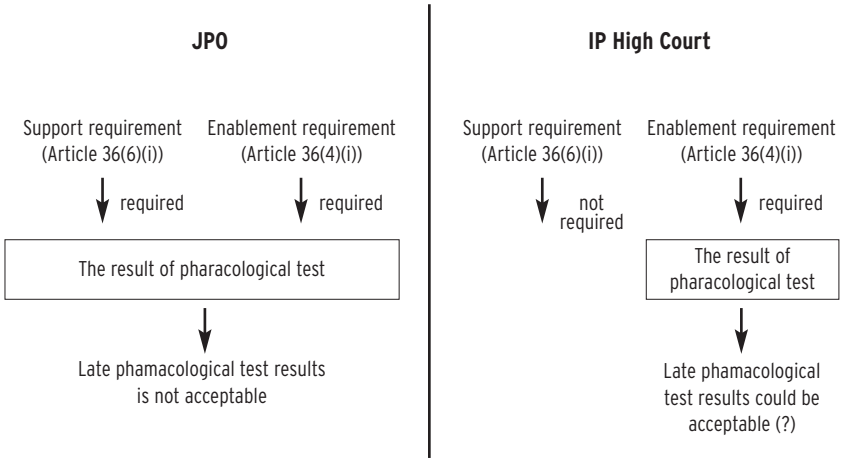
JAPAN

ABE & PARTNERS
Osaka

Takanori Abe

and
Michiko Kinoshita

Late pharmacological test results and disclosure



Japanese practice, under which late pharmacological test results are rarely accepted, has been criticised by foreign pharmaceutical companies for being in discord with western practice and making it difficult to pursue a global IP strategy. Recently, the IP High Court warned against too strict examination by the JPO and rendered a judgment that should promote international harmonisation.

Late pharmacological test results

The Japanese Patent Act contains an enablement requirement and a support requirement as disclosure requirements. The enablement requirement is related to the detailed description of the invention and the support requirement is related to the scope of patent claims. Article 36(4)(i) provides that "the statement of the detailed explanation of the invention shall be clear and sufficient as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention" (the enablement requirement) while Article 36(6)(i) provides that "the statement of the scope of claims shall comply that the invention for which a patent is sought is stated in the detailed explanation of the invention" (the support requirement).

JPO Examination Guidelines provide, regarding the enablement requirement of medical inventions, that a medicinal invention resides in a technical field where it is generally difficult to infer how to make and use a material on the basis of its structure and its name, a description of the pharmacological test result or a statement that should be deemed to be equivalent thereto is usually required as for working examples supporting the medicinal use. It is still difficult for a person skilled in the art to predict whether the compound and so on is actually usable for the specific medicinal use when the pharmacological test result or a statement that should be deemed to be equivalent is not described in the description as filed. Accordingly in such a case, in principle, reasons for refusal are sent. It should be noted that even if the pharmacological test result is submitted later, the reasons for refusal are not overcome. JPO Examination Guidelines also provide regarding the support requirement of medical inventions that when the pharmacological test result or a statement that should be deemed to be equivalent is not described in the description as filed, the support requirement is not fulfilled.

The JPO has frequently refused applications on the ground of violation of the support requirement in cases where the pharmacological test result is not described. Court precedent has shown the same tendency. Similarly, regarding the enablement requirement, court precedent seems to adopt the same criteria as JPO Examination Guidelines and late pharmacological test results were rarely accepted. However, a recent judgment warned against the JPO's frequent refusal on the ground of violation of the support requirement and indicated the possibility of accepting a late pharmacological test result less strictly regarding the enablement requirement. The chief judge in this case was Judge Iimura, the current chief judge of the IP High Court, who was also the chief judge for the judgment of July 15 2010, where the IP High Court accepted late experimental data regarding inventive step.

The case

Boehringer Ingelheim filed a patent application with regard to an invention relating to the use of a drug – "use of Flibanserin for the treatment of a sexual disorder" – but was refused by a JPO examiner. Although Boehringer Ingelheim appealed to the Trial Board of the JPO, the request was dismissed. The reason for the JPO's decision was as follows: In the case of an invention relating to the use of a drug, the detailed explanation of the invention must include pharmacological data or a statement that should be deemed to be equivalent, thereby proving the usefulness of such use. In this case, the detailed explanation of the invention includes nothing to prove the usefulness of Flibanserin. Consequently, the support requirement is not satisfied. Boehringer Ingelheim appealed to the IP High Court seeking rescission of the JPO's decision.

In a judgment on January 28 2010, the IP High Court rescinded the JPO's decision. The court held that except where there are special circumstances, "pharmacological date or a statement that should be deemed to be equivalent thereto" cannot be regarded as a necessary prerequisite in terms of satisfaction of the support requirement, because the support requirement and the enablement requirement are mutually independent. Regarding the enablement requirement, the court stated that it cannot be satisfied in most cases if "pharmacological date or a statement that should be deemed to be equivalent thereto" is not described, however the court stated as *obiter dictum* that when the court decides whether the enablement requirement is satisfied or not, even if there is no specific description, the court should consider all the circumstances and decide whether a person skilled in the art can understand the technical meanings, such as problems to be solved by the invention and means for solutions, and can practice the invention.

Practical tips

According to Judge Iimura's article (Toshiaki Iimura, Current State of Disclosure Requirements in Japan: A

Judge's View, in Patent Practice in Japan and Europe 107, 118-119 (Bernd Hansen & Dirk Schüssler-Langeheine eds., 2011)), the intent of the IP High Court was as follows: As using the same method for both requirements would give rise to severer results for the applicant, the judgment is able to avoid to some degree the risk that pioneering inventions would not be patented. In addition, the judgment has put the brakes on a trend at the JPO toward stricter judgment standards. However, since this judgment the JPO has tended to apply both the support requirement and the enablement requirement together and is not following this judgment.

Regarding the enablement requirement and a late pharmacological test result, the JPO and the former court precedents have adopted the following criterion: a late pharmacological test result is not accepted in general because it is against the first-to-file system and the exchange for secrets theory, however if there are descriptions which enable to infer the effect in the specification, a late pharmacological test result could be accepted. Japanese practice has been criticised by foreign pharmaceutical companies for not being in line with western practice and making it difficult to pursue global IP strategy. The *obiter dictum* that said regarding the enablement requirement that the court should consider all the circumstances even if the fact is not specifically described in the specification seems to imply that there would be a case where a late pharmacological test result could be accepted even if there is no specific description in the specification.

Half a year after this judgment, Judge Iimura rendered a judgment (July 15 2010, IP High Court) and accepted late experimental data regarding inventive step less strictly than before. He seems to promote international harmonisation and correct the situation where only Japan has too strict a standard by accepting late experimental data or pharmacological test results less strictly regardless of inventive step or the enablement requirement. We will have to wait and see whether this tendency will be followed elsewhere.