appellant's view, the paragraphs bridging pages 203 and 204, and pages 213 and 214, of D2 taught that the beneficial effects of the tested CMS compositions, in particular on liver steatosis, were due to their reduced lipid content, rather than to their n-3 fatty acid content. This was also logical, because liver steatosis was characterised by an accumulation of fat in the liver.

- 1.11 These arguments are not persuasive either.

- 1.12 When reading D2, the appellant selectively focused on certain passages to draw conclusions which do not

reflect the overall teaching of this document. In fact, an unbiased reading of D2 reveals that both the increased content of the n-3 fatty acid EPA and the reduced lipid content in the CSM compositions are considered beneficial for fish affected by CMS and liver steatosis induced by PMCV. This teaching is repeated consistently in the different sections of D2: see page 156, lines 9 to 12, page 161, lines 15 to 17, page 162, lines 18 to 21, page 203, lines 1 to 5, page 211, lines 14 to 17 and the concluding passage bridging pages 213 and 214. Accordingly, contrary to the appellant's submissions, D2 does not raise doubts as to the therapeutic utility of n-3 fatty acids.

1.13 The appellant also submitted that the observed results, obtained using compositions enriched primarily with EPA, could not be generalised to also apply to compositions comprising other n-3 fatty acids. This objection is not persuasive either: EPA is an n-3 fatty acid. "n-3 fatty acids" are polyunsaturated fatty acids containing conjugated double bonds. They are all characterised in that the first conjugated double bond is three atoms away from the terminal methyl group in the carbon chain. In the absence of any evidence to the contrary, it can be reasonably expected that, having the same scaffold and structural arrangement of double bonds, n-3 fatty acids will share similar chemical and biological properties. The appellant's objection that the results obtained with compositions enriched primarily with EPA cannot be generalised to also apply to other compositions remains unsubstantiated.

1.14 Furthermore, the skilled person would not, as the appellant suggested, interpret claim 1, which refers to a feed composition for fish, as encompassing compositions including insignificant amounts of n-3

fatty acids or composed almost exclusively thereof. As shown in paragraph [0042] of the patent, a "standard" fish feed contains around 30% fatty acids; an amount in this order is thus to be considered the basis for calculating the 20% content of n-3 fatty acids specified in claim 1. The appellant attempts to tear down the invention, focusing deliberately on embodiments the skilled person would avoid when construing claim 1 based on the teaching of the patent and their common general knowledge.

1.15 The appellant has also criticised the fact that the patent does not clarify the mechanism of action underlying the therapeutic action of n-3 fatty acids. Showing that a compound influences the mechanism of action underlying a disease may in some cases make it credible that a compound is suitable for treating that disease; however, this is not always necessary for the requirement of sufficiency to be fulfilled. The suitability of a compound for a therapeutic treatment may become apparent in different ways. One of these is, like in the patent, monitoring the markers of a disease after administration of a composition according to the claimed invention. The appellant mentioned decision T 1685/10, in which sufficiency was denied because there was no evidence that a compound modulated a relevant metabolic pathway; however, in that case the patentee had only relied on tests investigating the underlying mechanism to make the therapeutic effect credible and counter-evidence was provided disproving the observed results; thus, the situation was different from the one in the present case.

1.16 For these reasons, and considering the fact that the content of n-3 fatty acids, EPA in particular, was considerably higher in the CMS diet than in the

reference diet, it is plausible that, as postulated in paragraphs [0009], [0010], [0011] and [0061] of the opposed patent, compositions comprising n-3 fatty acids in the claimed proportions are suitable for treating and preventing the relevant disorders. The appellant suggested numerous alternative explanations for the effects shown in the patent. However, there is no evidence that the skilled person, relying on the information given in the opposed patent and on common general knowledge, would not have been able to prepare a composition as described in claim 1 which is suitable for treating the relevant diseases. It has thus been concluded that the claimed invention is sufficiently disclosed (Article 83 EPC).

