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**Datasheet for the decision
of 13 October 2023**

Case Number: T 1879/21 - 3.3.09

Application Number: 15766520.9

Publication Number: 3197290

IPC: A23K20/142, A23K20/22,
A23K20/24, A23K50/80

Language of the proceedings: EN

Title of invention:

A FISH FEED AND ITS USE IN THE PROPHYLAXIS AND TREATMENT OF
HAEMORRHAGIC SMOLT SYNDROME (HSS) IN SALMONIDAE

Patent Proprietor:

Europharma AS

Opponents:

Cargill, Incorporated
BioMar Group A/S
Nutreco IP Assets BV

Headword:

Fish feed/EUROPHARMA

Relevant legal provisions:

EPC Art. 83, 123(2)
RPBA 2020 Art. 13(2)

Keyword:

Sufficiency of disclosure - (no)

Amendments - added subject-matter (yes)

Amendment after summons - taken into account (no)

Decisions cited:

G 0001/03, G 0002/21, T 2767/18



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Case Number: T 1879/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 13 October 2023

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
18 August 2021 concerning maintenance of the
European Patent No. 3197290 in amended form.

Composition of the Board:

Chairman A. Haderlein
Members: C. Meiners
N. Obrovski

Summary of Facts and Submissions

- I. This decision concerns the appeals filed by the patent proprietor and opponents 1 to 3 (all appellants) against the opposition division's interlocutory decision that, on the basis of the second auxiliary request filed during oral proceedings before the opposition division, the patent in suit (the patent) met the requirements of the EPC. As all involved parties lodged an appeal, they are referred to as the patent proprietor and opponents 1 to 3.
- II. In their notices of opposition, the opponents had requested that the patent be revoked in its entirety on the ground for opposition under Article 100(b) EPC (insufficiency of disclosure), among other reasons.
- III. In its decision, the opposition division found, among other things, that the subject-matter of the second auxiliary request pending at that time, which had been filed in the oral proceedings before the opposition division, was sufficiently disclosed and thus met the requirement of Article 83 EPC.
- IV. The following documents, submitted by the parties in the opposition and appeal proceedings, are relevant to the present decision:
- D2 WO 02/30182 A2
- D31 Expert declaration of 30 September 2019 by Dr H. William Harris filed in national proceedings in Norway by the Proprietor

- D44 Expert report of Dr H. William Harris, including his CV
- D48 K. Dabrowski *et. al.*, "Protein digestion and ion concentrations in rainbow trout (*Salmo gairdnerii* Rich.) digestive tract in sea and fresh water", *Comp. Biochem. Physiol.* 83A, 1986, 27-39
- D61 A. Striberny *et al.*, "More than one way to smoltify a salmon? Effects of dietary and light treatment on smolt development and seawater growth performance in Atlantic salmon", *Aquaculture*, 532, 736044, 2021, 1-16
- D62 Copy of "Feed Only - benchmarking" ppt presentation by Børge Takvam
- D66 *Lyngøy v Stim* - judgment of 20 May 2020, Sunnmøre District Court, Norway
- D70 Second declaration by Dr Harris
- D130 Declaration by Dr Harris dated 6 September 2023
- D131 Declaration by Mr A. Lyngøy dated 4 September 2023

V. With its reply to the opponents' statements of grounds of appeal, the patent proprietor submitted a main request and auxiliary requests 1 to 6.

VI. The board issued a communication pursuant to Article 15(1) RPBA 2020 (the communication) in which it advised the parties of its preliminary assessment that the subject-matter of the independent claims of the main request and auxiliary requests 1 to 6 lacked sufficiency of disclosure.

VII. As a reaction to the board's communication, the patent proprietor filed auxiliary request 7 and, among others, documents D130 and D131.

VIII. During the oral proceedings before the board, the patent proprietor orally submitted auxiliary request 8, corresponding to claim 1 of auxiliary request 4.

IX. Wording of the relevant claims

Claim 1 of the main request reads as follows.

