Osamu Yamamoto

Digital health in Japan

Mr. Yamamoto from Yuasa & Hara International Law shares his knowledge of the current situation of Japanese digital health.

There is no widely agreed upon and standardized definition of the term "Digital Health." In reality, the term covers a number of emerging technologies and refers to the collaborative integration of different technologies into the provision of healthcare for the management of personal health and wellness, and the prevention, diagnosis, control, and treatment of disease. The technologies that comprise digital health bring about improvements in health care by tailoring care to individual needs, and help to reduce medical costs. So-called 'big data', inherent in existing health records, holds tremendous potential for improvement in the provision of health care. While it is often the case that a particular technology - or group of technologies - may undergo rapid development, it is also true that the necessary drafting of new laws and revision of existing laws inevitably lags behind.

Mr. Yamamoto will here provide an explanation of the current situation of digital health in Japan.

Conditions in Japan

Japan is a so-called super-aging society in which the ratio of people aged 65 years or over to the total population reached a record 26.7% in 2015. Consequently, there exists in Japan a strong demand for innovative health care. Responsive to this demand, the Japanese government has adopted a number of measures to promote the development of digital health care.

Under Japanese law, with exceptions to patients living on remote islands etc, "Remote medical treatment" was essentially prohibited. A result of this conservative approach has been that the development of digital health technologies lies far behind that of the US and EU. However, in 2015, the Ministry of Health, Labor and Welfare substantially liberalized this area of health care provision and, as a result, rapid progress has been made in developing these technologies. Thus, for example, it is now possible to receive certain medical services without any need to visit a hospital, regardless of whether the hospital is geographically proximate. Following on, acquisition of vital data, such as a heart rate and blood glucose levels via wearable devices is now possible. As a result of liberalization, multiple IT ventures announced new applications and systems for remote medical treatment.

In Japan, the revised Act on the Protection of Personal Information was enacted in May 2017. The revised law clearly defines the definition of personal information and made it possible to utilize anonymously processed personal information under certain conditions. One effect of this revision is that anonymized and statistically processed data can be used for improving service provision and the creation of new businesses.

Pharmaceutical companies are keen to participate in the digital health field, recognizing that digital health impacts drug discovery, clinical development, and commercialization. Accordingly, there is now a tendency for big pharma companies to commence activities in the field of digital health in collaboration with other companies specializing in different technical fields, including a variety of start-up companies. The opportunities in the digital health era appear to be limitless, and the role of existing players will begin to change, while that of new players in the field will increase in importance. In any

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Résumé

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Osamu has extensive experience in biotechnology and pharmaceutical research and development at a chemical company for 10 years before specializing in intellectual property. He has represented a variety of companies in the fields of biotechnology, diagnostics, pharmaceuticals, and food and beverages. In addition to patent prosecution he is experienced in handling invalidation trials and providing expert opinions. He was recognized by LegalComprehensive as one of the Top 100 Lawyers 2016/17.

event, it is apparent that given the abundant competition and competition among startups to obtain venture capital funding, these digital health companies need to protect their innovations with intellectual property rights.

Patentable subject matter

In the U.S., the Supreme Court ruling in the case of *Mayo Collaborative Services v. Prometheus Laboratories* in 2012 concerning a diagnostic test stated that the correlation between the naturally-produced metabolites and therapeutic efficacy and toxicity to be an unpatentable "natural law" under Article 101. As a consequence, in the U.S. it is substantially difficult to obtain a patent directed to that type of diagnostics. On the other hand, in Japan it is possible to obtain a patent for an invention directed to diagnostics simply by employing careful claim drafting techniques, despite the fact that in Japan an invention of diagnosing a human is not a patentable subject matter. So, for example, a claim that is drafted to set forth "A method for providing an indicator to diagnose lung cancer, which comprising a step of measuring…" is patentable in Japan.

Following the disastrous Prometheus case, the U.S. Supreme Court then handed down a decision in the case of the Association for *Molecular Pathology v. Myriad Genetics* in 2013, stating that isolated naturally occurring genomic DNA is not patentable. Before issuance of the decision, such DNA patents provided auxiliary patent protection for diagnostic methods involving genetic testing. Again, in Japan, isolated genomic DNA is patentable. Thus, where a thing exists in nature but a need exists to artificially isolate that thing from its surroundings by use of a certain technique then such things are deemed creations. A potential exists under this system for ownership of diagnostic gene patents to become fragmented and to create an 'anticommons' in the area of genomic diagnostics. Consequently, there is both difficulty and expense involved in assembling the patent rights necessary to develop a panel of genetic tests. In Japan, at present, the situation is that major genes/mutations have been patented but, under the circumstances, at least one party held the collective rights - often as a result of licensing agreements entered into so as to conduct diagnostics tests.