2. *Novelty*

Oral disclosure by Mr Marthinussen

2.1 According to the appellant, the claimed subject-matter lacked novelty over the alleged public prior oral disclosure by Mr A Marthinussen during the MonAqua conference held on 2 November 2005, i.e. before the priority date. The appellant referred to the following documents to substantiate this disclosure:

- D14 and D14a: Brochure containing the programme of the MonAqua conference and a translation thereof
- D16: Declaration by Ms Vikene
- D16a: Translation of invoices annexed to D16
- D17: Declaration by Mr Marthinussen relating to his oral disclosure during the MonAqua conference
- D18: Declaration by Ms Karlsen

- 2.2 However, these documents do not provide convincing evidence that the claimed subject-matter was directly and unambiguously disclosed during the conference.
- 2.3 In particular, D14 and D14a contain no indication as to the content of Mr Marthinussen's talk and its potential relevance to the present proceedings. As the opposition division correctly pointed out, the title is quite generic. "Epidemiology in practice" could indeed cover a rather broad spectrum of issues.
- 2.4 While it is not contested that the topic of the talk referred to in D17 focused on issues closely related to the present case, Mr Marthinussen's declaration cannot establish that:
- the "fish feeds with high omega three fatty acids levels" mentioned during the MonAqua conference comprised more than 20% n-3 fatty acids calculated on the basis of the total fatty acids
 - the fish feeds mentioned during the conference correspond to the "FUTURA" compositions described in D16, D16a and D18 (which apparently comprised these amounts of n-3 fatty acids)
- 2.5 The declarations by Ms Vikene (D16) and Ms Karlsen (D18) contain no indication linking the FUTURA feed to a specific event, in particular the MonAqua conference, in which the composition of the feed and its utility in the treatment of conditions caused by PMCV were disclosed.
- 2.6 Thus, the alleged prior oral disclosure has not been proven to anticipate the claimed subject-matter.

Alleged public prior use

- 2.7 According to the appellant, the claimed subject-matter lacks novelty over an alleged instance of public prior use substantiated by D16, D17 and D18.
- 2.8 However, these documents do not provide convincing evidence that the claimed subject-matter was directly and unambiguously disclosed before the relevant date, regardless of the standard of proof applied.
- 2.9 According to Ms Vikene's declaration (D16), a fish feed named "FUTURA" was manufactured by the firm "Skretting" at the request of Ms Karlsen of "Hydrotech". Ms Vikene states that Hydrotech "had big issues" with cardiomyopathy syndrome and liver steatosis in fish.
- 2.10 First, the board notes that D16 does not directly and unambiguously disclose that "FUTURA" was effectively administered to fish for treating or preventing the specific conditions of cardiomyopathy syndrome and liver steatosis. This information cannot be found in D17 or D18 either.
- 2.11 Furthermore, as noted by the respondent, it is not possible to determine with certainty whether the compositions mentioned by Ms Vikene and described in Annex A of D16 were effectively those mentioned in D17 and D18. The values in Annex A are said to be taken from a "screen shot from the recipe formulation program Format". There is no extemporaneous evidence confirming the year 2004 mentioned in the title of the annex. Even if the relevant assertions in both D16 and D18 are considered to be correct, it remains unclear whether the product according to Annex A, bearing the article number 86832, and the description CMS 2000-30 12, is

the same as the product sold according to the invoices listed in Annex B and attached to D16 and D18; these bear the article number H68287 and the description FUTURA CMS 2000-30A 9 (invoices 894826 and 894558) and article number H68327 and the description FUTURA CMS 2000-30A 12 (invoice 898934).

2.12 The evidence provided has not convinced the board that a product as defined in claim 1 was sold and used by Hydrotech for the claimed therapeutic use. Accordingly, it has been concluded that the claimed subject-matter is not anticipated by the alleged public prior use either.

2.13 The claimed subject-matter is therefore novel (Articles 54(2) and 54(5) EPC).

2.14 In view of this finding, there is no need to decide whether or not the opposition division's decision to admit D14, D14a, D16, D16a, D17 and D18 was correct. It is also noted that according to established case law, such discretionary decisions are only revisited if the opposition division used the wrong criteria or applied them incorrectly or unreasonably, which does not appear to be the case here.

3. *Inventive step*

Public availability of D1 and D2

3.1 The appellant considered D1 and D2 relevant in the context of the inventive step discussion. D2 is a thesis by Ms L. Martinez-Rubio, entitled "Use of functional feeding strategies to protect Atlantic salmon from virally-induced inflammatory diseases - mechanistic insights revealed by transcriptomic

analysis". D1 is an abstract of this thesis. A full version of the abstract which includes the complete metadata record was filed as D1a.

3.2 D1, D1a and D2 were downloaded from the University of Stirling Online Research Repository (STORRE).

3.3 On its front page, the thesis D2 bears the date "December 2012". However, this is not necessarily the date on which D2 was made available to the public; it could be the date on which the final version of the thesis was redacted by its author or the date on which it was printed or intended to be submitted.

