Therapeutic Antibody Invention Claimed by Functional Limitations: Intellectual Property High Court Ruled the Claim Did Not Fulfill the Support Requirement
Judgment of the Intellectual Property High Court, Fourth Division on January 26, 2023 (2021 (Gyo-Ke) 10093, 10094; "Antibody Preparation Case")

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The Judgment
Judgment of the Intellectual Property High Court, Fourth Division on January 26, 2023 (2020 (Gyo-Ke) 10093, 10094), Case seeking, inter alia, rescission of the JPO decision
Plaintiff: Regeneron Pharmaceuticals, Inc.
Defendant: Amgen Inc.

1. Outline of the Case

In the past, typical contentious cases on patents related to pharmaceuticals arose between original drug pharmaceutical companies and generic pharmaceutical companies. However, recently, they have become more complicated. There are patent disputes between original drug pharmaceutical companies (for example, in cases where, since a broad range of compounds are specified in a Markush claim, pharmaceutical compounds of other generic pharmaceutical companies that are not worked by themselves are included in the claim) and patent disputes between generic pharmaceutical companies (for example, with the entry of a new generic, a patent is obtained in order to add value and other generics come into conflict with the generic). In addition, typical pharmaceuticals were mainly small molecule organic compounds; recently, however, a type of polymer consisting of mainly 20 kinds of amino acids (proteins), are used as therapeutic antibodies, and are drawing attention.[1,2] Compared with previous small molecule compounds, the 3D structure of an antibody has a shape conforming to binding with specific antigens. Therefore, antibodies have the following advantages: strong neutralizing effect (therapeutic efficacy) can be expected against specific antigens; development of a new drug can be achieved in a relatively brief period of time; and mass production is relatively easy with the biosynthetic method using gene encoding of its amino acid sequence and enzymes promoting the expression.[3] The building blocks of therapeutic antibodies are mainly the 20 types of amino

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acids. Assuming the polymerization degree is n, there are 20^n patterns of combinations by a simple calculation. From the perspective of patent practice, a considerable number of kinds of antibodies can be included in the scope of right, including those for which the characteristics cannot be predicted at the time of filing the patent application, and those for which the sequence is very different than what is described in the working example, depending on the way the claims are specified. Therefore, it is a field where it is difficult to adjust the interests between a patentee and a third party.

This case is related to the invention of a therapeutic antibody with an aim of treating hypercholesterolemia by using an antibody with the specific function of inhibiting binding between proprotein convertase subtilisin/kexin type 9 (PCSK9), which is involved with the homeostasis of serum cholesterol, and low-density lipoprotein receptor (LDLR).

This litigation (hereinafter the "Litigation") is a case seeking rescission of the trial decision for invalidation. The Plaintiff (demandant of the trial) is Regeneron Pharmaceutical Inc. (hereinafter "Regeneron") and the Defendant (patentee) is Amgen Inc. (hereinafter "Amgen"). This case originally arose as a dispute between the original drug pharmaceutical companies, Amgen and Sanofi K.K. (hereinafter "Sanofi"). In other words, Amgen and Sanofi sold therapeutic antibodies related to the aforementioned PCSK9 respectively in the U.S., Europe, Japan, and other countries. However, since the products of Sanofi conflicted with patents held by Amgen (the claim language differs by jurisdiction, however, the claims share in common that a broad range of antibodies are covered through the use of functional claim language), it resulted in infringement lawsuits, oppositions to the decisions of invalidation trials, and other disputes in each jurisdiction. Among the above, the dispute between Amgen and Sanofi in Japan is summarized below.

January 18, 2016: Sanofi requested a trial of invalidation against Patent No. 5705288 held by Amgen (hereinafter referred to as "'288 patent") (Invalidation Case No. 2016-800004).

May 31, 2016: Sanofi requested a trial of invalidation against Patent No. 5906333 held by Amgen (hereinafter referred to as "'333 patent") (Invalidation Case No. 2016-800066).

March 9, 2017: Advance notice of a trial decision to invalidate both '288 patent and '333 patent by the Japan Patent Office (hereafter referred to as "JPO").

May 8, 2017: Request for correction of claims of '288 patent and '333 patent by Amgen (hereinafter, collectively referred to as the "Correction" in some cases). The claims after the correction read as follows:

('288 patent)
"[Claim 1] An isolated monoclonal antibody, which can neutralize the binding of PCSK9 and LDLR protein and, concerning the binding with PCSK9, which competes with an antibody that is comprised of a heavy chain containing a heavy chain variable region consisting of an amino acid sequence, Sequence No. 49, and a light chain containing a light chain variable

region consisting of an amino acid sequence, Sequence No. 23.
[Claim 9] A pharmaceutical composition containing the isolated monoclonal antibody stated in Claim 1."

('333 patent)
"[Claim 1] An isolated monoclonal antibody, which can neutralize the binding of PCSK9 and LDLR protein and, concerning the binding with PCSK9, which competes with an antibody that is comprised of a heavy chain containing a heavy chain variable region consisting of an amino acid sequence, Sequence No. 67, and a light chain containing a light chain variable region consisting of an amino acid sequence, Sequence No. 12.
[Claim 5] A pharmaceutical composition containing the isolated monoclonal antibody stated in Claim 1."

* "An antibody that is comprised of a heavy chain containing a heavy chain variable region consisting of an amino acid sequence, Sequence No. 49, and a light chain containing a light chain variable region consisting of an amino acid sequence, Sequence No. 23" related to '288 patent may be referred to as "21B12 antibody" or "reference antibody," and "An antibody that is comprised of a heavy chain containing a heavy chain variable region consisting of an amino acid sequence, Sequence No. 67, and a light chain containing a light chain variable region consisting of an amino acid sequence, Sequence No. 12" related to '333 patent may be referred to as "31H4 antibody" or "reference antibody" in some cases.

August 2, 2017: Decision of the trial that approved all the aforementioned corrections and maintained the patent (hereinafter referred to as the "first trial decision" in some cases).

December 8, 2017: Sanofi filed litigation to rescind the trial decisions before the IP High Court requesting rescission of the aforementioned trial decisions (Intellectual Property High Court, 2017 (Gyo-ke) 10225, 10226).

December 27, 2018: The IP High Court dismissed all requests of Sanofi (the judgment denied the existence of all grounds for rescission alleged by Sanofi (error in the determination of an inventive step, error in the determination of support requirements, error in the determination of enablement requirements); hereinafter referred to as the "first judgments" in some cases). Subsequently, Sanofi filed a petition for acceptance of a final appeal.

April 24, 2000: The Supreme Court decided to reject the final appeal and all the aforementioned judgments became final and binding.

In 2017, the year after requesting the trial, Amgen filed patent infringement litigation requesting an injunction against the antibody product imported and sold by Sanofi. Both the first instance (the Tokyo District Court, 2017 (Wa) 16468; the judgment rendered on January 17, 2019) and the second instance (the IP High Court, 2019 (Ne) 10014; the judgment rendered on October 30, 2019) determined that Amgen won the case. In response to the judgments, Sanofi filed a petition for acceptance of final appeal.

