

Patent Right	Date	July 2, 2020	Court	Intellectual Property High Court, Third Division
	Case number	2018 (Gyo-Ke) 10159, 10153		
<p>- A case in which it was determined that a determination of a trial decision that an invention does not comply with the support requirement was erroneous.</p> <p>- A case in which it was determined that a determination of a trial decision that an invention does not lack an inventive step was not erroneous.</p>				

Case type: Rescission of Trial Decision of Invalidation

Result: Granted

References: Article 36, paragraph (6), item (i), and Article 29, paragraph (2) of the Patent Act

Related rights, etc.: Patent No. 4162491

Decision of JPO: Invalidation Trial No. 2016-800130

### Summary of the Judgment

1. The present case is a lawsuit for rescission of a trial decision for a trial for patent invalidation concerning the invention of "FORMULATION OF BORONIC ACID COMPOUNDS". The trial decision determined that there is no ground for invalidation due to lack of an inventive step of the invention, but there is a ground for invalidation due to non-compliance with the support requirement.

2. This judgment held on the support requirement as follows, and held that it was erroneous for the trial decision to determine that the invention does not comply with the support requirement.

#### (1) Procedure for Determination on Compliance with the Support Requirement

A determination on whether the statement of the Scope of Claims complies with the support requirement of the description shall be made as follows. First, a comparison is made between the statement of the Scope of Claims and the statement of the Detailed Description of the Invention. Then, a consideration is made on whether or not the invention stated in the Scope of Claims is the invention stated in the Detailed Description of the Invention, and is within the scope where a person ordinarily skilled in the art can recognize that the statement or the suggestion of the Detailed Description of the Invention can solve the problem of the invention, and even if there is neither such statement nor such suggestion, whether or not the invention stated in the Scope of Claims is within the scope where a person ordinarily skilled in the art can recognize that the problem of the invention can be solved in light of common general technical knowledge at the time of filing the application. Based on the comparison and the

consideration as mentioned above, the determination on the compliance with the support requirement shall be made.

In order to comply with the support requirement, it is construed that it is sufficient for a person ordinarily skilled in the art, who has read the description, to reasonably recognize that the claimed invention is stated in the description. With regard to the solution to the problem, it is construed that it is sufficient to state the solution to the problem to the extent that a person ordinarily skilled in the art can reasonably expect that the problem can be solved in light of common general technical knowledge, and it is construed that it is not necessary to state the extent to which the statement reaches a rigorous scientific proof. This is because the support requirement is derived from the essence of the patent system, which grants a patent right as a reward for laying the invention open to the public, and therefore the purpose of imposing the support requirement can be achieved to some extent if a person ordinarily skilled in the art, who has read the description, can contribute to the further development of the art by conducting a retest and an analysis of the invention. In addition, this is also because it is not reasonable to require that the contents of the description be demonstrated to the same degree of rigor as required in a scientific paper, taking into consideration that the description is prepared under the time constraints of the first-to-file system.

#### (2) Problem of the Present Invention

According to the statement of the present description, the problem to be solved by the present invention is to provide the present compound (bortezomib mannitol ester in the form of a lyophilized powder) which can be a stable pharmaceutical agent when formulated and which can be a composition which readily releases a boronic acid compound upon dissolution in aqueous media. In order that it can be deemed that this problem has been solved, it is construed that it is necessary that a considerable amount of bortezomib mannitol ester in the form of a lyophilized powder has been produced, and that the bortezomib mannitol ester has certain levels of storage stability, easiness of dissolution, and easiness of hydrolysis. Therefore, it will be considered whether it can be deemed that these points are stated or suggested in the present description in the sense as mentioned in the above (1). It should be noted that the "considerable amount" as used herein means an amount which can provide a solution to the above problem as a pharmaceutical agent.

#### (3) Determination Results on Compliance with the Support Requirement

It can be deemed that in light of common general technical knowledge at the time of filing the present application, a person ordinarily skilled in the art can understand from the statement, etc. in the working examples in the present description that the

present invention can solve the above problem in the sense as mentioned in the above (1).

3. With regard to an inventive step, this judgment upheld the determination of the trial decision that it cannot be deemed that the invention lacks an inventive step.