3.4 As noted by the respondent, D1a, the full version of D1, contains an entry which reads:
"dc.rights.embargodate 2013-12-15".

3.5 The explanatory notes found on the website of the University of Sterling (shown in D1b) show that a request for an "embargo" is a request to delay public access to the electronic version of a thesis through the university database system. The request can be filed, for example, if the thesis or an excerpt thereof has been submitted to a journal but has not yet been published. D1a confirms that an embargo was requested for D2 because parts of the thesis were submitted or were going to be submitted to certain scientific journals. The University of Sterling was thus requested to delay the publication of D2 at least through its electronic database. It is therefore credible that D2 was not disclosed to the public until after the expiry of the embargo period, i.e. after 15 December 2013.

3.6 Concerning D1, the full version of this document (D1a) contains several entries, including:

"dc.date.accessioned"	2013-01-09T16:38:49Z
"dc.date.available"	2013-01-09T16:38:49Z
"dc.date.issued"	2012-09

3.7 The opposition division assumed that the content of D1 was made available to the public on 9 January 2013, the date indicated in the entries "dc.date.accessioned" and "dc.date.available".

3.8 The board concurs with the appellant that this is an unsubstantiated assumption, because no evidence is available as to the meaning of these entries within the STORRE system. However, for the same reasons, the board does not agree with the appellant that the technical content of D1 was available to the public in September 2012, i.e. on the date of the entry "dc.date.issued".

3.9 Furthermore, as mentioned above, the publication of the electronic version of the thesis was subjected to an embargo lasting until 15 December 2013. This raises significant doubts that the technical content of D1, i.e. of the abstract of the thesis, was made available to the public on an earlier date. Rendering accessible the crucial aspects of the thesis in the abstract could, in fact, undermine the reasons for requesting the embargo. Therefore, it is not possible to establish whether any part of D1 was made available to the public on any of the aforementioned dates.

3.10 With its statement setting out the grounds of appeal, the appellant filed two new documents, D19 and D20, and argued that:

- D19 taught that the "issue date" (in the specific case the entry "dc.date.issued 2012-09") was the

date assigned by the system when an item became part of the "repository"

- D20 showed that a printed copy of the thesis was available at the library of the University of Sterling in 2012. Furthermore, D1b taught that the embargo applied only to the electronic version of the thesis as "Most publishers will not be concerned about the paper copy of your thesis being available for consultation in our Library".

3.11 The appellant submitted that D19 and D20 were filed in reaction to the opposition division's decision that D1 and D2 were not part of the state of the art. The opposition division had expressed the preliminary opinion that D2 was part of the state of the art as far as the priority claim was invalid. This opinion was reversed in the decision. Thus, D19 and D20 had to be admitted into the appeal proceedings.

3.12 The board does not agree. In its preliminary opinion in preparation for the oral proceedings, the opposition division explicitly requested the parties to comment on the publication date of D1. Thus, D19 and D20 should (and could) have been filed during the opposition proceedings in reply to this request.

3.13 Moreover, as noted by the respondent, D19 does not allow the conclusion that the "issue date" mentioned in D1a is the date on which D1 was made available to the public. The issue of public availability is in fact not addressed in sufficient detail. This means that D19 raises new complex issues which should have been presented during the opposition proceedings.

- 3.14 The allegation that the thesis by Ms L. Martinez-Rubio as shown in D2 was made available to the public before the priority date in printed form by the library of the University of Stirling was not made during the opposition proceedings either. Thus, by filing D20 and referring to a printed publication, the appellant raises completely new issues in the appeal proceedings: whether and when the printed copy of the thesis was available for consultation in the library and whether the content of this copy corresponded to that of the electronic copy shown in D2. The appeal stage is not the right time or the right place to raise new issues of fact.
- 3.15 Furthermore, as already mentioned above, in its preliminary opinion the opposition division explicitly requested comments on the publication date of D1. D1 and D2 being inextricably linked, the appellant should have taken the opportunity to provide any evidence relating to the publication date of both documents during the opposition proceedings.
- 3.16 Finally, as noted by the respondent, D19 and D20 were retrieved and printed on 28 May 2019 to demonstrate the state of affairs in 2012/2013. Since they are not extemporaneous, they do not necessarily reflect events which occurred in 2012/2013. The board notes in this regard that despite stating that publishers will not be interested in the paper copy being available in the library, D20 goes on to set out an elaborate system allowing authors to request an embargo also on the accessibility of their printed work.
- 3.17 For these reasons, D19 and D20 and the arguments based thereon are not admitted into the appeal proceedings (Article 12(4) RPBA 2007). Accordingly, it cannot be

established whether the technical content of D1 and D2 was made available to the public before the expiry of the embargo period, i.e. before 15 December 2013. Thus, neither D1 nor D2 is part of the state of the art.