However, the Supreme Court also decided to reject the final appeal (2000 (Ju) 166, April 24, 2000) and the aforementioned judgment became final and binding (however, the case requesting compensation for damages related to the same antibody product was filed after the request for injunction, and, therefore, it is still pending at the first instance (the Tokyo District Court)).

The trial for invalidation and the litigation requesting rescissions of the trial decisions between Regeneron and Amgen in this case have different parties than the aforementioned disputes formally; however, since Regeneron was a joint development company of Sanofi concerning the aforementioned antibody preparation, Regeneron and Sanofi are in the same position with respect to the contentious cases and, therefore, Regeneron is eligible to request the trial.[4] The litigation counsel for Regeneron are also almost the same members as the litigation counsel for Sanofi in the contentious case, as well as the counsel for Amgen.[5] Based on the above, the Litigation could be viewed as a revenge trial by Sanofi related to the dispute. However, the litigation claiming compensation for damages by Amgen from Sanofi was also pending at the Tokyo District Court almost at the same time as the Litigation and the patent invalidity defense (Article 104-3 of the Patent Act) on the grounds of invalidation was alleged for the same grounds. Thus, the Litigation is perhaps more nearly an overtime dispute between Amgen and Sanofi. The background to the Litigation is presented below.

First, on February 12, 2020, Regeneron requested a trial for invalidation based on the violation of support requirements (hereinafter referred to as the "Trial") concerning '288 patent and '333 patent (related to the Correction).[6] Concerning the allegation of violation of support requirements in this case, there were written statements from Dr. André Frenzel and from Dr. Lutz Reichmann, etc. as new evidence that was not submitted in the aforementioned disputes. In these written statements, the following knowledge that is different than the facts used as the basic facts in the aforementioned disputes was stated: An antibody competing with the 21B12 antibody and the 31H4 antibody does not necessarily have the same function (function neutralizing the binding of PCSK9 and LDLR protein) as those do, among other matters. For this, the JPO examined them as Invalidation No. 2020-800011 and -800012; however, the JPO decided that the request for trial is groundless as of April 7, 2021 (hereinafter collectively referred to as the "Trial Decision") without conducting oral proceedings. In response to these trial decisions, Regeneron filed the Litigation requesting rescission of the Trial Decision (2021 (Gyo-ke) 10093, 10094) on August 13, 2021. The aforementioned are the details of this case.

It is noteworthy that this judgment (hereinafter the "Judgment") reached a different conclusion than the Trial Decision and the first judgment, and so this article will focus on the grounds for invalidation of the violation of support requirements, etc., the interpretation of functional claim language, etc., in the following section and after (the same decision was made for both '288 patent and '333 patent; the trial decision on invalidation No. 2020-800011 for '288 patent and the judgment of 2021 (Gyo-ke) 10093 are mainly introduced here). In

addition, similar disputes have also occurred in the U.S. and Europe. In particular, since a similar issue to the Litigation was argued at the U.S. Supreme Court,[7] the relationship between the Judgment and the judgments in the U.S. and Europe is also briefly discussed.

2. Introduction of the Judgment

2-1 Outline of the Trial Decision

In invalidation trials, oral proceedings are usually held; however, without even holding oral proceedings, the Trial Decision was issued in which the grounds for invalidation alleged by Regeneron were determined to be without merit, and thus the request for invalidation was without merit.[8] An important issue in the decision concerned support requirements, and these are pointed out below (see text underlined by the author).

> (Trial Decision, p. 22, line 9 from bottom - p. 23, line 5 from bottom)
> "B. Conformity to the support requirement
>
> As mentioned in No. 2 (author's note: it is internal reference of the decision that is not included in this article) above, the Patented Invention is 'an isolated monoclonal antibody,' which has both the characteristic that it 'can neutralize the binding of PCSK9 and LDLR protein' (invention-specifying matter) and the characteristic that it 'competes for binding to PCSK9 with 21B12 antibody (invention-specifying matter), and 'a pharmaceutical composition thereof.' According to the statements in the Description (A (A) and (F) above), the issue of the Patented Invention can be understood as follows: the binding of PCSK9 and LDLR is neutralized and LDLR amount is increased by providing the aforementioned new antibody and producing the pharmaceutical composition thereof; thereby, it shows the effect of decreasing serum cholesterol in the subject, treats or prevents diseases related to increased cholesterol levels, such as hypercholesterolemia, etc., and reduces disease risks.
>
> On the other hand, the Description expressly discloses the method for producing anti-PCSK9 monoclonal antibody (producing immunized mice, producing hybridoma using immunized mice), the method for screening antibodies that neutralize the binding of PCSK9 and LDLR, and the screening method for identifying antibodies that compete with 21B12 antibody (A (G), (H), and (I)). The working examples disclose the results of two independent experiments that were conducted: hybridoma producing antibodies that strongly neutralize the binding of PCSK9 and LDLR were selected from among those obtained by injecting human PCSK9 antibody in mice in two groups containing human immunoglobulin genes, and epitope binning of said antibodies. In Working Example 10 (A (J) and (K) above), from among 32 antibodies that neutralized the binding of PCSK9 and LDLR, there were 19 antibodies (59%) competing with 21B12 antibody (Bin 1). In Working Example 37 (A (L) and (M) above), from among 39 antibodies that neutralized the binding of PCSK9 and LDLR, there were 22 antibodies (56%) competing with 21B12 antibody (Bin 1 and Bin 2). As mentioned above, <u>in the</u>

Description, it is expressly disclosed that by conducting two kinds of screening: a screening to select an anti-PCSK9 monoclonal antibody that 'can neutralize the binding of PCSK9 and LDLR' and a screening to select an antibody that 'can complete with 21B12 antibody,' multiple antibodies in the Patented Invention can be identified repeatedly at a fully high percentage. In addition, the Description discloses a mechanism of action whereby the amount of LDLR increases due to neutralization of the binding of PCSK9 and LDLR, and serum cholesterol in the subject is decreased (A (F) above). Therefore, it can be reasonably recognized that an antibody according to the Patented Invention having the characteristic that it 'can neutralize the binding of PCSK9 and LDLR protein' has the effect of reducing serum cholesterol in the subject and can be used to treat or prevent diseases related to increased cholesterol, such as hypercholesterolemia, etc., and to reduce disease risks.

Consequently, it can be found that a person skilled in the art can recognize, based on the statements in the Description, that an antibody according to the Patented Invention can resolve the aforementioned issues and that the Patented Invention is within the scope of the description. Therefore, the Patent conforms to the support requirements."

(Trial Decision, p. 23, line 4 from bottom - p. 24, line 2 from bottom)

"C. Grounds for Invalidation 1-1

The demandant alleged that the issue to be resolved in the Patented Invention is a well-known issue to provide an antibody that neutralizes the binding of PCSK9 and LDLR, while the structure of the Patented Invention is only an 'antibody competing with 21B12 antibody.' The demandant also alleged that the support requirement is not fulfilled when the description states only that a person skilled in the art can understand that 'if an antibody competes with a 21B12 antibody, then, with high probability, it neutralizes the binding of PCS9 and LDLR.'

