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Oslo, 2021.12.07

Your ref.:	137759/MWW
Application no.:	20210585 (please include in your reply)
Applicant:	NORD UNIVERSITET
Due date:	

Office action in patent application no. 20210585

Basis of the opinion

Description	received 2021.05.10
Claims	received 2021.05.10
Drawings	received 2021.05.10

Conclusion

The subject-matter of the claims is not new or does not involve an inventive step and therefore does not meet the patentability criteria.

Results of the novelty search

Reference is made to the following documents:

D1: EP 2659786 A2

D2: KR 100685237 B1

D3: EP 3747989 A1

D4: EP 2521459 B1

D5: H.R.R. ANDANI et al., 2012. « Antagonistic activity of two potentialprobiotic bacteria…», Journ. Of Appl. Icht., vol 28, issue 5, page 728-734.

D6: JOSÈ L. BALCÀZAR et al., 2008, « Characterization of probiotic properties of lactic acid bacteria isolated from intestinal microbiota of fish», Aquaculture, 278, page 188-191.

D7: D.L. MERRIFIELD et al., 2010, «Probiotic applications of rainbow trout (Oncorhynchus mykiss Walbaum)….», Aquaculture nutrition, 16, page 504-510.

D8: EHSAN AHMADIFAR et al., 2019, « Lactobacillus fermentum and / or ferulic acid improved the immune responses, antioxidative defence and resistance against Aeromonas hydrophila in common carp…», Fish and Shellfish immunology, 94, page 916-923.

D9: US 20200239971 A1

Assessment of patentability
The following is a reasoned statement with regard to novelty and inventive step, ref. Norwegian Patents Act, Section 2, first paragraph.

The invention provides fish feed compositions found useful in improving the intestinal health of farmed fish. The feed comprises probiotics (lactic acid bacteria), *Lactobacillus fermentum (LF) and Lactobacillus plantarum*(LP) for improving the fish's general health through better intestinal health.

The following is a reasoned statement with regard to novelty and inventive step, ref. Norwegian Patents Act, Section 2, first paragraph.

Novelty
The present invention according to claim 1 relates to a fish feed composition comprising at least one of the lactic acid bacteria *Lactobacillus fermentum* and *Lactobacillus plantarum.*
D1 describes a probiotic feed pellet for salmonids containing at least one lactic acid strain with immunostimulant and protective properties. The probiotic feed includes *L.plantarum* obtained from salmonids with excellent colonization properties and protective properties against some microbial agents.

D2 discloses use of a novel strain of *Lactobacillus fermentum as* a probiotic for cultivated fish to improve the intestinal health and effect against bacterial diseases.

D3 discloses a feed additive which includes *L.plantarum*. The feed additive can be used in fish feed for the purpose of providing an enhanced immunity [0047-0050].

D4 describes a fish feed product comprising probiotic bacterial strain (*Lactobacillus plantarum* I-UL4) capable of significantly increasing the resistance of a fish against pathogenic microorganisms. Oral administration of probiotics induce increased resistance to enteric infections and enhances the general immune response of the treated animal [004, line 8].

D5 describes probiotics as feed supplements which benefits the host by improving feed utilization, enhancing digestion, inhibiting pathogenic microbes, increasing the immune response and improving survival and growth rates. Food pellets supplemented with *L. plantarum* and *L. casei*, were prepared by slowly spraying a suspension containing live *L. plantarum* and *L. casei.*

The study in D6 investigated the adhesion of LAB strains to skin and intestinal mucus isolated from healthy rainbow trout. The results demonstrated that LAB strains (*Lc lactis, l.plantarum and L.fermentum*) were highly capable of adhering to fish intestinal mucus. The results showed that the different LAB reduced adhesion of different pathogens.

D7 investigated the effect of dietary probiotics (*Bacillus sp* and *Enterococcus)* used singularly and synergistically on the growth performance, intestinal microbiota and health status of rainbow trout. The results demonstrates the potential for these probiotics to improve feed utilization, modulate intestinal microbiota and the health status of rainbow trout. Commercial feed was top-dressed, i. e. coated with oil containing the probionts. The study demonstrates that the probionts can survive transit through the digestive tract and successfully colonize the intestine of rainbow trout.