The closest prior art and its teaching

- 3.18 When discussing inventive step, the appellant relied on D1 and, in the alternative, on D5 as the closest prior art. Since D1 was not available to the public before the filing date and is not part of the state of the art, only the attack based on D5 was considered at the oral proceedings and will be elaborated upon here.
- 3.19 D5 is a thesis describing a study "aimed at increasing the general knowledge" regarding host-virus responses in Atlantic salmon, in particular responses to the virus causing cardiomyopathy syndrome (CMS): see page 7, first paragraph, "Aim of the study". Piscine myocarditis virus (PMCV) is considered the most likely causative agent of CMS (page 17, third paragraph).
- 3.20 Section 5.2.2.2 of D5 ("Pathology", pages 17 and 18) describes the histopathological changes in the salmon heart induced by CMS. It teaches that multifocal lesions appear in the heart, which gradually develop into extensive lesions leaving no intact cell in the atrium and a spongy layer on the ventricle. A study aimed at identifying the genes which are activated in CMS and other diseases induced by the virus, such as heart and skeletal muscle inflammation (HSMI) and infectious pancreatic necrosis (IPN), is described in section 6.3 on page 48.
- 3.21 Sections 5.3.3, 5.3.4 and 5.3.5 (on pages 24 and 25) discuss some of the therapeutic options for treating

and preventing viral infections in Atlantic salmon. Section 5.3.5 and the conclusions in section 4 on page 51 mention the possibility of using feeding strategies for therapeutic purposes.

3.22 D5 thus provides a comprehensive picture of the state of the art in the relevant field. Since it was published on 13 March 2012 (see D15), a few months before the priority date of the patent (1 November 2012), D5 represents the common general knowledge in the field on the date of priority. The opposition division decided, and the parties agreed, that D5 is the closest prior art. The board does not see any reason to diverge from this finding.

3.23 The appellant submitted that the use of the claimed composition for treating CMS was obvious over a combination of D5 with D2, D3 and D9. D2 will not be considered in the following because, as concluded above, it is not part of the state of the art.

Distinguishing features, effect and underlying problem

3.24 The appellant considered that the subject-matter of claim 1 differed from that of D5 in that it related to a feed composition for fish in which more than 20% of the total fatty acids were n-3 fatty acids.

3.25 It also submitted that the opposed patent at best provided evidence that the claimed composition reduced the symptoms of CMS, specifically inflammation of the atrium and the ventricle. Thus, the problem was "the provision of a food composition for fish which reduces inflammation in the atrium and the ventricle". Its solution, namely the use of the claimed feed composition, was obvious in view of D3, which disclosed

the beneficial effects of the same composition on heart and liver inflammation in fish affected by HSMI, a viral infection related to CMS.

- 3.26 The board does not agree.
- 3.27 It is undisputed that the subject-matter of claim 1 differs from the teaching of D5 in that it relates to a feed composition in which more than 20% of the total fatty acids are n-3 fatty acids.
- 3.28 However, it cannot be overlooked that, while thoroughly describing the aetiology and pathophysiology of CMS, D5 is very speculative when discussing the possible therapeutic options for preventing and treating CMS.
- 3.29 Section 5.3.3 ("Vaccines", on page 24) envisages the possibility of using vaccines to prevent the outbreak of viral diseases and concludes that their benefits outweigh the negative effects. Section 5.3.4 ("Selective breeding", on page 24) discusses how to develop resistance to viral diseases by selective breeding. Yet no effective vaccine or salmon breed resistant to PMCV infections is mentioned.
- 3.30 Section 5.3.5 ("Clinical nutrition", on page 25) states that "In addition to preventive measures that reduce losses due to diseases in aquacultures (e.g. vaccination, reduction of stress) different feeding strategies and diet formulations are being used". However, no specific feed composition for treating viral diseases is disclosed. The potential utility of food deprivation and vitamin supplementation in viral pancreatic disease (PD) and infection pancreatic necrosis (IPN) are briefly discussed. Yet PMCV and diseases caused by it, e.g. CMS, are not even

mentioned. In fact, the author concedes that "Not much research has been conducted with clinical nutrition of salmon" and that "studying the effects of nutrition on the transcriptome in fish might provide insight in this field".