However, the Patented Invention is as stated in No. 2 above. The characteristic (invention-specifying matter) 'which can neutralize the binding of PCSK9 and LDLR protein' and the characteristic (invention-specifying matter) 'which competes with 21B12 antibody' are individual invention-specifying matters related to the characteristics of the 'antibody' stated independently and in parallel with identifying the product invention of an 'antibody.' Therefore, in order for this case to conform with the support requirements, as determined in B. above, it is enough to state in the description that it is a 'monoclonal antibody' which has both characteristics 'which can neutralize the binding of PCSK9 and LDLR protein' and 'which competes with 21B12 antibody.' The aforementioned allegation of the demandant which relates the two different invention-specifying matters mentioned above in a way of issues and structures or in the form of results and causes, are not based on the statement in claims and, therefore, it cannot be adopted.

The Demandant alleges that it is wrong also from the scientific perspective that 'if it is an antibody competing

with 21B12 antibody, it is highly probable to be an antibody neutralizing the binding of PCSK9 and LDLR' in view of the testing reported in the written statement (1) of Dr. Frenzel (Exhibit Ko 2-1) that out of 13 antibodies that compete with 21B12 antibody (approximately 80%) that were known art, 10 antibodies could not neutralize the binding of PCSK9 and LDLR, and also according to the written statement (1) of Dr. Reichmann (Exhibit Ko 2-2) that referred to the testing results. However, as stated above, the results of the testing in the written statement (1) of Dr. Frenzel (Exhibit Ko 2-1) and the written statement (1) of Dr. Reichmann (Exhibit Ko 2-2) related thereto do not affect the conformity to the support requirement in this case. Rather, the results of the aforementioned testing support that this case conforms to the support requirement. In other words, the aforementioned testing shows that 3 (23%) out of 13 antibodies competing with 21B12 antibody that were screened from anti-PCSK9 monoclonal antibody, which were produced in the same method as the one stated in the Description, neutralized the binding of PCSK9 and LDLR. This demonstrates that multiple antibodies in the Patented Invention can be fully obtained at high probability even if the order of the screening of antibodies 'which can neutralize the binding of PCSK9 and LDLR' and the screening of antibodies 'which compete with 21B12 antibody' is reversed from the working example stated in the Descriptions.

Consequently, even if the content of the written statement (1) of Dr. Frenzel and the written statement (1) of Dr. Reichmann were examined, the Patent does not violate the support requirements due to the Grounds for Invalidation 1-1."

As mentioned above, the Trial Decision determined that the Description can be read to identify multiple antibodies in the Patented Invention repeatedly by conducting two kinds of screening, including the screening of monoclonal antibodies neutralizing the binding of PCSK9 and LDLR and the screening to select antibodies competing with 21B12 antibody, that this can achieve the objective to treat diseases related to the increased cholesterol level, such as hypercholesterolemia, etc., and that, therefore, it fulfills the support requirements. In addition, concerning the relation between the elements of the Invention, "which can neutralize the binding of PCSK9 and LDLR protein" and "which competes with 21B12 antibody," the Trial Decision determined that they are different invention-specifying matters that are stated independently and in parallel to identifying the product invention of an "antibody," and, therefore, if the Description describes a "monoclonal antibody" that has both characteristics, it fulfills the support requirements.

2-2 Decision in the Judgment

In the Litigation, it was determined that the Trial Decision had an error with regard to the support requirements, as further explained below, that affected the conclusions, and thus the trial decision was rescinded (see text underlined by the author).

(Judgement, p. 71, line 16 - p. 79, line 5)
"the term 'neutralize' in the present invention includes an aspect of altering a binding ability of PCSK9 to LDLR protein through indirect means (such as structural or energetic alterations in the ligand) in addition to interfering with, blocking, reducing, or modulating the interaction between PCSK9 and LDLR protein by directly blocking the protein binding site. However, as mentioned in 1(1) above, the reference antibody itself can be acknowledged as a neutralizing antibody which sterically interferes with binding between PCSK9 and LDLR protein and which strongly blocks the binding. On this basis, it should be deemed that the invention-specifying matter of "which competes for binding to PCSK9 with 21B12 antibody" in the present invention also has a technical significance in that it is revealed that an antibody which competes with the 21B12 antibody interferes with, blocks, reduces, or modulates the interaction between PCSK9 and LDLR protein by directly blocking the binding site of LDLR protein (specifically, by the antibody binding to PCSK9 at a position which overlaps with a position of the EGFa domain of LDLR in the crystal structure) by a mechanism similar to that of the 21B12 antibody. Conversely, it can also be deemed that precisely because an antibody which competes with the reference antibody binds at such a position, it makes neutralization possible. (...) In addition, according to the disclosures of the Exhibit Ko 1 document as found in 1(2) above, familial hypercholesterolemia results from elevated LDL cholesterol levels in plasma. In this regard, since PCSK9 reduces the abundance of LDLR protein present on cell surfaces, it can be found to have already been shown that PCSK9 is an attractive target for the treatment and that antibodies or the like which bind to PCSK9 in plasma and which inhibit its binding to LDLR protein can be effective inhibitors. Thus, from these points of view as well, the technical significance of the present invention can also be deemed to lie in the point that it has been identified that an antibody which competes with 21B12 antibody has a functional property as an antibody which inhibits the binding to LDLR protein as mentioned above by a mechanism similar to that of the 21B12 antibody; i.e., a binding neutralizing antibody. (...) Further, it is obvious that an antibody having a property 'which competes for binding to PCSK9 with a reference antibody' of the present invention encompasses a very wide variety of antibodies in addition to several groups of antibodies specifically stated in the Detailed Description of the Invention in the present description mentioned above. Furthermore, as mentioned in 2(3)B above, the antibody of the present invention encompasses not only an antibody which prevents or inhibits (e.g., reduces) specific binding of the reference antibody by binding to a site which overlaps with a site on PCSK9 where 21B12 antibody binds to PCSK9, but also an antibody which prevents or inhibits (e.g., reduces) specific binding of the reference antibody to PCSK9 in various degrees by binding to PCSK9 in a manner that sterically interferes with binding between the reference

antibody and PCSK9, as the Defendant asserts. Then, the antibodies mentioned above can include, for example, an antibody which prevents or inhibits (e.g., reduces) specific binding of the 21B12 antibody to PCSK9 by binding to a site which differs from a site where the 21B12 antibody binds to PCSK9 and which differs from a position of EGFa domain of LDLR in the crystal structure and bringing minor steric hindrance to the 21B12 antibody. However, a site where such an antibody binds to PCSK9 is not a position where the antibody overlaps with a position of EGFa domain of LDLR in the crystal structure. Thus, such an antibody cannot be deemed to interfere with, block, reduce, or modulate the interaction between PCSK9 and LDLR protein by directly blocking the binding site of LDLR protein. (...) as mentioned above, it cannot be deemed that an antibody which competes with 21B12 antibody would not directly block the binding site between PCSK9 and LDLR protein by binding to the site where the antibody interacts with the EGFa domain of LDLR. (...) Other than the above, there is no disclosure on the mechanism by which any antibody which competes with 21B12 antibody will be an antibody which inhibits the interaction (binding) between PCSK9 and the EGFa domain of LDLR (and/or LDLR in general). Therefore, it can only be deemed to be difficult for a person ordinarily skilled in the art to arrive at the understanding that an antibody which competes with 21B12 antibody is a binding-neutralizing antibody. (...) These points are supported by the results of the demonstration experiment by Dr. [A], the reliability of which has been acknowledged in 1(3) above, and Affidavit (1) by Dr. [B] based on the same demonstration experiment. That is, in this demonstration experiment, 63 antibodies of Regeneron were tested for competition with the reference antibody and their binding-neutralizing activity. As a result of using a threshold value of 50% for competition, it was confirmed that 13 antibodies competed with the reference antibody, among which 10 antibodies (about 80%) had no binding-neutralizing activity (Material B1 of Attachment 3 and 1(3)A(B)b above). Thus, the specific experimental result demonstrates that it cannot be deemed that an antibody which competes with the reference antibody has a binding-neutralizing activity. Further, in addition to this experimental result, Dr. [B] (...) provides an opinion that it is scientifically erroneous to state that 'an antibody which competes with 21B12 antibody' would 'neutralize binding to LDLR' (1(3)A(B)c above).