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Further, in 2014, the U.S. Supreme Court in *Alice Corp. v. CLS Bank International* strengthened Prometheus by holding that abstract inventions, such as an algorithm, are not made patentable merely by implementing them on a computer. Under Japanese patent law, an "invention" is defined as a "creation of a technical idea at a high level which utilizes a law of nature." Here, the expression "a high level" is used to distinguish patents from utility models, so it is important to focus on the phrase "creation of a technical idea which utilizes a law of nature" to judge whether the subject is patent eligible.

In Japan, software-related inventions can be patent protected both as methods and things, so long as information processing by software is concretely realized by using hardware resources.

Regarding the inventions of IoT related technology, in order to improve predictability for obtaining patents relating to such technology the Japan Patent Office released a revised examination handbook that provides new case examples of patent examination of IoT related technology in September 2016, with a supplemental version being issued in March this year. Some examples relate to digital health: in this regard, please refer to the document at the JPO website titled "Case examples pertinent to IoT, etc. related technology" and visit: http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/ files_handbook_sinsa_e/app_z_e.pdf .

Personalized Medicine

Thanks to the great progress that has been made in next generation gene sequencers and artificial intelligence, personalized medicine is now a "hot' area within digital health; particularly in the treatment of cancer. Diseases and treatments are frequently dependent on combinations of multiple genetic variables and environmental factors. If it is possible to match patients to diseases and treatments more precisely, huge benefits can be gained from improved quality of treatment, reduced side effects, and reduction in medical treatment costs. Further, genomic big data analysis progress paves the way for the possibility of new drug exploration, including repurposing already-approved drugs for new or more targeted uses.

In Japan, there is a project titled "SCRUM-Japan": this is the first industry-academia collaboration undertaken in cooperation to conduct nation-wide genome screenings. The aims of the project are to develop new drugs and diagnostic techniques, to match a variety of genetic defects that exist in common among Japanese cancer patients.

As for patents, with regard to what constitutes a patentable subject matter, although applicants may find it challenging to obtain personalized medicine patents in the US, they may well have success in Japan and, as such, should be encouraged to seek Japanese patent protection in respect of their inventions. On the other hand, difficulties that such inventions may face are likely to be those relating to support and enablement requirements, particularly where it comes to obtaining a broad or even reasonable scope of invention. This is due to the complex relations that exist among combinations of multiple genetic variables and diseases.

Patent Infringement by multiple parties

The problem of patent infringement involving multiple entities may become more obvious with the progress of digital health technologies. In the case of a method invention, competitor digital health companies may not themselves perform all of the steps of a method claim but rather by collaboration among multiple entities the entire method is carried out. The same point applies to system inventions. The legal issue of infringement of patents involving multiple entities is roughly divided into two areas: direct infringement and indirect infringement. In the U.S., the stance implied by the so-called dependent thesis is that it is a necessary prerequisite that there be present the existence of direct infringement in order to establish indirect infringement. In Japan, no theories or judicial precedents have been established with regard to whether the existence of direct infringement as a prerequisite is necessary for establishing indirect infringement, and thus examination of this matter tends to be judged on a case-by-case basis.

US § 271 (b) stipulates a type of infringement referred to as "induced infringement." This is a provision by which indirect infringement is assessed based on the teaching and facilitating of infringement. Under Japanese Patent Law, there is no stipulation corresponding to "induced infringement."

Trade secret

In Japan, the Unfair Competition Prevention Act (UCPA) regulates trade secret infringement. The revised UCPA came into effect in January 2016, and the purpose of the revision was to amend both civil and criminal articles of the UCPA to deter infringement of trade secrets. Three key components of a trade secret are the act of keeping a thing secret, that the thing kept secret consists of valuable information, and public disclosure of the object of secrecy has not occurred. Evaluation needs to be applied to determine whether such innovation constitutes a type of invention that can actually be maintained secret. The company Myriad has a very large test-results database that is classified as a trade secret. The company's strategy is to retain and expand its secrecy-based advantage of knowledge of mutation data and applicable relatively simple algorithms.

"Secrecy" is not desirable for development of technologies, especially in medical fields. Since personalized medicine involves complex and frequently implicit relationships, it is crucial to maintain as much transparency as possible for the purposes of validation and recognition of oversight. In this context, cumulative innovation established based on shared data and algorithms is preferable.

Final remarks

Digital Health is a new area of technology and it is of high importance to adopt the best IP tactics in order to properly appraise value. For example, for pharmaceutical or biotech companies, there may be a need to file a relatively large number of patent applications unlike in conventional practice, and to actively apply a system of accelerated examination. If a digital health product belongs to a class over a certain risk criteria, it is necessary to obtain appropriate approval from the Japanese government. Many issues remain to be tackled within the technical and legal fields of digital health, and proper consideration should be given to valid ways of implementing intellectual property that is supportive of the development of products globally.