

Research and Study on the Way of Protection and Utilization of Intellectual Property for Formulation of Intellectual Property Strategy in Genomic Medicine Field (Summary)

Recent years, with advances and cost reduction of genome information decoding technology, and development of data analysis technology, it has become possible to test genome information of individuals more simply, so that such efforts is advanced toward realizing "genomic medicine" that enables more effective or efficient diagnosis, treatment and prevention of disease appropriate to constitutions or medical conditions of individual patients by using such information.

In particular, with regard to "genomic medicine" targeting cancer, following that "cancer genomic medicine" was explicitly stated as a priority issue in the "Basic Plan to Promote Cancer Control Programs of Third Term" (Cabinet decision on March 9, 2018 (Heisei 30)) and so forth, in cooperation with the government, research institutes, hospitals across the country and so on, the Cancer Genomic Medicine Promotion Consortium has been formed, and the effort toward practical applications have been promoted.

A major feature of the effort is that genomic test is performed under the health insurance treatment, so it is assumed that the patient's genomic and clinical information will be accumulated on an unprecedented scale. While the genome information and clinical information themselves are potentially useful as intellectual property, besides by utilizing these primary genome information and so on, it is expected that a large amount of intellectual property useful in the fields of diagnosis, treatment, drug discovery and so on will be yielded. In order to timely protect such a large amount of data and intellectual property produced at an accelerated pace, it is necessary to set up a new intellectual property strategy different from at the time of analyzing genes one by one and filing patent applications one by one.

Besides, the genomic test is funded by the national expense or the health insurance payment made by the general public, and the genome information is derived from the patient, so that the result of the genomic test is appropriately protected as the intellectual property of the general public on the one hand, whereas it is also necessary to exploit it effectively and to give back widely to the general public the obtained results (new diagnostic methods, treatments, drugs, etc.). Furthermore, in order for the government, research institutes, hospitals, and secondary user organizations to be able to effectively connect to their results achieving both protection and exploitation, it is urgently necessary to consider the way of relationship between these organizations about intellectual property and to establish the system for smooth implementation of genome medicine.

Accordingly, in the research study, the situation of intellectual property protection and utilization in public sector projects or private sector of genome information or related fields (bio-resources, medical related information) of Japan and foreign countries were researched. At the same time, it was clarified what kind protection and utilization of intellectual property regarding related technology are made through the research of intellectual property trends such as patents on genome medicine related technology. Through these, it was aimed to produce basic materials for consideration of the future direction of intellectual property strategy and intellectual property structure in the field of genomic medicine.