Decision on Opposition

Opposition No. 2020-700606

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The case of opposition against the invention "FOWL ADENOVIRUS VACCINE" of Patent No. 6649255 has resulted in the following decision.

Conclusion

The correction of the scope of claims of Patent No. 6649255 shall be approved as the corrected scope of claims attached to the Written Correction Request, with respect to Claims [19-25] after correction.

The patents according to Claims 1 to 25 of Patent No. 6649255 shall be maintained.

Reason

I. History of the procedures

The application for the patent for Claims 1 to 25 of Patent No. 6649255 was filed on August 19, 2014. The establishment of patent right was registered on January 20, 2020, and the Gazette containing the patent was published on February, 19, 2020. Thereafter, an Opposition to the granted patent was filed by the Opponent, YAMADA, Hiroki (hereinafter, referred to as "the Opponent") on August 17, 2020.

The history of the procedures after that is as follows:
October 23, 2020 : Notice of Reasons for Revocation
January 25, 2021 : Submission of the Written Correction Request and the Written Opinion (by the Patentee).

It is noted that the Opponent did not respond within the specified period at all to the Notice on February 1, 2021 that the correction request was made.

II. Suitability of correction

Hereinafter, the written correction request submitted on January 25, 2021 is referred to as the "present written correction request," the correction request by the present written correction request is referred to as the "present correction request," and the correction by the present correction request is referred to as the "present correction."

1. Contents of the present correction

The correction matters according to the present correction request are as follows:

(1) Correction Matter 1

The recitation of "comprising a fiber-2 protein of FAdV-C or an immunogenic fragment thereof immobilized on a solid surface" in Claim 19 in the scope of claims is corrected to "comprising a fiber-2 protein of FAdV-C immobilized on a solid surface."

(2) Correction Matter 2

The recitation of "the antibody to the immobilized fiber-2 protein of FAdV-C or the immobilized immunogenic fragment thereof" in Claim 20 in the scope of claims is corrected to "the antibody to the immobilized fiber-2 protein of FAdV-C."

It is noted that regarding Claims 19 to 25 before the correction, Claims 20 to 25 are directly or indirectly dependent on Claim 19, and are corrected in association with Claims 19 and 20 in which the recitations are corrected by Correction Matters 1 and 2, and therefore, Claims 19 to 25 after the correction corresponding to Claims 19 to 25 before the correction are of a group of claims stipulated in Patent Act Article 120-5(4).

2. Judgment on suitability of correction

(1) Regarding Correction Matter 1

a. Regarding the purpose of correction

Correction Matter 1 is to correct the recitation of "comprising a fiber-2 protein of FAdV-C or an immunogenic fragment thereof immobilized on a solid surface" in Claim 19 before the correction to "comprising a fiber-2 protein of FAdV-C immobilized on a solid surface," which limits the scope of claims by deleting an option, and thus is intended for the purpose of the restriction of the scope of claims prescribed in item (i) of the proviso to Patent Act Article 120-5(2).

The correction for Claims 20 to 25, which is in association with the above correction for Claim 19, is also intended for the purpose of the restriction of the scope of claims prescribed in item (i) of the proviso to Patent Act Article 120-5(2) for the same reason.

b. Regarding presence or absence of new matters and enlargement or alteration of the scope of claims

Correction Matter 1 is intended for the purpose of the restriction of the scope of claims, and thus is a correction within the scope of the matters described in the description, scope of claims, or drawings attached to the application, and complies with Patent Act Article 126(5) as applied mutatis mutandis to Patent Act Article 120-5(9).

In addition, Correction Matter 1 is intended for the purpose of the restriction of the scope of claims and does not change the category, object, or purpose of the invention, and thus does not substantially enlarge or alter the scope of claims, and complies with Patent Act Article 126(6) as applied mutatis mutandis to Patent Act Article 120-4(9).

Further, it is also obvious that the correction for Claims 20 to 25 in association with the above correction for Claim 19 is made within the scope of the matters described in the description or scope of claims attached to the application and does not substantially enlarge or alter the scope of claims for the same reason.

Therefore, Correction Matter 1 complies with the provisions of Patent Act Article 126(5) as applied mutatis mutandis to Patent Act Article 120-5(9) and the Patent Act Article 126(6).

(2) Regarding Correction Matter 2

a. Regarding the purpose of correction

Correction Matter 2 is to correct the recitation of "the antibody to the fiber-2 protein of FAdV-C or an immunogenic fragment thereof immobilized on a solid surface" in Claim 20 before the correction to "the antibody to the immobilized fiber-2 protein of FAdV-C," which limits the scope of claims by deleting an option, and thus is intended for the purpose

of the restriction of the scope of claims prescribed in item (i) of the proviso to Patent Act Article 120-5(2).

The correction for Claims 21 to 25, which is in association with the above correction for Claim 20, is also intended for the purpose of the restriction of the scope of claims prescribed in item (i) of the proviso to Patent Act Article 120-5(2) for the same reason.

b. Regarding presence or absence of new matters and enlargement or alteration of the scope of claims

Correction Matter 2 is intended for the purpose of the restriction of the scope of claims, and thus is a correction within the scope of the matters described in the description, scope of claims, or drawings attached to the application, and complies with Patent Act Article 126(5) as applied mutatis mutandis to Patent Act Article 120-5(9).

In addition, Correction Matter 2 is intended for the purpose of the restriction of the scope of claims and does not change the category, object, or purpose of the invention, and thus does not substantially extend or change the scope of claims, and complies with the Patent Act Article 126(6) as applied mutatis mutandis to Patent Act Article 120-4(9).

Further, it is also obvious that the correction for Claims 21 to 25 in association with the above correction for Claim 20 is made within the scope of the matters described in the description or scope of claims attached to the application and does not substantially enlarge or alter the scope of claims for the same reason.

Therefore, Correction Matter 2 complies with the provisions of the Patent Act Article 126(5) as applied mutatis mutandis to Patent Act Article 120-5(9) and the Patent Act Article 126(6).

3. Summary of correction request

As stated above, the present correction is intended for the purpose of the matter prescribed in item (i) of the proviso to Patent Act Article 120-5(2), and complies with the provisions of Patent Act Article 126(5) as applied mutatis mutandis to Patent Act Article 120-5(9) and Patent Act Article 126(6).

Therefore, the correction of the scope of claims shall be approved, with respect to Claims [19 to 25] after the correction.

