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Our ref.: 137759/MWW

Patent application no. 20210585 Nord Universitet

Reference is made to the official action dated 28 December 2021.

Herewith, the applicant wishes to file an amended set of claims. Further in this letter of reply, the applicant provides an overview of the amendments, detailed arguments in support of the patentability of the amended claims and a rebuttal to the objections raised in the office action.

Amendments

The following amendments have been made to the claims:

Claim 1 has been amended to specify that both the lactic acid bacteria *Lactobacillus fermentum* (LF) and *Lactobacillus plantarum* (LP) are comprised in the feed.

Further, claim 1 has been amended to specify that the bacteria are comprised in the feed as living and active cultures of bacteria. The features are taken from former claim 2.

Claim 2; The former features have been included in amended claim 1. The claim is amended to specify that the bacteria is isolated from the intestinal content of rainbow trout. Basis is found on page 10, lines 22-24.

Claims 3, 4 and 5: minor language amendments have been done to clarify that these are product claims. Basis is found on page 12, lines 14-16, lines 18-20.

Claim 10: The method has been limited to preparation of a feed comprising *Lactobacillus fermentum* and *Lactobacillus plantarum*. The feature is taken from former claim 11 and the description page 20, lines 19-23.

Following the amendment to claim 10, former claim 11 is deleted.

Former claim 13, now claim 12, has been amended as claim 1 and claim 10 to a feed comprising both LF and LP. Further, it has been specified that the feed is a granular feed, and that the LAB is in the coating, hence the subject matter of former claim 14 has been included in amended claim 12.

Following the inclusion of the subject-matter of claim 14 into claim 12, claim 14 is deleted.

The remaining claims have been renumbered accordingly.

The requirements of Section 13 of the Patent act are hence met.

Patentability

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Novelty:

The examiner argues that the subject matter of pending claim 1 lacks novelty over either of D1, D3, D4 and D8.

Claim 1 has been amended to include that the feed comprises both *Lactobacillus fermentum* (LF) and *Lactobacillus plantarum* (LP). Neither of D1, D3, D4 and D8 disclose a fish feed comprising both LF and LP. Hence, the subject matter of amended claim 1 is novel over D1, D3, D4 and D8.

The examiner states that claim 10 lacks novelty over either of D5, D7 and D9. The claim has been amended to specify that both LF and LP are present in the produced feed.

The claimed method further differentiates over the methods of the prior art as explained below: D5 reports disease preventing effects when feeds were supplemented with the two LAB strains *Lactobacillus casei* and *Lactobacillus plantarum*, isolated from common carp. The study was performed with rainbow trout in fresh water. The two LAB strains were fed individually to different groups of rainbow trout. In addition to the bacteria being different, the method steps for applying the LAB to the feed differs from the claimed method. In the method of D5 the food pellets supplemented with the bacteria were prepared by slowly spraying a suspension of the bacteria onto a clean plate containing the dry pellets (bottom of page 4). The claimed method differs over the D5 method at least in that the bacteria are applied from an evacuated atmosphere.

D7 reports from a study where the probiotic strains *Bacillus subtilis*, *Bacillus licheniformis* and *Enterococcus faecium* were fed alone or in cocktail to rainbow trout. The bacteria included in the feed of D7 are different from the bacteria of the claimed method. The feed of D7 was produced by using a commercial feed, top-dressed with fish oil containing the probiotics, by slowly mixing in a food mixer (p. 505, first column). Hence, the method steps for applying the LAB to the feed differ from the claimed method. The claimed method differs over the D7 method at least in that the bacteria are applied from an evacuated atmosphere.

D9 relates to a probiotic composition. The LAB used in D9 are different from those used in the claimed composition, and also the method of application differs from the claimed method. As D7, also D9 is using top dressing by spraying a suspension of the culture onto the feed ([0050]), which is different from the claimed step of applying the bacteria from a suspension at an evacuated atmosphere.

Accordingly, the method of claim 10 is different from the method of D5, D7 and D9 and is hence novel.

Claim 12 has been amended to clarify that the feed for use includes both LF and LP. Furthermore, amended claim 12 also specifies that the LAB is in the coating of the feed. Neither of D1, DD3, D4 and D8 discloses use of a feed comprising both LF and LP. Hence the subject matter of claim 12 is novel over either of D1, D3, D4 and D8. It follows that dependent claims 13 and 14, are also novel.

Inventive step:

D1 (EP2659786) relates to probiotic feed for salmonid containing at least one lactic acid strain. It discloses different probiotic bacteria isolated from salmonids, amongst others, *Lactobacillus plantarum* isolated from Atlantic salmon. The feed production technology of D1 is very different from the method claimed and is not likely to be implemented in modern commercial scale feed production. The adherence properties to different mucus were performed with in vitro studies and disease preventive properties were tested in infection trials with *Aeromonas hydrophilia* and *Yersinia ruckeri*. The invention is also describing production of probiotic feed with probiotic bacteria. The feed processing technology described in the invention is different from the one the claimed invention. It is not likely that the method described in D1 will be commercially implemented.