E. The Defendant asserts in No. 3, 3(2)C above that there is no reason why the present invention violates the support requirement, on the grounds that even if there exists an antibody which competes with 21B12 antibody (a reference antibody) but which cannot neutralize binding between PCSK9 and LDLR protein, such an antibody is literally excluded from the technical scope of Present Invention 1. However, as already explained, the technical significance of the present invention should be deemed to lie in the point that it has been identified that an antibody which competes with 21B12 antibody has a functional

property as an antibody that neutralizes binding between PCSK9 and LDLR protein by a mechanism similar to that of the 21B12 antibody. If an antibody that competes with 21B12 antibody includes one that does not have a binding-neutralizing activity, it is apparent that the assumption of its technical significance will collapse. (In an instance like the present case, if it were interpreted to be sufficient to literally exclude an antibody that does not have a binding-neutralizing activity, it would be allowed to make a very broad definition of a position where the antibody binds to PCSK9, such as most of PCSK9, which would allow the scope of claims to be made broad without a justifiable basis. Therefore, such an interpretation is not reasonable.) In addition, even if it is interpreted that the scope of claims of Present Invention 1 is, as asserted by the Defendant, directed to only an antibody which "can neutralize binding between PCSK9 and LDLR protein" among antibodies which compete for binding to PCSK9 with a reference antibody, the invention-specifying matter of that which competes for binding to PCSK9 with a reference antibody according to the present invention is not limited to an antibody which binds to a position that is the same as or overlaps with a position where the reference antibody binds as asserted by the Defendant, but also includes an antibody which competes in a manner that binds to a position for steric interference with the binding between PCSK9 and LDLR protein to occur, as explained above. Thus, it must be supported that such an antibody is also a binding-neutralizing antibody. In this regard, unlike the case of an antibody which binds to a position that is the same as or overlaps with a position where the reference antibody binds, the present description does not state anything about a mechanism by which an antibody neutralizes the binding between PCSK9 and LDLR protein in which the antibody competes in a manner that binds to a position for steric interference with the binding to occur. In addition, binding-neutralizing antibodies based on experimental results by binning ((4)B(B) above) are all likely to be antibodies which bind to a position that is the same as or overlaps with a position where the reference antibody binds, whose mechanism on binding-neutralizing is disclosed. Even if this point is excluded, at least, the present description does not state anything to suggest that these are sterically interfering antibodies. Thus, it must be deemed that the Detailed Description of the Invention in the present description does not disclose anything about the fact that among antibodies which compete with a reference antibody, when an antibody competes in a manner that binds to a position for steric interference with the binding between PCSK9 and LDLR protein to occur, the antibody has a binding-neutralizing activity. From this point as well, the present invention does not comply with the support requirement.

Further, as mentioned in No. 2, 3(1) above, the trial decision of the present case determines that the present description specifically demonstrates that a number of antibodies of the present invention are repeatedly identified with sufficiently high proba-

bility by performing the preparation and selection of immunized mice according to the procedure and schedule of the immunization program as stated in the present description, the production of hybridomas using the selected immunized mice, and the screening and epitope binning assay for identifying an antibody which strongly blocks the binding interaction between PCSK9 and LDLR as stated in the present description from the beginning, repeatedly. However, as the second Expert Opinion by Professor [F] (referred to as Professor [F]) (Exhibit Ko 230) states: 'It is impossible to generate and screen all possible candidate antibodies, because whether a particular mouse generates a particular antibody is controlled by luck,' even if the production process of antibodies stated in the present description has been undergone, it is "controlled by luck" what position on PCSK9 an antibody obtained in an immunized mouse will bind to. Also, it cannot be deemed that a method of producing an antibody which binds to an antigen protein in a manner that sterically interferes with binding of the antibody to the antigen protein was common general technical knowledge at the time of filing of the present application. Therefore, on the basis of the statement on a method of producing an antibody as stated in the present description, it cannot be deemed that various antibodies encompassed in the present invention were stated in the Detailed Description of the Invention in the present description.'

As mentioned above, the Judgment focused on the fact that it was publicly known that antibodies, etc. binding to PCSK9 in plasma and inhibiting the binding with the LDLR protein can be an attractive target for familial hypercholesterolemia, and the technical significance of the Invention is that it has identified that the antibody has a functional property as the aforementioned antibody which neutralizes the binding of PCSK9 and LDLR protein by a mechanism similar to that of the 21B12 antibody. In addition, the Judgment deems that the relationship between the element of the Invention, "which can neutralize the binding of PCSK9 and LDLR protein," and the element, "which competes with 21B12 antibody," are not distinct invention-specifying matters, but rather the element, "which competes with 21B12 antibody," is a means of obtaining the effect, "which can neutralize the binding of PCSK9 and LDLR protein." In this regard, the Judgment differs significantly from the Trial Decision.

3. Examination of the Judgment

3-1 Comparison of decisions between the Judgment and the Trial Decision

The Invention is related to an isolated monoclonal antibody comprising the element, "which can neutralize the binding of PCSK9 and LDLR protein," and the element, "which competes with 21B12 antibody" and both elements define functional features, and the Invention is deemed to be related to a typical "functional claim" that is characterized by having no limit on the specific structure, such as the amino acid sequence. In particular, the element, "which can neutralize the binding of PCSK9 and

LDLR protein," is equivalent to specifying the technical issue and the effects themselves of the Invention. Therefore, how to deem the relationship between that element and an element, "which competes with 21B12 antibody," becomes very important. In this regard, the Trial Decision deemed them to be different and independent elements and determined that it is enough if the "monoclonal antibody" that has both elements is the one stated in the descriptions. On the other hand, the Judgment deemed the relationship to be the relationship between objective and means, and interpreted that it is necessary for it to be acknowledged that competing with 21B12 antibody results in the function of neutralizing the binding of PCSK9 and LDLR protein. This is a significant point to cause different decisions.

