

Patent Right	Date	September 28, 2023	Court	Tokyo District Court, 47th Civil Division
	Case number	2020 (Wa) 8642		
- A case in which in a patent infringement lawsuit concerning two patents for inventions titled "ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)," it was held that the patents violate the support requirement and the enablement requirement.				

### Summary of the Judgment

The present case is one in which the Plaintiff, who holds patent rights under two patents for inventions titled "ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)" (the Present Patents), claims compensation for damages based on a tort of infringement of the patent rights against the Defendant that is engaged in the sale, etc. of the Defendant's product.

The issues of the present case are wide-ranging. Among the issues, on the basis of such circumstances as the fact that the Present Inventions encompass an EGFA mimic antibody (binding-neutralizing antibody that recognizes most of 15 core residues of PCSK9) and that the Plaintiff acknowledges that the EGFA mimic antibody cannot be obtained even after about four years from the filing date of the Present Patent, and states that finding the EGFA mimic antibody would not be a straightforward task, this judgment determined that the Present Patents violate the support requirement and the enablement requirement, and dismissed the Plaintiff's claims, on the grounds that it can be recognized that the present description does not state the EGFA mimic antibody and the specific method for producing it and that a person ordinarily skilled in the art cannot produce this EGFA mimic antibody by the statement of the present description and the common general technical knowledge at the time of filing the present patent application.

The Plaintiff asserted that it cannot be determined that the Present Patents violate the support requirement and the enablement requirement on the grounds that the EGFA mimic antibody that had never been recognized as a problem at the time of filing the application is not stated in the present description, because the patent system in our country does not require providing a means for solving the problem that did not exist at the time of filing the application. This judgment held that "even on the premise of the Plaintiff's assertions, protecting the Present Inventions as patented inventions in spite of the fact that the problem to be solved in the future, which is to produce the EGFA mimic antibody, and a structure of a means for solving the problem are not stated in the present description and cannot be considered to be made open to the public does not comply with the purpose and objective of the patent system in which a

patent right is granted in return for making an invention open to the public. Thus, protecting the Present Inventions as patented inventions in spite of the above fact is not reasonable. This is even more so considering that even the Plaintiff, who is a patentee, cannot have obtained the EGFa mimic antibody encompassed in the Present Inventions."