Appeal Decision

Appeal No.2020－8792

Appellant OSTRICH PHARMA KK

Patent Attorney HIROKOH, Masaki

The case of appeal against the examiner's decision of refusal of Patent Application No. 2015-214827, entitled “ANTIBODY AGAINST EBOLA VIRUS AND METHODS FOR PRODUCING ANTIBODY” (application published on May 23, 2016, Japanese Unexamined Patent Application Publication No. 2016-88937) has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

I. History of the procedures

The present application is an application filed on October 30, 2015 (claim of priority; October 31, 2014; Japan). Against Notice of Reasons for Refusal dated on September 19, 2019, a Written Opinion was submitted on January 1, 2020, a Decision of Refusal was made by an examiner on June 24, 2020, and a Request for Appeal against an Examiner's Decision of Refusal was made on March 11, 2020 and, simultaneously, a Written Amendment was submitted.

II. Decision to dismiss amendment by the Written Amendment filed on June 24, 2020

[Conclusion]

The amendment by the Written Amendment filed on June 24, 2020 (hereinafter, referred to as "the Amendment") shall be dismissed.

[Reason]

1. The Amendment

The Amendment includes the one amends Claim 1 of the Scope of Claims originally attached to the application, which recited as:

(before amendment) “Claim 1

A method for producing an anti-Ebola virus antibody, comprising the steps of immunizing a female bird using a recombinant protein of the Ebola virus as an antigen, and obtaining an antibody from the yolk of an egg laid by said female bird.”

to the one which recites as:

(after amendment) “Claim 1

A method for producing Anti-Ebola virus antibody <u>for the use of Ebola virus</u>

masking, comprising the steps of immunizing a female bird using a recombinant protein of the Ebola virus as an antigen, and obtaining an antibody from the yolk of an egg laid by said female bird, wherein said female bird is an ostrich."
Amended matters are underlined.

2. Regarding requirements for purpose of amendment

According to the above amendment, "female bird" recited in Claim 1 before the amendment was specified as "ostrich" (Amended matter 1), and Claim 1 after amendment recites "anti-Ebola virus antibody for the use of Ebola virus masking", which identifies the antibody produced is "for the use of Ebola virus masking" (Amended matter 2).

In the Amended matter 1, the "female bird" to be immunized was limited to "ostrich", and since the field of the industrial application and the problems to be solved of the invention recited in Claim 1 before and after the amendment are identical, it can be said that the amendment falls under the one which is made for the purpose of the restriction in a limited way of Claim 1 before the amendment.

Therefore, whether the invention according to Claim 1 after the amendment (hereinafter referred to as "amended invention") satisfies the provision of Article 126 (7) of the Patent Act, which is applied mutatis mutandis pursuant to Article 17-2(6) of the Patent Act (whether the invention could have been patented independently at the time of filing the patent application) is examined below.

3. Regarding requirements for independent patentability
(1) Matters described in Cited Document
A. Document 1

International Publication No. 2007/0266889, which is a publicly known document before the priority date of the present application, cited as Document 1 in the Decision of Refusal, describes the following matters. The underlines were added by the Body.

A-1. "[1] An antibody produced by using an ostrich.
…
[6] The Antibody according to claim 1, wherein said antibody was produced by using a viral protein as an antigen.
…
[11] A method for producing an antibody, comprising the steps of immunizing an ostrich against a protein, a peptide fragment thereof or other substances as an antigen, and producing a polyclonal or a monoclonal antibody.
…
[13] The method for producing an antibody according to claim 11, comprising the steps

of immunizing a female ostrich, and producing an antibody from the yolk of an egg laid by said female ostrich."

(Scope of claims)

A-2. "[0009] In this DESCRIPTION, "ostrich" means one of the birds that belong to the Struthioniformes. Among them, it is preferable to use ostrich (Struthio camelus) that belongs to the Struthionidae. A female or male ostrich may be used. Here "using an ostrich" means that the ostrich is used as an animal to which an antigen is administered for production of an antibody. A substance, which is administered as an antigen is not particularly limited, and can be proteins, peptides (including naturally occurring peptides, synthetic peptides, or recombinant peptides), or other biological substance such as polysaccharides. Also, methods for preparing and administering an antigen are not particularly limited, although preferable embodiments are described later."

