ANTIEMETIC COMPOUND CASE

Tokyo High Court

Case H8 (Gyoke) 201 (Oct. 30, 1998(H10))

FACTS

The case is a litigation rescinding the JPO trial decision which dismissed a request for a trial against a final rejection. The present invention relates to a formulation comprising Rhizoma Zingiberis and specific extracts of Ginkgo biloba as active ingredients used for prevention of nausea and vomiting. The specification describes medication effects (both ingredients work coefficiently and phenomenally potentiate the effect) and some dose amounts and administration periods.

However, in the specification, no concrete descriptions or experimental data are described regarding what level of nausea and vomiting are prevented by administration with the described amounts and periods, or what synergetic effect there is with reference to a single dose.

ISSUE

Does the enablement requirement require pharmacological data or the same level description in the specification?

HOLDING

Generally with a pharmaceutical application invention, it is usually difficult to predict its usefulness (effect) based on its name or chemical structure, thus one skilled in the art cannot understand whether the pharmaceutical agent has actual usefulness (effect) only from amounts of the active ingredient, dosing method, preparation condition and the like described in the specification.

Hence, the pharmacological effect of a pharmaceutical application invention should be described in the form of pharmacological data or at the same level of description in the specification. Assertion or explanation based on new example data is not accepted when no working example supporting the new example data is described in the original specification.