Patent Right	Date	December 27, 2018	Court	Intellectual Property High Court, Fourth Division
	Case number	2017 (Gyo-Ke) 10226		
- A case in which, with regard to a patent titled "ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)", the court determined that it did not lack inventive step, nor does it violate the provision of the support requirement or the enablement requirement.				

Case type: Rescission of Trial Decision to Maintain

Result: Dismissed

References: Article 29, paragraph (2), Article 36, paragraph (4), item (i), and Article 36, paragraph (6), item (i) of the Patent Act

Number of related rights, etc.: Patent No. 5906333

Summary of the Judgment

The present case is a case of seeking rescission of a JPO decision that dismissed claims for invalidation trial according to Claims 1 and 5 of Patent (Patent No. 5906333), titled "ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)". In the present case, Plaintiff argued about the errors in the determination of inventive step, nonconformance to the support requirement, and nonconformance to the enablement requirement as a ground for rescission.

In summary, the court decision has made the following determination and dismissed the Plaintiff's claims.

1. Errors in the determination of inventive step

A person skilled in the art who reads Exhibit Ko 1 would be motivated to obtain binding neutralizing antibodies of PCSK9 and LDLR, and could have obtained certain monoclonal antibodies (the constitution of Corrected Invention 1 according to different feature A) capable of neutralizing the binding of PCSK9 and LDLR, on the basis of Exhibit Ko 1 and well-known techniques.

On the other hand, in producing an antibody with an animal immunization method, it is common technical knowledge that antibodies with different reactivities against an antigen may be obtained by the difference in "an infusion condition" including the selection of animals, a dosage amount, and a dosage form of an antigen, the use of immunization adjuvant, the infusion route and times, and an interval between infusions. It is recognized that an antibody produced from an immunized mouse that is immunized according to an immunization program described in the description and

an antibody produced from an immunized mouse that is immunized according to an immunization program with different conditions and a different schedule from the above has different reactivities against PCSK9.

Therefore, it is recognized that it takes trials and errors that go beyond the extent that could be usually expected to optimize a condition and a schedule of an immunization program and produce an immunized mouse suitable for obtaining a reference antibody.

Further, the use of transgenic mouse for the manufacture of human antibody and a method of immobilizing an antigen by biotinylation for screening an antibody were well-known as of the priority date in a process of producing a monoclonal antibody; however, a certain level of originality is required in constructing a screening system suitable for obtaining a reference antibody from a hybridoma produced by use of the above immunized mouse by utilizing these techniques.

However, Exhibit Ko 1 fails to describe or suggest a condition and a schedule of immunization program described in the description. First of all it fails to describe a method for producing an antibody that inhibits the binding of PCSK9 and LDLR.

Therefore, a person skilled in the art who read Exhibit Ko 1 could not have easily conceived of obtaining a reference antibody on the basis of Exhibit Ko 1 and well-known techniques. It cannot be recognized that an antibody "competing with" the reference antibody (the constitution of Corrected Invention 1 according to different feature B) was easily conceivable.

2. Error in the determination of nonconformance to the support requirement

A person skilled in the art who read the description could recognize that various neutralizing antibodies competing with the reference antibody included in the scope of the claims of the Corrected Invention 1 (Claim 1) other than neutralizing antibodies competing with the reference antibody in the description might be obtained by repetitively implementing the manufacture and selection of immunized mouse in accordance with a procedure and a schedule of immunization program in the description, the hybridoma generation in which a selected immunized mouse is used, a screening, and an epitope binning assay for identifying an antibody that strongly blocks a binding interaction between PCSK9 and LDLR in the description from the start.

Therefore, it is recognized that Corrected Invention 1 (Claim 1) conforms to the support requirement.

Further, in view of the description that it may be therapeutically beneficial since it

may treat or prevent the diseases or reduce the risk of the diseases associated with increased cholesterol level such as hypercholesteremia, it can be seen from the description that a person skilled in the art can use an antibody of Corrected Invention 1 as a pharmaceutical composition.

Therefore, it is recognized that Corrected Invention 5 (Claim 5) conforms to the support requirement.

3. Error in the determination of nonconformance to the enablement requirement

It can be seen from the description that an antibody of Corrected Invention 1 and a pharmaceutical composition of Corrected Invention 5 may be produced and used. Therefore, the Detailed Description of the Invention of the description is clear and sufficient to enable a person skilled in the art to work Corrected Inventions 1 and 5.

Therefore, it is recognized that Corrected Inventions 1 and 5 conform to the enablement requirement.