A-3. "[0018] The use of the antibody of the present invention is not particularly limited, and the antibody of the present invention can be used as antibodies currently used in various fields, in addition to antibodies for medical use as described above. In particular, since the antibody of the present invention can be mass-produced using an ostrich, by applying the present invention to the production of antibodies for examination used in a cancer examination kit, a kit for examining viral infection, etc., it becomes possible to easily and promptly prepare a large number of examination kits required for the examination from a single ostrich, which are required to examine enormous samples in the physical examination, examination of infectious diseases or food poisoning, etc.

[0019] For example, since the IBV (avian infectious bronchitis virus) is a coronavirus closely related to the SARS virus, it becomes possible to produce a large amount of antibodies against the SARS virus by using an ostrich, and it is also possible to produce a large amount of antibodies for detection of pathogenic virus such as avian influenza virus. Moreover, it is also possible to produce a large amount of antibodies for examination of prion diseases such as BSE (bovine spongiform encephalopathy) and other diseases. Furthermore, the antibody of the present invention can also be applied as an industrial antibody, that is, it can be applied as antibodies for removal of pathogenic substances, allergens, and other antigenic substances in various industrial products such as air-conditioner filters, masks, and water filtration filters.

[0020] As described above, the present invention can be applied as an industrial antibody for removal of virus by applying to an air-conditioner filter, a face mask, or other products, in addition to using as antibodies for detection of virus or for examination of diseases. Of course, it is also possible to be applied as an antibody for detecting and removal of pathogens other than viruses (such as bacteria causing infectious diseases or food poisoning), allergens in foods (such as buckwheat and ovalbumin), and pathogens within

drinking water.
[0021] The antibody of the present invention may be produced as a polyclonal antibody or a monoclonal antibody."

B. Document 2

Japanese Unexamined Patent Application Publication No. 2010/13361, which is a publicly known document before the priority date of the present application, cited as Document 2 in the Decision of Refusal, describes the following matters.

"Claim 1
An antibody purified from the blood or yolk of female ostriches immunized with norovirus VLP produced by insect cells."
(Scope of claims)

C. Document 3

Japanese Unexamined Patent Application Publication No. 2009-23985, which is a publicly known document before the priority date of the present application, cited as Document 3 in the Decision of Refusal, describes the following matters.
"Claim 1

A method for producing an anti-influenza virus antibody comprising the steps of simultaneously immunizing a female bird with influenza virus-derived HA including one or more of each types H1, H3 and B, and collecting IgY from the yolk of an egg laid by said bird.

…
Claim 3

The method according to Claim 1 or 2, wherein the bird is an ostrich."
(Scope of claims)

D. Document 4

US Patent Application Publication No. 2012/0164153, which is a publicly known document before the priority date of the present application, cited as Document 4 in the Decision of Refusal, describes the following matters. Since the text is in English, a translation is described.

"ABSTRACT
The inventors disclose Ebola-Sudan Boniface virus GP monoclonal antibodies, epitopes recognized by these monoclonal antibodies, and the sequences of the variable regions of some of these antibodies. Also provided are mixtures of antibodies of the invention, as

well as methods of using individual antibodies or mixtures thereof for the detection, prevention, and/or therapeutic treatment of Ebola-Sudan Boniface virus infections in vitro and in vivo."

E. Document 5

US Patent No. 6630144, which is a publicly known document before the priority date of the present application, cited as Document 5 in the Decision of Refusal, describes the following matters. Since the text is in English, a translation is described.

"ABSTRACT
In this application are described Ebola GP monoclonal antibodies and epitopes recognized by these monoclonal antibodies. Also provided are mixtures of antibodies of the invention, as well as methods using individual antibodies or mixtures thereof for the detection, prevention, and/or therapeutical treatment of Ebola virus infections in vitro and in vivo."

F. Document 6

International Publication No. 2012/050193, which is a publicly known document before the priority date of the present application, cited as Document 6 in the Decision of Refusal, describes the following matters.

