Major Judicial Precedents of Biological Invention

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Appeals Department, JPO (Japan Patent Office)

In this summary, the court decisions for suits against appeal decisions by the Tokyo High Court (Intellectual Property High Court) corresponding to the following examination standards have been posted as a reference for appropriate responses to (i) notification of reasons for refusal, (ii) request for examination, and (iii) appeal, regarding the patentability of a biological invention.

[1]. Court decision regarding the judgment of an inventive step

[2]. Court decision regarding description requirements

[3]. Others

In addition, it is necessary to note that the technological level at the time of the application date (priority date) greatly influences the judgment of the description requirements, etc .

[1] Court Decision regarding Judgment of Inventive Step

Example 1-1 The claimed invention lacks an inventive step, as a person skilled in the art could have easily have obtained a recombinant cytokine (r-CYT) by using the publicly known knowledge of the gene sequence of a corresponding cytokine derived from other species, and the several biological activities (multipotency) of r-CYT could have been foreseen because the recombinant cytokine derived from other species had been confirmed to have several such biological activities (i.e., multipotency beyond species), and it also could have been foreseen by a person skilled in the art that r-CYT had other biological activities similar to the activities of other cytokine variations.

○ **Heisei 14 (Gyo-ke) 505**

"Novel Cytokine"

(Priority date: 1990/11/8)

Partial excerpt from Court Decision:…As long as the three types of activities of monkey IL-11 in various kinds of cultured cells of mice of different species are disclosed in the cited document 1, it can be understood without a doubt that IL-11 has generality and a broad spectrum beyond species.

Therefore, since the nucleotide sequence of the ORF of human IL-11 has

high homology with that of monkey IL-11, it is assumed that a person skilled in the art can easily obtain purified human matured IL-11 having an activity equivalent to monkey IL-11 using the same method by which the purified monkey matured IL-11 has been actually obtained through the COS-1 cell gene expression system disclosed in the cited document 1. …As "IL-11" is named after IL-6, IL-11 has been regarded as a substance similar to IL-6, which has been known as "multipotent cytokine," and therefore, it is assumed that IL-11 has been fully foreseen to have biological activities other than those which have been actually confirmed. As it is disclosed in the cited document 3 (Ko 8), that the recombinant human IL-6 has an activity to inhibit adipocyte formation, it should be deemed that a person skilled in the art could have foreseen before the priority date of this case that IL-11 also has an activity to inhibit adipocyte formation in view of the similarity between IL-11 and IL-6.

Example 1-2 The amended claimed invention lacks an inventive step; i.e., even if the matters described in the cited documents are disclaimed from the technical scope of the amended claimed invention, a person skilled in the art could nevertheless have easily arrived at the remaining part of the scope of the amended claimed invention.

○ **Heisei 17 (Gyo-ke) 10197**

"Recombinant Thermostable DNA Polymerase from Archaebacteria"

(Priority date: 1991/12/18)

Partial excerpt from Court Decision: In the scope of the present amended claimed invention, even though the DNA present in nature has already been disclaimed by the amended sentence following the word "but," DNA with very high homology to the disclaimed DNA is still included. … In the cited document 1, a detailed explanation of the methods for isolating the DNA encoding DNA polymerase from *Thermococcus litoralis* NS-C strain and determining its nucleotide sequence as working examples in the specification is provided, and its DNA sequence consisting of 5837 nucleotides is also described… In addition, archaebacteria containing the DNA whose nucleotide sequence is represented by (a'), for example A3 strain, has been deposited and can be easily obtained at the time of the priority date of the application concerned as stated above. Therefore, it should be deemed that a person skilled in the art is able to easily isolate the DNA with sequence (a') from such an archaebacteria by the method of "labeling overall DNAs by the Nick translation method, etc. and by the hybridization method with the synthesized labeling probes", which disclosed in the cited document 1.

Note: Nucleotide sequence (a') is a similar sequence to that of sequence (a) , which is disclaimed by the amended sentence following the word "but".

Example 1-3 The claimed invention related to a certain protein with a newly found function lacks an inventive step, as the protein function must be foreseen, and there could have been strong motivation to confirm the existence of the protein function before the filing date (priority date).

