Trial decision

Correction No. 2017-390124

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The case of trial for correction of Japanese Patent No. 6097946 has resulted in the following trial decision:

Conclusion

The trial of the case was groundless.

Reason

No. 1 History of the procedures

The application (Patent application No. 2007-542886) for Patent No. 6097946 (hereinafter, the "Patent") related to the demand for trial for correction was filed on October 18, 2005 (Priority date November 17, 2004, KR, 2 applications) as international filing, and the Patent for inventions according to Claims 1 to 8 was established and registered on March 3, 2017.

The trial for the correction of the case was requested on November 20, 2017. A notice of reasons for refusal of correction dated January 5, 2018 was issued and a written opinion and Evidence A No. 1 were submitted on March 1, 2018.

No. 2 Object of the demand and the contents of the corrections

The object of the demand is "a trial decision should be made to the effect that the corrections regarding Claims 1 to 8 of Patent No. 6097946 to corrected Claims 1 to 8 as attached in the written demand for the trial for the corrections of the case."

The corrections demanded by Demandant (hereinafter, the "correction of the case") are as follows.

1 Corrections related to Claim 1

(1) Correction A

"X and Y are independently N or C-R7" in Claim 1 before the correction is corrected to "X and Y are C-H."

(2) Correction B

"R2 is chlorine" in Claim 1 before the correction is corrected to "R2 is

hydrogen."

(3) Correction C

"R3 is C1-C3 alkyl" in Claim 1 before the correction is corrected to "R3 is methyl."

(4) Correction D

"R4," in Claim 1 before the correction is corrected to "R4 is methoxy,"

(5) Correction E

"R5," in Claim 1 before the correction is corrected to "R5 is hydrogen,"

(6) Correction F

"R6 and" in Claim 1 before the correction is corrected to "and R6 is methoxy."

(7) Correction G

"R7 is" in Claim 1 before the correction is deleted.

(8) Correction H

The statement, "independently, hydrogen, C1-C3 alkoxy, C1-C3 alkyl, C1-C3 haloalkyl, C1-C3 alkylcarbonyl, halogen, cyano, or nitro" in Claim 1 before the correction is deleted.

(9) Correction I

The statement, "however, R1 and R2 may never be hydrogen atoms simultaneously" (hereinafter, the "Proviso") in Claim 1 before correction is deleted.

2 Corrections related to Claims 2 to 5 (1) Correction J Claim 2 is deleted.

- (2) Correction K Claim 3 is deleted.
- (3) Correction L Claim 4 is deleted.
- (4) Correction M Claim 5 is deleted.

No. 3 Suitability of the correction

1 Regarding request of correction for groups of claims

Since the correction of the case contain corrections of two or more claims in the scope of the claims, it is examined whether or not the requested correction of the case complies with the requirement set forth in Article 126(3) of the Patent Act.

Corrections A to I are corrections related to Claim 1 before the correction. Since

Claims 2 to 8 directly or indirectly refer to Claim 1, they are substantially corrected in accordance with Corrections A to I. So, those claims form a group of claims as set forth in Article 126(3) of the Patent Act.

Since the correction of the case comprises request of corrections according to each of groups of claims, it complies with the provisions of Article 126(3) of the Patent Act.

2 Correction B among corrections related to Claim 1

Correction B in the correction of the case is examined below.

(1) Purpose of the correction

It is examined whether or not Correction B suits the purpose set forth in each item of the proviso to Article 126(1) of the Patent Act

To examine whether or not the requested corrections suits the purpose set forth in each item of proviso to Article 126(1) of the Patent Act, in view of the case, examinations will be carried out by considering whether or not it pertains to firstly clarification of an ambiguous statement, secondly restriction of the claims and correction of errors or mistranslations, and lastly change of a form of claims from dependent claims to independent claims.