"A fish feed for inducing smoltification of Salmonidae, comprising protein, fat, carbohydrates, vitamins, minerals and water, CHARACTERIZED IN THAT the fish feed further comprises Na^+ from 3.934 - 39.340 g/kg by weight, Mg^{2+} from 0.026 - 25.530 g/kg by weight, Ca^{2+} from 0.036 - 36.110 g/kg by weight, and Cl^- from 6.202 - 199.020 g/kg by weight, polyvalent cation receptor modulator (PVCR) in the form of tryptophan from 2 -10 g/kg by weight, wherein the polyvalent cation receptor modulator is in the form of free amino acids, where the Na^+ , Mg^{2+} , and Ca^{2+} are provided as salts in the ranges of 10-100 g/ kg, 0.1 - 100 g/kg, 0.1 - 100 g/ kg, respectively."

Claim 6 of the main request reads as follows.

"Use of a fish feed comprising protein, fat, carbohydrates, vitamins, minerals and water, wherein the fish feed further comprises Na^+ from 3.934 - 39.340 g/kg by weight, Mg^{2+} from 0.026 - 25.530 g/kg by weight, Ca^{2+} from 0.036 - 36.110 g/kg by weight, and Cl^- from 6.202 - 199.020 g/kg by weight, and polyvalent cation receptor modulator (PVCR) in the form of tryptophan from 1-10 g/kg by weight, wherein the polyvalent cation receptor modulator is in the form of free amino acids, where the Na^+ , Mg^{2+} , and Ca^{2+} are provided as salts in the ranges of 10-100 g/ kg, 0.1 -

100 g/kg, 0.1 - 100 g/ kg, respectively, for inducing smoltification in Salmonidae."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the expression "A fish feed for inducing smoltification of Salmonidae" has been replaced with "A fish feed for smoltification of Salmonidae" (underlining by the board). Claim 6 remains unchanged.

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the expression "for inducing smoltification of Salmonidae" is omitted and by the following disclaimer:

"[,] and provided that the fish feed does not consist of the following composition:

40% Herring fish meal

8% squid meal

12% defatted soybean meal

5% *Acetes sp*

5% wheat pollard

16.96 % bread flour

3% cod liver oil

0.5% soy lecithin

2% dicalcium phosphate

1 % carboxymethyl cellulose

3 % vitamin mix (unit/kg), consisting of vit.A,

10000000 IU, vit. D₃, 3000000 IU, vit. E, 10000 IU,

vit.B₁, 400 mg, Vit.B₂, 1200 mg, vit. B₆, 1200 mg, vit.

C (coated), 25000 mg, folic acid, 600 mg, niacin, 60000

mg, pantothenic acid, 10000 mg, and biotin, 10000 mg,

2% mineral mix, consisting of calcium, 0.02%, chlorine,

54.71%, copper, 0.44%, iodine, 0.01%, iron, 3.97%,

magnesium, 0.04%, manganese, 0.44%, selenium, 0.01%,

zinc, 4.41%, and sodium, 35.95%,

0.04 % vit.C

1.07% rice bran and 0.43% L-Trp; or 0.82% rice bran and 0.68% L-Trp"

Independent claim 7 of the second auxiliary request is identical to claim 6 of the main request.

Claim 1 of auxiliary request 3 corresponds to claim 1 of the second auxiliary request, except for disclaiming not only the aforementioned composition as "composition b)", but also a "composition a)" as also defined in the claim:

"a)

50% fish meal
16% soybean meal
4.4 % wheat meal
3.5% Corn meal
2.5 % Weat gluten
3% Barely meal
8% Meat meal
3% Cottonseed
0.1 % antioxidant
0.5 % salt
1% mineral mix
1% vitamin mix
1% binder
3% fish oil
3% soybean oil
48.8 % crude protein
7.4% crude lipid
21.1 % carbohydrate
4% ash
15% Moisture
0.5% Trp"

Independent claim 7 of the third auxiliary request remains unchanged.

Claim 1 of auxiliary request 4 is restricted by the levels of salts and tryptophan added. It reads as follows.

"A fish feed, comprising protein, fat, carbohydrates, vitamins, minerals and water, CHARACTERIZED IN THAT the fish feed further comprises NaCl from 60 -100 g/kg by weight, MgCl₂ from 2.5 - 100 g/kg by weight, and CaCl₂ from 7.5 -100 g/kg by weight, Na⁺ from 3.934 - 39.340 g/kg by weight, polyvalent cation receptor modulator (PVCR) in the form of tryptophan from 4-10 g/kg by weight, Mg²⁺ from 0.026 - 25.530 g/kg by weight, Ca²⁺ from 0.036 - 36.110 g/kg by weight, and Cl⁻ from 6.202 - 199.020 g/kg by weight, wherein the polyvalent cation receptor modulator is in the form of free amino acids." (Underlining by the board.)

