Research Study on Optimization of Strategy and Utilization regarding Intellectual Property in Biopharmaceutical Field (Summary)

I. Purpose of the Research Study

In the research study, it was aimed to prepare basic materials for support of intellectual property strategy or the like at the Japan Agency for Medical Research and Development, by

1) surveying and organizing domestic and foreign policies, laws and regulations, and court precedents, regarding presence or absence of special handling related to intellectual property at the time of research and developments and sales promotion in the biopharmaceutical field, and

2) surveying and exhaustively organizing the current situation and issues over the intellectual property rights of domestic and foreign institutions and companies conducting the research and development of biopharmaceuticals.

II. Content of the Research Study

(1) Public information survey

The following were surveyed, i.e. intellectual property related laws, regulations and guidelines, frameworks, public support and technology transfer policy of industry-academia-and government cooperation on intellectual property, patent term extension system and pharmaceutical regulatory system, etc. (the countries and region surveyed: Japan, the United States, European Union, United Kingdom, Germany, France, Switzerland, Sweden, South Korea, China, Singapore, India, Australia).

(2) Domestic questionnaire survey

With regard to the present situation of patent applications, strategy and policy of the right acquisition, status and strategy of licensing, joint research, and conflict with the third-party patent rights, etc., responces to the questionnaire were obtained from 61 universities and public research institutions (hereinafter, universities or the like) and 48 companies.

(3) Domestic interview survey

The interviews with 5 universities and 6 companies were carried out.

(4) Overseas interview survey

The interviews were carried out in Europe (7 companies and 1 technology transfer organization), the United States (3 companies, 1 university and 1 public research institution), South Korea (3 companies, 2 universities, the Korean Patent Office and 1 law firm), and China (1 company,

1 university and 1 patent firm).

III. Summary

(1) Summary of domestic questionnaire survey (excerpt)

(i) General overview of the situation at universities or the like

1) Role sharing of research stages among universities and companies

The high priority of the patent applications and right acquisition was given, relating to, in universities or the like, the genes and target biomolecules regarding the development of the disease, and, in companies, candidate substance and use of the biopharmaceuticals, respectively. It seems that the roles are so shared to each other that the researches at the early stages are weighted at universities or the like, and researches for practical applications in companies.

2) Handlings when third-party patent is found out

Many of the universities or the like conduct the validity search, when third-party patent (application or patent right) is found out in the research and development process. More universities or the like than companies answered to stop the research and development, if third-party patent is found out.

3) Likelyhood of patent applications under insufficient consideration of intellectual property strategy

(a) the number of patent applications by universities or the like is larger than that by companies,

(b) number of universities or the like who responsed that there are issues particular to biopharmaceutical in patent applications and right acquisition is much less than that of companies, so that recognition of the issues such as strategies setting or the like is significantly different between universities or the like and companies.

From the above, it is likely that universities or the like have less recognition of issues on strategy for patent applications and right acquisition and file patent applications with insufficient consideration on the intellectual property strategy aspect.

4) Collaborative research experiences with companies that compensate for shortage of experts resouces

While a relatively high proportion of respondants cited the shortage of human resources as an issue on strategy for patent applications and right acquisition, the issues on shortage of human resources have been less and the issues on aspect of intellectual property strategy have been recognized at universities or the like having an experience of joint application with a company. It is likely observed that universities or the like have acquired and utilized the know-how related to

intellectual property strategy through the experiences of collaborative research.

(ii) General overview of the situation in companies

1) Handlings when finding out third-party patent

There was the response that when third-party patent application is found out during the research, they consider to investigate the validity of it, avoid the conflict with it or the like, and invalidate, obtain expert opinion or the like for applications for substances or uses. Many of respondants consider concrete actions such as licensing, avoidance, invalidation, obtaining an expert opinion when third-party patent right is found out, and there were some respondants who consider to wait for the expiration of the patent right.

2) Difficult strategy on patent application and right acquisition of biopharmaceuticals

Regardless of the company size and whether the original biopharmaceutical manufacturers or biosimilar companies, many respondants answer that there are issues particular to biopharmaceuticals on strategy of patent applications and right acquisition.

3) Impact of patents of original biopharmaceutical manufacturers on biosimilar industry

In companies carring out research and development of biosimilar, the high ratio of respondants feel that much effort is required to ensure FTO (Freedom to Operate) to the patent portfolio of the original manufacturers, so the actual situation is observed that patent strategy of the original manufacturers functions effectively.

(2) Summary of domestic and overseas interview surveys (excerpt)

(i) patents on biopharmaceuticals

1) Case where broad scope patents are accepted

Majority of interviewees in Japan and overseas have the opinions that they can be convinced if the scope of right is appropriate in consideration of the technical significance of the invention (whether pioneer invention or improvement invention, or the like) and the balance of the extent of disclosures in the specification.

2) Strategy for patent application and right acquisition

In the domestic companies carring out reaseach and development of original pharmaceuticals, each company has different application strategy, and many of interviewees have the opinion that they pursue broad scope patents by using functional descriptions in right acquisition, if possible.

In domestic universities, there was the opinion that they consider the application and right

acquisition based on market research, commercial feasibility and the opinion of the companies, or the like. On the other hand, there was also the opinion that it is difficult to prepare broad claims due to lack of embodiments or the like, so that the current state that appropriate right acquisition is difficult was observed.

Many of overseas interviewees have the opinions that the discovery of new drug target molecule becomes difficult and broad scope patents were hardly accepted in any country.

3) Issues peculiar to patent applications for biopharmaceuticals

In domestic companies, while there is the opinion that it is difficult to specify the invention of the antibody in the structure, so that it is forced to use functional description, they have recognition of such issues that there is no sufficient skill to draft claims so that scope of the right become broader than disclosure by functional description, and it is difficult to determine whether to express the necessary scope of the right, etc. Domestic universities have felt such difficulties in preparing specification and claims that it is difficult to obtain broad scope right due to the lack of embodiements, and to define the biopharmaceutical products in the structure, etc.

In overseas companies, there were the comments that the inventions of antibodies are forced to use functional descriptions as it is difficult to define it structurally, and the opinions that many embodiements are necessary to support functional description, and that it is difficult to determine validity of patents for second medical use invention.

4) Handlings to third-party broad scope patents

In domestic and overseas companies, there were many opinions that since third-party broad scope patent has a big impact on research and development and they carry out sufficient FTO search and take measures. In domestic universities, there were many opinions that there is less impact of third-party patent on research and development (FTO search is carried out by the company in charge of collaboration).

(ii) The way of thinking about the injunction in right infringement action

In domestic and overseas companies carrying out research and development of original pharmaceuticals, majority of opinions is to delibarately determine whether or not to request for injunction in accordance with the case.