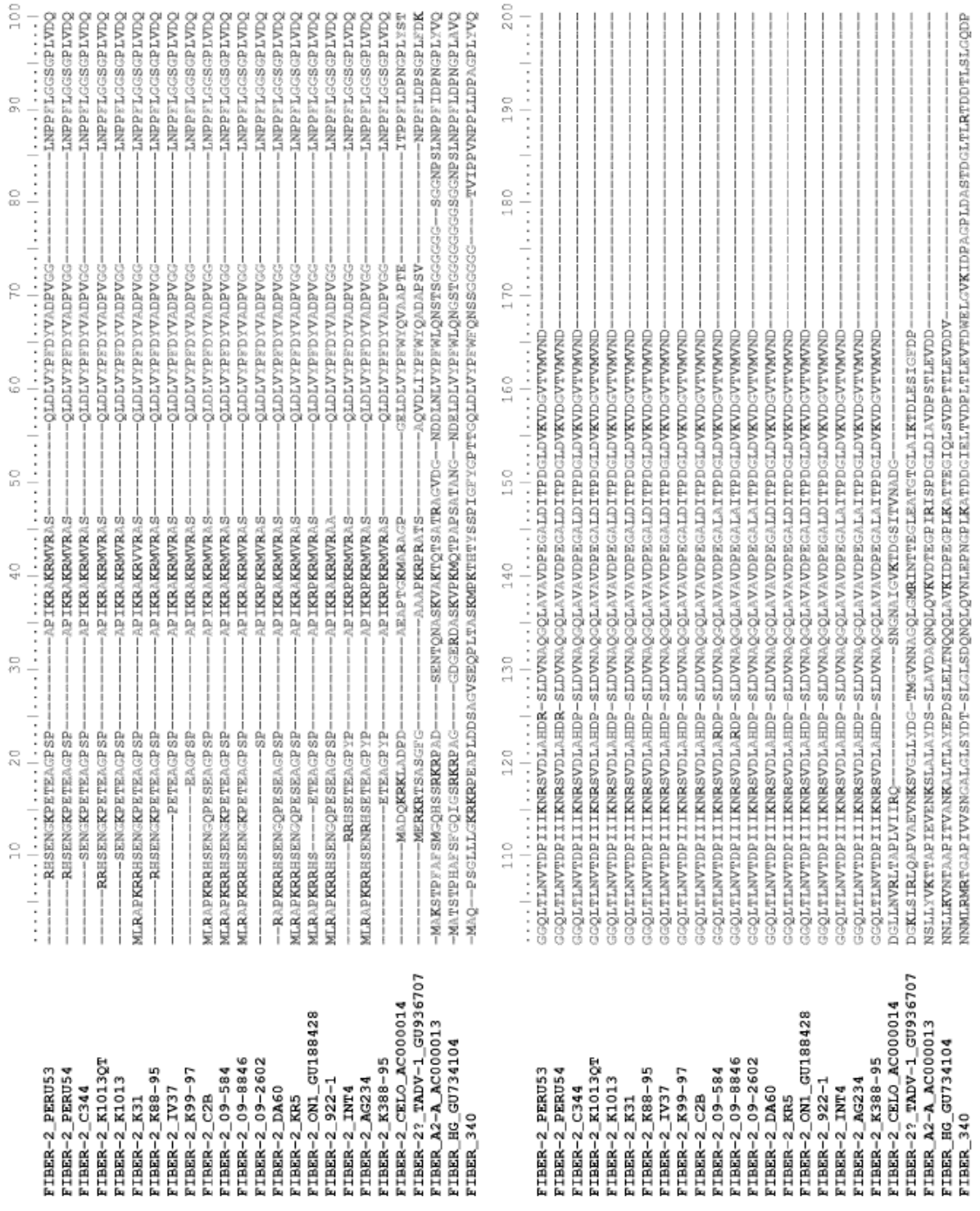
III.Regarding the present invention

The inventions according to Claims 1 to 25 in the scope of claims corrected by the present correction (hereinafter, referred to as "Present Invention 1" to "Present Invention

25," respectively, and may be collectively referred to as the "Present Invention") are as follows, which are specified by the matters recited in Claims 1 to 25 in the scope of claims, respectively.

"[Claim 1]
A vaccine comprising a fiber-2 protein of Fowl Adenovirus C (FAdV-C) for use in preventing hepatitis-hydropericardium syndrome (HHS) in a birds;
wherein the vaccine is a subunit vaccine.
[Claim 2]
The vaccine according to Claim 1, wherein the birds are poultry.
[Claim 3]
The vaccine according to Claim 1 or 2, wherein the birds are broilers.
[Claim 4]
The vaccine according to any one of Claims 1 to 3, further comprising an adjuvant.
The vaccine according to Claim 4, wherein the adjuvant is selected from the group consisting of a Freund's complete adjuvant, a Freund's incomplete adjuvant, aluminum hydroxide, Bordetella pertussis, saponin, muramyl dipeptide, an ethylene vinyl acetate copolymer, an oil, a vegetable oil or a mineral oil, and a combination thereof.
[Claim 6]
The vaccine according to any one of Claims 1 to 5, wherein the fiber-2 protein of FAdV-C is selected from the protein sequences represented by

[chemical formula 1]



,

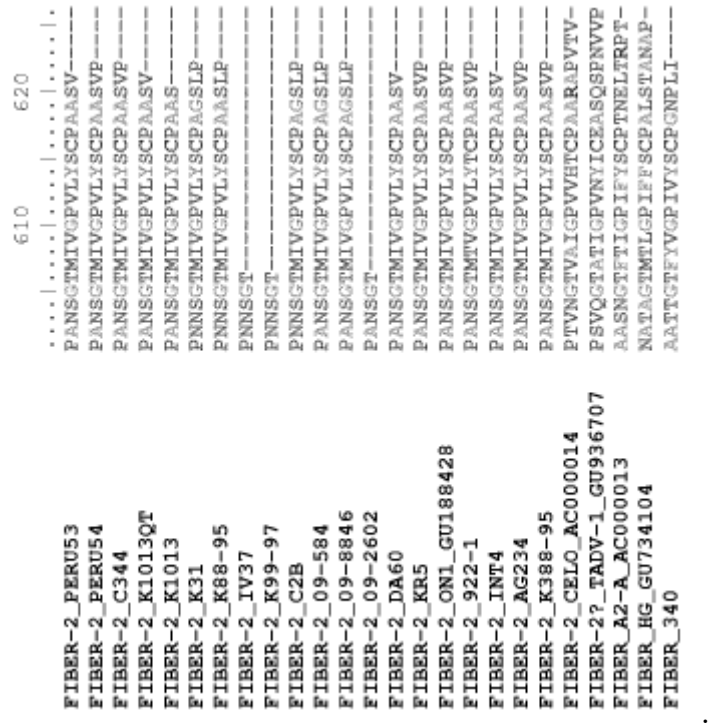
[chemical formula 2]

,

[chemical formula 3]

, and

[chemical formula 4]



[Claim 7]

The vaccine according to Claim 6, wherein the fiber-2 protein of FAdV-C is FIBER-2_KR5 in the protein sequences.

[Claim 8]

The vaccine according to any one of Claims 1 to 7, further comprising a pharmaceutically acceptable diluent and/or carrier.

[Claim 9]

The vaccine according to Claim 8, wherein the pharmaceutically acceptable diluent and/or carrier is selected from the group consisting of water-for-injection, physiological saline, tissue culture medium, propylene glycol, polyethylene glycol, vegetable oils, and injectable organic esters.

[Claim 10]

The vaccine according to any one of Claims 1 to 9, wherein the fiber-2 protein of FAdV-C is produced by recombination.

[Claim 11]

The vaccine according to Claim 10, wherein the fiber-2 protein of FAdV-C is produced by recombination in a baculovirus expression system, in an *Escherichia coli* expression system, or in a *Pichia pastoris* expression system.

[Claim 12]

The vaccine according to any one of Claims 1 to 11, wherein the fiber-2 protein of FAdV-C is contained in an amount of 0.1 μg/ml to 10 mg/ml.

[Claim 13]

The vaccine according to any one of Claims 1 to 12, consisting of a fiber-2 protein of FAdV-C; and

a pharmaceutically acceptable carrier and/or diluent and/or adjuvant.

[Claim 14]

The vaccine according to Claim 13, wherein the fiber-2 protein of FAdV-C is contained in an amount of 0.1 μg to 10 mg.

[Claim 15]

A method for preventing HHS in birds, the method comprising:

administering to poultry a vaccine comprising a fiber-2 protein of Fowl Adenovirus Serotype C (FAdV-C), wherein

the vaccine is a subunit vaccine.

[Claim 16]

The method according to Claim 15, wherein the birds are poultry.

[Claim 17]

The method according to Claim 15 or 16, wherein the birds are broilers.

[Claim 18]

The method according to any one of Claims 15 to 17, wherein the vaccine is administered to parent flock.

[Claim 19]

A kit for detecting an anti-fiber-2 antibody, the kit comprising a fiber-2 protein of FAdV-C immobilized on a solid surface.

[Claim 20]

The kit according to Claim 19, further comprising means for detection of binding of an antibody to the immobilized fiber-2 protein of FAdV-C.

[Claim 21]

The kit according to Claim 20, wherein the means for detection is an antibody being specific for bird antibody.

[Claim 22]

The kit according to Claim 20 or 21, wherein the means for detection is an anti-chicken IgG antibody or an anti-turkey IgG antibody.

[Claim 23]

The kit according to Claim 22, wherein the anti-chicken IgG antibody or the anti-turkey IgG antibody is a labeled antibody.