Independent claim 2 is identical to claim 6 of the main request.

Claim 1 of auxiliary request 5 corresponds to claim 6 of the main request, with the expression "for inducing smoltification" replacing "for inducing smoltification in Salmonidae".

Claim 1 of auxiliary request 6 differs from claim 6 of the main request in that the expression "for smoltification of parr for transfer to seawater" replaces the limitation "for inducing smoltification in Salmonidae".

Claim 1 of auxiliary request 7 corresponds to claim 6 of the main request but has the additional limitation:

"[,] without adding Ca^{2+} and Mg^{2+} to the operating water of the fish for the purpose of inducing smoltification"

The sole claim of the orally submitted auxiliary request 8 is identical to claim 1 of auxiliary request 4.

X. The patent proprietor's arguments relevant to the present decision can be summarised as follows.

(a) Documents D130 and D131 were filed in response to the preliminary opinion of the board, which could not have been expected. Thus, exceptional circumstances justified the admittance of D130 and D131.

(b) The burden of proof for insufficiency of disclosure lied primarily with the opponents. However, the opponents had failed to discharge their burden of proof. In line with G 2/21 (Reasons 77), the patent contained experimental data demonstrating the desired technical effect. This also followed from benchmark studies D61 and D62.

By contrast, the opponents had not provided any data that substantiated non-working embodiments, nor had they demonstrated the lack of reproducibility referred to in G 1/03 (Reasons 2.5.2).

No particular ratio between negative and positive polyvalent cation receptor ("PVCR") modulators was believed to be critical in the fish feed, apart from the claimed ranges. Due to sodium-removal

mechanisms in the intestinal tract, the broad ranges for the PVCR modulators in claim 1 were believed to work. This elimination mechanism allowed for PVCR activation even when the fish feed comprised significantly more sodium as a negative PVCR modulator than calcium and magnesium ions as positive modulators. The statements made in documents D31 and D66 had been interpreted by the board out of context. Moreover, the feed compositions referred to on page 2 of D31 were not tailored in terms of the ratios of divalent cations and sodium chloride, unlike the feeds of the patent. Furthermore, that passage did not relate to the invention but to the SuperSmolt® process.

When wishing to provide further feed compositions effecting smoltification, a skilled person could start from test diet 2 disclosed in the patent rather than from the endpoints of the ranges and vary one parameter. Higher levels of sodium as the negative modulator could bring about slower PVCR activation as it would take some time to remove sodium (from the fed fish). Hence, the patent contained sufficient information to implement the invention over the whole area claimed without undue burden and without inventive skill.

- (c) The subject-matter of claim 1 of auxiliary request 4 was directly and unambiguously derivable from the application as filed and thus met the requirements of Article 123(2) EPC.
- (d) Auxiliary request 8, orally submitted during the oral proceedings, should be admitted.

XI. The opponents' arguments relevant to the present decision can be summarised as follows.

- (a) The objections and reasoning which led to the filing of D130 and D131 had been brought up by the opponents and not the board. The fact that the board agreed with arguments presented by the opponents could not be considered cogent reasons that justified admitting late-filed new arguments, auxiliary requests and evidence. Hence, documents D130 and D131 and the related arguments should not be admitted into the proceedings.

- (b) The ranges of the claims held allowable by the opposition division and of the main request allowed the concentration of Na^+ versus Mg^{2+} and Ca^{2+} to vary by a factor of 10 000. It was therefore not plausible that the claimed effect of (inducing) smoltification could be achieved across the full breadth of the scope of claims 1 and 6 of the main request. Similarly, the amounts of Ca^{2+} and Mg^{2+} in the single example feed provided in the patent was about a factor of 75 and 25 times higher than the respective lower endpoint amounts in granted claim 1. It was thus not credible that trace amounts of such divalent ions would provide any effect compared to the data in the application. Thus, there existed serious doubts that the claimed effect could be obtained across the entire scope of the claims. One example in the patent was thus not sufficient to support the broad scope of claims 1 and 6 held allowable by the opposition division and of the main request. For these reasons, the burden of proof shifted to the patentee.