A Clarification of an ambiguous statement (item (iii) of the proviso to Article 126(1) of the Patent Act)

(A) Judgment

When a correction is approved as a correction made for the purpose of clarification of an ambiguous statement, it is necessary to correct a statement in the patented specification or the claims whose meaning per se is ambiguous or a statement that became ambiguous because of unreasonableness caused in relation to other statements in the patented specification or the claims, and then clarify the original meaning of the statement.

Regarding Examining Correction B, the statement "R2 is chlorine" in 1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of the General Formula 1 disclosed in Claim 1 of the patented claims, per se, is clear and comprises no ambiguous statement. In addition, with respect to compounds of this General Formula 1, the statement cannot be deemed to be any statement that creates any unreasonableness, since the fact that R2 that is a substituent in the compound is chlorine is stated in the patented specification as "R2" is a "hydrogen atom, C1-C6 alkoxy, C1-C6 alkyl, or halogen," and as "the designation halogen represents F, Cl, Br, or I" (See [0009]), and, as specific compounds in which "R2" is chlorine, compounds Nos. 106 to 126 and 176 to 182 are pointed out.

In addition, Claim 1 states that "however, R1 and R2 may never be hydrogen atoms simultaneously,"(the Proviso) but, as described in F, (A), b, (a) below, since this statement does not cause any discrepancy as an expression of the structure of the compounds expressed with General Formula 1 specified by the statement preceding the Proviso, the statement of this Proviso should be understood to be a statement that specifies the compound redundantly, and it does not restrict the scope anew, it cannot be understood that the existence of the Proviso makes the compounds of General Formula 1 ambiguous. Accordingly, it cannot be said that the Proviso makes the statement "R2 is chlorine" unreasonable.

As described above, Correction B per se cannot be deemed as an ambiguous statement, and it is not any statement that became ambiguous because of any unreasonableness caused in relation to other statements in the patented specification or the claims, but it is examined whether or not Correction B clarifies the original meaning, just in case.

The detailed description of the invention disclosed that in compounds of General Formula 1, "R2" is a "hydrogen atom, C1-C6 alkoxy, C1-C6 alkyl, or halogen," and also that "the designation halogen represents F, Cl, Br, or I" (See [0009]). Judging from the fact that, in Examples also, since many specific substituents are pointed out as specific examples of R2, there are many possibilities and it cannot be deemed that changing R2 to "hydrogen" is a correction to clarify the original meaning. In addition, in Examples in the detailed description of the invention, the fact that a compound having a combination in which R1 is "fluorine" and R2 is "hydrogen" delivers a prominent effect cannot be any reason as described in F, (E), b below, that the fact that R1 is "fluorine" and R2 is "hydrogen" makes the original meaning clear.

Accordingly, Correction B cannot be deemed to be a correction that makes a statement unambiguously correct and meaningfully clear.

(B) Summary

As described above, it cannot be approved that Correction B is a correction for the purpose of clarification of an ambiguous statement.

B Restriction of the claims (item (i) of the proviso to Article 126(1) of the Patent Act)(A) Judgment

When a correction is approved as a correction for the purpose of restriction of the claims, it is necessary to restrict the claims by restricting statements in the claims.

Since Correction B is made for correcting a substituent, "R2 is chlorine" in Claim 1 to "R2 is hydrogen," and the scope of the claim shall be changed, it is made apparently not for the purpose of restricting the claims.

(B) Summary

As described above, it cannot be acknowledged that Correction B is a correction for the purpose of restriction of the claims.

C Correction of errors or mistranslations (item (ii) of proviso to Article 126(1) of the Patent Act)

(A) Correction of errors

When a correction can be approved as a correction made for the purpose of correction of errors, it is necessary that any statement in the claims per se or in relation to statements in the patented specification contains apparently an error, and a correct statement should be considered obvious according to the patent specification or the claims as a whole.