D8 teaches that in aquaculture, a probiotic is a live microbial adjunct that confers benefits to host by modification of host microbial community. The ability of probiotics to promote and / or improve fish health is related to their capacity to stimulate immune response and inhibit growth of pathogenic bacteria. It has been reported that *Lactobacillus* sp. have the strong capability of adherence and colonization that make them efficient probiotics to be used in aquaculture. *Lactobacillus fermentum* (LF) is a common bacteria strain, which has been used as a feed additive, see page 916-917.

D9 describes a probiotic feed additive for fish feed comprising *Lactococcus lactis* isolate. A feed comprising the additive may be prepared by spraying a suspension onto the feed, and naturally drying the feed [0050]. The feed may be dry pellett feed [0052].

Document D1, D3, D4 and D8 describe a probiotic fish feed containing at least one lactic acid strain including *L. plantarum* or *L. fermentum* with immunostimulant and protective properties. Accordingly, the subject matter of claim 1 thus lacks novelty over D1, D3, D4 and D8.

Claims 2-9 comprises a fish feed composition comprising both *Lactobacillus fermentum* and *Lactobacillus plantarum* as living and active cultures of bacteria. A fish feed composition comprising both *Lactobacillus fermentum* and *Lactobacillus plantarum* as living and active cultures of bacteria, is not disclosed in D1, D3, D4 or D8. Therefore, claims 2-9 are novel.

Claim10 regards a method for producing a granular fish feed comprising at least one lactic acid bacteria, the method comprising a step of coating feed granulates with at least one lactic acid bacteria, applying the bacteria from a bacterial suspension at an evacuated atmosphere, wherein the bacterial suspension comprises at least one lactic acid bacteria. D9 which is considered to represent the prior art closest to the subject-matter of independent claim 10, describes preparation of coated probiotic pellets for fish comprising one lactic acid bacteria. D5 and D7 also describe coating of pellets with lactic acid bacteria. Coating feed pellets with different nutrients is a routine task for a skilled person in the art. Consequently, the subject matter of claim 10 thus lacks novelty over D5, D7 and D9.

Claim 11 regards a method wherein the bacterial suspension used for the coating in claim 10 comprises cultures of at least one of *Lactobacillus fermentum* and *Lactobacillus*

plantarum. Coating of pellets with *Lactobacillus plantarum* is disclosed in D5. Accordingly, the subject matter of claim 11 thus lacks novelty over D5.

Claim 12 regards a method as claimed in claim 10 wherein the stabilizer is an emulsifier selected from the group of lecithins. The method in claim 12 differs from any of D5, D7 and D9 in that the use of lecithin as a stabilizer is not mentioned. Prior art teaches the use of lecithins as stabilizer in fish feed, and is a routine task for a skilled person in the art. Consequently, the subject matter of claim 12 thus lacks novelty over common knowledge.

Claim 13 regards a fish feed for use in treatment of fish, for improving at least one of intestinal health and innate immune response, administering a fish feed composition comprising at least one of the lactic acid bacteria *Lactobacillus fermentum* and *Lactobacillus plantarum* to the fish. Document D1, D3, D4 and D8 describe a probiotic fish feed containing at least one lactic acid strain including *L.plantarum* or *L.fermentum* with immunostimulant and protective properties. A person skilled in the art knows that Lactobacillus strains are known to be used in fish food with the results shown by the applicant. All the effects shown in the present application are indeed already known from the prior art. It is reported that the action of lactic acid bacteria is caused by activating cellular immunity of the host and promoting secretion of IgA from the mucosa of intestinal tract and respiratory organs. Accordingly, the subject matter of claim 13 thus lacks novelty over D1, D3, D4 and D8. The same reasoning applies to the independent claims 14-16.

Inventive step
The subject-matter of claims 1 and 10-16 does not meet the criteria for novelty, and is therefore not inventive.

D1 describes probiotic fishfood pellets comprising *L.plantarum.* The fish feed composition of claim 2-9 differs from the disclosure in D1 in that the composition comprises both *Lactobacillus fermentum* and *Lactobacillus plantarum* as living and active cultures of bacteria. The objective technical problem to be solved by the invention according to claims 2-9 in view of D1, may be regarded as the provision of alternative a fish feed composition comprising lactic acid bacteria.