Document D48, in particular Figure 1, did not discharge this burden. D48 showed sodium levels in fish feed comparable with D2 and the patent. It was, however, silent about Ca^{2+} and Mg^{2+} amounts that can vary by a factor of 1 000 as in claim 1 of the main request. Furthermore, document D70 taught on page 3 that the deactivation of PVCRs by sodium ions was not linear over a range of concentrations of sodium chloride present in salt-added fish diets. It also followed from Figure 2 and the text in the right-hand column on page 28 of D48 that the sodium level in the intestines of trout maintained in fresh water rose by an active process (rather than decreased).

Declaration D31 supported that if the ratio of positive and negative PVCR modulators was not properly tailored, a haphazard PVCR activation process resulted in unreliable outcomes not sufficiently repeatable for genuine commercial use. Similarly, document D66 contained quoted statements of the inventor that contradicted the assertion that any combination of Na^+ , Ca^{2+} and Mg^{2+} , Cl^- and tryptophan that fell within the scope of claims 1 and 6 of the main request would induce smoltification. If that were the case, it was hard to see how the development process towards the product could have been as complex as claimed in D66. D66 also set out that titration studies were needed to adjust the amounts of the different ingredients. This gave rise to an insurmountable task, and the knowledge needed had not been disclosed in the patent.

It was not possible to take test diet 2 of the patent as a starting point when wishing to provide

further fish feeds of claim 1 of the main request. The reason was that the complete composition of that feed was not indicated in the patent. The calcium, magnesium and sodium levels of test diet 2 were thus not known.

Establishing suitable combinations of positive and negative PVCR modulators in case of failure also required a skilled person to embark on a research programme and thus imposed an undue burden.

For these reasons, the subject-matter of claims 1 and 6 of the main request was insufficiently disclosed and thus did not meet the requirement of Article 83 EPC. This reasoning likewise applied to the auxiliary requests.

(c) The subject-matter of claim 1 of auxiliary request 4 was not allowable under Article 123(2) EPC.

(d) Auxiliary request 8 should not be admitted.

XII. Final requests

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or any of auxiliary requests 1 to 6, all filed with the reply to the opponents' statements of grounds of appeal; auxiliary request 7 filed with the letter dated 12 September 2023; or auxiliary request 8 orally submitted during the oral proceedings before the board.

The appellants (opponents 1, 2 and 3) requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. *Admittance of documents D130 and D131 (Article 13(2) RPBA 2020)*
 - 1.1 Documents D130 and D131 were submitted by the patent proprietor for the first time after notification of the summons to oral proceedings before the board. Consequently, the filing of these documents constitutes an amendment to the patent proprietor's case, and the provisions of Article 13(2) RPBA 2020 apply. As a rule, such amendments must not be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned.
 - 1.2 The patent proprietor argued that documents D130 and D131 had been filed in response to the preliminary opinion of the board, which could not have been expected. The board had seemed to arrive at its preliminary assessment on sufficiency of disclosure based on interpretations of statements from the technical expert and inventor in documents D31 and D66, respectively. For this reason, the patent proprietor had cogent reasons to consult the inventor and the expert again to address the objections. Thus, exceptional circumstances justified the admittance of D130 and D131.
 - 1.3 The board does not agree. The objections and reasoning which led to the filing of D130 and D131 had been brought up by the opponents in their statements of grounds of appeal and replies to the patent proprietor's statement of grounds of appeal, not by the

board. Thus, the amendment could and should have been filed earlier. No exceptional circumstances apply that justified taking the amendment into account (see e.g. Case Law of the Boards of Appeal of the EPO, tenth edition, 2022, V.A.4.5.6.c).

1.4 Already in its statement of grounds of appeal, opponent 2 had argued that it was not credible that all compositions covered by the claims induced smoltification. Similar arguments were provided for ranges for the polyvalent cation receptor ("PVCR") activators and deactivators.