[Claim 24]
The kit according to Claim 23, wherein the labeled antibody is an antibody labeled with a colourigenic, fluorescent, luminescent, or radioactive label.
[Claim 25]
The kit according to any one of Claims 19 to 24, comprising fiber-2 protein of FAdV-C."

IV. Regarding reasons for revocation in the Notice of Reasons for Revocation
1. Outline of reasons for revocation
The gist of the reasons for revocation notified to the Patentee on October 23, 2020 with respect to the patent according to Claims 19 to 24 before the correction is as follows:

(1) Reason 1 for Revocation (enablement requirement)
It cannot be said that the patent according to Claims 19 to 24 before the correction is clearly and sufficiently described in the detailed description of the invention to the extent that a person skilled in the art can implement the invention, and thus the description of the detailed description of the invention does not comply with the Patent Act Article 36(4)(i).
Therefore, the patent according to Claims 19 to 24 before the correction is made with respect to the patent application not satisfying the provisions of the Patent Act Article 36(4)(i), falls under the Patent Act Article 113(iv), and should be revoked.

(2) Reason 2 for Revocation (support requirement)
For the patent according to Claims 19 to 24 before the correction, it cannot be said that the invention for which the patent is sought recited in the scope of claims is described in the detailed description of the invention, and thus the recitation in the scope of claims does not comply with the Patent Act Article 36(6)(i).
Therefore, the patent according to Claims 19 to 24 before the correction is made with respect to the patent application not satisfying the provisions of the Patent Act Article 36(6)(i), falls under the Patent Act Article 113(iv), and should be revoked.

(3) Reason 3 for Revocation (clarity)
For the patent according to Claims 19 to 24 before the correction, the recitation in the scope of claims does not comply with the Patent Act Article 36(6)(ii).
Therefore, the patent according to Claims 19 to 24 before the correction is made with respect to the patent application not satisfying the provisions of the Patent Act Article 36(6)(ii), falls under the Patent Act Article 113(iv), and should be revoked.

2. Judgment by the body

(1) Regarding Reason 1 for Revocation (enablement requirement)

A. Outline of Reason 1 for Revocation

The outline of Reason 1 for Revocation is as follows:

Present Invention 19 is an invention of "a kit for detecting an anti-fiber-2 antibody, the kit comprising a fiber-2 protein of FAdV-C or an immunogenic fragment thereof immobilized on a solid surface."

The kit according to Present Invention 19 includes a kit in which an immunogenic fragment of a fiber-2 protein of FAdV-C is immobilized on a solid surface, but in the description of the application of the present patent, only proteins which are actually confirmed to be able to detect an anti-fiber-2 antibody by being immobilized on the solid surface is "recombinant affinity purified Fib-2 protein" ([0062]), that is, a fiber-2 protein of FAdV-C as the whole length, and no description is made for an example in which an immunogenic fragment is immobilized.

In [0021] to [0022] of the description of the present patent, many fragments are shown as immunogenic fragments of the fiber-2 protein of FAdV-C, but it is difficult to predict immunogenic fragments capable of binding to the anti-fiber-2 antibody based only on amino acid sequences of fiber-2 proteins. When considering that it is the common technical knowledge at the time of filing of the application of the present patent that it is necessary to perform experimental verification, a person skilled in the art is required to perform excessive trial and error in selecting immunogenic fragments capable of detecting the anti-fiber-2 antibody among them.

Therefore, the description of the detailed description of the invention of the present patent is not clearly and sufficiently described to the extent that a person skilled in the art can implement the invention recited in Claim 19.

B. Judgment by the body for Reason 1 for Revocation

Based on the present correction, the recitation of "comprising a fiber-2 protein of FAdV-C or an immunogenic fragment thereof immobilized on a solid surface" in Claim 19 before the correction is corrected to "comprising a fiber-2 protein of FAdV-C immobilized on a solid surface," and the recitation of "an antibody against the immobilized fiber-2 protein of FAdV-C or the immobilized immunogenic fragment thereof" in Claim 20 before the correction is corrected to "an antibody against the immobilized fiber-2 protein of FAdV-C."

Based on the present correction, the recitation itself of the "immunogenic fragment thereof", which is considered to violate the enablement requirement in Reason 1 for Revocation, is removed from Claims 19 and 20, and therefore Reason 1 for Revocation is unreasonable.

Thus, the patent according to Present Inventions 19 to 24 should not be revoked due to Reason 1 for Revocation.

(2) Regarding Reason 2 for Revocation (support requirement)

A. Outline of Reason 2 for Revocation

The outline of Reason 2 for Revocation 2 is as follows:

The problem to be solved by Present Inventions 19 to 24 is to provide a "kit for detecting an anti-fiber-2 antibody" based on the recitation itself in Claim 19, but as described in the section of the violation of the enablement requirement, it cannot be said that the detailed description of the invention of the present patent is described to the extent that a person skilled in the art can implement Present Inventions 19 to 24 based on the description of the detailed description of the invention and the common technical knowledge at the time of filing of the application of the present patent without requiring undue trial and error. Therefore, it cannot be recognized that Present Inventions 19 to 24 are within a range that could have been recognized by a person skilled in the art as being able to solve the above problem addressed by the invention according to the description of the detailed description of the invention, and it cannot be recognized that Present Inventions 19 to 24 are within a range that could have been recognized by a person skilled in the art as being able to solve the problem addressed by the invention in light of the common technical knowledge at the time of filing of the application of the present patent even without description or suggestion in the detailed description of the invention.

Thus, it cannot be said that Present Inventions 19 to 24 are described in the detailed description of the invention.

B. Judgment by the body for Reason 2 for Revocation

Based on the present correction, the recitation of "containing a fiber-2 protein of FAdV-C or an immunogenic fragment thereof immobilized on a solid surface" in Claim 19 before the correction is corrected to "containing a fiber-2 protein of FAdV-C immobilized on a solid surface," and the recitation of "an antibody against the immobilized fiber-2 protein of FAdV-C or the immobilized immunogenic fragment thereof" in Claim 20 before the correction is corrected to "an antibody against the immobilized fiber-2 protein of FAdV-C."

Based on the present correction, the recitation itself of the "immunogenic fragment thereof", which is considered to violate the support requirement in Reason 2 for Revocation, is removed from Claims 19 and 20, and therefore Reason for Revocation 2 is unreasonable.

Thus, the patent according to Present Inventions 19 to 24 should not be revoked due to Reason 2 for Revocation.

(3) Regarding Reason 3 for Revocation (clarity)

A. Outline of Reason 3 for Revocation

The outline of Reason 3 for Revocation is as follows:

It is not clear what is included in the "immunogenic fragment thereof" in Present Invention 19, and thus the inventions according to Claims 20 to 24 specified by directly or indirectly depending on the recitation in Claim 19 of the present patent are not clear for the same reason as the invention according to Claim 19.

B. Judgment by the body for Reason 3 for Revocation

Based on the present correction, the recitation of "containing a fiber-2 protein of FAdV-C or an immunogenic fragment thereof immobilized on a solid surface" in Claim 19 before the correction is corrected to "containing a fiber-2 protein of FAdV-C immobilized on a solid surface," and the recitation of "an antibody against the immobilized fiber-2 protein of FAdV-C or the immobilized immunogenic fragment thereof" in Claim 20 before the correction is corrected to "an antibody against the immobilized fiber-2 protein of FAdV-C."

Based on the present correction, the recitation itself of the "immunogenic fragment thereof," which is considered to violate the clarity requirement in Reason 3 for Revocation, is removed from Claims 19 and 20, and therefore Reason 3 for Revocation is unreasonable.

Thus, the patent according to Present Inventions 19 to 24 should not be revoked due to Reason for Revocation 3.

V. Reasons for Opposition not adopted in the Notice of Reasons for Revocation

(1) Reasons for Opposition alleged by the Opponent and submitted evidences

The Opponent submits the following Evidence A No. 1 to Evidence A No. 15, and alleges the following Reason for Opposition 1 to the present patent before the correction.

