

Patent Right	Date	December 27, 2021	Court	Intellectual Property High Court, First Division
	Case number	2020 (Gyo-Ke) 10077		
<p>- A case in which, with regard to a patent for a series of inventions titled "5-HT<sub>1A</sub> receptor subtype agonist," the court found that there was an error in the JPO Decision that held that the inventions do not satisfy the enablement requirement and support requirement.</p>				

Case type: Rescission of Trial Decision of Invalidation

Result: Granted

References: Article 36, paragraph (4), item (i) and paragraph (6), item (i) of the Patent Act

Related rights, etc.: Patent No. 4178032

Decision of the JPO: Invalidation Trial No. 2018-800113

### Summary of the Judgment

1. (1) In connection with the Plaintiff's patent for a series of inventions titled "5-HT<sub>1A</sub> receptor subtype agonist" (hereinafter referred to as the "Patent"; and each of the inventions as "Invention 1" to "Invention 5," respectively), in response to a request for a trial for invalidation of the Patent, the JPO rendered a decision (the "JPO Decision") to (a) invalidate the patent relating to inventions claimed in Claims 1, 4 and 5 and to (b) dismiss the request for invalidation concerning an invention claimed in Claim 2. The Plaintiff filed this lawsuit to seek rescission of the JPO Decision with respect to the point (a) above.

(2) Claim 1 of the Patent discloses an invention, "a pharmaceutical composition for treating a disorder of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype, selected from the group consisting of depression, ... bipolar I disorder, ... and bipolar II disorder"; Claim 2 of the Patent discloses an invention, "a pharmaceutical composition for treating depression, which is a disorder of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype"; Claim 4 discloses an invention, "the pharmaceutical composition claimed in Claim 1, wherein the disorder is ... bipolar I disorder"; and Claim 5 discloses an invention, "the pharmaceutical composition claimed in Claim 1, wherein the disorder is ... bipolar II disorder."

(3) The JPO Decision held that the inventions claimed in Claims 1, 4 and 5 do not satisfy the enablement requirement and support requirement. The summary of the reasons for the JPO Decision is as follows:

A. Ground for Invalidation 1 (violation of the enablement requirement)

(A) A person ordinarily skilled in the art would be able to understand that aripiprazole which is the carbostyryl compound in question (the "Carbostyryl Compound") is a 5-HT<sub>1A</sub> partial agonist, based on the results of the pharmacological test (an in-vitro test) described in the detailed explanation of the invention contained in the description for the Patent (the "Description"). However, the detailed explanation of the invention does not disclose the results of any clinical test that demonstrates the practical effectiveness of the Carbostyryl Compound for the treatment of the depression, bipolar I disorder and bipolar II disorder mentioned in Claim 1, which are disorders of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype, based on the effect of the 5-HT<sub>1A</sub> partial agonist of the Carbostyryl Compound, by administering the compound to patients contracting any of these disorders. In addition, even taking into account any statement other than those concerning the pharmacological test (an in-vitro test), it would not be possible for a person ordinarily skilled in the art to understand the ability of Invention 1 for treatment based on the description contained in the detailed explanation of the invention contained in the Description.

(B) That being said, from the description of publications other than the Description attached to the application for the Patent, "the ability of 5-HT<sub>1A</sub> partial agonist for the treatment of depression" is considered as common technical knowledge. Therefore, considering the results of the pharmacological test (an in-vitro test) mentioned above while taking into account this common technical knowledge, a person ordinarily skilled in the art would be able to understand that the Carbostyryl Compound is effective for the treatment of the depression mentioned in Claim 1 based on its 5-HT<sub>1A</sub> partial agonist effect, by administering the compound to patients contracting this disorder.

(C) As opposed to this, "the ability of 5-HT<sub>1A</sub> partial agonist for the treatment of bipolar disorders" is not considered as common technical knowledge. Therefore, even considering the results of the pharmacological test (an in-vitro test) mentioned above while taking into account common technical knowledge, a person ordinarily skilled in the art would be unable to understand that the Carbostyryl Compound is effective for the treatment of the bipolar I disorder or bipolar II disorder mentioned in Claim 1 by administering the compound to patients contracting either of these disorders.

(D) Consequently, the detailed explanation of the invention contained in the Description cannot be considered to disclose Invention 1 clearly and sufficiently enough to enable the use of this invention. Further, for the same reason, the detailed explanation of the invention contained in the Description cannot be considered to disclose Inventions 4 and 5 clearly and sufficiently enough to enable the use of these inventions.