1.5 Consequently, the board decided not to take documents D130 and D131 into account (Article 13(2) RPBA 2020).

2. *Sufficiency of disclosure - main request*

2.1 The patent is concerned with the provision of fish feed that induces smoltification of *Salmonidae*. This family of fish includes Atlantic salmon and rainbow trout. Salmonids in freshwater which decide to migrate to seawater undergo a physiological process called smoltification. Smolt refers to a salmon fish in freshwater ready for migration to seawater (see paragraphs [0002] and [0003] of the patent). Through smoltification, salmonids become capable of pumping salt out of the body, such as sodium chloride through the gills. During smoltification, an increasing amount of a $\text{Na}^+\text{-K}^+\text{-ATPase}$ enzyme is observed in the gills that is needed to pump salts out of the fish's body, this being necessary to maintain osmotic balance in seawater. Correspondingly, a decreased amount of the enzyme (freshwater ATPase) needed to pump ions from the fresh water into the fish's body is observed.

- 2.2 Organs involved in the smoltification process (such as the intestines, gills and skin) have receptors (called PVCR or calcium sensing receptors) that may be affected by different modulators. The modulators include negative modulators (including Na^+) and positive modulators (such as Ca^{2+} and Mg^{2+} ions and the amino acid tryptophan), see e.g. paragraph [0013] of the patent.
- 2.3 A controlled stimulation of the receptors can provide a response that corresponds to the smoltification process. An example of such a controlled stimulation, mentioned in the patent, is the SuperSmolt® method, in which ions are added to the operating water (Ca^{2+} , Mg^{2+} , Cl^-) in combination with fish food containing added Na^+ -ions, Cl^- -ions and tryptophan. The patent (paragraph [0014]) refers to D2. D2 explains that sodium chloride is a negative modulator of PVCRs, and Mg^{2+} , Ca^{2+} and tryptophan are positive modulators (see pages 17 to 19 of D2). This process is said to make it possible to smoltify salmonids without traditional photomanipulation (i.e. the use of a winter and a summer signal). Thus, the use of a growth-reducing winter signal can be avoided.
- 2.4 To meet the requirements of sufficiency of disclosure, an invention has to be disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person without undue burden and without needing inventive skill on the basis of the information provided in the patent specification and, possibly, common general knowledge.
- 2.5 Claims 1 and 6 comprise the functional feature "for inducing smoltification of Salmonidae" or "for inducing smoltification in Salmonidae", respectively. In

accordance with G 1/03 (Reasons 2.5.2), if an effect forms part of the claimed subject-matter and there is lack of reproducibility of the effect, there is lack of sufficiency of disclosure. For the reasons set out below, the board concludes that the specification does not contain sufficient information on relevant criteria for finding appropriate alternatives over the whole scope of the claims with reasonable effort.

- 2.6 The assessment of sufficiency of disclosure of the current case covers two questions.
- 2.6.1 i) Are there serious doubts substantiated by verifiable facts about whether the information provided in the patent, possibly supplemented by common general knowledge, enables a skilled person to implement the claimed subject-matter across the entire breadth of independent claims 1 and 6 without imposing an undue burden?
- 2.6.2 ii) Does the disclosure of the patent or common general knowledge overcome any serious doubts?
- 2.7 As to the first question, the board notes that the statements in declaration D31 from an expert and in D66 by the inventor support the view that the relative concentrations of activators/positive modulators and deactivators/negative modulators of PVCRs need to be adjusted (or "tailored") to obtain a non-haphazard and reproducible activation and smoltification.
- 2.8 The patentee's expert states in D31: "Importantly, inclusion of various combinations of divalent cations and NaCl together in ratios and compositions that are not tailored with the knowledge of PVCRs (both external and internal) can result in some changes similar to the

Supersmolt process but such activations do not occur in a controlled and consistent manner. This haphazard PVCRC activation process results in unreliable outcomes that are not sufficient repeatable for genuine commercial deployment." This statement clearly relates to the composition of a feed as claimed, comprising all relevant components, including sodium, and not to a feed in accordance with the SuperSmolt® process as featured in D2.