In this regard, the Trial Decision focused on whether it is possible to obtain a monoclonal antibody that has the structure of the Invention when making a decision on the support requirement. However, the question remains that, although it is a product invention (unless it is an invention of a manufacturing method), the technical meaning of the element, "which competes with 21B12 antibody" was hardly examined at all. In addition, the Trial Decision determined regarding the decision on an inventive step that "Even a person skilled in the art cannot arrive at obtaining a monoclonal antibody which competes with 21B12 antibody. Therefore, it cannot be deemed that Invention 1, comprising the invention-specifying matter 'which competes with 21B12 antibody,' could have easily been made by a person skilled in the art on the basis of the Exhibit Ko 1 invention and well-known art." The Trial Decision focused on the element "which competes with 21B12 antibody," but did not fully examine the technical significance as a means of resolving it. In this regard, the appropriateness of the decision is also questioned. Therefore, the author considers that the decision in the Litigation, which looked to the nature of the invention, considered the state of the technical art and statements in the Description, and made reasonable interpretations of the technical significance of each element, is more appropriate.

In the following sections, some of the legal issues related to the Litigation are examined, primarily with regard to the interpretation of functional claims.

3-2 Interpretation of the functional claim

In principle, a patented invention should be defined by stating the technical elements by which the technical issues may be resolved.[9] However, there are patented inventions where the means of resolving the technical issues are not expressly stated, but instead their function or resolution results are specified. That is called a "functional claim" (or a "desire claim" in some cases).

As an extreme example, consider the invention of an automobile that, using a special engine, can be driven at a speed of 500km/h. If the claim recites "an automobile that can be driven at a speed of 500km/h" and it is interpreted literally, even if another person develops an automobile that can be driven at a speed of 500km/h by an engine with a totally different mechanism than said engine or by means other than an engine, it would infringe the patent. If such a claim is allowed without limitation and an exclusive right is granted to the overall vehicle

structure that has the function or capability (i.e., can be driven at a speed of 500km/h), this would result in the grant of an unreasonably broad range of protection, exceeding the range of what was actually invented. Needless to say, such a result is contrary to the system and purport of the Patent Act, which is intended to harmonize the protection and use of inventions.

One famous court precedent where this point was clearly determined was the judgment of the Tokyo District Court on December 22, 1998 (Case No.: 1996 (Wa) 22124; "Magnetic Medium Reader Case"). In this case, the court determined as follows: "From among the claim for utility model registration related to constituent feature F, the statement that 'when the aforementioned magnetic head is in a descended position, it controls the pivoting of the magnetic head,' only stated the purpose of this device that 'even if a magnetic head stops at a home position or end position, the device can set the magnetic head in a normal position.' It only expresses the function or the effects to be achieved by the magnetic medium reader in the Device by using an abstract expression, 'pivot control means.' Therefore, it does not define the specific structure necessary for achieving the purpose and effects of the Device. As mentioned above, in cases where the structure of the device recited in the claim of a utility model registration is stated using a functional, abstract expression, if it is construed that any structure capable of fulfilling said function or effect is within the technical scope, this would result in the inclusion of structures that belong to a technical idea that has not been disclosed in the description of the technical scope of the device, and it may grant protection under the utility model right that exceeds the scope of what the applicant devised. Causing such a result is against the principle underlying the Utility Model Act, which is that the exclusive right of a creator arising from the utility model right is granted in compensation for disclosure of the device to public" (underlined by the author). It stated that even if the structure stated in a functional, abstract expression has the structure formally, rights should not be granted that exceed the scope of the structure under the technical idea that is disclosed in the description.[10]

As seen above, with respect to functional claims, there are many court precedents that adjust the balance of the scope of the right between the patentee and a third party by interpretation of the claim under the Infringement Theory instead of the Invalidation Theory. In concrete terms, in the aforementioned Magnetic Media Reader Case, the court stated as follows: "Consequently, in cases where the claim in a utility model registration is set forth by said expressions, it is impossible to define the technical scope of the device by said statement alone. It is reasonable to construe that the statements of the detailed explanation of the device in the descriptions should be considered in addition to said statement, and the technical scope of the device should be determined based on the technical idea indicated in the concrete structure that is disclosed in the statements in the detailed explanation. However, this does not limit the technical scope of the device to the specific working examples stated in the descriptions, but even if a structure is not disclosed as a working example, if it is a structure that a person of ordinary knowledge in the technology field to

which said device belongs (hereinafter referred to as a "person skilled in the art") can work the device based on the content of the statements related to the device disclosed in the description, it should be construed that the structure is included in the technical scope" (underlined by the author). It indicates that the technical scope of the device should be determined based on the technical idea (the structure that a person skilled in the art in the technical field to which the device belongs can work the device based on the content of the statements related to the device disclosed in the description) stated in the specific structure that has been disclosed.

Actually, among court precedents related to functional claims, in addition to the court precedents indicating that the technical scope should be determined by limiting the scope to the technical idea that is indicated in the specific structure that has been disclosed,[11] there are court precedents indicating that the technical scope should be limited to the content disclosed in the detailed scope in the description,[12] and court precedents that interpret it literally without imposing a limitation. If problems unique to the functional claim are handled as problems related to claim interpretation, literal interpretation is against the purport of the Patent Act as mentioned above. However, it is extreme to limit the technical scope to the content disclosed in the detailed scope in the description as shown at the working example level. In consideration of the fact that the invention is the creation of a technical idea (Article 2, paragraph (1) of the Patent Act), it is most reasonable to interpret it by limiting the scope to the technical idea stated in the specific structure that has been disclosed among the aforementioned interpretations.

However, it must of course also be examined whether the aforementioned claim interpretation conforms to Article 70 of the Patent Act, which governs the interpretation of the technical scope of an invention. In other words, it is stipulated under Article 70, paragraph (1) of the Patent Act that "The technical scope of a patented invention must be determined based upon the statements in the claims attached to the written application." Therefore, the technical scope is determined based on the statement in the claim in principle. However, paragraph (2) of said Article stipulates that "In the case referred to in the preceding paragraph, the meanings of terms used in the claims are to be interpreted in consideration of the statements in the description and drawings attached to the written application." This means that consideration of descriptions and other information is naturally allowed. However, it is conducted to the extent of the interpretation of terms stated in the claim. It does not allow replacement of the term with another term or adding another limitation that is not stated in the claim.

Based on the above, the interpretation in the judgment of the Magnetic Media Reader Case, where it is limited to a structure that a person skilled in the art can work it based on the technical idea stated in the specific structure that has been disclosed in the description, in other words, based on the content of the statements related to the device disclosed in the description, cannot be derived from the provisions of Article 70 of the Patent Act. In addition, whether a person skilled in the art can work it based on the statements related to the device disclosed in the description must be determined based not only on the statements in the descrip-

tion, but also the technical level at the time when the application was filed. However, it is not easy at all to investigate literature consisting of the technical level and to identify the extent of the structure that a person skilled in the art can work. It may impose an excess burden.