Based on the above premise, Correction B is examined.

a Whether or not it is apparent that any statement in the claims per se or in relation to statements in the patented specification is an error

(a) Statement in the claims

Patented Claim 1 recites as follows:

"1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of General Formula 1, or pharmaceutically acceptable salts thereof,



wherein X and Y are independently N or C-R7; R1 is fluorine; R2 is chlorine; R3 is C1-C3 alkyl; R4, R5, R6, and R7 are independently hydrogen, a C1-C3 alkoxy, a C1-C3 alkyl, a C1-C3 haloalkyl, a C1-C3 alkylcarbonyl, halogen, cyano, or nitro, however, R1 and R2 may never be hydrogen atoms simultaneously."

(b) Statements in the patented specification

The patented specification has the following general statement.

"[0008]

Compounds used in the method of the invention

Compounds used in the method of the invention include quinoxaline-piperazine derivatives including 1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of General Formula 1. [0009]

General Formula 1:



wherein X and Y are independently N or C-R7; R1 and R2 are independently a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen; R3 is a C1-C6 alkyl; R4, R5, R6 and R7 are independently hydrogen, a C1-C6 alkoxy, a C1-C6 alkyl, a C1-C6 haloalkyl, a C1-C6 alkylcarbonyl, a halogen, cyano, or nitro.

The designation halogen represents F, Cl, Br, or I.

Alkoxy means a C1-C6 alkoxy including methoxy, ethoxy, propoxy, isopropoxy, butoxy, isobutoxy, and t-butoxy.

Alkyl means a C1-C6 alkyl including methyl, ethyl, propyl, isopropyl, n-butyl, isobutyl, t-butyl, n-pentyl, isopentyl, n-hexyl, isohexyl, and cyclohexyl.

Haloalkyl means a C1-C6 alkyl substituted with halogen such as F and Cl as in trifluoromethyl.

Alkylcarbonyl means a carbonyl ketonized with an alkyl such as methylcarbonyl

and ethylcarbonyl. [0010]

In compounds of General Formula 1 of the invention, especially preferably, X and Y are independently N, C-H, C-F, C-Cl, C-CN, C-CH3, or C-OCH3; R1 and R2 are a hydrogen atom, F, Cl, methyl, or methoxy; R3 is methyl; R4, R5, and R6 are independently a hydrogen atom, Cl, Br, nitro, methyl, trifluoromethyl, methoxy, or acetyl; and, R7 is a hydrogen atom, F, Cl, cyano, methyl, or methoxy."

In Examples in paragraphs [0023] infra, manufacture of compounds 1 to 196 of General Formula 1 is specifically described, and Table 1 in paragraphs [0248] to [0253] indicates a specific partial structural formula of each substituent shown together with General Formula (1).

(c) Judgment

First, judging from statement in the claims, in 1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of General Formula 1 before the correction of the case, since there is no unreasonable point from a technological point of view in that R2 that is a substituent in the compound is chlorine, and, as described above, is compatible with the description in the Proviso, it cannot be deemed that it is obvious that the statement in claims itself is incorrect.

Furthermore, judging from the statement in the detailed description of the invention, as a general statement with respect to General Formula 1, it is disclosed that "R2" is "a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen," and that "the designation halogen represents F, Cl, Br, or I" (See paragraph [0009]) and, putting those statements together, it can be deemed that it is disclosed that "R2" is chlorine, and, in addition, compounds 106 to 126 and compounds 176 to 182 are pointed out as compounds in which R2 is chlorine, together with specific manufacturing methods in Examples.

Then, since it can be deemed that the patented specification discloses that "R2" is chlorine in General Formula 1 accompanied by specific statements, it can never be judged that it is obvious in relation to the statement in the specification that the statement in claims is incorrect.

b Whether or not correct statements can be defined as obvious matters based on the statements in the patented specification or the claims as a whole

As stated in above a, (c) that it cannot be deemed obvious that the statement in claims before the correction of the case per se or in relation to statements in the patented specification are is incorrect. However, supposing that the statement that R2 is chlorine is incorrect, for confirmation purpose, it is examined, from statements in the patented specification or the claims as a whole, whether correct statement can be determined as an obvious matter.

