Appeal decision

Appeal No. 2014- 3794

Italy
Appellant NOVARTIS VACCINES & DIAGNOSTICS SRL

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The case of appeal against an examiner's decision of refusal of Japanese Patent Application No. 2011-139927, entitled "Nucleic acids and proteins from streptococcus groups a and b" [the application published on December 1, 2011, Japanese Unexamined Patent Application Publication No. 2011-239783] has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

1. History of the procedure and the Invention

The present application is a divisional application filed on June 23,2011 under

the provisions of Article 44(1) of the Patent Act from Patent Application No.2008-317741, which is a divisional application under the provisions of Article 44(1) of the Patent Act from Patent Application No. 2004-571012 filed on October 29,2001 as an international filing date (priority claim under the Paris Convention: October 27, 2000, GB; November 24, 2000, GB; March 7, 2001, GB). The inventions according to Claims 1 to 21 of the present application are specified by matters specifying the inventions described in Claims 1 to 21 according to the scope of claims amended by written amendment which was submitted on February 28, 2014. It is found that the invention according to Claim 1 above (hereinafter referred to as the "Invention") is as follows.

"A protein comprising an amino acid sequence of SEQ ID 6298."

2. Reasons for refusal of the examiner's decision

Reasons for refusal of the examiner's decision are that the application does not meet the requirement under the provisions of Article 36(4) of the Patent Act because the detailed description of the Invention is not be clear and sufficient as to enable any person ordinarily skilled in the art to which the inventions described in Claims 1 to 23 of the present application pertains to carry out the invention, and that the application does not meet the requirement under the provisions of Article 36(6)(i) of the Patent Act because the inventions described in Claims 1 to 23 of the present application are not described in the detailed description of the Invention.

No. 3 Judgment by the body

1. Article 36(4) of the Patent Act

(1) Described matters of the Description

In the paragraph [0078] of the Description, it is described that "The invention provides proteins comprising the S. agalactiae amino acid sequences disclosed in the Examples, and proteins comprising the S. pyogenes amino acid sequences disclosed in the Examples. These amino acid sequences are the even SEQ ID NOS: between 1 and 10960." It is found that protein of the Invention is one of about 5,500 proteins provided as protein derived from S. agalactiae or S. pyogenes.

According to the description in the paragraph [0112] of the Description that " A process for identifying an amino acid sequence is provided, comprising the step of searching for putative open reading frames or protein-coding regions within a

genome sequence of S. agalactiae. This will typically involve in silico searching of the sequence for an initiation codon and for an in-frame termination codon in the downstream sequence. The region between these initiation and termination codons is a putative protein-coding sequence. Typically, all six possible reading frames will be searched. Suitable software for such analysis includes ORFFINDER (NCBI), GENEMARK [Borodovsky & McIninch (1993) Computers Chem. 17:122-133), GLIMMER [Salzberg et al. (1998) Nucleic Acids Res. 26:544-548; Salzberg et al. (1999) Genomics 59:24-31; Delcher et al. (1999) Nucleic Acids Res. 27:4636-4641], or other software which uses Markov models [e.g. Shmatkov et al. (1999) Bioinformatics 15:874-876]." and the description in the paragraph [0287] that Open reading frames (ORFs) within nucleotide sequences were predicted using the GLIMMER program [Salzberg et al. (1998) Nucleic Acids Res 26:544-8]. Where necessary, start codons were modified and corrected manually on the basis of the presence of ribosome-binding sites and promoter regions on the upstream DNA sequence.", it is found that the above about 5,500 proteins are based on the matter coded by the open reading frames which are predicted using the program.

In paragraphs [0008] and [0096] to [0100], it is generally described that the above about 5,500 proteins disclosed in the Description may be used for the development of vaccines, diagnosis, and passive immunization.

However, in the Examples, relating to some specific proteins among the above 5,500 proteins, the result of passive protection assay for GBS serotype III COH1 strain is only described (paragraphs [1125] to [1135]), it is not clear whether protein of the Invention is derived from S. agalactiae or S. pyogenes, and the specific function including provision of passive immunization or application as vaccines is not shown at all.

(2) Judgment

To find that the invention relating to chemical substance is described in the Description so that a person ordinarily skilled in the art can carry out the invention, the invention shall be described in the detailed description of the Invention so that a person ordinarily skilled in the art can make and use the substance.

With respect to protein as a chemical substance, if the function and activity of protein is not described in the Description, or cannot be presumed even taking into consideration the technical common sense as of filing the application, the description in the detailed description of the invention is not so clear and sufficient that a person ordinarily skilled in the art can carry out the Invention, since there is

no description how to use the chemical substance.

As described above in No. 3-1(1), although it is described that the protein of the Invention may be used for the development of vaccines, diagnosis, and passive immunization in the detailed description of the invention, it is not cleared whether the protein of the Invention is derived from S. agalactiae or S. pyogenes, and the specific functions, such as providing passive immunization or being used as vaccines, are not shown at all. To begin with, the protein of the Invention is based on the matter encoded by predicted ORF using the program, and the predicted amino acid sequence is only described, and it is not certain that the protein of the Invention is actually present in S. agalactiae or S. pyogenes.

To find that protein derived from certain microorganisms can be used for providing vaccines or passive immunization, in a case where the protein is administered to an animal, it is necessary that the protein induces neutralizing antibodies in the animal capable of preventing infection, and there is no technical common sense that optional protein derived from microorganisms has a function to induce such neutralizing antibodies.

Considering the technical common sense upon filing the application, there is no specific description evidencing that the protein can be used for providing vaccines or passive immunization, and it is not presumed that the protein of the Invention can be used for providing vaccines or passive immunization.

Therefore, in the detailed description of the invention, there is no description that a person skilled in the art can use the protein of the Invention.

(3) Appellant's allegation

The appellant alleges in Response letter that the experimental result that excellent protection effect of protein of the Invention was confirmed is disclosed in Evidence A No. 1 (National Publication of International Patent Application No. 2010-538634 (filed on September 12, 2008)), which is a patent application filed after filing of the present application.

However, in a case where the description of the detailed description of the invention is not so clear and sufficient that a person ordinarily skilled in the art can carry out the claimed invention even taking into consideration the technical common sense upon filing of the application, it is not permitted that experimental data are submitted after the application, the description of the detailed description of the invention is supplemented and expanded, and therefore, the application does not comply with the enablement requirement, due to violation of purpose of the patent

system in which a patent is granted as a prerequisite for disclosing the invention under the first-to-file principle, and the appellant's allegation described above cannot be accepted.

2. Article 36(6)(i) of the Patent Act

According to the description of paragraphs [0007], [0008] and the like of the Description, it is found that the problem to be solved by the Invention is to provide protein capable of being used for development of vaccines effective for infection with S. agalactiae or S. pyogenes.

However, according to the description of the detailed description of the invention in the Description described in No. 3-1 and the technical common sense upon filing the application, the Invention is not described in the detailed description of the invention so that a person ordinarily skilled in the art can recognize that problems of the Invention can be solved.

No. 4 Conclusion

As described above, relating to the invention according to Claim 1 of the present application, the application does not meet the requirement under the provisions of Article 36(4) and Article 36(6)(i) of the Patent Act, the appellant should not be granted a patent for the invention, and thus should be rejected, without examining inventions relating to other claims.

June 23, 2015

Chief administrative judge: IMAMURA, Reeko
Administrative judge: IIMURO, Satomi
Administrative judge: KORIYAMA, Jun