Evidence A No. 1: Annual Report of Institute of Health and Nutrition Nagoya University of Arts and Sciences, 2010, No.4, p.47-64

Evidence A No. 2: The Veterinary Record, 1989, Vol.124, p.655-658
Evidence A No. 3: Journal of VIROLOGY, 2000, Vol.74, No. 7, p.3217-3226
Evidence A No. 4: Vaccine, 2003, Vol.21, p.2761-2766
Evidence A No. 5: Scientific reports of the Chemo-Sero-Therapeutic Research Institute, Reimei, 2010, 19, p.51-60
Evidence A No. 6: Virology, 1997, Vol.238, p.145-156
Evidence A No. 7: Arch. Virol., 1994, Vol.138, p.117-134
Evidence A No. 8: Virology, 1995, Vol.213, p.503-516
Evidence A No. 9: J.gen.Virol., 1983, Vol.64, p.2577-2583
Evidence A No. 10: Virology, 1995, Vol.214, p.110-117
Evidence A No. 11: United States Patent Application Publication No. 2011/0165224
Evidence A No. 12: Veterinary Microbiology, 2012, Vol.156, p.411-417
Evidence A No. 13: Korean J. Poult. Sci., 2010, Vol.37, No.3, p.255-263
Evidence A No. 14: Avian Diseases, 2010, Vol.54, p.905-910
Evidence A No. 15: Trop Anim Health Prod, 2011, Vol.43, p.331-338
Hereinafter, "Evidence A No. 1" to "Evidence A No. 15" are referred to as "A-1" to "A-15," respectively.

A. Reason 1 for Opposition (inventive step)
(Reason 1-A for Opposition)

The inventions according to Claims 1 to 18 before the correction could have been easily made by a person skilled in the art based on the invention described in A-11 and the matters described in A-1 to A-9 and A-12 to A-15, and cannot be granted a patent under the provisions of the Patent Act Article 29(2), and thus the present patent falls under the Patent Act Article 113(ii).

(Reason 1-B for Opposition)

The inventions according to Claims 19 to 25 before the correction could have been easily made by a person skilled in the art based on the invention described in A-12 and the matters described in A-1 to A-10 and A-13 to A-15, and cannot be granted a patent under the provisions of the Patent Act Article 29(2), and thus the present patent falls under the Patent Act Article 113(ii).

(2) Description of Evidence A
A. A-11

The following matters are described in A-11 (the underline is added by the body. The same applies hereinafter.).

(11-1) (Claims 1, 21, and 24)

"Claim 1

A composition or a vaccine composition comprising isolated live and/or dead fowl adenovirus (FAdV), wherein the FAdV is a strain selected from FAdV-2, FAdV-7, FAdV-8a, FAdV-8b, FAdV-8a/8b, and/or FAdV-11 serotype strains.

...

Claim 21

A method for eliciting an immune response in a subject, for producing antibodies in a subject and/or its progeny, or for inducing protective immunity against a FAdV-related disease or syndrome in a subject and/or its progeny, the method comprising: a step of administering an effective amount of the composition according to Claim 1 or a vaccine containing the composition to the subject.

...

Claim 24

The method according to Claim 22, wherein the FAdV-related disease or syndrome is one or more of pneumonia and tracheitis, proventriculitis, inclusion body hepatitis (IBH), quail bronchitis, hydropericardium syndrome, gizzard erosions, and pancreatic necrosis."

(11-2) ([0003])

"[0003]

The disclosure pertains to methods and compositions for inducing an immune response against fowl adenovirus (FAdV) infection and particularly to methods and compositions for inducing immune protection in poultry from infection with FAdV to prevent inclusion body hepatitis (IBH)."

(11-3) ([0012], [0013], [0071], [0082])

"[0012]

An aspect of the disclosure provides a composition comprising a fowl adenovirus (FAdV) that is an isolated live or inactivated virus and/or a protein subunit thereof, wherein the FAdV is a strain selected from FAdV-2, FAdV-7, FAdV-8a, FAdV-8b, FAdV-8a/8b or FAdV-11 serotype strains."

"[0013]

In an embodiment, the subunit is a hexon and/or fiber protein."

"[0071]
The term "subject" as used herein refers to any animal that is susceptible to FAdV infection. The animal includes, for example, species such as a chicken (broiler, broiler parent, broiler grand-parent, broiler great-grand parent), and pigeon."

"[0082]
...
In an embodiment, the composition contains a suitable carrier".

(11-4) (Table 1 in [0086])
"

TABLE 1

Classification of avian adenoviruses.
Serotype is in bold; species names are in italic script; strain names are in roman script.

Fowl adenovirus species[1]	ICTV FAdV serotype/strain[2]	USA FAdV serotype/strain[3]	Europe FAdV serotype/strain[3]
Fowl adenovirus A	**FAdV-1** CELO, 112, Phelps	**FAdV-1** QBV, Indiana C, T3, QT	**FAdV-1** CELO
Fowl adenovirus B	**FAdV-5** 340, TR-22	**FAdV-3** 340-5, M2, IBH, Tipton	**FAdV-5**
Fowl adenovirus C	**FAdV-4** KR95, J2, KR5, J2A	**FAdV-4** 506-1, HR-5	**FAdV-4** KR-5
	FAdV-10 CFA20, C-2B, M11	**FAdV-10** C-2B	**FAdV-11** C-2B
Fowl adenovirus D	**FAdV-2** P7-A, GAL-1, 685, Merlin	**FAdV-2** GAL-1A, P7, Z7, SSR-48	**FAdV-2** GAL-1
	FAdV-3 75, SR-49		
	FAdV-9 A2-A, 90	**FAdV-9 (FAdV-8)**[1] A2	**FAdV-10** A-2A
	FAdV-11 380, 1047	?	**FAdV-12** 380
	FAdV-6 CR119, 168	?	**FAdV-5** CR119
Fowl adenovirus E	**FAdV-7** YR36, x-11, x11a[4]	**FAdV-10** x-11	**FAdV-7** x-11
	FAdV-8a TR-59, T-8, CFA40, T8-A[4]	**FAdV-5** 58-1, T-8, TR-59, U-6, Q-1A	**FAdV-8** TR-59
	FAdV-8b Stanford[5] 764, B3	**FAdV-7** 764, B3	**FAdV-9** 764
	FAdV-8a/8b Ontario[6]		

[1](Zsak and Kisary, 1984);
[2](Benko et al., 2005);
[3]McFerran et al., 1977;
[4](Meulemans et al., 2001);
[5](Alvarado et al., 2007),
[6](Ojkic et al., 2008b);
? not available

"

(11-5) ([0120], [0126], [0129])

"[0120]

Suitable carriers and/or pharmaceutically acceptable carriers include, for example, water such as sterilized distilled water, saline, ethanol, ethylene glycol, glycerol, water in oil emulsions, oil in water emulsions, saponins, and alum-based carriers. An adjuvant may be added to the carrier ... ."

"[0126]

In an embodiment, the composition or vaccine contains an adjuvant ... ."

"[0129]

Conventional inactivated vaccines are generally formulated with adjuvants such as aluminum salts (aluminum hydroxide or alum, and aluminum hydroxyphosphate), emulsions, or suspensions to enhance the immunostimulatory effects ... ."

(11-6) ([0214], [0216], [0218], [0219], [0221])

"[0214]

...

Example 2: Killed Vaccine

Material and Methods

...

[0216]

The objective of this experiment was to demonstrate protection of broilers against IBH by vaccinating their parents with an inactivated adenovirus vaccine.

...

Nine groups of broiler breeders, each group containing five females and one male were vaccinated at 12 and 15 weeks with inactivated 1×10^5 pfu (low dose) or 1×10^8 pfu (high dose) of FAdV-8a/8b or FAdV-7 formulated with Emulsigen or oligonucleotide containing CpG-ODN as an adjuvant (Table 2) (CpG-ODN TCGTCGTTGTCGTTTTGTCGTT (SEQ ID NO:22) Emulsigen®] (Ralston, Nebr.). Progenies of these broiler breeders were challenged at day-14. Briefly, groups containing 60 broilers were intramuscularly vaccinated with 1×10^7 pfu of FAdV-8a/8b. Clinical signs were recorded for 10 days following challenge.