The subject-matter of claim 1 differs from D1 in that it comprises a feed comprising both LF and LP.

The effect of this distinguishing feature is at least that the claimed composition, when fed fish, has positive effects on the mucosal barriers in the fish.

An objective technical problem might therefore be seen as the aim and task of modifying the feed of D1 to provide new fish feed compositions which have positive effects on the mucosal barriers in the fish.

There is no teaching, or even a hint, in D1, that a fish feed comprising both LP and LF should be provided.

D2 relates to a novel strain *Lactobacillus fermentum* isolated from a human body.

D3 is describing use of *L. Plantarum* isolated from colostrum of sows and feces from sows and piglets. The documented health benefit was to prevent diarrhea in piglets during weaning. The effects were studied in vitro as well as in vivo. The pathogens creating illness in pigs are different from those in fish. This strain of plantarum has not been documented in fish and may not colonize the intestine of salmon – important to give the health benefit. It is not likely that the strains colonizing an omnivore homothermic gastrointestinal tract will colonize the intestine of a fish, such as a cold-water adapted carnivore fish.

D4 describes the use of a feed supplemented with the metabolites of a probiotic bacteria, *Lactobacillus fermentum*, UL4. D4 is limited to describing the metabolites of probiotic LAB and the supplementation of a product – an emulsion of probiotic bacteria in combination with furanone (that inhibits the colonization of microorganism on surfaces). The metabolites produced by *Lactobacillus plantarum* include bacteriocins, vitamin B and organic acids such as formic acid, acetic acid and lactic acid. Hence, the technology is very different from the claimed invention.

As stated above, D5 reports disease preventing effects when feeds were supplemented with the two LAB strains *Lactobacillus casei* and *Lactobacillus plantarum*. The two LAB strains were fed individually to different groups of rainbow trout.

D6 refers to a study of three lactic acid bacteria isolated from intestinal microbiota of rainbow trout. The LAB were *Lactococcus lactis*, *Lactobacillus plantarum*, *Lactobacillus fermentum*. An in vitro study was performed to study the adhesion of the fish bacteria *Aeromonas hydrophila*, *Aeromonas salmonicida*, *Uersinia ruckeri* and *Vibrio anguillarum* to host intestinal mucus. D6 is only reporting data from in vitro studies, and there is no teaching that LP and LF should be provided in a fish feed.

D7 is a study where the probiotic strains *Bacillus subtilis*, *Bacillus licheniformis* and *Enterococcus faecium*) were fed alone or in cocktail to rainbow trout. The feeds were produced by using a commercial feed top-dressed with fish oil containing the probiotics. Feeding the probiotics increased the probiotic species in the posterial gastrointestinal tract. Increased lysozyme activity was observed when fish was fed *Bacillus* + *E. faecium* in a blend.

D8 is studying the feeding of *Lactobacillus fermentum* and ferulic acid to common carp. The authors reported positive effects on haematological parameters as well as serum antioxidant enzymes.

As argued above, D9 relates to a probiotic composition using different LABs than the current invention. Also the method of application differs from the claimed invention.

Starting from D1 and faced with the objective technical problem, we submit that the solution provided by the claimed invention would not have been obvious to the skilled person in the light of the prior art D2-D19. The skilled person starting from D1, in combination with common technical knowledge, would therefore not arrive at the present solution.

Specifically, we submit that it cannot be said that the skilled person would (not simply could, but would) have modified the feed of D1 to arrive at the feed of claim 1 in order to solve the objective technical problem, while taking the prior art into account.

Similar arguments apply for the amended method claim 10. There is no teaching, or even a hint, in D5 of a method for provision of a feed comprising both LF and LP bacteria, by applying the bacteria at an evacuated atmosphere. Starting from D5, in combination with common technical knowledge, such as D9 using top dressing by spraying, the skilled person would therefore not arrive at the present solution. Thus, the subject-matter of amended claim 10 involves an inventive step.

The applicant has shown surprising results that a combination of LF and LP in fish feed has positive effects on the mucosal barriers in the fish, as detailed in Examples 1 and 2. The skilled person reading either of the D1, D3, D4 and D8 would not be motivated to provide a combination of the two LABs in the same feed, and test such for use in treatment of fish. Thus, the subject-matter of amended claim 12 involves an inventive step.

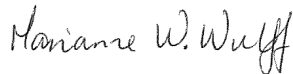
The subject-matter of the remaining claims is new and involves an inventive step by way of their dependencies.

Certain defects

We believe the amendments to claim 3-6 clarify the issues raised by the examiner.

The applicant believes that the objections raised in the official action dated 28 December 2021 have been addressed, and that patentability of the invention has been demonstrated, and thus requests favourable consideration.

Yours sincerely,
Bryn Aarflot AS



Marianne W. Wulff

Enclosure:
Amended claims, annotated and clean