Furthermore, whereas there was once a deep-rooted belief that the determination of the validity of patent rights was the exclusive jurisdiction of the Patent Office, an administrative agency, therefore defense of patent invalidity could not be claimed in court, this need not be the case if we base our assumptions on the current law where the defenses under Article 104(3) of the Patent Law have been established. There is no need to unnecessarily adhere to such an excessively restrictive interpretation, and it would seem sufficient to conduct discussions based on theories of invalidity, such as issues with the description requirements. In fact, from the perspective of a third party, it would be more stable to handle it as a theory of invalidity rather than a theory of infringement, as this allows for responses through less contentious procedures, such as opposition or invalidation trials, compared to infringement litigation, thereby stabilizing the legal status. Furthermore, for the patent holder, having chosen such an irregular claim format, it is not at all unreasonable to bear the responsibility for it, and if necessary, it is also possible to avoid issues with the description requirements by making amendments to specify concrete solutions, so it can't be said to be particularly disadvantageous.

Based on the above, the author considers that it is reasonable to handle the functional claim (but not denying the interpretation with limitation) as a problem of the Invalidation Theory, in particular, as a problem of the violation of description requirements. As a violation of description requirements, any violation of the requirements for clarity, the enablement requirements, or the support requirement can apply. [13] However, in cases of a product invention like the Invention, and where there is no dispute that the antibody included in the structure can be obtained (regardless of the difficulty and burden), the most often argued ground for invalidity is the support requirement.

In the next section, the criteria of support requirements for these functional claims are examined and the appropriateness of the Judgment is also examined.

3-3 Judging Method of Support Requirements for Functional Claim

The decision on the support requirements under current patent practice is generally made based on the indication in the judgment of the Intellectual Property High Court on November 11, 2005 (2005 (Gyo-ke) 10042; “Grand Panel Judgment in the Polarizing Film Case”). In this case, it is indicated as general criteria for the support requirement that “whether a statement in the claims conforms to the support requirement for a patent specification should be determined by comparing the statement in the claims and the statement in the detailed explanation of the invention and by examining whether an invention stated in the claims is an invention stated in the detailed explanation of the invention and the invention is in the scope where a person skilled in the art can recognize that the problems of the invention can be solved based on the statement in the detailed explanation of

the invention and whether it is in the scope where a person skilled in the art can solve the problems of the invention in light of the common general technical knowledge at the time of filing of the application even without any statements or suggestions in the detailed explanation of the invention."

This means that whether it can be recognized that the invention stated in the claim can resolve the technical issue is an index. In terms of the functional claim, since the issue itself (in this case, the structure "which can neutralize the binding of PCSK9 and LDLR protein") is substantially specified, it results in the interpretation that the aspect where the issue cannot be resolved is not originally included in the claim. For this reason, at a glance, concerning the functional claim, the aspect that can necessarily resolve the issue alone is specified in the claim and it seems that there may not be aspects that fulfill the support requirements. Needless to say, however, that it is significantly against the purport of the patent system to grant the exclusive right to a claim such as that a question is answered by another question, e.g. "An automobile that can be driven at a speed of 500km/h," as stated as an example in section 3-2 above, based on the aforementioned grounds. In other words, whether the support requirements for the invention related to said form of claims are fulfilled should be determined by examining whether the principle of resolving the issues that are substantially stated as the technical idea in the Descriptions is reflected as a structure and whether it can be recognized that the effects can be obtained from the specific technical means specified in the claim (in the case of example of the automobile, the major premise is that the engine that is a feature of the invention is specified as a structure; and then, whether the engine has a function "to drive an automobile at a speed of 500km/h" must be examined).

Actually, the Grand Panel judgment in the Polarizing Film Case ruled as stated below. If the statement in the "claim" exceeds the scope of technical matters that were stated and disclosed in the "detailed explanation of the invention," it deviates from the purpose of the patent system to grant the exclusive right in exchange for the disclosure and, therefore, it violates the support requirement. The same notes are also indicated in the JPO's Examination Standards.[14] (underlined by the author.)

> (The Grand Panel Judgment in the Polarizing Film Case)
> "Article 36, paragraph (6), item (i) of the Act requires for the statement in 'the claim' to be 'the invention for which the patent is sought that is stated in the detailed explanation of the invention.' Said item is a provision established to make provisions effective where the patentee has the exclusive right to work the patented invention as a business and where the technical scope of the patented invention shall be specified based on the 'statements in the claim' attached to the written application (Article 68 and Article 79, paragraph (1) of the Act). <u>In cases where the recitation in the 'claim' exceeds the scope of technical matters stated and disclosed in the "detailed explanation of the invention," if the exclusive right is granted to the broad technical scope, it deviates from the purpose of the patent system to grant the exclusive right in exchange for the disclosure and, therefore, the</u>

recitation in the claim is not allowed. For example, if there is a statement including the broad technical scope, exceeding the technical matters, in the 'claim,' although it is construed that narrow and limited technical matters alone are disclosed according to the statement in the 'Working example' of the 'detailed explanation of the invention,' it is found to be against said item and it is not allowed."

In this regard, in the first judgment in the case between Amgen and Sanofi, the court determined that "If it is an antibody 'competing' with a reference antibody, even if it cannot be deemed to be one neutralizing the binding of PCSK9 and LDLR, since Corrected Invention 1 is based on the invention-specifying matter that it is an antibody, 'which can neutralize the binding of PDSK9 and LDLR protein,' this fact does not have an impact on the aforementioned findings" and the court found fulfillment of the support requirement. The Trial Decision followed the initial judgment and indicated that it is enough to state in the description that a "monoclonal antibody" which has both characteristics "which can neutralize the binding of PCSK9 and LDLR protein" and "which competes with 21B12 antibody," and it determined that "the allegation of the demandant which relates the two aforementioned different invention-specifying matters as issues and structure or results and causes, is not based on the statement in the claim and, therefore, it cannot be adopted" and rejected Sanofi's allegation of violation of the support requirements. On the contrary, in the Litigation, the court indicated that "in an instance like the present case, if it were interpreted to be sufficient to literally exclude an antibody that does not have a binding-neutralizing activity, it would be allowed to make a very broad definition of a position where the antibody binds to PCSK9, such as most of PCSK9, which would allow the scope of claims to be made broad without a justifiable basis. Therefore, such an interpretation is not reasonable," and rejected Amgen's allegation that since an antibody that cannot neutralize the binding of PCSK9 and LDLR protein is literally excluded from the technical scope, it is not against the support requirement.

It must be noted here that elements that have a correlation with the resolution of issues do not always contribute as a means or cause of resolving the issue. In other words, even if there is a correlation to some extent between the fact of neutralizing the binding of PCSK9 and LDLR and the fact of competing with 21B12 antibody, it does not always mean that competing with 21B12 antibody enables neutralization of the binding of PCSK9 and LDLR. The possibility cannot be denied that an antibody that can neutralize the binding of PCSK9 and LDLR (due to some reason) only tends to compete with 21B12 antibody in a certain percentage of cases. [15] As mentioned above, correlation and causal relationship are different ideas. In cases where there is a Structure A related to the invention's issues (or the effects) and a Structure B that is specified along with Structure A, if the way that Structure B contributes to Structure A in a specific manner is not fully examined, it has the risk that something looks like an invention, for which no technical means for resolving the issue are not specified, may be protected as an "invention" (there is no benefit to granting the exclusive right and protect it). In

this regard, the determination method in the Judgment is appreciated because it examined for determining whether it falls under an invention that should be truly protected without persisting with the formal specification in the claim.

