ColumnNo.8

Acts Related to Medical Services and Patent Protection

【2005/2/23】

Do you know that Japan's Patent Law does not approve a patent right on a medical act to human beings? For example, so-called medical acts performed by physicians, such as operating a human body (using medical equipment such as a surgical knife), treating (with medication or injection), or diagnosing (by X-ray or electrocardiogram) are not objects for protection as they are not industrially applicable inventions (the Patent Law Article 29, main paragraph). Meanwhile, medicines and medical equipment themselves are included in objects of patent protection.

Despite the fact that the modern medical practice itself owes so highly to medical products and medical devices, why is only a medical act not included in the objects of protection? There is one trial example that gave a clear answer to this question (Tokyo High Court, April 11, 2002: 2000 (gyo-ke) No. 65).
Here, it is discussed that a physician's medical act in a medical site should be freely performed. That is, where medicines and medical devices are objects of patent, a physician may not be able to use them; however, when he/she is going to do a medical act by preparing medicines and medical devices within a range he/she can use, the physician can demonstrate his/her own ability, without worrying about whether or not such a medical act is an object of a patent. On the other hand, if patentability is approved for a medical act itself, physicians may treat patients with a fear that he/she may be accused of infringing on a patent. So, it is held that such a system as to drive a doctor who is going to perform a medical act into such a situation is extremely unjust and that the patent system in our country does not approve such a result.

Then, how are medical acts considered in countries other than Japan? Let's compare our system with the U.S. and Europe which are great patent countries like Japan. First, the U.S. Patent Law has no rule to exclude a medical act, and all of medical acts are protected, but at the same time, it provides that the effect of the patent right does not extend to medical acts by physicians. Meanwhile, in European Patent Convention, in consideration of social ethics and public health, methods of surgery, treatment and diagnosis for not only human beings but also animals are excluded from the protection object. However, in Europe, the contents of methods of diagnosis are interpreted somewhat more mildly than in Japan, and testing methods by NMR and X-ray (namely, methods to obtain only an intermediate result for diagnosis) can be objects of patent.

Under these circumstances, in Japan, too, a "Specialized Investigation Committee to Deliberate on Method of Patent Protection for Acts Related to Medical Services" was established in the Intellectual Property Strategy Headquarters in July 2003, and a review on whether or not our patent protection relative to medical-related acts is enough was underway. The results of the review were reported recently (on the method of how patent protection for medical acts related to medical services should be).

According to the report, "methods of operating medical devices" regarding how medical devices should be operated to enable the devices to display their intended functions can be distinguished from "medical acts" by physicians (medical acts exclusively done by physicians), and it was concluded that their entirety should be protected.

Along with this "operation method of medical equipment," "a method of producing new efficacy/effect of medicines" (a method of using medicines) on devises about a combination of plural medicines, dosage, interval of administration have also been studied. However, as for this, there remained a problem that is hardly distinguishable from a physician's act, and the case was shelved at that time, so as to pursue a possibility to expand protection as a patent of product and clarify it in the examination standard or the like.

At any rate, relief of a patient is a primary objective, and it is the basic premise not to affect a physician's act. It remains unchanged that skills relating to a physicians' act does not become an object for patent in Japan.