TABLE 2

Inactivated adenovirus vaccination in broiler breeders at 12 and 15 week of age.

Groups	Broiler breeders (n = 6)	Experimental challenge (progeny; n = 60)
1	FAdV-8a/8b-1 × 10^5 pfu's with 20% Emulsigen-D	FAdV-8a/8b
2	FAdV-8a/8b-1 × 10^8 pfu's with 20% Emulsigen-D	FAdV-8a/8b
3	FAdV-8a/8b-1 × 10^5 pfu's with 50 µg CpG-ODN	FAdV-8a/8b
4	FAdV-8a/8b-1 × 10^8 pfu's with 50 µg CpG-ODN	FAdV-8a/8b
5	FAdV-7-1 × 10^5 pfu's with 20% Emulsigen-D	FAdV-8a/8b
6	FAdV-7-1 × 10^8 pfu's with 20% Emulsigen-D	FAdV-8a/8b
7	FAdV-7-1 × 10^5 pfu's with 50 µg of CpG-ODN	FAdV-8a/8b
8	FAdV-7-1 × 10^8 pfu's with 50 µg of CpG-ODN	FAdV-8a/8b
9	Control	FAdV-8a/8b

Strain isolates used in experiments are listed in Table 6 of sequences below.

Results:

...

[0218]

There was a significant protection of broilers against IBH in broiler breeder parents vaccinated with a high dose of inactivated antigens of FAdV-8a/8b adjuvanted with CpG-ODN ($p < 0.05$) [homologous challenge protection] (Fig. 7).

[0219] Furthermore, there is a significant protection of broilers against IBH in broiler breeder parents vaccinated with a high dose of inactivated antigens of FAdV-7 adjuvanted with CpG-ODN ($p < 0.05$) [heterologous challenge protection] (Fig. 8).

...

[0221]

It was demonstrated that a significant level of protection of broilers against inclusion body hepatitis (IBH) can be provided by vaccinating multiple broiler breeder parents with FAdV-8a/8b or FAdV-7".

B. A-12

The following matters are described in A-12.

(12-1) (Abstract on page 411)

"The complete genome or the genome region containing the two fiber genes of two reference strains and one field isolate representing both serotypes of *Fowl adenovirus C* were sequenced. Two fiber genes were revealed in the genomes of all three isolates. Fiber-1 and fiber-2 genes of several *Fowl adenovirus C* isolates were sequenced as well. Both serotypes 4 and 10 have two fiber genes. The genome region containing the fiber gene was also sequenced for the reference strain of *Fowl adenovirus B*. Just one fiber gene was revealed in this strain. Predicted amino acid sequences were compared to already published fiber sequences of different adenovirus isolates. One amino acid substitution within fiber-2 was detected in all *Fowl adenovirus C* isolates that were isolated from chickens with hepatitis-hydropericardium syndrome in comparison to apathogenic isolates. Phylogenetic analysis provided insights about the evolution of fiber genes in avian adenovirus and their genetic relationship."

(12-2) (Page 441, the left column, the section "Introduction," lines 1 to 14)

"Fowl adenovirus (FAdV) belongs to the genus *Aviadenovirus*. The FAdVs are mainly responsible for naturally acquired outbreaks of inclusion body hepatitis (IBH), hepatitis-hydropericardium syndrome (HHS), respiratory tract disease. Some strains of FAdV-1 are reported in connection with gizzard erosions in chickens (...). FAdVs were grouped into five different species (FAdV-A to FAdV-E), based on their molecular structure. They are further subdivided into 12 serotypes (FAdV 1 - 8a and 8b - 11) based on a cross-neutralization test (...). Recently, at least 12 genotypes within the five species were revealed by sequence analysis of the hexon loop 1 (L1) gene region (...)."

(12-3) (Lines 1 to 7 in the section "*Genome of KR5 strain*" in the right column on page 413)

"*De novo* assembly of strain KR5 and subsequent Gap closure by conventional Sanger sequencing yielded a KR5 genome sequence of 45,810 bp. The G + C content of the KR5 genome was 54.6%. This content was very similar to those of the other FAdV strains. The percents sequence identity for available aviadenovirus whole genomes are given in Table 1."

C. A-1

The following matters are described in A-1.

(1-1) (Lines 1 to 6 in the right column on page 55)
"The transition of the virus strain of seasonal influenza vaccination currently being carried out is shown. The basic strain is a combination vaccine of Soviet Union type A (H1N1), Hong Kong type A (H3N2), and type B, and is a split vaccine using the HA protein of the virus as an antigen."

D. A-2

The following matters are described in A-2.

(2-1) (Abstract in the left column on page 655)

"The immune response of cattle and pigs to vaccinia recombinant virus containing the fusion (F) protein gene of rinderpest virus was examined. Half the cattle and all the pigs gave a humoral response to primary vaccination. All the cattle gave an anamnestic response to a second vaccination 28 days after the primary vaccination. All the cattle after a single or secondary vaccinations were completely protected clinically after exposure to a lethal dose of the Saudi 1/81 strain of virus. Prior vaccination with another TK^- vaccinia recombinant (VVCAT) suppressed, but did not abrogate, the immune response to the rinderpest F recombinant F. The pigs gave a humoral immune response in the absence of any local reaction at the site of vaccination."

E. A-3

The following matters are described in A-3.

(3-1) (Abstract on page 3217)

"An earlier report (...) showed that recombinant Marek's disease virus type 1 (rMDV1) expresses the fusion (F) protein of the Newcastle's disease virus (NDV-F) under the control of the simian virus 40 late promoter [rMDV1-US10L(F)] protected specific pathogen-free chickens from NDV challenge, but not commercial chickens with maternal antibodies against MDV1 and NDV. In the present study, we constructed an improved polyvalent vaccine based on MDV1 against MDV and NDV in the commercial chickens with maternal antibodies. The study can be summarized as follows. (i) We constructed rMDV1 expressing NDV-F under the control of MDV1 glycoprotein B (gB) promoter [rMDV1-US10P(F)]. (ii) Much less NDV-F protein was expressed in cells infected with rMDV1-US10L(F) than in those infected with rMDV1-US10L(F). (iii) The antibody response against MDV1 and NDV-F antigens of commercial chickens vaccinated with rMDV1-US10P(F) was much stronger and faster than with rMDV1-US10L(F), and a high level of antibody against the NDV-F persisted for over 80 weeks postvaccination. (iv) rMDV1-US10P(F) was readily reisolated from the vaccinated chickens, and the

recovered viruses were found to express NDV-F. (v) Vaccination of commercial chickens having maternal antibodies to rMDV1-US10P(F) completely protected them from NDV challenge. (vi) rMDV1-US10P(F) offered the same degree of protection against very virulent MDV1 as the parental MDV1 and commercial vaccines. These results indicate that rMDV1-US10P(F) is an effective and stable polyvalent vaccine against both Marek's and Newcastle disease even in the presence of maternal antibodies."

F A-4

The following matters are described in A-4.

(4-1) (Abstract on page 2761)

"In this study, the effectiveness of antibodies against the hexon, fiber, or fiber fragment of an avian adenovirus egg-drop syndrome (EDS), in neutralizing the virus was tested. The fiber protein is responsible for binding the virus to the target cell. The fiber fragment knob-s (knob-s) comprises the carboxy-terminal knob domain and 34 amino acids of the immediately adjacent shaft domain of the adenovirus fiber protein. The hexon, fiber capsid protein, and knob-s were produced in *Escherichia coli* and injected into chickens. Antibodies that were produced against the whole fiber protein showed some hemagglutination inhibition (HI) activity. Antibodies produced against the knob-s protein showed HI activity and serum neutralization (SN) activity similar to the positive control-- whole virus vaccine. We assume that production of only part of the fiber enables the protein produced in *Escherichia coli* to fold correctly. Antibodies produced against the hexon protein showed no SN activity. In summary, knob-s induced SN and HI antibodies against EDS virus at a rate similar to the whole virus and were significantly more efficient than full-length fiber. The recombinant knob-s protein may be used as a vaccine against pathogenic adenovirus infections."

