REQUESTS OR OPINIONS

Addressed to the Trilateral Patent Office Commissioners* December 22, 2000

Suggestions regarding Patent for Bioscience Inventions*

Kunio OBARA**

Suggestion 1

To grant patents for genetic inventions, only in those cases where, at the time of filing application, the substantial utility of that invention has been made clear on the basis of actual proof or scientific evidence.

Recently, in the biotechnology field, due to the rapid developments in genetic sequence analysis means and accumulation of analysis data, a change has been made from the former research strategy, which was to "Search for and find genes having previously specified functions, and then analyze those sequences," to the current mainstream strategy, which is to "First clarify a genetic sequence, and then analyze its functions."

Consequently, for genetic inventions (ESTs, SNPs, full-length cDNAs, etc.), there has been a rapid increase in patent applications in which sequences have been disclosed while their utilities have not yet been established. Whether or not these should be patented has become a matter of international concern, and this topic has been debated in the Trilateral Patent Offices and at G7 meetings, among others.

In regards to this issue, we JIPA praise, as a step towards a solution, the conclusion reached in the Trilateral Patent Office Expert Committee meeting of June 2000, namely that "All nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, without indication of function or specific, substantial and credible utility, do not satisfy industrial applicability, enablement or written description requirements."

Indeed, A Trilateral Project "Comparative study on biotechnology patent practices: Nucleic Acid molecule-related inventions whose functions are inferred based on homology search", which has been made public in November 2000, shows that the examination standards on utility in each office almost meet the above conclusion though there are some differences between the practices in the Trilateral Offices. However, since the "Comparative study" teaches only the first official actions, the final patentability determinations considering the applicants' responses to such actions are still left uncertain.

Thus, in regard to the utility of genetic inventions, as based on the premise that, "To grant patents for genetic inventions, only in those cases where, at the time of filing application, the substantial utility of that invention has been made clear on the basis of actual proof or scientific evidence," we desire that the Trilateral Patent Offices as well as the Patent Offices of each member-country of the Patent G7 immediately strive for the harmonization of concrete examination practices. Most desirable would be the harmonization of examination practices on the following issues: what types of information are needed at the filing date to comply with the utility requirement standards; and the final patentability determinations on the utility requirements considering applicants' responses to the official actions.

* Mr. Kozo Oikawa, Commissioner of the Japanese Patent Office, Mr. Q. Todd Dickinson, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and Dr. h.c. Ingo Kober, President of the European Patent Office

** President of JIPA (the fiscal year 2000)

On the other hand, the "Comparative study" reveals that there are significant differences among the examination practices of the Trilateral Offices on inventive step/unobviousness. These differences may allow the existence of different scopes of patent right for a certain invention among the Trilateral countries. That is, the Trilateral examination practices have not yet harmonized. Thus, we also desire that the Trilateral Offices immediately strive for the harmonization of examination practices on inventive step/unobviousness of genetic inventions, as well as on utility, for reasonable protection for the level of technology.

Suggestion 2

Patents for compounds which have been specified only via screening methods should not be granted.

In the Post-Genomic Era, when the spotlight is now on the elucidation of functions, renewed attention will be given to such inventions as analysis methods for genetic functions and screening methods for useful compounds. These are so-called "screening patents." While large numbers of such patent applications have been filed and proceeded to examination at the Trilateral Patent Offices, various problems are arising, including determining what is to be patented; for patented rights determining in what ways they will obstruct the research of a third party; and whether or not such rights can be extended to cover future substances created as a result of research.

Screening-related technologies have hitherto been technologies implemented within the research and development stages of research institutions and private companies. In recent years, due to the fact that there has been a wave of novel, useful compounds which target specific genes or proteins, attention has been focusing on patent applications which have claims for "compounds specified but only via a screening method." A screening method is in no way a method for producing a product, nor a testing method incorporated within a manufacturing process.

If such claims are patented, the claimed compounds will be undistinguishable from known compounds, and problems will arise in terms of their novelty and clarity. In addition, these claims attempt to cover compounds which do not exist at the time of filing but which may be obtained in the future. However, there may be a problem from the point of view of enablement, considering that in a situation where the starting material has not been specified, actual compounds cannot be made.

These problems are not limited to only those cases where compounds have been specified via screening: common problems will also arise regarding claims for a product specified by only its function (method-of-use invention), for example, a claim in the form of "therapeutic agent for ailment X having a selective inhibitor of enzyme A as its effective component."

The Japanese Patent Office (JPO) published in June 2000 a case study, which showed that the JPO will not patent claims in the form of "compounds which have been specified only via a screening method." We JIPA highly regard this practice.

Nevertheless, agreement in regards to this practice among the Trilateral Patent Offices has not been appeared. Furthermore, even with respect to the granting of patents for a product only specified by its function, no clear and definite agreement has been reached.

Considering the fact that the impact of screening patents will greatly influence the way that patent rights are viewed, we strongly recommend that, a consensus be reached among all Trilateral Patent Offices and that appropriate protection along the lines of this suggestion be provided as soon as possible.