

Judicial decision indicating that it is inappropriate to make a decision of an violation of support requirements on the ground of lack of pharmacological data in the specification at the time of the filing of the application.	<ul style="list-style-type: none"> - Pharmacological Data - Inappropriate Description - Support Requirements
Case No :	No.10033 (Year 2009) Intellectual Property Court No.3
Date of Judgment:	January 28, 2010
Plaintiff:	BOEHRINGER INGELHEIM PHARMA [DE]
Defendant:	Commissioner of the Patent Office
Application No:	WO03035072(A1) / Patent Application Publication 2005-506370
Related Provisions: Article 36, Paragraph(6), Item(i) Article 36, Paragraph(4), Item(i)	Summarized by: Hitoshi MAEDA <i>Patent Attorney</i>

Point of Issue:

This case was referred to a judicial court to judge whether it is appropriate or not in medical-related invention, in terms of recognizing a violation of support requirements [Article 36(6)(i)] because of a lack of description regarding pharmacological data in the specification at the time of the filing of the application.

Plaintiff's Assertion:

In the invention of use regarding medication, it is necessary to show the utility of its use, however, it does not mean that there always has to be the description of “pharmacological data or other similar description” in order to back up the utility of its use. The point is that the description which enables the skilled person to confirm the utility of its use should be enough.

Defendant's Assertion:

In order to clarify that the invention supposed to be patentable is well described in the detailed explanation of the invention, it is necessary to be backed up the utility of its use by describing “pharmacological data or other similar description” in the detailed explanation of the invention. Japan Patent Office also indicates the same way in the criteria for examination guideline.

Judicial Decision:

Regarding the description of “the scope of claims”, the provision of support requirements [Article 36(6)(i)] was set to the following spirit that a grant of overbroad exclusive rights is to be eliminated in contrast with the description of “the detailed explanation of the invention”. From this intent of the provision, it was determined that it is inappropriate to make a judgment of a violation of support requirements [Article 36(6)(i)] only because of a lack of description of “pharmacological data or other similar description”. However, it is required that the technical matters stated in the scope of claims has to be described in the detailed explanation of the invention. This application was recognized that it satisfies the above requirement.

Note:

In Japan, the enablement requirements [Article 36(4)(i)] is requested along with the support requirements for the description requirements. In the judgment of this case, the enablement requirements did not become a point of issue, however, there is a possibility that this case becomes a problem in the future in decision of Board of Appeal to which this case is went back. More specifically, even though the support requirements are recognized, there remains a possibility that this case is to be rejected as a violation of enablement requirements, on the ground that the specification did not mention about the pharmacological data. In addition, the enablement requirements means that the detailed explanation of the invention has to be described so that the skilled person could implement the invention described in the scope of claims based on the detailed explanation of the invention.

For the existing judicial decisions in Japan, there are many precedents that were judged as inappropriate descriptions on the ground of lack of description of pharmacological data. For example, case no. 104(Year 2003), case no. 10312(Year 2005), case no. 10818(Year 2005), case no. 10134(Year 2009) and the like.

However, in Japan, it is expected to approach the Western precedents that “the pharmacological data is not always necessary”, after the judicial decision of this case.