G. A-5

(5-1) (Line 1 in the left column to line 8 in the right column on page 51)

"Introduction

Egg drop syndrome (EDS) is a chicken disease whose cardinal symptoms are decreased egg production and abnormal egg production [1) 2)]. The EDS virus (EDSV), which is the cause of the disease, is classified into Group III avian adenovirus, and is characterized by having hemagglutination activity and growing in the oviduct of chickens [2)]. The clinical symptoms of EDS range from none to mild diarrhea, and it occurs frequently at 30 to 40 weeks of age at the peak of laying. In the infected chicken flock, it causes production of eggs with abnormal shells or a laying decrease for 3 to 8 weeks [2)], and thus the economic

damage is very large. Since the effectiveness of vaccines for prevention [1) 3)], inactivated vaccines have been widely incorporated into the vaccination program for hens for egg collection, and outbreaks in Japan are sporadic."

(5-2) (Fig. 1 on page 52)

"

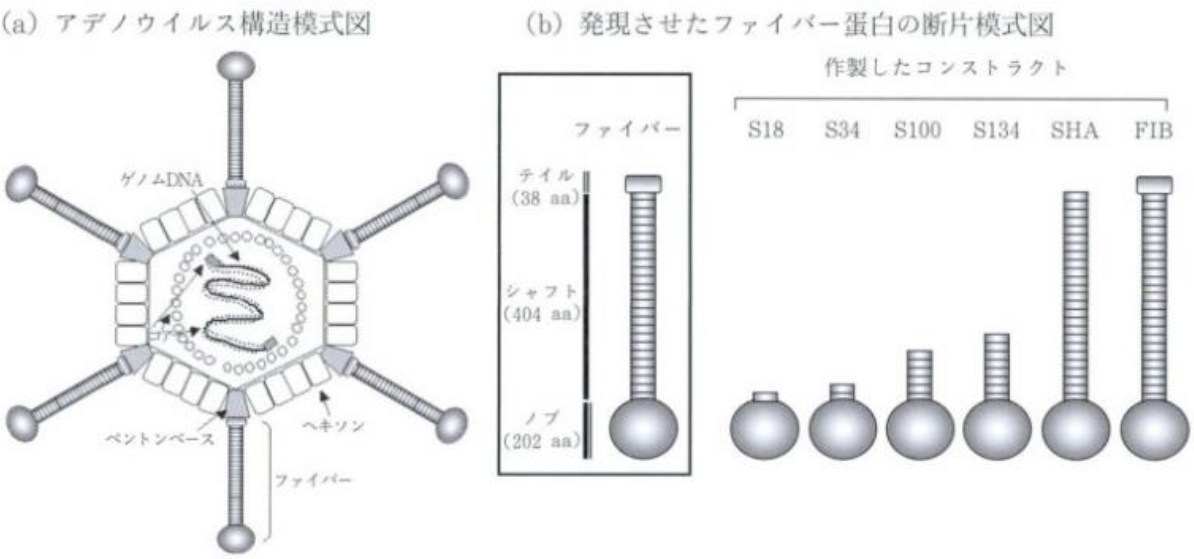


図1 アデノウイルスの構造と構築したコンストラクト模式図
構造模式図（a）に示したファイバーは，3つの領域に分かれる（bの枠内）．EDSVでは，ファイバーの軸を構成するシャフトはβらせん構造の1回転が25回繰り返す構造を取る．コンストラクトS18～S134では，ノブに隣接するシャフトの長さがそれぞれ1, 2, 6, 8リピートとなるよう設計してある（b）．

"

(a)アデノウイルス構造模式図	(a) Schematic diagram of adenovirus structure
ゲノム DNA	Genomic DNA
ペントンベース	Penton base
ヘキソン	Hexon
ファイバー	Fiber
(b)発現させたファイバー蛋白の断片模式図	(b) Schematic diagram of the expressed fiber protein fragment
ファイバー	Fiber
テイル	Tail
シャフト	Shaft
ノブ	Knob

作製したコンストラクト	Constructed construct
図1　アデノウイルスの構造と構築したコンストラクト模式図	Fig. 1 Schematic diagram of the structure of adenovirus and the constructed construct
構造模式図(a)に示したファイバーは，三つの領域に分かれる(b の枠内)．EDSVでは，ファイバー軸を構成するシャフトは β らせん構造の1回転が25回繰り返す構造を取る．コンストラクトS18～S134では、ノブに隣接するシャフトの長さがそれぞれ1、2、6、8リピートとなるように設計してある(b)．	The fiber shown in the schematic structural diagram (a) is divided into three regions (within the frame in b). In EDSV, the shaft constituting the fiber shaft has a structure in which one rotation of the β-helical structure is repeated 25 times. The constructs S18 to S134 are designed such that the lengths of the shafts adjacent to the knobs are 1, 2, 6, and 8 repeats, respectively (b).

(5-3) (The column "2. Immune test" on page 57)

"2. Immune test

In Immune Test 1, an oil vaccine was prepared using inclusion body fractions suspended in PBS(-) and used for the test. In addition, vaccines for S18 and S34 were prepared in the same manner for soluble fractions and used for the test.

A HI antibody titer after 5 weeks of immunization increased to the same level as that of OEDS in the soluble fractions of S18 and S34 and the inclusion body fractions of S100 and S134 (Table 3). On the other hand, the inclusion body fractions of S18, S34, SHA, and FIB were at a low level. A neutralizing antibody titer was also at a high level in the group with a high HI antibody titer, but was lower than that of OEDS in each case.

According to the results of S18 and S34, the antibody elevation was poor in the vaccine in which the inclusion body was emulsified as it was. Therefore, in Immune Test 2, a vaccine was prepared using an antigen in which an inclusion body fraction was solubilized with urea, and used for the test. As a result, an antibody titer was significantly increased in any of the constructs as compared with a vaccine in which an inclusion body fraction was emulsified as it was (Table 4). Among them, the antibody response was good in the S100 and S134 groups, and the HI antibody was induced 5 times higher than that of OEDS at 5 weeks after immunization. The neutralizing antibody titer was lower than that of OEDS, but showed a high value at S134. Based on the above results, S134 (knob + 134 amino acids at the C-terminus of the shaft) was evaluated as a vaccine antigen in the next attack test.

Note that a ratio of neutralizing antibody titer / HI antibody titer was lower than that of OEDS in any of the constructs. It was speculated that this was due to the presence of antigens with neutralizing epitopes such as hexone or penton base in the virus particles in addition to fibers."

(5-4) (Table 3 and Table 4 on page 57)
"

表 3 免疫試験 1 成績

抗 原	HI 抗体価 (2^n)	中和抗体価 (CK, 4^n)
S18(sup)	8.7	4.7
S34(sup)	10.4	5.9
S18(IB)	5.4	3.5
S34(IB)	7.0	4.5
S100(IB)	9.0	5.3
S134(IB)	8.7	5.5
SHA(IB)	1.0	1.0
FIB(IB)	6.7	4.8
OEDS	9.2	8.7

いずれも 2 クローンを評価し，抗体応答の良好であったクローンの抗体価のみを表示した．ワクチン抗原として，可溶性画分（Sup）または封入体画分（IB）を用いた．

表 4 免疫試験 2 成績

抗 原	HI 抗体価 (2^n)	中和抗体価 (CK, 4^n)
S18	8.2	5.4
S34	10.4	6.5
S100	12.2	7.7
S134	12.2	8.5
SHA	6.9	4.5
FIB	11.0	6.7
OEDS	9.7	9.2

いずれも 2 クローンを評価し，抗体応答の良好であったクローンの抗体価のみを表示した．ワクチン抗原としては，封入体画分を可溶化後，PBS(−)に対して透析したものを用いた．

"

表3	Table 3
免疫試験1	Immune Test 1
成績	Results
抗原	Antigen
HI 抗体値	HI antibody titer
中和抗体価	Neutralizing antibody titer
いずれも2クローンを評価し，抗体応答の良好であったクローンの抗体価のみを表示した．ワクチン抗原として，可溶性画分(Sup)または封入体画分(IB)を用いた．	In each case, 2 clones were evaluated, and only the antibody titer of the clone with a good antibody response was displayed. soluble fraction (Sup) or inclusion body fraction (IB) was used as the vaccine antigen.
表4	Table 4
免疫試験2	Immune Test ２
成績	Results

抗原	Antigen
HI 抗体値	HI antibody titer
中和抗体価	Neutralizing antibody titer
いずれも2クローンを評価し，抗体応答の良好であったクローンの抗体価のみを表示した．ワクチン抗原としては，封入体画分を可溶化後，PBS（－）に対して透析したものを用いた．	In each case, 2 clones were evaluated, and only the antibody titer of the clone with a good antibody response was displayed. As the vaccine antigen, the inclusion body fraction was solubilized and then dialyzed against PBS (-).

