

Judgments of Intellectual Property High Court, First Division

Date of the Judgment: 2005.10.19

Case Number: 2005 (Gyo-Ke) No.10013

Title (Case):

A case wherein, holding that in the case of inventions of gene-related chemical substances, their utility should be proved by a detailed explanation of the invention in the specification, the court determined that the application in dispute does not satisfy the enablement requirement and support requirement for the specification on the grounds that the scope of claims of which the major part is described with functional claims includes nucleic acid molecules that are not useful

References: Article 36(4) and Article 36(6) (i) of the Patent Act (prior to the revision by Act No. 24 of 2002)

Summary of the Case:

The plaintiff filed a patent application with respect to an invention entitled “weight modulator, corresponding nucleic acid and protein.” Subsequently, with respect to part of the invention, the plaintiff filed a divisional application under the title of “weight modulator, and corresponding nucleic acid and protein, and diagnostic and therapeutic use thereof,” which was refused by the examiner (this divisional application shall hereinafter be referred to as the “Application”). The plaintiff filed an appeal against the examiner’s decision of refusal. In the appeal proceedings, the JPO determined that the Application should be refused and the plaintiff’s claim cannot be accepted, holding as follows. (i) The scope of nucleic acid molecules relating to the present invention is unclear because it would include an infinite number of nucleic acid molecules of which nucleotide sequences irregularly differ from those of the nucleic acid molecules in the original scope, which are defined as “contiguous sequences of specific DNA molecules numbered 1, 3, 22 or 24 or complementary strands thereof,” and therefore the Application does not satisfy the requirement prescribed in Article 36(6) (ii) of the Patent Act. (ii) Since the scope of nucleic acid molecules relating to the present invention includes those that cannot be used as probes or primers, the present invention cannot be regarded as an “industrially applicable invention” and therefore the Application does not satisfy the requirement prescribed in the main clause of Article 29(1) of the said Act. (iii) The detailed explanation of the invention in the specification cannot be deemed to describe the present invention clearly and sufficiently enough to enable persons skilled in the art to easily exploit the invention, and therefore the Application does not satisfy the requirement prescribed in Article 36(4) of the Patent Act (prior to the revision by Act No. 24 of 2002) (this requirement shall hereinafter be referred to as the “enablement requirement”). (iv) The present invention cannot

be deemed to be effectively described in the detailed explanation of the invention in the specification, and therefore the Application does not satisfy the requirement prescribed in Article 36(6) (i) of the said Act (this requirement shall hereinafter be referred to as the “support requirement”). The plaintiff filed this lawsuit to seek reversal of the JPO appeal decision. The court upheld the JPO decision and dismissed the plaintiff’s claim, holding as follows.

(Concerning the enablement requirement)

(a) “In general, the essential purpose for inventions of chemical substances can be construed to be to provide new and industrially applicable chemical substances (or in other words, useful chemical substances). In the case of chemical substances that originally exist in nature, such as genes, a person who has only proved or identified the existence of such chemical substances should be regarded as having only discovered the substances, and even if he has separated the substances from their original state in nature and made some modifications to them, he cannot be regarded as having provided industrially applicable chemical substances in the form of product inventions. It is not until such chemical substances have been proved to be useful and given new technical aspects that cannot be found in prior art that they can be regarded as having been completed as industrially applicable inventions. In the case of inventions of gene-related chemical substances, their utility should be proved by a detailed explanation of the invention in the specification, and to this, the enablement requirement under Article 36 (4) of the old Patent Act that provided for how to describe the detailed explanation of the invention in the specification, applies.” “The purpose of the present invention is to provide ‘nucleic acid molecules with detectable labels that can hybridize with DNA molecules that encode weight modulators that can control fat accumulation and fat content of mammals.’ More specifically, the present invention is an “invention of chemical substances that are useful because they can detect and amplify ‘DNA molecules that encode weight modulators (OB genes)’ when they are used as probes or primers.” “The major part of the claims are described by way of functional claims.” “According to the descriptions of the claims, the scope of the present invention would include any nucleic acid molecules relating to the present invention that have the nature or effect of ‘being capable of hybridizing with the OB genes under highly strict conditions’ ; therefore, from the perspective of utility, it is necessary to examine the nature or effect that is required from the nucleic acid molecules in relation to the present invention.”

(b) “In order for nucleic acid molecules relating to the present invention to be used as probes or primers and correctly detect and amplify the OB genes, the nucleic acid molecules must hybridize with the OB genes in a unique manner. In this context, “in a unique manner” means that the nucleic acid molecules hybridize only with the OB genes, or in other words, they are clearly distinct from the OB genes.” “The scope of

the present invention would, according to the description thereof, include any nucleic acid molecules relating to the present invention that can be specified to have the nature or effect of 'being capable of hybridizing with the OB genes under highly strict conditions' ; therefore, the Application should be deemed to be in violation of the enablement requirement under Article 36(4) of the old Patent Act unless a detailed explanation of the invention in the specification describes the present invention clearly and sufficiently enough to show that all nucleic acid molecules relating to the present invention that have the above-mentioned nature or effect are useful, or in other words, can detect and amplify the OB genes in a unique manner when they are used as probes or primers."

(C) The results of more than 50 examples described in the detailed explanation of the invention in the specification cannot be deemed to be sufficient to enable persons skilled in the art to recognize utility or clear distinctiveness in the present invention.

Additionally, there is the objective fact that some nucleic acid molecules cannot be expected to hybridize with the OB genes in a unique manner, or in other words, are not useful. Consequently, it is obvious that the detailed explanation of the invention in the specification does not describe the present invention clearly and sufficiently enough to enable persons skilled in the art to exploit the invention, and therefore the Application does not satisfy the description requirement prescribed in Article 36(4) of the old Patent Act.

(Concerning the support requirement)

"The description requirement prescribed in Article 36(6) (i) of the Patent Act relates to the issue of whether or not the claims are supported by the detailed explanation of the invention, which is inseparably linked with the issue on the description requirement prescribed in Article 36(4) of the said Act." "According to the descriptions of the claims, the scope of the present invention would include any nucleic acid molecules relating to the present invention that have the nature or effect of 'being capable of hybridizing with the OB genes under highly strict conditions.' The results of more than 50 examples described in the detailed explanation of the invention in the specification cannot be deemed to be sufficient to enable persons skilled in the art to recognize utility or clear distinctiveness of the present invention. Additionally, there is the objective fact that some nucleic acid molecules are not useful. Gene-related inventions should not be regarded as industrially applicable inventions unless they are proved to be useful. The scope of claims for the present invention includes not only useful nucleic acid molecules described in the detailed explanation of the invention but also nucleic acid molecules that are not useful. In other words, the scope of claims goes beyond the scope of the invention described in the detailed explanation of the invention. Therefore, it is clear that the Application does not satisfy the description requirement prescribed in Article 36(6) (i)."

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