(a) Judgment on whether the statement, "R2 is hydrogen" after the correction can be determined as a correct statement as an obvious matter

As indicated in above a, (b), it is disclosed in paragraph [0009] in the patent specification that "R1 and R2 are independently a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen," and that "the designation halogen represents F, Cl, Br, or I," and putting those statements together, it can be deemed that it is disclosed that "R2" is chlorine, and, in addition, in Examples, compounds in which "R2" is respectively, "hydrogen, fluorine, chlorine, a methyl group, and a methoxy group" are specifically disclosed.

In addition, as specific examples of combinations of "R1" and "R2," groups of compounds that can be divided into two categories in the case in which "R1" is "fluorine," and "R2" is "hydrogen or fluorine" are disclosed. (For specific examples in which "R2" is "hydrogen," refer to compounds 1 to 21. In addition, for specific examples in which "R2" is "fluorine," refer to compounds 169 to 175.)

As far as those descriptions are concerned, the patented specification discloses various substituents including hydrogen atom as alternatives for "R2," and even in Examples, compounds with hydrogen, fluorine, chlorine, methyl group, and methoxy group are disclosed. Also, judging from the fact that, among specific compounds, even in the case in which "R1" is "fluorine," two types of groups of compounds comprising "hydrogen or fluorine" as "R2" exist, it cannot be deemed so far that the statement, "R2 is hydrogen" is a correct statement and can be determined as an obvious matter.

(B) Correction of mistranslations

When a correction can be approved as a correction for the purpose of correction of mistranslations, it must be the case in which meaning of a statement in the patented specification or the claims is different from the meaning of the corresponding statement in the specification and the claims described as of the international filing date under Article 184-4(1) of the Patent Act (hereinafter, "specification, etc. of the international application as of the international filing date"), and it is necessary to correct the statement to a statement that correctly expresses the meaning of the specification, etc. of the international application as of the international filing date.

With respect to R2, since Claim 1 of the claims in the specification, etc. of the international application as of the international filing date has a statement that "... R2 are independently hydrogen, a C1-C6 alkoxy, a C1-C6 alkyl or a halogen;" and paragraphs [22] and [23] in the specification have a statement that "... R2 are independently hydrogen, a C1-C6 alkoxy, a C1-C6 alkyl or a halogen; ... In the above definitions, the designation 'halogen' represents F, Cl, Br, or I," and in its patented claims, it is described as "R2 is chlorine" and paragraph [0009] recites "... R2 is independently a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen ...

the designation halogen represents F, Cl, Br, or I," the meaning of the statement in the patented specification or the claims does not differ from the meaning of the corresponding statement in the specification, etc. of the international application as of the international filing date, and it is obvious that it is not any correction of mistranslation.

(C) Summary

As described above, Correction B cannot be approved as any correction for the purpose of correction of errors or mistranslation.

D Correction to change a statement in a claim that cites a statement in another claim to a statement that does not cite the statement in the other claim (item 4 of proviso to Article 126(1) of the Patent Act)

It is obvious that Correction B is not a correction for the purpose of changing a statement in a claim that cites a statement in another claim to a statement that does not cite the statement in the other claim.

E Demandant's assertions with respect to purposes of corrections

Demandant asserts in Written Demand for Trial and Written Opinion as follows: (A) Demandant asserts that Claim 1 before correction has a statement that "R2 is chlorine" and simultaneously a statement that "however, R1 and R2 may never be hydrogen atoms simultaneously," and, looking at those statements together, the statement with respect to R2 does not literally cover any hydrogen, and it is inconsistent with the Proviso and is an ambiguous statement; judging from the statement in the Proviso, since R1 and R2 respectively comprise hydrogen, the substantially understood definition of R1 is "hydrogen or fluorine" and the substantially understood definition of R2 is "hydrogen or chlorine," and the correction is to restrict the scope of the substantially understood definition of R2, and deleting chlorine, for the purposes set forth item iii of proviso to Article 126(1) of the Patent Act (clarification of an ambiguous statement) and item i (restriction of the claims) (Written Demand for Trial, page 6, line 23 to page 7, line 15; Written Opinion, page 2, line 16 to page 3, line 9, page 3, line 16 to page 4, line 14) (hereinafter, "Assertion a").