"Background Art
[0002] Ebola virus is a Negative-strand RNA virus of the Filoviridae family. The Ebola virus causes severe Ebola hemorrhagic fever in primates, including humans. Its fatality rate is extremely high, sometimes exceeding 90%. Therefore, strict containment of BSL4 is necessary when conducting research. It has been reported that bats may be the natural host of Ebola virus, but much remains unknown. Ebola hemorrhagic fever was a pandemic in Sudan and Zaire in 1976, followed by sporadic epidemics in Central and West Africa. Initially, Ebola virus was thought to be a endemic disease in Africa, but the epidemic in the US monkey quarantine room in 1989 led to renewed recognition of the threat of the virus in developed countries. In recent years, it has been pointed out that the increased risks of spread of Ebola virus by importing pet monkeys or by travelers as well as bioterrorism using Ebola virus are increasing, therefore the development of effective methods of prevention or treatment of Ebola hemorrhagic fever has been sought. However, there are still no effective prophylactic or therapeutic methods or vaccines."

(2) Cited Invention

From (1) A-1 above, it is recognized that the following invention (hereinafter referred to as "Cited Invention") is described in Document 1.

“A method for producing an anti-viral antibody, comprising the steps of immunizing a female ostrich using a viral protein as an antigen, and producing a polyclonal antibody from the yolk of an egg laid by said female ostrich.”

(3) Comparison

The invention according to Claim 1 after the amendment (hereinafter referred to as “Amended Invention”) is compared with the Cited Invention.

The antigen that is “a viral protein” of the Cited Invention is common in that it is a viral protein with the antigen that is “a recombinant protein of the Ebolavirus” of the Amended Invention.

Therefore, it is recognized that those two correspond with each other in that:
“A method for producing an anti-viral antibody, comprising the steps of immunizing a female bird using a viral protein as an antigen, and obtaining an antibody from the yolk of an egg laid by said female bird, wherein said female bird is an ostrich”,
but differ in the following features.

(Difference 1)

Regarding the antigen, in the Amended Invention, “a recombinant protein of the Ebola virus” is used, so that the type of virus and protein are specified to Ebola virus and recombinant, respectively, whereas in the Cited Invention, "a viral protein” is used, and the type of virus and protein are not specified.

(Difference 2)

The Amended Invention is directed to “anti-Ebola virus antibody for the use of Ebola virus masking”, so that the antibody is specified as “for Ebola virus masking”, whereas the Cited Invention does not specify the use of the anti-viral antibody.

(4) Judgment

Regarding (Difference 1)

As described in Document 6, it is well known that the Ebola virus, which infects humans and causes severe symptoms, is a target virus for protection from infection, and it is also well known that the purpose of producing an antibody against Ebola virus is to protect from infection of Ebola virus (see Documents 4 and 5, if necessary). It is also a well-known technique to use a recombinant protein as an antigen (see Document 1 [A-2 above] and Document 2, if necessary). Moreover, as described in Document 3, it is clear that an antiviral antibodies can be obtained by immunizing ostriches with viral proteins.

Therefore, a person skilled in the art can easily prepare an anti-Ebola virus antibody, and in that case, use a recombinant protein of Ebola virus as a viral protein

antigen.

Regarding (Difference 2)

It cannot be said clear what kind of matter is specified for the anti-Ebola virus antibody by the phrase “for the use of Ebola virus masking” in the Amended Invention. Even if this phrase specifies some sort of use of the anti-Ebola virus antibody, it is unclear how exactly the antibody specified by this use differs from the antibody not specified by this use. In addition, even if the phrase “for the use of Ebola virus masking” does not indicate the use but specifies some sort of function of the anti-Ebola virus antibody, such as “Ebola virus masking properties”, it is not clear how exactly the antibody specified by this function differs from the antibody without this function.

Therefore, the description in the present Specification regarding the phrase “for the use of Ebola virus masking" is referred to. As Example 3 in the present Specification, it is described that based on sandwich ELISA method, wherein a primary antibody consisting of an anti-Ebola mouse antibody immobilized on an ELISA plate, an Ebola protein antigen, and an HRP-labeled anti-Ebola rabbit antibody were used, the anti-Ebola ostrich antibody was reacted as a measurement sample, and the binding of the measurement sample to the antigen was measured as the decrease in absorbance with the passage of reaction time. Regarding the measurement result, it is described as follows: “Reaction time 0 min is the absorbance in the state where the ostrich antibody was not added. This indicates the amount of each antigen immobilized on the primary antibody. As the reaction time between the ostrich antibody and each antigen is lengthened, the ostrich antibody binds to each antigen immobilized on the primary antibody. Then, the antigen to which the secondary antibody binds is masked by the ostrich antibody, so that the number of binding sites is reduced. Therefore, if the absorbance decreases, the amount of antigen that is not bound to the ostrich antibody decreases. (Paragraph [0055])”, and succeeded by the description as follows: “From the above, the anti-Sudan Ebola ostrich antibody and the anti-Zaire Ebola ostrich antibody produced in an ostrich enable masking of Ebola virus. From this, it was found that each antibody can suppress the infection of the virus to the cells. (Paragraph [0057])”.