2.9 Similarly, the judgement from separate national proceedings in Norway (D66) found that the inventor of the current patent had solved the problem of inducing smoltification by using the correct balance of free amino acids and free ions in the feed. The inventor is said to have achieved this by adding Na^+ , Ca^{2+} , Mg^{2+} and Cl^- in the right ratios in combination with the correct amount of tryptophan. Furthermore, the inventor is quoted directly as follows: "The product is complex. It consists of 5 different ingredients which are functional. The most usual method to discover which amounts one must have of the different ingredients is by titration studies. If one chooses 10 different concentrations for each of the ingredients, this will amount to 100.000 combinations, an insurmountable task practically and economically. Based on this an outsider would immediately understand that the product is unique. Through my own knowledge if [sic] was able to limit the complexity, but there was plenty still left."

2.10 While these statements in D66 were made in a dispute over inventorship and remuneration under Norwegian law, they support that the amounts of the components need to be tailored to achieve the desired effect of (inducing) smoltification. The patent mentions neither titration studies to establish suitable combinations of

ingredients nor the knowledge of PVCRs (referred to in D31).

2.11 It is not apparent from the statements quoted from D66 either that titration studies would only have to be done at the ends of the ranges for the active components, as was argued by the patent proprietor. The proprietor stated that titration studies could be needed (if at all) at the ends of the ranges for the modulators where the effect could be lost.

2.12 The board thus agrees with the opponents that the knowledge to carry out the claimed invention is not shared with the public via the patent. By contrast, the statements in D31 and D66 undermine the patent proprietor's assertion that the *broad* ranges for the positive and negative PVCR modulators provided in the claims were already "tailored" (or optimised) and that thus any ratio of the modulators could be combined to induce smoltification. The statements in D31 and D66 thus support that there is a lack of guidance for the selection of suitable combinations of modulators. This amounts to an undue burden imposed on a skilled person wishing to carry out the subject-matter over the full scope of the claims. Similarly, document D70 states that the deactivation of PVCRs by Na^+ is *non-linear*. This statement has not been challenged by the patent proprietor. It can thus be expected that this non-linearity further complicates adjusting the modulator ratios.

Therefore, the board concluded that the statements in D31 and D66, stemming from the patent proprietor's sphere, cast serious doubts substantiated by verifiable facts that the claimed subject-matter can be carried

out using the information of the patent and common general knowledge without imposing an undue burden.

- 2.13 The patent proprietor correctly stated that, under established case law of the boards, the burden of proof of insufficiency of disclosure initially lies with the opponent(s). The latter must establish, on the balance of probabilities, that a skilled person using the information in the patent and common general knowledge would be unable to carry out the invention (over the full breadth of the claims) (see Case Law of the Boards of Appeal of the EPO, tenth edition, 2022, II.C.9).
- 2.14 However, for the aforementioned reasons, it has indeed been established that a skilled person using the information in the patent and common general knowledge would be unable to carry out the invention. The burden of proof for any rebuttal thus lies with the patent proprietor. For the following reasons, the patent proprietor's arguments are not persuasive.
- 2.15 As to point ii) in section 2.6.2 above, opponent 2 referred to a possible ratio of deactivators (sodium ions) of PVCs over activators (Ca^{2+} , Mg^{2+} and tryptophan) which far exceeds the corresponding ratio in test diet 2 of the patent. Likewise, the ratio of Na^+ to Ca^{2+} and Mg^{2+} encompassed by the ranges provided in claims 1 and 6 can vary by a factor of 10 000. Ca^{2+} and Mg^{2+} provided as salts in claim 1 and claim 6 can - at the lower end of the divalent cation ranges - be merely present in trace amounts. By contrast, the amounts of these cations used in test diet 2 are about a factor of 75 and 25 times higher, respectively. It is thus not credible that variants of claims 1 or 6 comprising very low amounts of Ca^{2+} and Mg^{2+} would provide *any effect* on the induction of smoltification.