○ **Heisei 17 (Gyo-ke) 10073**

"Immunoreactive Polypeptide Composition of Hepatitis C Virus"

(Priority date: 1991/9/13)

Partial excerpt from Court Decision: In consideration of both the suggestion of the cited document 1 and the description of the cited document 3, a person skilled in the art can foresee that HCV must also have immunoreactive parts, including one or more epitopes in the hypervariable regions of HCV envelope polypeptides like HIV－1, and is strongly motivated to try to confirm this fact. Therefore, even if immunoreactivity in the hypervariable regions of HCV envelope polypeptides had been actually discovered in such trials, it was not deemed to be a remarkable working effect that exceeded the prediction of a person skilled in the art …

Example 1-4 The claimed invention, which related to an expression method of a publicly known gene using an expression system with a specific vector, lacked an inventive step, as the method using the expression system and its general versatility had been common general technical knowledge.

○ **Heisei 15 (Gyo-ke) 33**

"Synthesis and Immunogenicity of Rotavirus Genes using a Baculovirus System"

(Priority date: 1986/12/30)

Partial excerpt from Court Decision: As stated above, the publication A discloses that the expression of a protein encoded by any of the "Simian Rotavirus genes" in a baculovirus system has been successful. Also, the method for expressing various foreign genes by introducing them into a baculovirus system has been known in detail and should be common general technical knowledge at the time of the priority date of the application concerned. In addition, it is publicly known that a baculovirus system has high general versatility and that the expression in insect cells using the baculovirus system can achieve a large amount of expressed recombinant products compared with other known expression systems, where the recombinant protein through translation and processing has biological

characteristics which are quite similar to those of the corresponding natural protein... Thus, the system should be recognized to be highly useful.

Therefore, for a person skilled in the art who reads the publication A, it is natural to conceive that in the case that a gene which encodes a rotavirus protein is introduced to insect cells by using the baculovirus system, the rotavirus protein expressed could be quite similar to its corresponding natural protein.

Example 1-5 The claimed invention related to a method, where co-expression of both sub-units of protein (heterodimer) in an identical host cell was conducted to obtain a biological active protein (heterodimer) consisting of sub-units with carbohydrates, lacks an inventive step, since the genes encoding the sub-unit proteins have already been known.

○ **Heisei 14 (Gyo-ke) 258**

"Heteropolymeic Protein"

(Priority date: 1983/11/2)

Partial excerpt from Court Decision: As previously reported, the carbohydrates of hCG have an effect on its biological activity, so it is quite natural for a person skilled in the art to conceive of the selection of

mammalian cells as a host in order to obtain biological active recombinant hCG proteins with carbohydrates.

In addition, before the priority date, the hCG biosynthesis pathway has been well clarified, and it is assumed that in the case that the genes which encode an α subunit and ß subunit are expressed in the identical mammalian host cell, both subunit proteins are connected in the endoplasmic reticulum at an earlier stage and folded up in the matured protein conformation and secreted in the culture supernatant in the form given with some carbohydrate modification before being excreted out of the Golgi body and the cell.

Therefore, it should be quite simple for a person skilled in the art to conceive of introducing both genes which encode an α subunit and ß subunit respectively into the identical host cell genome, expecting the expression of recombinant hCG proteins with biological activities.

[2] Court Decisions regarding Description Requirements

Example 2-1 The enablement requirement and support requirement are violated due to failure to disclose "usefulness" of all embodiments of nucleic acid molecules included in the claimed invention when the claim includes the statements totally defining the nucleic acid molecule by its characteristics or

function, etc.

○ Heisei 17 (Gyo-ke) 10013

"Modulator of Body Weight, corresponding Nucleic Acids and Proteins, and Diagnostic and Therapeutic Uses thereof"

(Priority date: 1994/8/17)

Partial excerpt from Court Decision: The scope of the claimed invention covers all the nucleic acid molecules specified by their characteristics or biological effects ; i.e., "they are hybridizable to the OB gene of this case under high stringent hybridization condition" in the statement of claims, Therefore, as to all embodiments of the nucleic acids included in the claimed invention that have the above characteristics and biological effects, their significant usefulness should be sufficiently presented in the detailed description of the invention for a person skilled in the art to understand that all of the aforementioned nucleic acids can be utilized as probes or primers to detect or amplify the OB gene specifically… However, a person skilled in the art does not recognize that all of them have usefulness such as abilities to distinguish clearly in case that they are used as probes or primers, even if he takes the results of more than 50 working examples in the detailed

description of the invention into consideration. Moreover…some of the nucleic acid molecules are never expected to hybridize specifically with the concerned OB gene; in other words, there is no utility over some embodiments of the claimed invention. Therefore, it is clear that the detailed description of the invention has not disclosed clear and sufficient information in such a manner that a person skilled in the art can use the claimed invention. Consequently, this patent application does not meet the description requirement of Patent Law ex. Section 36(4).