(5-5) (Line 5 in the right column on page 58 to line 4 in the left column on page 59)

"Summary

As a result of examining the expression of fiber protein of EDSV, the HI antibody and the neutralizing antibody were induced at the highest level in S134 (knob + 134 amino acids at the C-terminus of the shaft), and the onset protection effect and immune persistence equal to or higher than those of the current vaccine were confirmed. From the above results, it was shown that S134, which is a part of the fiber protein, may be a substitute for the viral antigen currently produced in duck eggs."

H. A-6

The following matters are described in A-6.

(6-1) (Lines 9 to 10 in the abstract on page 145)

"Our results demonstrate that the avian EDS virus represents an intermediate between mammalian and avian adenovirus."

I. A-7

The following matters are described in A-7.

(7-1) (Summary on page 117)

"The S1, N and M proteins, obtained from the nephropathogenic N1/62 strain of infectious bronchitis virus (IBV) by immunoaffinity purification with monoclonal antibodies, were used for immunization of chickens. For all three antigens multiple immunizations were necessary for induction of an antibody response. Protection of chickens vaccinated with the S1 glycoprotein against virulent challenge was demonstrated by the complete absence of virus in tracheas and kidneys of vaccinated chickens. Following four immunizations with the S1 glycoprotein 71% and 86% of chickens were protected at the level of tracheas and kidneys, respectively. Three

immunizations with the S1 glycoprotein protected 70% and 10% of chickens at the level of kidney and trachea, respectively. Neither the N nor M antigen induced protection to a virulent challenge with the nephropathogenic N1/62 strain of IBV after four immunizations. Virus neutralizing, heamagglutination inhibiting and ELISA antibodies were detected in chickens immunized with the S1 glycoprotein and inactivated N1/62 virus, however there was no correlation between the presence of any three antibodies and protection."

J. A-8

The following matters are described in A-8.

(8-1) (Abstract on page 503)

"Ten recombinant adenoviruses expressing either fragments of 1135, 1587, or 3329 nt or the full-length spike gene of transmissible gastroenteritis coronavirus (TGEV) have been constructed. These recombinants produce S polypeptides with apparent molecular masses of 68, 86, 135, and 200 kDa, respectively. Expression of the recombinant antigen driven by Ad5 promoters was inhibited by the insertion of an exogenous SV-40 promoter. Most of the recombinant antigens remain intracytoplasmic in infected cells. … The recombinant antigen of 135 kDa and that of 200 kDa, which represents the whole spike protein, also contain antigenic sites D and A, which have previously been shown to be the major inducers of TGEV-neutralizing antibodies. Interestingly, here we show that the recombinant S protein fragments expressing only sites C and B also induced TGEV-neutralizing antibodies. The chimeric Ad5-TGEV recombinants elicited lactogenic immunity in hamsters, including the production of TGEV-neutralizing antibodies. The antisera induced in swine by the Ad5 recombinants expressing the amino-terminal 26% of the spike protein (containing sites C and B) or the full-length spike protein, when mixed with a lethal dose of virus prior to administration to susceptible piglets, delayed or completely prevented the induction of symptoms of disease, respectively."

K. A-9

The following matters are described in A-9.

(9-1) (Lines 1 to 3 in the SUMMARY on page 2577)

"The spike protein (…) of the avian infectious bronchitis virus (IBV) strain M41 comprises two glycopolypeptides, S1 (mol.wt.90 $\times 10^3$) and S2 (mol.wt.84 $\times 10^3$), in equimolar proportions."

L. A-10

The following matters are described in A-10.

(10-1) (Abstract on page 110)

"The trimeric fiber of adenovirus type 2 (Ad2) mediates the first stage of virus-cell attachment, and the distal head region of the fibers has been implicated as the receptor-binding domain. To locate a region on the primary polypeptide sequence of the fiber which may be involved in the virus-cell interaction, peptide-based epitope mapping was performed using (1) polyclonal antibodies prepared against both native Ad2 fibers and Ad2 head protein expressed in *Escherichia coli* and (2) 18 monoclonal antibodies prepared against trimeric Ad2 head protein expressed in baculovirus. The approach using polyclonal antibodies revealed eight domains on the primary sequence of the head which contain one or more contiguous epitopes. At least two of these regions were also recognized by monoclonal antibodies that reacting against both monomeric and trimer fiber head protein. The majority of monoclonal antibodies which did not recognize the Ad2 head-specific peptides in ELISA were also nonreactive against the monomeric form of proteins in Western blots, suggesting that their recognition of trimers is due to the existence of as yet undefined discontinuous epitopes or to alterations in monomer configuration. Our results correspond well with the recently published X-ray crystal model of the Ad5 fiber head (D. Xia, L.J. Henry, R.D. Gerard, and J. Deisenhofer, Structure 2, 1259-1270, 1994), since most antigenic determinants containing linear epitopes mapped to the outer loops or uppermost β-sheets in this structure. Four of the five neutralizing monoclonal antibodies recognized trimers only and none recognized linear peptides. This might suggest that the trimeric form of fiber is necessary for making contact with the receptor(s) and that discontinuous epitopes on the head domain may be involved in the fiber-cell interaction."

M. A-13

The following matters are described in A-13.

(13-1) (Lines 4 to 11 in the abstract)

"To prevent a these IBH-HPS outbreaks in Korea, we developed the FAdV-4 inactivated vaccine using Korean isolate (ADL070244) and evaluated the efficacy of this vaccine. For the efficacy test, 2-week-old specific pathogen-free (SPF) chickens intramuscularly inoculated with 1 or 2 doses of inactivated vaccine were used and challenged with FAdV-4 through either intramuscular or oral route at 2 weeks after vaccination. The vaccine induced good seroconversion which was confirmed by agar gel precipitation (AGP). In addition, the vaccine could decrease the FAdV-4 detection rate and histological lesion severity such as lymphocyte infiltration and necrosis in the liver comparing with those of

non-vaccinated group. Based on the current results, the developed FAdV-4 inactivated vaccine in this study was effective in the terms of reduction of virus detection rate and histological lesions severity."

N. A-14

The following matters are described in A-14.

(14-1) (Title)

"Specific-Pathogen-Free Chickens Vaccinated with a Live FAdV-4 Vaccine Are Fully Protected Against a Severe Challenges Even in the Absence of Neutralizing Antibodies."

(14-2) (Lines 46 to 49 on page 909)

"In this context the present findings underline the importance of the cell-mediated immunity for protection of birds against virulent FadVs, a feature known other live vaccines."

O. A-15

The following matters are described in A-15.

(15-1) (Lines 8 to 11 on page 337)

"Observations based on challenge protection clearly suggested that the birds vaccinated with live attenuated virus were more resistant to challenge as compared to commercial liver organ virus vaccine-administered birds."

(3) Judgment by the body

A. Reason 1-A for Opposition that the invention described in A-11 is a cited invention (inventive step)

(A) The invention described in A-11

According to the above-described matters (11-6) of A-11, it is recognized that the following invention is described in A-11.

"An inactivated vaccine of FadV-8a/8b or FAdV-7 for use in prevention of inclusion body hepatitis (IBH) in a broiler" (hereinafter, referred to as "Invention A-11").

The Opponent alleges that A-11 describes an invention of "a vaccine containing a fowl adenovirus C (FAdV-C) inactivated virus and being for use in prevention of FAdV-related diseases in a bird, in which the vaccine is a subunit vaccine."