(B) Based on an assumption that, in the above Assertion a, since the statement "R2 is chlorine" and the statement "however, R1 and R2 may never be hydrogen atoms simultaneously" are inconsistent with each other, they are ambiguous statements, and, judging from the statement in the Proviso, the substantially understood definition of R1 is "hydrogen or fluorine" and the substantially understood definition of R2 is "hydrogen or chlorine," Demandant asserts as follows:

a Assertion b-1

Demandant asserts that, judging from the statement in the Proviso, alternatives for R1 are "hydrogen or fluorine" and alternatives for R2 are "hydrogen or chlorine," as a combination of R1 and R2 for Claim 1,

a) R1 is fluorine, and R2 is chlorine,

b) R1 is fluorine, and R2 is hydrogen, and

c) R1 is hydrogen, and R2 is chlorine

can be considered, and, since no specific compound is disclosed in Examples for alternative a), and since specific compound 115 disclosed in Examples has been rejected as having no prominent effect for alternative c), alternative b) is the only reasonable alternative (Written Opinion, page 4, line 20 to page 5, line 2; page 5 lines 9 to 25).

Demandant asserts that, since compound 10 that has been acknowledged in the decision for refusal as having high activity is a combination of "fluorine" as R1 and

"hydrogen" as R2, the combination of "fluorine" as R1 and "hydrogen" as R2 is a reasonable alternative (Written Opinion, page 6, line 20 to page 7, line 1).

b Assertion b-2

Next, Demandant asserts that, with respect to the case in which R1 is "fluorine," a specific example in which R2 is "fluorine or hydrogen" is disclosed, and, judging from the fact that compound 172 in which R2 is "fluorine" does not deliver any prominent effect, the combination of "fluorine" as R1 and "hydrogen" as R2 is a reasonable alternative (Written Opinion, page 4, line 20 to page 5, line 8; Evidence A1, page 5, line 27 to Table in page 6).

(C) Demandant asserts that there is a false recognition between statements in claims before correction and the detailed description of the invention in the specification, and no specific compound of combination of "fluorine" as R1 and "chlorine" as R2 is disclosed in Examples in the specification (Written Opinion page 4, lines 15 to 19; page 5, lines 17 to 19)(hereinafter, "Assertion c").

(D) Demandant asserts that, taking into consideration the progress of the case including communications with a home attorney after the decision to grant a patent for the application recorded in Evidence A, No. 1 (Statement dated January 27, 2012 by a patent attorney, Mr. Nobuo Ogawa, who was the attorney in charge of the application of the case), the invention according to Claim 1 before correction in the case is ambiguous, and it is obvious that R2 should include hydrogen(Written Opinion, page 6, lines 1 to 19 (hereinafter, "Assertion d").

F Examination of Demandant's assertion with respect to the purpose of the correction (A) Assertion a

In examining assertion a, in addition to examination of the statement in the claims, the statements "R2 is chlorine" and "however, R1 and R2 may never be hydrogen atoms simultaneously" in General Formula 1 disclosed in Claim 1 is examined by examining the statement in Claim 1 in the claims including prosecution history.

a Statement in Claim 1 in line with prosecution history of the application

(a) Statement in translation of the claims in international application

i Statement in Claim 1

"1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of General Formula 1, or pharmaceutically acceptable salts thereof.



wherein X and Y are independently N or C-R7; R1 and R2 are independently a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen; R3 is a C1-C6 alkyl; R4, R5, R6, and R7 are independently hydrogen, a C1-C6 alkoxy, a C1-C6 alkyl, a C1-C6

haloalkyl, a C1-C6 alkylcarbonyl, a halogen, cyano, or nitro."

ii Statement with respect to R2, etc.

