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Oslo, 2024.07.04

Your ref.: 137759/MWW/IMO Application no.: 20210585 (please include in your reply) Applicant: NORD UNIVERSITET Due date: 2024.10.04

Office action in patent application no. 20210585

| Basis of the | opinion | |
|--------------|----------|------------|
| Description | received | 2021.05.10 |
| Claims | received | 2022.06.03 |
| Drawings | received | 2021.05.10 |

Assessment of patentability

The invention in the present application concerns naturally occurring biological material. In accordance with the statements in the preparatory works to the Act on amendements to the Patents Act of 2004.03.01 to implement directive 98/44/EC on legal protection of biotechnological inventions, Norway shall follow a restrictive practice in this area. See Examination guidelines, Part C, Chap. IV, Section 2a. 2

The Norwegian Industrial Property Office may demand a copy of the receipt that the depositary institution has issued as proof of the correctness of the information provided in accordance with patl. § 8 the second and third paragraphs. The isolated probiotics in the present invention were isolated from the intestinal content of a rainbow trout from a fish farm in the Slovak Republic, Lactobacillus plantarum (CCM 8674) and Lactobacillus fermentum (CCM 8675).

Inventive step

Document D1 discloses a fish feed product comprising different probiotic strains, including Lactobacillus plantarum LPS47 and Lactobacillus plantarum LPT87.

D1 mentions a study [0018-0019] related to increased fish immunity acquired through the use of a Lactobacillus strain. Results showed that the immune parameters of rainbow trout improved considerably through the use of the probiotic strain.

D1 further reveals [0026] that an important stage associated with the probiotic action mechanism is the adhesion and subsequent colonisation of the epithelium, which is the attraction of the tested bacterium to the surface of the tissues of interest, followed by the association of the mucus with epithelial cells. The adhesion and colonisation of the mucus to the surface of the tissues are possible protection mechanisms against pathogens because of competition for sites and the stimulation of the immune system.



The subject-matter of claim 1 of the present application differs from the subject-matter of D1 by the presence of both lactic acid bacterias *Lactobacillus plantarum* and *Lactobacillus fermentum*.

The objective technical problem to be solved can therefore be regarded as the provision of an alternative fish feed product.

The person skilled in the art will know that different *Lactobacillus* probiotic strains have different qualities and have the potential to increase the barrier status of the fish, which in turn improves the fish`s health status and prevent disease.

The example study of the present invention reveals that the LP and LF bacteria strains were isolated from the intestinal content of rainbow trout. We agree with the applicant that it is not trivial for the skilled person that both these lactic acid bacteria will be capable to colonise the gut of a saltwater fish species and have a positive contribution on the fish welfare. We agree with the applicant in that it is important to consider differences between fish species which will impact their effect of probiotic fish feed supplementation. The Lactobacillus strains in the present invention deposited at the CCM with the deposition numbers CCM 8674 and CCM 8675 and its use in fish feed is not disclosed in prior art. Therefore it would not be obvious that the deposited Lactobacillus strains CCM 8674 and CCM 8675 have the described qualities as fish feed supplementation.

The reguirement for an invention to be considered susceptible of industrial application is that the technical teaching disclosed in the application is reproducible. In this application the effect of the deposited claims CCM 8674 and CCM 8675 is crucial.

Claim 1 will fulfill the patentability criterion if it is limited to the deposited strains CCM 8674 and CCM 8675. The same comment relates to independent claims 10 and 12.

Instructions

Prior art documents should be identified in the description and the relevant background art disclosed therein should be briefly discussed, see «patentretningslinjene (pr) Del C, Kap. II, punkt 3.2.1» (guidelines for examination).

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.

Time limit for response

You are invited to submit a written response within the due date above. You may respond via <u>Altinn</u>. If you fail to respond, the application will be shelved. However, the processing of 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 on fees, Sections 1-6 and 8.

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

For the application to be approved for 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.

For your information

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

Information to applicants using Altinn: You will find cited publications linked in the enclosed search report or as electronic attachments. They will be forwarded in paper format only if not available in electronic format or if protected by copyright.

Please contact us if you have any questions

Sincerely,

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Enclosures: none