- 2.16 The patent proprietor did not adduce any evidence of common general knowledge or otherwise that would support its assertion that the huge differences between the levels of sodium (as a deactivator of PVCs) and divalent cations Ca^{2+} and Mg^{2+} encompassed by the subject-matter of claims 1 and 6 could be compensated and equalised by the fish ingesting such a feed. Such a compensation would mean that smoltification would also occur when feed comprising large amounts of sodium ions is administered to the fish. This would also be at odds with the inventor, who states in D66 that the development process of the fish feed encompassed by claim 1 (SuperSmolt FeedOnly) was *challenging* and *complex*.
- 2.17 Similarly, as stated above, in the expert declaration D31, it is held that inclusion of various combinations of divalent cations and NaCl in ratios and compositions not tailored with the knowledge of PVCs can result in an activation that does not occur in a controlled and consistent manner (page 2, second paragraph).
- 2.18 Concerning point 2.16 above, the patent proprietor referred to Figure 1 and the accompanying text on page 28 of D48 to support its contention that fish could markedly reduce the level of sodium and increase the level of divalent cations (stemming from the feed) when passing through the intestines. This sodium-removal mechanism allowed the fish to activate the PVC in the intestines (that had been sensitised by tryptophan) even when the feed contained significantly more Na^+ than Ca^{2+} and Mg^{2+} . While sodium removal could take some time and the PVC activation could be slower, it was still feasible.

2.19 However, as correctly pointed out by the opponents, it is Figure 2 which is relevant, not Figure 1. Figure 1 depicts the ion concentration in different segments of the digestive tract of rainbow trout first maintained in *salt water* then fed and sacrificed six hours after feeding. By contrast, Figure 2 depicts the situation for fish kept in *freshwater* (as in the patent) prior to and after feeding. Figure 2 shows an *increase* (rather than a decrease as in Figure 1) of sodium concentration along the digestive tract of the fish fed previously. This is also reflected by the accompanying text on page 28, right-hand column of D48. There it is stated: "Trout maintained in fresh water appeared to raise Na^+ level in the intestine by an active process."

In addition, as argued by the opponents in the oral proceedings, D48 reflects the situation encountered by the absorption of a feed comprising significant amounts of added Ca^{2+} in the intestinal tract and does not represent the respective variation of the Ca^{2+} and Mg^{2+} levels in claim 1 *by a factor of 1 000*. Also for this reason, D48 cannot support the operability of the subject-matter of the claims over their full scope. As observed by the opponents, referring to pages 3 and 4 of D44, PVCRs are found throughout the gastrointestinal tract epithelial cells, including the stomach, of Atlantic salmon. Hence, it is not excluded either that the large amounts of sodium entering the stomach could still deactivate these PVCRs.

What is more, the sodium ions are removed from the gastrointestinal tract and pass through the gills. As discussed during the oral proceedings, the gill cells also have PVCN receptors. The patent proprietor argued that the sodium ions passing the gill cells would be diluted by the surrounding fresh water. Such little

amounts of sodium ions were thus not relevant (for PVCR deactivation). To the board, these considerations are speculative. It remains uncertain whether by this sodium-removal mechanism large differences between concentrations of PVCR deactivators and activators can be compensated. The activators Ca^{2+} and Mg^{2+} can be present in marginal amounts in the feed of claim 1.

2.20 For these reasons, the above arguments of the patent proprietor did not convince the board that the ratio between the negative and positive PVCR modulators was of considerably less importance for the fish feed described in the patent compared to the earlier SuperSmolt® method (as described, for instance, in D2).

2.21 While the patent proprietor asserts that the four ion ranges called for in the claims were based on what was reasonably expected based on the data generated from test diet 2 and other experiments, no such additional data were presented, in particular for low levels of Ca^{2+} and Mg^{2+} .

2.22 In addition, the patent proprietor itself stated that "[t]he mechanisms in a living fish are as difficult to verify as the theories of working of medicine in the human body. It could be difficult - or even impossible in the not too distant future - to verify such mechanisms so that they could be considered verifiable facts in the sense of the case law" (see point 1.3 of the submission dated 12 September 2023).

2.23 Given these considerations and the serious doubts substantiated by verifiable facts, the single example feed of the patent does not have sufficient probative value to show that the invention is operable across the entire scope claimed. Although that feed composition

(test diet 2) is in line with the invention as claimed, by itself it is insufficient given that the metal ion content is not specified and the amounts of activator species far exceed the minimum amounts required in claim 1. Nor do the benchmark studies D61 and D62, on which the patent proprietor relied to support that the invention can be carried out, provide this proof. The proprietor referred to decisions of the boards, in particular G 2/21. This decision is, however, about a patent proprietor's or applicant's reliance on evidence made available after the effective date of a patent or patent application. This question is not relevant to the current case.