According to the court precedents, for example, there are court precedents that indicate criteria in consideration of the particularity of the functional claim in the same way as the Litigation, such as the judgment of the Intellectual Property High Court on October 25, 2017[16] (Case No.: 2016 (Gyo-ke) 10189; Source: The Supreme Court's website). In recent trends, in particular in the JPO's procedures, the claim in question is regarded formally in the same way as other claims, such as the one in the initial judgment, and the aspects that cannot resolve the issue are excluded. Therefore, there are many cases where it is easily determined that the claim fulfills the support requirement. It is expected that the Judgment will serve as a trigger to change the trend so that a more substantial decision is made on the support requirement.

3-4 Relationship between the Judgment and Previous Procedures

As mentioned above, the first trial decision and the first judgment related to the invalidation trial case disputed between Amgen and Sanofi, and the judgment that upheld the request for an injunction against the antibody preparation imported and sold by Sanofi have become final and binding. The relationship between the aforementioned decisions and judgments, the Litigation, and the case requesting compensation for damages related to the same antibody preparations becomes a problem. Among them, the relationship between the first judgment and the Judgment was indicated as follows: "In the unrelated case seeking rescission of the trial decision related to the Invention, the allegation related to the violation of the support requirement was rejected as stated in No.2, 1. (2) above. However, in view of the allegations and presentation status of evidence at that time, it can be understood that the following facts are used as a natural premise that an antibody competing with 21B12 antibody combines at almost the same position as 21B12 antibody on PCSK9 and has the same function as 21B12 antibody. On the contrary, in the Litigation, according to the new allegation based on the written statements of Dr. [A] and Dr. [B], structural analysis based on the expert written opinion of Prof. [F] (Exhibits Ko 18 and 230), relevant documentary evidence related to 'EGFa-mimic antibody' (Exhibits Ko 4-1 and 4-2) and other new evidence, although questions arose on the aforementioned premise, information for making a decision to support the premise cannot be found. Therefore, it is deemed that there are proper reasons that the conclusions in the unrelated judgment and the Judgment are different." It defined that since they are not based on the same facts and the same evidence, it is not subject to double jeopardy under Article 167 of the Patent Act.

In addition, in the case requesting compensation for damages related to the same antibody preparation sold by Sanofi subject to injunction, the Tokyo District Court found the defense of patent invalidation (Article 104-3 of the Patent Act) due to the same grounds as the Judgment and has already disclosed the conviction that rejected the request by Amgen.[17] Concerning the Judgment, the final

appeal was filed before the Supreme Court. However, the Supreme Court determined to reject the final appeal on September 22, 2023, and it became final and binding. The fact that the trial decision to invalidate the patent became final and binding does not serve as grounds for re-examination due to Article 104-4 of the Patent Act. Therefore, the judgment to approve the injunction against the antibody preparation imported and sold by Sanofi is not overturned.

As a result, a rare situation was caused where different conclusions were made on the request for injunction and the request of compensation for damages even though they are infringement litigations on the same product based on the same patent.

3-5 Comparison with Judgments in the U.S. and Europe

As mentioned at the beginning, similar disputes have also occurred in the U.S. and Europe. In particular, a similar issue to the Litigation was argued at the U.S. Supreme Court.[18]

However, the description provided in the specification is different in each case. According to US Patent No. 8,829,165, it is specified that an isolated monoclonal antibody, which, when binding to PCSK9, binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO: 3, and inhibits PCSK9 from binding to LDLR and the monoclonal antibody blocks the binding of PCSK9 and LDLR. The validity of the patent was eventually argued before the Supreme Court; however, the Supreme Court indicated that the invention covers a far broader scope than the exemplary antibody identified by the amino acid sequence. It indicated that the invention, "which intends to monopolize the overall class that is defined by the function" only by "ligand binding" and "receptor block" and it cannot be found that the descriptions have statements to the extent that a person skilled in the art can manufacture and use the overall class, and, therefore, it upheld the judgment of the CAFC and determined that it violated the enablement requirement.

In Europe, in relation to the corresponding patent No. 2,215,124 thereto, the perspective of a lack of inventive step was mainly argued in an objection case, which is different from Japan and the U.S. The EPO Board of Appeal determined that the claim defined by function does not show the technical effects of inhibiting the binding of PCSK9 and LDLR in the overall technical scope, and the claim is invalid due to the lack of an inventive step. For this reason, the right is eventually maintained by Amgen by correcting the claim. However, since the complementarity determining region (CDR) is defined and its effects do not affect other antibodies substantially, it seems that the patentee abandoned the protection in the form of a functional claim based on the judgment of the EPO Board of Appeal.

In this regard, before the US Supreme Court judgment was rendered, the Judgment indicated that "With regard to the international situation surrounding the present invention, the Plaintiff asserts that in Europe, the corresponding European patent, which is substantially the same as the present invention, was judged to be invalid for lack of an inventive step in 2020 in the court of appeal against opposition, and that in the U.S., the corresponding U.S. patent, which is more limited than the present

invention, was judged to be invalid for lack of the enablement requirement on February 11, 2021, in the Court of Appeals for the Federal Circuit of the United States, and that Japan is currently the only country in the world where the validity of the present patent has been maintained by the courts. On the other hand, with regard to the above judgment by the Court of Appeals for the Federal Circuit, the Defendant asserts that since the United States Supreme Court granted the petition for certiorari on November 4, 2022, the above judgment is extremely likely to be overturned. Needless to say, however, it is apparent that the judgments in other countries do not immediately affect the judgment in the present case." From the perspective of the territoriality principle, it is natural to give the decision that the judgment made in other countries does not immediately affect the Judgment. However, concerning the point that a right with a broader scope exceeding the disclosure in the descriptions is eventually not approved based on the functional claim, judgments based on the same line of reasoning were rendered in Japan, U.S., and Europe.

4. Closing

In this article, the judgment of the Intellectual Property High Court that denied fulfillment of the support requirement for the invention claiming an antibody preparation stated in the form of the functional claim was discussed by comparing it with the trend of court precedents and judgments made in foreign countries on corresponding overseas patents. As described at the beginning, since the form of claims related to pharmaceuticals has become diversified recently it is difficult for companies engaging in the development of ethical drugs, regardless of whether it is an original drug pharmaceutical company or a generic pharmaceutical company, to predict when and how they are involved in a patent dispute. Therefore, it is important to study trends in decisions made by the courts and the JPO on a routine basis through cases like this case.
End of text

(Notes)

[1] Generally, research and development for new drug development by structure-activity relationships have considerably progressed mainly in leading pharmaceutical companies, thus it has become increasingly difficult to develop new pharmaceuticals of small molecule compounds.

[2] Concerning antibody preparations, for example, there are those based on the assumption of treatment of infectious disease, such as antibody cocktails targeting the recent coronavirus and other antigens. However, like the invention in question in this case (hereinafter referred to as the "Invention"), there are also therapeutic antibodies used to inhibit the binding reaction of proteins related to intravital homeostasis and to improve lifestyle diseases and other diseases.

[3] On the other hand, there are the following disadvantages: the antibody preparation does not have a neutralizing effect against antigens other than the specific antigen in principle; if the 3D structure changes due to a mutation to the antigen, the binding ability of antigens drastically decreases and, in particular, the neutralizing effect can be drastically decreased.

[4] Article 123, paragraph (2) of the current Patent Act stipulates that the demandant of a trial for invalidation is limited to an interested person.

[5] The major cause of requesting a trial in this case was not based on the same facts and same evidence as the previous trial for invalidation. Therefore, logically, even if Sanofi is a demandant as in the previous case, it is not subject to the prohibition of double jeopardy as set forth in Article 167 of the Patent Act and the same trial decision could have been obtained. However, the reasons why the Sanofi

side newly established Regeneron as a demandant are considered to be the following: the grounds for invalidation that are substantially the same as in the case of the previous trial decision can be subject to examination; and it is based on the strategy that allegations can be made without restrictions such as estoppel to the allegation in the previous trial.

[6] As grounds for invalidation, in addition to the violation of support requirements (Grounds for Invalidation 1), the violation of enabling requirements (Grounds for Invalidation 2), Grounds for Invalidation 3 (lack of an inventive step), Grounds for Invalidation 4 (the violation of clarity requirements), and Grounds for Invalidation 5 (the violation of patentability) were alleged.

[7] The judgment of the U.S. Supreme Court, reported at Amgen, Inc. v. Sanofi, 143 S. Ct. 1243 (2023), is explained in detail in AIPPI (2024) Vol. 69, No. 1, pp. 6 -29.

[8] As stated above, the allegations on the violation of support requirements in this case include new evidence. Compared with the allegations on the support requirements in the previous trial for invalidation, it is not deemed to be the same facts and the same evidence. However, the JPO did not emphasize this point and seems to have determined the conclusion from the beginning.

[9] Under Article 36 of the Patent Act before the amendment in 1994, it is required to state in the detailed explanation of the invention the purpose, structure, and effects of the invention and to state in the claim only the matters that cannot be stated in the structure of the invention that was stated in the detailed explanation of the invention. Therefore, there is less room for a functional claim to be established. However, under Article 36 of the current Patent Act after the amendment in 1994, there is no such limitation, and it is considered that the room for a functional claim to be established became larger.

[10] As court precedents with the same purport, for example, there is the judgment of the Tokyo District Court on December 28, 2002 (Case No.: 2003 (Wa) 19733, 19739; "Ice Cream-filled Strawberry Case"). In this case, the court determined as follows: "The statement, 'It is characterized by having softness and maintaining the form to the extent that the ice cream inside does not flow out when the outside strawberry is defrosted,' is the purpose of Invention B. The expression, 'having softness and maintaining the form to the extent that the ice cream inside does not flow out,' only expresses the function and the effects of the ice cream-filled strawberry in Invention B but does not define the specific structure necessary to achieve the purpose and effects of Invention B. As mentioned above, in cases where the structure of the invention stated in the claim is described in a functional, abstract expression, if it is construed that any structure that can fulfill said function and effects is included in the technical scope, it results in including a structure that belongs to the technical idea that has not been disclosed in the descriptions in the technical scope of the invention. It may grant protection by the patent right exceeding the scope that the applicant invented. However, causing such results is against the principle of the Patent Act that the exclusive right of an inventor based on the patent right is granted in compensation for disclosure of the invention to the public" (underlined by the author). Almost the same decision is granted as in the aforementioned Magnetic Media Reader Case.

[11] As the court precedents in said case, in addition to the aforementioned Magnetic Media Reader Case and Ice Cream-filled Strawberry Case, there is the judgment of the Tokyo District Court on December 20, 1978 (Hanrei Times No. 381, p. 165; "Automatic Ball Bearing Assembly Machine Case"). In relation to the aforementioned determination method, a separate volume of Jurist, "Tokkyo Hanrei Hyakusen (100 Selected Court Precedents on Patents) [3rd edition]" (Nakayama et. al edited; pp. 142-143; the part written by Takabayashi) stated that they adopted the same method as 35 U.S. Code § 112 (f), which stipulates that a functional claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

[12] For example, there is the judgment of the Tokyo District Court on July 22, 1977 (Mutaireishu Vol. 9, No. 2, p. 544; "Coin Locker Case").

[13] In fact, with respect to the grounds for invalidation of the Trial Decision, all of these grounds for invalidation in relation to the functional claim have been alleged.

[14] According to the JPO's Examination Guidelines for Patent and Utility Model in Japan, in "2.1 Basic ideas on determination of the support requirement" (1), it is stipulated that "It is determined whether the statement in the claims

satisfies the support requirement by comparing the claimed invention and the invention stated in the description." Then, in (2), it is indicated as follows: "In performing this comparison, the examiner examines a substantial correspondence between the claimed invention and the invention stated in the description regardless of the consistency of expression. Given that the support requirement is satisfied only by the consistency of expression, a patent right for the invention which has not been substantially disclosed to the public would be granted, thus it is against the purpose of the provision of Article 36(6)(i)." (underlined by the author). It is defined that the substantial corresponding relationship should be examined regardless of the consistency of expressions to prevent a right over the invention that is not substantially disclosed from arising.

[15] As a result of the testing by Dr. [A], it is confirmed that approximately 80% of antibodies do not have a binding-neutralizing activity from among antibodies competing with the reference antibody. In fact, it is a case where even correlation between them was doubtful.

[16] In said judgment, the court indicated as follows: "The statement in the claim (Claim 1) related to the invention in the present application identifies optical glass by the composition requirements in the present application and the physical property requirements in the present application. The physical application in the present application expresses quantitatively the issue of the invention in the present application, 'which provides optical glass with a high refractive index and high dispersion and with a small partial dispersion ratio' by an optical constant for 'which refractive index (nd) is 1.78 or higher and 1.90 or lower, for which Abbe's number (Vd) is 22 or higher and 28 or lower, and for which the partial dispersion ratio (θg, F) is 0.602 or higher and 0.620 or lower.' It is deemed to be the requirement to limit the optical glass that is identified by the composition requirements in the present application to be one that can resolve the issue of the invention in the present application. According to the structure of the claim related to the invention in the present application, in order to say that the statement conforms to the support requirements, it is necessary that a person skilled in the art can recognize that the optical glass identified by the composition requirements in the present application can fulfill the physical property requirements in the present application at a high probability based on the statements or suggestions in the detailed explanation of the invention or common general technical knowledge at the time of filing the application." It indicates that, in determination of the support requirements for said claim form, the composition requirements (provision related to the means of resolving the issue) and the physical property requirements (provision related to the functions and effects) must be clearly distinguished and it is necessary that the physical property requirements can be fulfilled at a high probability by the structure identified by the composition requirements.

[17] Since the final appeal was rejected concerning the Litigation, this case will be remanded to the trial by the JPO. It seems to be significantly difficult to avoid the invalidation grounds for violation of the support requirement in this case while Sanofi's product is still included in the scope of the right by the correction. Consequently, the possibility of overturning the judgment of the Tokyo District Court is low even if the appeal and final appeal (petition for acceptance of final appeal) of the case requesting compensation for damages is filed in the future.

[18] See the aforementioned AIPPI (2024) Vol. 69, No. 1, pp. 6 -29.