The description requirement of Patent Law Section 36(6)(i) concerns whether the invention is supported by the detailed description of the invention, and, therefore, it can be said to be another side of the discussion of the description requirements of the above Patent Law Section 36(4). …Inventions relating to genes are required to be industrially applicable inventions for patentability, and it is necessary for applicants to explain that the inventions have usefulness. In this case, the scope of the claimed invention of this patent application is beyond the matter described in the detailed description of the invention because it includes not only the nucleic acid molecules, which prove to be useful in the detailed description of the invention, but also the nucleic acid molecules which have no usefulness. Thus, it is clear that this

application lacks the sufficiency to meet the description requirement of Patent Law Section 36(6)(i).

Example 2-2 The enablement requirement is violated, as all of the positions of epitopes have not been identified and disclosed in such a manner that a person skilled in the art can carry out the invention relating to the composition for immunoassay, including plural antigen combinations.

○ **Heisei 15 (Gyo-ke) 220**

"Combination of Hepatitis C Virus (HCV) Antigens to be used for Anti-HCV Antibody Immunoassay"

(Priority date: 1990/4/4)

Partial excerpt from Court Decision: According to the expression of the scope of the claim of this invention, any reagents using any epitopes shall be included in the scope as reagents for the detection of anti-HCV antibodies, if once they are combinations of antigens including epitopes from the C domain and antigens including epitopes from other domains (excluding some combinations). In the meantime, as it cannot be said that all of the positions of epitopes on HCV polyproteins have already been identified and well-known as of the priority date of this case, it is only natural that the

applicant who wants to obtain the patent concerned with such a broad claimed invention as above must disclose sufficient information for a person skilled in the art to easily practice all of the claimed invention, according to the purpose of ex. Patent Law Section 36(4). …The antigens disclosed in this specification are only C22 (No. 1 HCV antigen), C33c, C100, S2 and NS5 (No. 2 HCV antigen).

In this case, one cannot specify all of the antigens included in the scope of this invention, other than the aforementioned antigens above, so it is necessary to test the antigen-antibody reaction with all of the antigen polypeptide candidates, namely polypeptides consisting of more than 5 amino acids, through a trial and error process; for example, synthesizing candidates of antigen polypeptides from the end of each domain, purifying them, and confirming the antigen-antibody reaction… In order to discover all of the antigen combinations which belong to the scope of claims of this invention, one is forced to carry out a large number of the experiments described above to confirm the antigenicity of polypeptides. Even if each experiment is routine work, considering the long amount of time and expense incurred by such work, the work naturally falls under the category of undue experiments; therefore, this patent application lacks an

enablement requirement, as such undue experiments are required to implement all of the antigen combinations included in this invention.

Example 2-3 The enablement requirement is violated, as the information disclosed in the specification in which a murine gene is merely obtained is not sufficient to enable a person skilled in the art to practice the claimed invention related to mammalian genes, including a human gene.

○ **Heisei 9 (Gyo-ke) 249**

"Recombinant DNA Molecule"

(Priority date: 1984/3/21)

Partial excerpt from Court Decision: Reviewing all the evidence of this case, one can find no documents demonstrating that a murine GM-CSF gene is a typical mammalian GM-CSF gene and that if once the murine GM-CSF gene has been clarified scientifically, it almost always turns out to be a mammalian GM-CSF gene.

Rather, …it is recognized that each human, monkey, mammal other than these two, and animal other than a mammal has a particular protein set for its species, respectively, which is passed on to and inherited by progeny for generations. Based on this recognition, the murine GM-CSF should be

considered only one of the quite different mammalian GM-CSF … as of the priority date of the application concerned, and one can find no evidence supporting the technical background or such common general technical knowledge where the human GM-CSF gene can be isolated automatically and without fail by the method insisted on by the plaintiff, using the murine GM-CSF gene isolated in this invention 1… The technical idea itself in isolating the human GM-CSF gene…is neither described literally in the specification of application concerned, nor is described essentially the idea for a person skilled in the art to clearly understand… Consequently, it cannot be said that such a technical idea is disclosed in the specification of application concerned.

Example 2-4 The enablement requirement is violated due to failure of the disclosure from the viewpoint of both of that all of chemical substances included the claimed invention are useful and that such useful substances can be selected easily.