2.24 Furthermore, the patent proprietor argued that, starting from test diet 2, a skilled person could vary a single parameter/modulator concentration at a time to arrive at further fish feeds in accordance with claim 1. In e.g. trial 6 described in the patent, an effective smoltification of Atlantic salmon using test diet 2 had been accomplished. However, as stated by the opponents in the oral proceedings, the exact composition of the only example feed indicated in the patent is unknown. Hence, test diet 2 is not a reworkable starting point for arriving at further feed compositions falling within the scope of claim 1.

2.25 Thus, the aforementioned serious doubts substantiated by verifiable facts are not overcome by the teaching contained in the patent or common general knowledge.

2.26 It is for these reasons that the board concluded that the subject-matter of claims 1 and 6 is insufficiently disclosed and thus does not meet the requirement of Article 83 EPC.

3. *Sufficiency of disclosure - auxiliary requests 1 to 7*

The finding of lack of sufficiency of disclosure for claims 1 and 6 of the main request applies equally to the independent claims of auxiliary requests 1 to 7 for the above reasons. This concerns independent claims 1 and 6 of auxiliary request 1, independent claim 7 of auxiliary requests 2 and 3, independent claim 2 of auxiliary request 4, independent claim 1 of auxiliary requests 5 and 6, and claim 1 of auxiliary request 7. The patent proprietor did not see any difference between the expressions "for smoltification" and "for inducing smoltification" (see e.g. sixth paragraph on page 9 of the proprietor's rejoinder). The board sees no reason to deviate from this assessment. In the opinion of the board, "for smoltification" necessarily involves the induction of smoltification. Hence, irrespective of whether the functional feature being assessed for fulfilment of the requirement of sufficiency of disclosure is "for smoltification" or "for inducing smoltification", the above considerations on sufficiency of disclosure for the main request apply *mutatis mutandis*. Auxiliary requests 1 to 7 thus do not meet the requirement of Article 83 EPC either.

4. *Amendments (Article 123(2) EPC) - auxiliary request 4*

4.1 Notwithstanding the above finding of lack of sufficiency of disclosure, auxiliary request 4 also does not comply with Article 123(2) EPC for the following reasons. This conclusion has a bearing on the admittance of auxiliary request 8 (see below).

4.2 Claim 1 of auxiliary request 4 contains new ranges for the NaCl, MgCl₂, CaCl₂ and tryptophan concentrations derived from a single and specific embodiment of

original claim 11. This corresponds to the values for these ingredients in test diet 2. The board sees no basis for the generalisation based on a *specific and preferred feature combination* in which all components seem to be closely associated in functional terms with the other features (here the specific concentrations of the remaining ingredients). This extraction of preferred values for components inextricably linked in functional terms to the remaining components, also acting as PVCR modulators and being present in specific amounts, gives rise to an inadmissible intermediate generalisation. For this reason alone, the current case is not comparable with the case underlying T 2767/18 to which the proprietor referred (see e.g. Reasons 1.2). For instance, claim 1 contains embodiments in which the preferred concentration for sodium chloride is combined with a value for the level of calcium chloride of 100 g/kg by weight. This feature combination is not directly and unambiguously derivable from the application as filed.

4.3 Moreover, original claim 11 discloses the concentration of L-tryptophan, whereas claim 1 merely refers to "tryptophan". While the paragraph of the application spanning page 7 to page 8 does indeed refer to "tryptophan" in general, it does not disclose the preferred combination of levels of the salts and L-tryptophan called for in claim 11 as originally filed.

4.4 The subject-matter of claim 1 is thus not directly and unambiguously derivable from the original application documents and does not comply with Article 123(2) EPC.

5. *Admittance of auxiliary request 8 (Article 13(2) RPBA 2020 and Article 123(2) EPC)*

Auxiliary request 8 was filed at the oral proceedings before the board. Its admittance is thus subject to the provision of Article 13(2) RPBA 2020. The only claim of the request is identical to claim 1 of auxiliary request 4, which had already been held to infringe Article 123(2) EPC in the oral proceedings before the board. Thus, auxiliary request 8 was *prima facie* not allowable under Article 123(2) EPC. It was therefore not taken into account by the board (Article 13(2) RPBA 2020).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated