Flibanserin Case

Intellectual Property High Court, Third Division

Case H21 (Gyo-Ke) 10033, Judgment on January 28, 2010

Facts

The plaintiff found in research on patients suffering from sexual dysfunction that Flibanserin, a compound which has conventionally been known as a drug for treating depression and the like, can exert a property enhancing sexual activity, and filed a patent application pertaining to an invention entitled "[u]se of Flibanserin for treatment of sexual disorder" (invention relating to the use of a drug).

The patent application was rejected by the Japan Patent Office (JPO) examiner on the grounds that the stated scope of claims regarding the invention in question did not satisfy the requirement prescribed by Article 36, paragraph (6), item (i) of the Patent Act, "the invention for which a patent is sought is stated in the detailed explanation of the invention (hereinafter referred to as "support requirement)." In the trial procedure contesting the rejection before the JPO, the plaintiff's request against this decision of refusal was also dismissed by the trial examiner.

The plaintiff filed a suit with this court to seek rescission of the JPO decision of dismissal.

The specification in the present case describes the target and scope over which Flibanserin can exert usefulness, the variation in chemical structure and formulation, the preferable application methods and dose range, permissible additional components and the like. As examples, the constitutional components and production methods of Flibanserin containing formulations are described.

However, the specification of the present case does not describe an experimental example that actually employs Flibanserin for the treatment of a sexual disorder. That is, no experimental result that can support the usefulness of Flibanserin as a treatment drug for a sexual disorder is found in the specification of the present case.

Main Issues

In the case of an invention relating to the use of a drug, is it necessary, for satisfying the support requirement, that a detailed explanation of the invention include pharmacological data or a statement that should be deemed to be equivalent thereto, thereby supporting the usefulness of such use?

Holding

Approved

The provisions of Article 36, paragraph (6), item (i) of the Patent Act are laid down for the purpose of excluding the possibility that too broad an exclusive right will be granted based on the statement of the "scope of claims," as compared to the statement in the "detailed explanation of the invention." Therefore, it is sufficient to compare the statement of the scope of claims and the statement of the detailed explanation of the invention, and examine whether the scope of the former goes beyond the scope of the latter, applying a construction method that is necessary and in line with the purpose.

In the process of construing said provisions and making a determination, it is impermissible to apply completely the same method as that applicable when examining whether the requirement under paragraph (4), item (i) of said Article (enablement requirement) is satisfied, except where there are special circumstances.

In this case, since there are no such special circumstances, and the statement of the scope of claims does not go beyond the scope of technical matters disclosed in the detailed explanation of the invention, the support requirement is satisfied.