○ **Heisei-10 (Gyo-ke) 95**

"T cell Receptor β - subunit Polypeptide"

(Priority date: 1984/3/1)

Partial excerpt from Court Decision: As of the priority date of the application concerned, it cannot be recognized that any peptide comprising at least 8 or more consecutive amino acids has immunogenic potential for inducing the production of antibodies which can detect its peptide itself, and that among a huge variety of peptides comprising 8 consecutive arbitrary amino acids, a person skilled in the art can easily select only the peptides enable to induce antibodies which can detect antigenenic determinants (epitopes) of "TCR- β"… It is true that epitope mapping is recognized to be a useful tool for selecting antigenic peptides among numerous peptide samples, which include no antigenic peptides for the most part, but considering that all peptides derived from proteins constituting tissues and cells within a living body can come under epitope mapping, disclosure of the usefulness of a peptide is considered to be insufficient for a chemical substance patent to be granted, even if the chemical substance (i.e., peptide) can be used as merely a testing sample.

Therefore, in order for this application to meet the Patent Law Section 36(3) requirements on usefulness, either its usefulness in regard to all peptides included in the scope of the claims should be described in the specifications

or such usefulness should be clear to a person skilled in the art from common general technical knowledge.

Additionally, as previously mentioned, this invention is related to both chemical substances referred to as “peptides or polypeptides,” and numerous independent chemical substance inventions on each peptide are included in the scope of claims 1, so the essence of the chemical invention is the creation of useful chemical substances. That means all of the many peptides included in the claimed invention are required to be useful chemical substances…

The application concerned violates Patent Law Section 36(3) as follows: (1) In regard to all peptides included in the scope of claims, their usefulness is neither described in the specifications nor is such usefulness clear to a person skilled in the art from common general technical knowledge, and (2) the specifications are not described sufficiently for a person skilled in the art to easily select only those peptides which are useful among all peptides included in the scope of claims…

Example 2-5 The enablement requirement is violated, as there are no working examples, which would enable a person skilled in the art to practice the claimed invention relating to the genetic engineering method.

○ **Heisei 10 (Gyo-ke) 28**

"Control of MicroSporogenesis using Externally Inducible Promoter Sequence"

(Priority date: 1990/6/12)

Partial excerpt from Court Decision: It is recognized that there are no working examples with regard to the first invention in the detailed description of the invention. Under such circumstances, it is necessary for applicants to explain that each process of the first invention is well-known technology as of the priority date of the application concerned, … to enable a person skilled in the art to practice the first invention, in order to meet the description requirement, that is to say, the constitution of the first invention could be disclosed in the detailed description of the invention insofar as a person skilled in the art can easily implement the first invention…

As of the priority date of the application concerned, as for a recombinant DNA technology, even if the technology becomes a common technique with regard to specific living organisms, it is not clear whether the technique can be applied to other living organisms, and the fact is that a desk theory is often proven to be false. That means that even if a certain technology succeeded by chance with regard to the specific gene or characteristic of a

specific living organism, no one can tell whether the technology can be applied directly to other genes or characteristics of the living organism or to the genes or characteristics of other living organisms.

Also, there is no telling whether the technology can be applied without trials, which require time and labor. Moreover, when it comes to Monocotyledoneae, the application of recombinant DNA technology is considered to be more difficult than with other higher eukaryotes, and it is publicly known that the technology of Monocotyledoneae is behind that of Dicotyledoneae or animals, and the techniques to generate products with special characteristics through the complex mechanism is regarded as a difficult one to apply to other products.

Therefore, as to the first invention related to the recombinant DNA technology whose purpose is to manipulate complex mechanisms, that is to say, biological activities relating to the reproduction of plants including Monocotyledoneae, it should not be said that the detailed description includes sufficient disclosure to enable a person skilled in the art to implement the first invention easily, even if the techniques of each process are described as a mere abstract explanation in the detailed description of the invention .

[3] Others

Example 3 The claimed invention is incomplete, as the utility of the claimed invention with regard to many genes is not disclosed, though one of the embodiments of the invention, namely the expressed products encoded by the gene, turned out to have useful function and activities after the filing date.

○ **Heisei 10 (Gyo ke) 393**

"Recombinant Techniques for the Production of Novel Natriuretic and Vasodilator Peptides"

(Priority date: 1998/5/31)

Partial excerpt from Court Decision: …In the "detailed description of the invention" of this specification, the peptide encoded by sequence-32 is disclosed as one of the examples among a group of numerous peptides assumed to have natriuretic activity.

However, it cannot be accepted that the detailed description of the invention clearly indicates the peptide encoded by sequence-32 is a specific kind of peptide in comparison to the other peptides…

It cannot be recognized that a person skilled in the art could have perceived

this invention 2 as a completed invention from the detailed description of the invention as of this filing (this priority) date, even if the peptide encoded by sequence-32 turned out to have natriuretic activity after the filing date.

References

URL of related materials

Examination Standards (Examination Standards of Specific Fields, Chapter 2, Biological Invention)

http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/PartVII-2.pdf