It is disclosed that "R2" is "a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen."

(b) Statement of the claims amended with Written Amendment dated March 25, 2008i Statement in Claim 1

"1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of General Formula 1, or pharmaceutically acceptable salts thereof,



wherein X and Y are independently N or C-R7; R1 and R2 are independently a hydrogen atom, a C1-C3 alkoxy, a C1-C3 alkyl or a halogen; R3 is a C1-C3 alkyl; R4, R5, R6, and R7 are independently hydrogen, a C1-C3 alkoxy, a C1-C3 alkyl, a C1-C3 alkyl

ii Statement with respect to R2, etc.

It is disclosed that "R2" is "a hydrogen atom, a C1-C3 alkoxy, a C1-C3 alkyl, or a halogen."

(c) Notice of the reasons for refusal dated July 8, 2010

Reasons for refusal for the invention according to Claim 1 of the application are reasons for refusal 1 (novelty) and 2 (inventive step) as described in the above notice of reasons for refusal, and Cited Document 3 (National Publication of International Patent Application No. 2002-538153) is cited and the following matters are shown in the items for remarks.

"[Reason 1]

•Remarks) Cited Document 3 discloses compounds that correspond to General Formula 1 of the application, and that the compounds show antitumor activity (Compounds: Example 36, etc.; Antitumor activity: Paragraphs [0332] to [0334]).

[Reason 2]

•••

•Remarks) Comparing inventions according to Claims 1 to 6, 9, and 10 and inventions disclosed in Cited Document 3, inventions according to the claims differ from the invention disclosed in Cited Document 3 in that the former covers compounds comprising functional groups other than hydrogen such as alkoxy, alkyl, and halogen, as substituents for positions 6 and 7 of a quinoxaline ring.

In the technical field of medicinal chemistry, however, since it is a mere technical matter that a person skilled in the art generally carries out to create compounds by fixing the central skeletal structure and variously modifying surrounding substituents expecting improvement in activity, a person skilled in the art can easily conceive, in the quinoxaline compound disclosed in Cited Document 3, to create compounds in which substituents that are generally used in medicinal chemistry such as alkoxy, alkyl, halogen are introduced at positions 6 and 7 in a quinoxaline ring, and check antitumor activity of the compounds. In addition, judging from statement in the Specification, the effect delivered by the invention cannot be recognized to be especially prominent for a person skilled in the art to positively infer the existence of an inventive step."

(d) Statement in the claims amended with Written Amendment of January 20, 2011i Statement in Claim 1

With this amendment, Claim 1 is stated as follows:

"1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of General Formula 1, or pharmaceutically acceptable salts thereof.



wherein X and Y are independently N or C-R7; R1 and R2 are independently a hydrogen atom, a C1-C3 alkoxy, a C1-C3 alkyl, or a halogen, R3 is a C1-C3 alkyl, and R4, R5, R6, and R7 are independently hydrogen, a C1-C3 alkoxy, a C1-C3 alkyl, a C1-C3 haloalkyl, a C1-C3 alkylcarbonyl, a halogen, cyano, or nitro, however, R1 and R2 may never be hydrogen atoms simultaneously."

ii Statement with respect to R2, etc.

"R2" is defined as "a hydrogen atom, a C1-C3 alkoxy, a C1-C3 alkyl or a halogen," and a statement "however, R1 and R2 may never be hydrogen atoms simultaneously" was added.

iii Assertion in Written Opinion dated January 20, 2010

Demandant asserts that, since the compounds disclosed in Cited Document 3 do not have any substituents at positions 6, and 7 of a quinoxaline ring, it is clearly discriminated with the invention that is defined as "however, R1 and R2 may never be hydrogen atoms simultaneously, and that the compound of the invention (compounds in which R1 and R2 can never be hydrogen atoms simultaneously) and delivers prominent effect compared to the compound disclosed in Cited Document 3 (a compound in which R1 and R2 are simultaneously hydrogen atoms).

