Column No.13

On Utilization of Patented Invention and Protection of Patent Right in Research Activities

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Restriction of Effects of Patent - Interpretation of "Experiment or Research" –

A cycle of intellectual creation means: (1) making an invention by research and development; (2) obtaining a patent right by the invention; (3) carrying out a business and generating profit by utilizing the right; and (4) carrying out new research and development using this profit. A speedy implementation of a cycle of intellectual creation is desired nowadays.

However, in order to promote a cycle of intellectual creation, freedom of research activities should not be disturbed. Especially, with respect to research activities in universities and public research institutes, there is a concern that "unless others' patented inventions are smoothly used, free research activities might be disturbed."

The Patent Law aims to contribute to industrial development by enabling the protection and use of inventions and to enhance the public benefit. In some cases, it is rather appropriate to limit the effects of a patent right in view of industrial development and public benefit. The effects of the patent right are made not to extend to such cases.

So, based on the above purport, Article 69 of the Patent Law defines the range that the effects of the patent right shall not extend. It specifies that "the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research"; however, this means that especially "experiment or research" does not originally aim at production of articles, use, and assignment related to the patent, but aims at advancing the technology to the next stage. It justifies that extending the effects of the patent right to the working would rather disturb the technical progress and spoil industrial development, and intends to bring about a balance between the patent right and the public benefit.

In addition, it was settled among the interpretations whether clinical experiments necessary for an application of manufacturing approval for generic medication and the like (various experiments and production of preparations used thereof) fall under the above-mentioned

"experiment or research" (see the decision by the second petty bench of the top court of April 16, 1999).

However, as regards the general interpretation of "experiment or research," there is not a sufficient accumulation of decisions, so the consensus is not definite, and we would have to say we greatly owe it to theory.

In the theory, the coverage of "experiment or research" is limited to experiments/research of a patented invention itself, and as for the purpose, it is limited to whichever experiments are aimed at **(a) investigation of patentability, (b) investigation of function, and (c) improvement/development.** That is, to acts aiming at advancement in technology, and it is said that an accepted theory is the same.

Instances Disturbing Free Research Activities

Since, in the field of biotechnology which is one of the recent advanced technologies, cases that disturb free research activities are noticeable, discussion about interpretation of "experiment or research" is frequently made. According to the accepted theory, it is interpreted that, as for working of the research tool patent such as the screening method, "exceptions to experiment or research" are not likely to be accepted except when the patented invention itself is intended for the "experiment or research."

Suppose, for instance, as an example of a research tool in biotechnology, that a patent has been granted to genes relevant to specified human diseases. Even if you produce and use the genes relevant to the diseases without prior consent, such conducts are "experiment or research" of the genes themselves and do not infringe if they meet any of the purposes (a) to (c).

However, to perform screening using genes relevant to the specified diseases to identify any pipeline compound for creating novel medicines does not meet any of the purposes (a) to (c). Therefore, according to the accepted theory, the act does not fall under "the exceptions to experiment or research."

Whereas, these research tools, which are higher technologies and substantially have no replaceability, are used without fail when new drugs are developed, and when used, the right-owners sometimes charge expensive royalties or force to conclude a license with a restrictive

use.

In such a current state, research activities in research institutes such as universities grow stagnant, and the advance in technology and industrial development which are naturally intended by the Patent Law might be disturbed. Hence discussions have been accumulated. (See "on Problems Relating to Smooth Use of Patented Inventions")

Which Course Should Be Taken in the Future?

In the above report "On Problems Relating to Smooth Use of Patented Invention" it is summarized that there is no particular problem in interpreting the accepted theory about the coverage of the exceptions to "experiment or research." However, to ensure free research activities in consideration of the patent owner's benefits, the report refers to reviewing reformed system/operation of compulsory license and other countermeasures. Although it may take time to study, we would like to watch the future development of the discussion.

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