However, in order to determine that an invention relating to a vaccine is described in a publication, a substance serving as an active ingredient of the vaccine is required to be described in the publication such that it is revealed that the substance can actually be used for an intended use, but according to the above (2) A, only the use of "FadV-8a/8b or FAdV-7 inactivated" virus for "prevention of inclusion body hepatitis (IBH) in a broiler" was revealed in A-11, and no test examples or the like are described in which it has been confirmed that "subunit vaccine" "containing a fowl adenovirus C (FAdV-C) inactivated virus" can actually be used for the prevention of "FAdV-related diseases in a bird" in general.

Further, there is no evidence indicating that there was a common technical knowledge that if the effect on the prevention of inclusion body hepatitis (IBH) is confirmed, it is naturally effective on the FAdV-related diseases in general. Thus, it cannot be said that A-11 describes the invention of the "vaccine containing a fowl adenovirus C (FAdV-C) inactivated virus and being for use in prevention of FAdV-related diseases in a bird, in which the vaccine is a subunit vaccine."

(B) Regarding Present Invention 1

a. Comparison

Present Invention 1 and Invention A-11 are compared.

The "broiler" in Invention A-11 is included in the "bird" in Present Invention 1.

The "inclusion body hepatitis (IBH) in a broiler" in Invention A-11 coincides with the "hepatitis-hydropericardium syndrome (HHS) in a bird" in Present Invention 1 as long as it is a "disease in a bird."

Thus, Present Invention 1 and Invention A-11 coincide with each other in that they are a "vaccine for use in prevention of diseases of a bird," and are different from each other in the following matters.

Difference 1

In Present Invention 1, the disease in the bird is "hepatitis-hydropericardium syndrome (HHS)," whereas in Invention A-11, the disease in the bird is "inclusion body hepatitis (IBH)."

Difference 2

Present Invention 1 is "vaccine comprising a fiber-2 protein of FAdV-C, which is a subunit vaccine," whereas Invention A-11 is "inactivated vaccine" of "FadV-8a/8b or FAdV-7."

b. Judgment

(a) Regarding Difference 1

Even if it was common technical knowledge that HHS is a FAdV-related disease (A-12), Invention A-11 is the vaccine for the prevention of inclusion body hepatitis (IBH), and it is not motivated by a person skilled in the art to use this vaccine for the prevention of hepatitis-hydropericardium syndrome (HHS) which is a different disease.

(b) Regarding Difference 2

When Invention A-11 is recognized based on the description of Example 2 in the A-11 (the described matters [11-6]), A-11 has no description that motivates a person skilled in the art to adopt a subunit vaccine instead of a vaccine in which the FAdV-8a/8b or FAdV-7 virus is inactivated, then to select FAdV-C from the five species (A to E), and further to select its fiber-2 protein.

A-4 and A-5 describe the use of the fragment of the fiber protein as a vaccine in an egg drop syndrome (EDS) virus due to avian adenovirus (*Adenoviridae Aviadenovirus*), but the genus of EDS virus is different from that of the virus which causes hepatitis-hydropericardium syndrome (HHS).

In addition, A-1 to A-3 and A-7 to A-9 are not documents related to fowl adenovirus, and A-6 is a document for showing that duck adenovirus is more closely related to fowl adenovirus than human adenovirus, and thus these documents do not bridge Difference 2.

(c) Regarding the effect

The description of the present patent shows that chickens intramuscularly administered with fiber-2 of FAdV-C have a significantly higher survival rate after challenge of a pathogenic FadV-C virus than chickens intramuscularly administered with fiber-1 of FAdV-C and hexon loop-1 (Example 1 and [Fig. 1]), and it should be said that this effect is not within the range that could have been predicted by a person skilled in the art based on the descriptions in A-1 to A-9 and A-11 to A-15.

c. Summary

Therefore, it cannot be said that Present Invention 1 could have been easily made by a person skilled in the art based on the invention described in A-11 and the matters described in A-1 to A-9 and A-12 to A-15.

(C) Regarding Present Inventions 2 to 14

Since Present Inventions 2 to 14 are inventions that further limit Present Invention 1, it also cannot be said that Present Inventions 2 to 14 could have been easily made by a person skilled in the art based on the invention described in A-11 and the matters described in A-1 to A-9 and A-12 to A-15 for the same reason as the judgment on Present Invention 1 described in the above (B).

(D) Regarding Present Inventions 15 to 18

Present Invention 15 specifies Present Invention 1 as an invention relating to a method for prevention of HHS in a bird, and thus Present Invention 15 and Invention A-11 are different from each other at least in Differences 1 and 2 examined in the above (B). Therefore, it cannot be said that Present Invention 15 could have been easily made by a person skilled in the art based on the invention described in A-11 and the matters described in A-1 to A-9 and A-13 to A-15 for the same reason as examined in Present Invention 1.

Since Present Inventions 16 to 18 are inventions that further limit Present Invention 15, it also cannot be said that Present Inventions 16 to 18 could have been easily made by a person skilled in the art based on the invention described in A-11 and the matters described in A-1 to A-9 and A-13 to A-15 for the same reason as the judgment on Present Invention 15.

(E) Summary

As described above, the patent according to Present Inventions 1 to 18 should not be revoked due to Reason for Opposition 1-A.

B. Reason 1-B for Opposition that the invention described in A-12 is a cited invention (inventive step)

(A) The invention described in A-12

According to the above-described matters (12-1) of A-12, it is recognized that the following invention is described in A-12.

"A fiber-2 protein of FAdV-C." (hereinafter, referred to as "Invention A-12.")

(B) Regarding Present Invention 19

a. Comparison

Comparing Present Invention 19 and Invention A-12, the two coincide with each other in that they are related to the fiber-2 protein of FAdV-C, and are different from each other in the following matters.

Difference 19-1

Present Invention 19 is a kit used for detecting an anti-fiber-2 antibody and containing a fiber-2 protein of FAdV-C immobilized on a solid surface, whereas Invention A-12 does not specify this matter.

b. Judgment

(a) Regarding Difference 19-1

Although A-12 describes the presence of the fiber-2 protein of FAdV-C, there is no description of an antibody against the protein, and there is no description of motivating the detection of the antibody.

Then, regarding A-1 to A-9 and A-13 to A-15, the contents are described as in the above section A and do not motivate a person skilled in the art "to detect an anti-fiber-2 antibody," and A-10 is a document for showing that an antigen epitope that elicits a neutralizing antibody is not present in all regions in human adenovirus, and does not motivate a person skilled in the art "to detect an anti-fiber-2 antibody."

(b) Regarding the effect

Present Invention 19 exerts an effect that a success level of vaccination can be detected by detecting a specific anti-fiber-2 antibody in a vaccinated parent ([0034]), and this effect cannot be expected by a person skilled in the art based on the matters described in A-1 to A-10 and A-12 to A-15.

c. Summary

Therefore, it is not recognized that Present Invention 19 could have been easily made by a person skilled in the art based on Invention A-12 and the matters described in A-1 to A-10 and A-13 to A-15.

(C) Present Invention 20 to 25

Since Present Inventions 20 to 25 are inventions that further limit Present Invention 19, it also cannot be said that Present Inventions 20 to 25 could have been easily made by a person skilled in the art based on the invention described in A-12 and the matters

described in A-1 to A-10 and A-13 to A-15 for the same reason as the judgment on Present Invention 19 described in the above (B).

(D) Summary

As described above, the patent according to Present Inventions 19 to 25 should not be revoked due to Reason for Opposition 1-B.

VI. Closing

As described above, the patents according to Claims 1 to 25 cannot be revoked according to either the Reasons for Revocation stated in the Notice of Reasons for Revocation or the Reasons for Opposition stated in the Written Opposition. Further, no other reason for revoking the patents according to Claims 1 to 25 is found.

Therefore, the decision shall be made as described in the conclusion.

April 5, 2021

Chief administrative judge: OKAZAKI, Miho
Administrative judge: TOMINAGA, Midori
Administrative judge: SAITO, Megumi