Japan

“Enablement and Support”

**Patent Act, Secs. 36(4)(i), 36(6)(i) – *Sawai Pharmaceutical Co., Ltd.*
*v. Takeda Pharmaceutical Co., Ltd.***

**Intellectual Property High Court
11 April 2012**

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The requirements of “enabling disclosure” and “support” are distinct from each other and must be assessed individually.

As working of an invention in the case of a product means producing and using, etc., an enabling disclosure according to Sec. 36(4)(i) Patent Act can be affirmed where a process of producing the product is specifically described in the detailed explanation of the invention. If there is no such description, it is sufficient if a person skilled in the art can produce that product based on the state of the art at the time of the application. The invention at issue was a medical drug produced from the combination of two different kinds of drugs. As the state of the art at the time of the application enabled a person skilled in the art to produce each of the drugs for such combination even without any description of the process for producing it, the court found that the invention was sufficiently disclosed.

The requirement that the claims must be supported by the description according to Sec. 36(6)(i) Patent Act requires an assessment whether or not an invention determined by the scope of claims is written in the detailed explanation of the invention and whether a person skilled in the art can recognize this description as solving the problem of the invention either based on the description of the detailed explanation of the invention, or based on the state of the art at the time of the application. As for the case in question, although there is no such description of experiments for the concomitant administration, the court found that a person skilled in the art when considering the state of the art at the time of the application can obviously assume that the concomitant administration can achieve the effect of the invention, for which reason the support requirement is satisfied.

Summarised by Hisayoshi Yokoyama.