JAPAN

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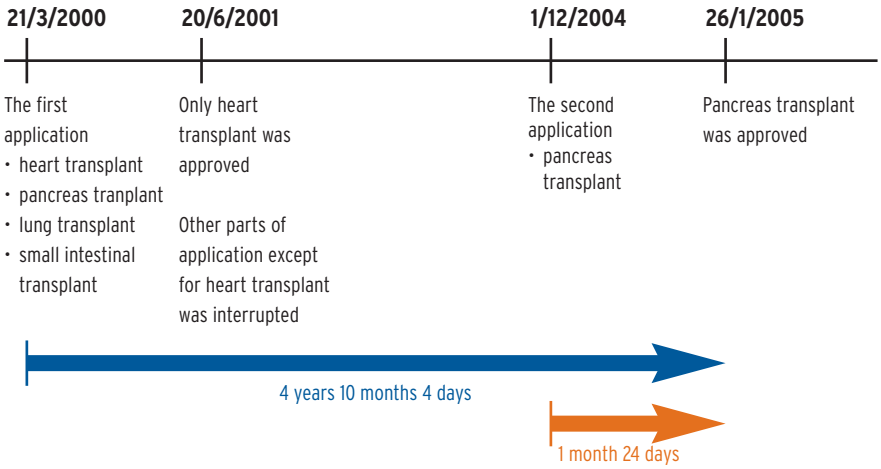
Ministry's convenience does not justify rejecting patent extension



Article 67-3(1)(iii) of the Patent Act provides that an application for patent term extension shall be rejected when the period for which the extension is requested exceeds the period during which the patented invention was unable to be practised. In this case, the issue was whether this case fell under this ground of rejection or not.

Summary of the case

Novartis, the plaintiff, is a patentee of an invention for "pharmaceutical composition comprising a cyclosporin". Nihon Chiba-Geigy, Novartis's affiliated company in Japan, filed an application for an approval on a use of a drug of which the active ingredient was cyclosporin for suppressing rejection of organ transplants of the heart, lung, pancreas and small intestine (the first application in the figure).

The first application was approved regarding only heart transplant. Regarding other parts of application except for heart transplant, the examination was interrupted. On December 1 2004, Nihon Chiba-Geigy filed an application for an approval on a use for pancreas transplant (the second application in the figure). The second application was approved on January 26 2005.

Novartis applied for patent term extension claiming that "the period during which the patented invention was unable to be practised" was four years 10 months and four days from March 21 2000, which was the date of the first application, to January 26 2005, which was the date of the approval on a use for pancreas transplant.

However, the JPO rejected this application and the trial board of JPO dismissed an appeal. The trial decision stated that "the period during which the patented invention was unable to be practised" was one month 24 days from the date of the second application to that of the approval on a use for pancreas transplant and that the application for four years 10 months four days fell under Article 67-3(1)(iii). Novartis appealed to the IP High Court seeking rescission of the trial decision. Our firm represented Novartis.

Background to the case

The reason Nihon Chiba-Geigy filed an application in two parts was as follows.

In Japan, the Act on organ transplant was enforced in 1997, and organ transplant under brain death became legally possible. Therefore, it had been deemed to be urgent that cyclosporin, which was used to suppress the rejection of organ transplants of heart, lung, pancreas and small intestine, be approved.

Because of this background, the Ministry of Health, Labour and Welfare (MHLW) encouraged Novartis Pharma, Novartis's subsidiary in Japan, to file an application for approval on a use of cyclosporin for suppressing rejection of organ transplants. In response to this, Nihon Chiba-Geigy filed the above-mentioned first application.

In examination to the application, granting approval on a use for organ transplants including the pancreas was assessed as allowable. However, on April 27 2001, MHLW informed Novartis Pharma that MHLW would interrupt the examination regarding the transplant of lung, pancreas and small intestine because the clinical site would be confused if only the drug were approved before the surgical form was granted an approval of highly advanced medical treatment.

In Japan, medical treatment is covered by national health insurance in general. Regarding an ordinary medical treatment, the government bears most of the medical expenses and a patient bears them only partially. Regarding advanced medical treatment, although it is originally not covered by national health insurance, some parts of the treatment come to be covered by national health insurance if the medical treatment is granted an approval as the highly advanced medical treatment.

On the other hand, when a drug is granted approval for producing and selling, the drug usually comes to be covered by national health insurance. According to the Council of MHLW, an official stance is that a surgical form should be granted approval of the highly advanced medical treatment after it achieves a certain number of satisfactory results, and at this time it should be incorporated into national health insurance for the first time. Therefore, MHLW would not grant a drug an approval for producing and selling which results in the incorporation into national health insurance before an approval of the highly advanced medical treatment.

After this explanation by MHLW, the first application was approved regarding only a heart transplant (in Japan in those days, a heart transplant had been granted approval as a highly advanced medical treatment). At that time, MHLW said that scientific examination on the remaining lung, pancreas and small intestine had already terminated and therefore an approval would be granted only with clerical examination.

After that, a pancreas transplant is granted approval as a highly advanced medical treatment. Therefore, on November 9 2004, MHLW encouraged Novartis Pharma to file an application for approval on a use of cyclosporin for pancreas transplant. In response, Nihon

Chiba-Geigy filed an application for partial changes which added a use for pancreas transplant to uses of cyclosporin (the second application) and it was approved.

Judgment of IP High Court

In the judgment of November 19 2009, the IP High Court accepted our arguments and rescinded the trial decision.

In view of these facts, Nihon Chiba-Geigy filed an application for approval on a use of cyclosporin for pancreas transplant on March 21 2000 and was granted approval on January 26 2005 without submitting a withdrawal application. During this period, objective circumstances where Nihon Chiba-Geigy should abandon the sale of cyclosporin for pancreas transplant were not found. Therefore, it is reasonable to say that during the period from April 27 2001, when MHLW informed that they would not approve use of cyclosporin for pancreas transplant for the moment, to November 9 2004, when MHLW encouraged the application, MHLW merely suspended an approval by the reason of adjustment with national health insurance. It is clear that Novartis, the patentee, could not practise the patented invention during the period. Therefore, it is not appropriate to exclude this period from the computation period.

Practical tips

The IP High Court's judgment concluding that the above period should not be excluded from the computation period is just and proper because in this case Novartis was forced to wait due to MHLW's convenience despite that approval should be granted in the usual course as the scientific examination confirming efficacy and safety was terminated.

This is the first patent term extension case for organ transplant drug where approval was suspended due to MHLW's convenience. Patent term extension will be granted regarding the suspended period similarly for other advanced medical treatment such as surgical methods using high technology, radiation therapy, regenerative medicine, anti cancer drug, and immunotherapy if the approval was suspended due to MHLW's convenience.