3.31 Section 8 ("Further perspectives", on page 51) does not disclose any specific nutritional composition for treating CMS caused by PMCV either. This section merely speculates on the possibility of conducting further studies aimed at the development of new strategies for controlling PMCV outbreaks. As far as feeding is concerned, it is only stated that "Feeding strategies and reduction of stress should be considered".

3.32 Thus, D5, which represents the common general knowledge at the time of priority, shows that at that time no therapy was known for treating and preventing infections caused by PMCV, including CMS.

3.33 It follows that the objective technical problem has to be formulated as the provision of a therapy for treating and preventing diseases caused by PMCV, in particular CMS and liver steatosis.

3.34 As set out above when discussing sufficiency of disclosure, the results shown in the opposed patent make it plausible that the claimed feed composition is suitable for treating these diseases and that the underlying problem has been solved.

Non-obviousness of the claimed solution

3.35 The appellant argued that the skilled person, starting from D5 and faced with the underlying problem, would have taken into account the teaching of D3. Like the

opposed patent, D3 related to a feed composition for treating inflammatory symptoms in the heart and the liver caused by HSMI, a viral disease. The composition of D3 contained, like the claimed one, more than 20% n-3 fatty acids based on the total amount of fatty acids. The teaching of D3 was limited to the treatment of HSMI. However, the pathology and the symptoms of CMS and HSMI were similar (D5, page 16, third paragraph). Furthermore, HSMI was considered a risk factor for CMS according to D9 (page 149, right-hand column). Therefore, the skilled person would have reasonably expected the composition of D3 to be beneficial in the treatment of CMS.

3.36 These arguments are not persuasive.

3.37 As mentioned above, D5 shows that no therapy was known for treating and preventing diseases caused by PMCV in fish at the time of priority. Furthermore, it shows that the field of clinical nutrition of salmon was still in its infancy and that the therapeutic utility of feed compositions for fish could only be speculated upon. This means that at the time of priority the skilled person could, at most, have had a tenuous hope that a fish feed composition for treating the claimed diseases would be developed in the future.

3.38 For these reasons, the skilled person starting from D5 would barely have considered the teaching of D3. Even if they had, they would not have considered the idea of using the composition of D3 to treat and prevent diseases caused by PMCV, in particular CMS, to have a reasonable expectation of success. Therefore, they would not have endeavoured to test the utility of this composition for these therapeutic uses.

- 3.39 The appellant selected D5 as the closest prior art. This is, in other words, what the appellant considers the "most promising springboard" towards the claimed invention. Nonetheless, this springboard is too short to allow the skilled person to reach out to D3 and to overcome the considerable gap separating the closest prior art from the subject-matter defined in claim 1.
- 3.40 The appellant mentioned decision T 1028/05. This related to a patent claiming the treatment of chronic obstructive pulmonary disease (COPD) with a combination of formoterol, a bronchodilator and budesonide, a steroid. This treatment was considered to lack an inventive step over a document disclosing the same drug combination for treating asthma, a respiratory disease related to COPD. According to the appellant, analogous conclusions should be drawn in the present case. The board does not agree. In T 1028/05, evidence was available showing that the use of anti-asthma drugs, including combinations of steroids and bronchodilators, for treating COPD was widespread before the relevant date. Furthermore, it showed that there was a strong opinion in the field that combinations of steroids and bronchodilators were effective for treating COPD. Since the circumstances were completely different, T 1028/05 is not relevant to the present case.
- 3.41 Finally, on pages 22 and 23 of its statement of grounds of appeal the appellant stated briefly that "it was entirely obvious to treat the symptoms of liver steatosis", in particular in view of the teaching of document D21. In the communication pursuant to Article 15(1) RPBA 2007, the board indicated that it intended not to admit the inventive step attack involving this document since no reasons had been provided as to why this attack was raised for the first

time in the appeal proceedings and because the attack had not been properly formulated using the problem-solution approach. At the oral proceedings, the appellant did not refer to D21 or this attack. The board sees no reason to further consider D21 and thus has not admitted this document or the corresponding inventive step attack into the appeal proceedings (Article 12(4) RPBA 2007).

- 3.42 For these reasons it has been concluded that the subject-matter of claim 1, as well as that of the following claims, which is narrower in scope, involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chairman:



M. Schalow

A. Haderlein

Decision electronically authenticated