The solution to this problem proposed by claims 2-9 of the present application is not considered to involve an inventive step for the following reasons:
Using lactic acid bacteria *Lactobacillus fermentum* and *Lactobacillus plantarum* in fish feed is known from D1, D2, D5 and D8. Fish feed pellets coated with lactic acid bacteria are known from prior art, i.e. D5 and D9. And further, at the filing date, the provision of a pellet coated with probiotics, lipids or vitamins/nutrients represents a routine task for the skilled person in the art as well as using lecithin as a stabilizer. The fact that phospholipids present in lecithin act as an emulsifier of lipids in the animal stomach and gut is also well known for the skilled person. And finally, it was also part of prior art to

add lecithin to fish and shrimp diets because of its nutritional benefits. In view of the technical teachings of D1 in combination with D2, D3, D5, D8, D9, the solution proposed by claims 2-9 of the present application can not be considered to be inventive.

Certain defects and observations

The application does not meet the requirements of the Norwegian Patents Act, section 8, seond paragraph, first sentence, because claims 3-6 are not clear. Present claim 1 is a product claim, providing a composition comprising lactic acid bacteria, while the subsequent dependent claims 3-6 are formulated as method claims adding the lactic acid bactera by coating. It therefore unclear how the lactic acid bacterias are added to the feed.

Instructions

If you disagree with our assessments please send us the reasons for your opinion and, if appropriate, an amended set of claims reflecting this.

If you amend the patent claims, you must state where in the application as filed support for the amendment is found, ref. Regulations to the Norwegian Patents Act (Patent Regulations), Section 20.

If you file an amended description, you must specify which parts of the description are not in accordance with the previously filed description and specify in which way the amendments imply anything new with respect to the substantive content, ref. Patent Regulations, Section 21.

Time limit for response

You are invited to submit a written response within the due date above. You may respond via Altinn. If you fail to respond, the application will be shelved. However, the processing o the application may be resumed by paying a fee. Ref. Norwegian Patents Act, Section 15, third paragraph and Regulation Relating to Payments etc. to the Norwegian Industrial Property Office and the Board of Appeal for Industrial Property Rights (Regulation on fees) Section 26. You may request an extension of the due date, see «patentretningslinjene del A, kap. I, punkt 5.1» Examination Guidelines, part A, Chapter I, 5.1 (in Norwegian only). This must be done within the due date.

For general provisions regarding submitting of documents and payments, see Regulation o fees, Sections 1-6 and 8.

Additional information to the applicant

Application documents in English - provisional protection

The patent application will be published 18 months after it was first submitted. In order to obtain provisional protection for the invention described in the application from the publishing date, you must submit a translation of the claims into Norwegian. The patent claims in Norwegian will form the basis for provisional protection during the application period. The provisional protection applies only insofar as the Norwegian and English texts correspond with each other. Provisional protection takes effect once you have supplied a translation of the claims and we have published a notice of this in the Norwegian Official Patent Gazette (Norsk patenttidende).

Supplementary search

A novelty search is not considered to be complete if it was carried out at a time when the newest relevant material was not yet included in the search material. You can request a supplementary search to disclose whether there exist older patent applications, not publicly available when the first novelty search was done. This may be national patent applications EPO applications that may apply to Norway, see Norwegian Patents Act, Section 66f or international patent applications that have been continued in Norway according to Norwegian Patents Act, Section 31. Such applications may prevent novelty according to Norwegian Patents Act, Section 2, second paragraph, second sentence. A supplementary search can not be carried out until after approximately 22 months from the filing date of the application.

Application documents in English – patent claims in Norwegian at the time of grant

We would like to remind you that before the time of grant of patent you must submit a translation into Norwegian of the approved claims, see Norwegian Patents Act, Section 21, third paragraph and Patent Regulations, Section 33a.

Information about patenting abroad

If your intention is to apply for patent abroad, please be aware of the following:

1. You can apply for patent abroad with priority from the Norwegian application within 12 months from the date it was filed in Norway (the priority year). This means that the patent application filed abroad gets the same effective filing date as the application has in Norway. If anyone else has applied for a similar patent during the priority year, your patent application will precede due to its older priority.

2. You may claim priority from this application (the priority application) at the time yo file the application abroad, or within 16 months from the Norwegian filing date and at the latest within four (4) months after filing abroad. You must also submit a certificate of priority. The Norwegian Industrial Property Office issues such a certificate of priority on demand if a set fee is paid.

For your information

Relevant laws and regulations, as well as Examination Guidelines are available on our webpage, www.nipo.no.

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Sincerely,

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Enclosures: cited publications, search report