Notice of Reasons for Refusal

Number of the request/demand for appeal/trial: Appeal 2020 - 6843
(Application number) : (Japanese Patent Application No. 2017-93750)
Date of Drafting: Reiwa 3(2021) August 3
Chief administrative judge Administrative judge: HARADA, Takaoki
Demandant: ModernaTX, Inc.
Representative patent attorney: ONDA, Makoto (and 3 others)

As a result of the consultation, the application for this trial case should be refused for the following reason(s). If you have any opinion on this, please submit your written opinion within 3 days from the date when this notice was sent.

Reason

Reason 1(Clarity) This patent application does not fulfill the requirement of the provision of Patent Act Article 36(6)(ii) in terms of the item(s) listed below regarding the statement of the scope of claims.

Reason 2(Enablement Requirement) This patent application does not fulfill the requirement of the provision of Patent Act Article 36(4)(i) in terms of the item(s) listed below regarding the statement of the detailed explanation of the invention.

References (see the list for reference documents, etc.)

The inventions according to Claims 1 to 11 of the scope of claims amended by the written amendment submitted on May 20, Reiwa 2(2020) may be referred to as "Invention 1" or the like according to the number of the claim, and collectively referred to as "the Invention.".

1. Regarding Reason 1 (Clarity)

(1) "Modification" in "(a) nucleosides selected from modified uridine, cytidine, adenosine, and guanosine" in Claim 1 It is not clear whether it is a term relating only to "uridine," or is a term that is relevant to "uridine, cytidine, adenosine, and guanosine".

(2) Regarding the "oncogenic proteins" in Claim 1, what proteins are included in the Description [0092][0095]Even if the description is considered to be unclear, it is not clear. (It is also unclear whether or not the G-CSF or the like described in the Examples is a "tumor ingenu-related protein.")

(3) It is not clear what "to down-regulate or inhibit expression in cells expressing miR-5" in Claim 1 is not clear. "([d] the expression in the cells expressing [d] -

[miR] - [122]) is not clear. (Whether or not the expression of the "cancer-associated protein" in (a) or the expression of any other polypeptide in the cells to which the lipid nanoparticle is administered is not clear is not clear.). )

(4) Therefore, Inventions 2 to 11 of the present application which cites Invention 1 and Claim 1 of the present application are not clear.

2. Regarding Reason 2 (Enablement Requirement)

(1) About an Invention 1
The matter specifying the invention of the present application 1, wherein the average particle diameter of the 85nm-153nm is expressed so that the protein encoded by the polynucleotide is expressed at a higher level, is Since there is a specification that "to be expressed at a higher level," it can be understood that the expression level of "the proteins encoded by the polynucleotides" is higher than that within the range of "the average particle size of the 85nm-153nm .".

If attention is focused on the average particle size only in the lipid nanoparticles described in Tables 53 54 and Tables 146 and 147 in the specification of the present application, it is within the range of "average particle size of 85nm-153nm ." Although the expression level of "the protein encoded by the polynucleotide" is high beyond that range, the types of fats used differ from each other in the lipid used.

However, when the lipid nanoparticle for the delivery of RNA is administered to the living body at the time of the filing date of the present application, it was common general technical knowledge that "an element of lipid nanoparticles other than the average particle size", such as the type of lipid, affects the expression level of protein (see the reference documents 1 and 2, if necessary).

In that case, from the statements in Tables 53 and 54 and Tables 146 and 147 in the specification of the present application, it is within the scope of "average particle size of 85nm-153nm ," not to be specified by other conditions not specified in Invention 1, such as the type of fat. A person skilled in the art cannot understand becoming what has an expression level of "the protein coded by the aforementioned polynucleotide" higher than the outside of the range, It cannot be understood by a person skilled in the art whether or not the lipid nanoparticle becomes an expression level of such a protein when the lipid is used as a lipid.

Therefore, in the light of the technical common sense at the time of submission of this application, it is based on the description of the detailed description of the invention of Description of this application, It cannot be said that a person skilled in the art can manufacture Invention 1, which has the matter specifying the invention in which "the average particle diameter of the 85nm-153nm is expressed so that the protein encoded by the polynucleotide is expressed at a higher level," without an undue trial-and-error.

(2) About Invention 2 -11
Inventions 2 to 11 in the present application include the matters specifying the invention, the matters specifying the invention "having an average particle diameter of 85nm-153nm so that proteins encoded by the polynucleotides will be expressed at a higher level" according to the matters specifying the invention specified further [2,

2006.01, 11] It cannot be said that a person ordinarily skilled in the art would have been able to manufacture it without undue trials and errors.

In the case of describing a written opinion for Reason 2, it will be concretely explained with reference to what lipids are used in the Examples (relation to lipids stated in Claims 7 and 8, etc.), and specifically will be explained.

<The reason for refusal to reserve>
Reasons for refusal 2 (inventive step) in the examiner's decision of refusal are held to be held. In creating a written opinion and a written amendment, attention is drawn to the appellant's opinion on the following demandant's allegation.

The demandant alleges that, in the written demand for trial, a person ordinarily skilled in the art would not be able to expect an advantageous effect of encapsulating mRNA by using lipid nanoparticles having an average particle size of 85 to 153 nm. However, in the case of administering lipid nanoparticles for the delivery of RNA to the living body at the time of the priority date of the application, it was a common general technical knowledge that elements other than the average particle size, such as the type of fat, affect the expression level of proteins (see the reference documents 1 and 2, if necessary). From the descriptions in Tables 53 and 54 and Tables 146 and 147 in the specification of the present application, it cannot be said that when lipid nanoparticles having an average particle size of 85 to 153 nm are used, an advantageous effect can be achieved compared to a case where lipid nanoparticles having an average particle size of from to nm are used. Therefore, at present, it is considered that the collegial body cannot be considered to have achieved an advantageous effect over the whole of the Invention of the present application using lipid nanoparticles with an average particle size of 85 to 153 nm.

<Lists, such as Reference documents>
Reference Document 1:Nano.Lett.,2015,15,7300 - 7306 (Reference Document submitted by Demandant) Reference Document 2 : National Publication of International patent application No. 2012 to 505250 (the "original instance") (Cited document 2 in the original instance court)

With regard to this notification, in addition to the telephone, communication may be made by e-mail. When requesting communication by e-mail, please refer to "name, affiliation, telephone number, and content of query," and refer to the following mail address (*). Regarding the telephone number, if there is a telephone number to be delivered to the Japan Patent Office (JPO). In order to confirm the content of the inquiry, a telephone communication may be made from the trial examiner. * ●●●@ jpo. go. jp (see "PA 6 A23" in place of the above "●●●」,").

In correcting the scope of claims, a full text unit is not a claim unit (Note (7), Form 13 of the Ordinance for Enforcement of the Patent Act). In addition, the extension of the response period is limited to those based on the acquisition of comparative experimental data or the translation of a trial document, unlike the practice at the examination stage. The extended claim after a time-limit-for-response lapse is not accepted. In detail, please refer to the trial guidelines 25 to 04.

A chief administrative judge, an Administrative judge, HARADA, Takaoki, 9167, an Administrative judge, FUCHINO, Ruka, 9048, an Administrative judge, FUJIWARA, Hiroko, 9155