Therefore, taking into consideration the description of Example 3 in the Specification of the present application, it can be understood that “masking” of an antigen means that a large number of ostrich antibodies bind onto the antigen, thereby the number of the binding sites of the primary and secondary antibodies on the antigen are reduced, so that the absorbance is reduced. Based on the description regarding this reduction of the number of the binding sites and the following description in the present Specification

“polyclonal antibodies that can bind to various sites are more effective for masking than monoclonal antibodies that bind to a single epitope (paragraph [0058])”, it is understood that the ostrich antibody described in Example 3 is a polyclonal antibody.

In short, it is understood that the polyclonal antibodies of anti-Ebola virus are suitable “for the use of Ebola virus masking” as referred to in the Amended Invention.

Compared with this, since the Cited Invention is also a polyclonal antibody, it contains many kinds of antibodies that bind to different epitopes on the antigen, and these antibodies bind to various sites of the antigenic viral protein. That is, the antibody of the Cited Invention is also recognized as “masking” the virus.

Further, as discussed in “Regarding (Difference 1) ”, in the Cited Invention, it is easy for a person skilled in the art to prepare an anti-Ebola virus antibody using the recombinant protein of the Ebola virus, and since the anti-Ebola antibody prepared in such a way are polyclonal antibody, it can be said that it function as “masking” the virus, that is, the one “for the use of masking the Ebola virus”.
Therefore, the (Difference 2) can also be easily made by those skilled in the art.

In addition, it cannot be recognized that the Amended Invention exhibited an effect that could not have been predicted from the description in Document 1 and well-known matters.

Therefore, the Amended Invention would have been easily invented by a person skilled in the art based on the invention described in Document 1 and the well-known art.

Thus, the invention recited in Claim 1 of the Scope of claims amended by the Amendment could not have been patented independently at the time of filing the patent application.

(5) Summary

As stated above, the Amendment does not comply with the provisions of Article 126(7) of the Patent Act, which is applied mutatis mutandis pursuant to Article 17-2(6) of the Patent Act. Accordingly, the Amendment should be dismissed under the provisions of Article 53(1) of the same Act which is applied mutatis mutandis by replacing certain terms pursuant to the provisions of Article 159(1) of the same Act.

III. Regarding the Present Invention

1. The invention according to the present application

Since the Amendment was dismissed as stated above, it is recognized that the invention according to Claims 1 to 9 of the present application are inventions specified

by the matters recited in Claims 1 to 9 of the Scope of Claims originally attached to the application.

2. Reasons for the Examiner's Decision of Refusal

Reasons for the Decision of Refusal dated on March 19, 2020 include one that the invention according to Claim 1 of the present application would have been easily invented by a person with ordinarily skill in the art in the art to which the invention belongs, prior to the filing of the present application, based on the inventions described in the Documents 1 to 6, which are distributed in Japan or foreign countries or made available to the public through electric communication lines prior to the priority date of the present application, and therefore, a patent shall not be granted for the invention under the provisions of Article 29(2) of the Patent Act.

3. Judgment by the Body

The invention according to Claim 1 (hereinafter referred to as "Present Invention") is shown as (before amendment) in above II.-1. Although the Present Invention does not have the matters that the female bird is "ostrich" and the anti-Ebola virus antibody is "for the use of Ebola virus masking", which are the matters specified in the Amended Invention, it is recognized that the Present Invention includes an embodiment which has the above-mentioned matters specified in the Amended Invention.

Therefore, for the same reason as the Amended Invention, the Present Invention would have been easily invented by a person skilled in the art based on the invention described in Document 1 and the well-known art.

IV. Closing

As stated above, a patent shall not be granted for the invention according to the Claim 1 under the provisions of Article 29(2) of the Patent Act. Accordingly, the present application should be rejected, without referring to the inventions according to the other claims.

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

June 23, 2021

Chief administrative judge: TAMURA, Kiyoko

Administrative judge: NAKAJIMA, Yoko

Administrative judge: MATSUNO, Hirokazu