Therefore, it is concluded that the patents relating to Inventions 1, 4 and 5 should be invalidated based on Ground for Invalidation 1 (violation of the enablement requirement).

B. Ground for Invalidation 2 (dissatisfaction of the support requirement)

(A) From the statement in the detailed explanation of the invention contained in the Description, the problem to be solved by Invention 1 is the treatment of patients with the depression, bipolar I disorder or bipolar II disorder mentioned in Claim 1, which are disorders of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype, and the method for solving the problem is to treat the depression, bipolar I disorder or bipolar II disorder mentioned in Claim 1, which are disorders of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype, based on the 5-HT<sub>1A</sub> partial agonist effect of the Carbostyryl Compound, by administering the compound to patients contracting any of these disorders.

A person ordinarily skilled in the art would be able to recognize that aripiprazole which is the Carbostyryl Compound is a 5-HT<sub>1A</sub> partial agonist, based on the results of the pharmacological test (an in-vitro test) described in the detailed explanation of the invention contained in the Description. However, the detailed explanation of the invention does not disclose the results of any clinical test that demonstrates the practical effectiveness of the Carbostyryl Compound for the treatment of the depression, bipolar I disorder and bipolar II disorder mentioned in Claim 1, which are disorders of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype, based on the 5-HT<sub>1A</sub> partial agonist effect of the Carbostyryl Compound, by administering the compound to patients contracting any of these disorders. In addition, even taking into account any statement other than those concerning the pharmacological test (an in-vitro test), the statement of the detailed explanation of the invention contained in the Description would not enable a person ordinarily skilled in the art to immediately understand that the problem in respect of Invention 1 mentioned above can be solved.

(B) That being said, "the ability of 5-HT<sub>1A</sub> partial agonist for the treatment of depression" is considered as common technical knowledge. Therefore, considering the results of the pharmacological test (an in-vitro test) mentioned above while taking into account this common technical knowledge, a person ordinarily skilled in the art would be able to recognize that the Carbostyryl Compound is effective for the treatment of the depression mentioned in Claim 1, which is a disorder of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype, based on its 5-HT<sub>1A</sub> partial agonist effect of the Carbostyryl Compound, by administering the compound to patients contracting this disorder.

(C) As opposed to this, "the ability of 5-HT<sub>1A</sub> partial agonist for the treatment of bipolar disorders" is not considered as common technical knowledge. Therefore, even considering the results of the pharmacological test (an in-vitro test) mentioned above while taking into account common technical knowledge, a person ordinarily skilled in the art would be unable to recognize that the Carbostyryl Compound is effective for the treatment of the bipolar I disorder or bipolar II disorder mentioned in Claim 1 by administering the compound to patients contracting either of these disorders.

(D) Therefore, even also taking into account common technical knowledge, the detailed explanation of the invention contained in the Description would not enable a person ordinarily skilled in the art to recognize that Invention 1 can solve the problem, namely to treat patients with the bipolar I disorder or bipolar II disorder mentioned in Claim 1, which are disorders of the central nervous system associated with a 5-HT<sub>1A</sub> receptor subtype. Therefore, Invention 1 is not considered to be stated in the detailed explanation of the invention contained in the Description. In addition, for the same reason, Inventions 4 and 5 cannot be considered to be stated in the detailed explanation of the invention contained in the Description.

Therefore, it is concluded that the patents relating to Inventions 1, 4 and 5 should be invalidated based on Ground for Invalidation 2 (violation of the support requirement).

2. The Plaintiff raised Ground for Rescission 1 (erroneous finding as to the enablement requirement) and Ground for Rescission 2 (erroneous finding as to the support requirement) as the grounds for rescission of the JPO Decision.
3. In this judgment, the court found Ground for Rescission 1 and Ground for Rescission 2 raised by the Plaintiff to be well-grounded, and upheld the Plaintiff's claim to seek rescission of the JPO Decision with respect to the portion that invalidated the patents relating to the inventions claimed in Claims 1, 4 and 5 of the Patent. (Note that the Patent was disputed in several cases of trial for invalidation and lawsuit to seek rescission of a trial decision (2020 (Gyo-Ke) 10078/82, 2020 (Gyo-Ke) 10079/83 and 2020 (Gyo-Ke) 10080/81), and decisions for these cases were also rendered on the same day as this decision.)