(e) Decision of refusal dated February 14, 2011

In the decision for refusal dated February 14, 2011, it is stated as "This application should be rejected based on Reason 2 in reasons for refusal dated July 7, 2010," and the following matters are shown in the item for remarks.

"With respect to the effect of the present invention, Applicant showed a comparison test result with compound 42 of Cited Document 3, and asserts that compounds of General Formula 1 of the invention in which substituents such as alkoxy,

alkyl, halogen, etc. are introduced at positions 6 and 7 of a quinoxaline ring deliver such excellent antitumor activity that a person skilled in the art cannot predict.

It is definitely acknowledged that compound 10 of the invention used for the comparison test result in Written Opinion has superior antitumor activity compared to compound 42 of Cited Document 3.

However, judging from the pharmacological test result shown in Table 2 in the specification, since there are compounds that have the same level of or lower activity compared to that of compound 42 of Cited Document 3 (for example, compounds 52, 73, 115, 136, 157, 172, 193, etc.), it cannot be acknowledged that all of the compounds of General Formula 1 have especially prominent effect.

Accordingly, above assertion by Applicant cannot be approved."

(f) Statement in the claims amended with Written Amendment dated June 20, 2011 (statement in the claims before the correction of the case)

i Statement in Claim 1

"1-[(6,7-substituted alkoxyquinoxalinyl)aminocarbonuyl]-4-(hetero)arylpiperazine derivatives of General Formula 1, or pharmaceutically acceptable salts thereof.



wherein X and Y are independently N or C-R7; R1 is fluorine and R2 is chlorine, R3 is a C1-C3 alkyl, and R4, R5, R6, and R7 are independently hydrogen, a C1-C3 alkoxy, a C1-C3 alkyl, a C1-C3 haloalkyl, a C1-C3 alkylcarbonyl, a halogen, cyano, or nitro, however, R1 and R2 may never be hydrogen atoms simultaneously.

ii Statement with respect to R2, etc.

It is disclosed that "R2 is chlorine," and a statement "however, R1 and R2 may never be hydrogen atoms simultaneously" remains as added.

b Examination

(a) First, looking at the statement in the claims, since it is disclosed as a statement with respect to compounds expressed with General Formula 1, other than the Proviso, as "General Formula 1



wherein X and Y are independently N or C-R7; R1 is fluorine and R2 is chlorine, R3 is a C1-C3 alkyl, and R4, R5, R6, and R7 are independently hydrogen, a C1-C3 alkoxy, a

C1-C3 alkyl, a C1-C3 haloalkyl, a C1-C3 alkylcarbonyl, a halogen, cyano, or nitro," there is no unreasonableness from chemical point of view even without the statement of the Proviso and it is clearly described.

Next, it is examined whether the statement "however, R1 and R2 may never be hydrogen atoms simultaneously" in Claim 1 of the claims makes the statement in the claims ambiguous including the history of addition of the statement of the Proviso.

The statement, "however, R1 and R2 may never be hydrogen atoms simultaneously" was added to Claim 1 by the amendment with Written Amendment dated January 20, 2011 (See above (d), i and ii), and, judging from the assertion in the Written Opinion of the same date (See above (d), iii), it can be deemed a statement to restrict compounds represented by General Formula 1 in order to avoid Reason 1 (novelty) and Reason 2 (inventive step) of the Notice of Reasons for Refusal dated July 8, 2010 (See above (c)).

Later, the decision for refusal was made on February 14, 2011, and with amendment of June 20, 2011, compounds of General Formula 1 were specified as "R1 is fluorine, and R2 is chlorine," and specification, "however, R1 and R2 may never be hydrogen atoms simultaneously" remained unamended.

As stated above, the compounds according to General Formula 1 even without the Proviso are clear without unreasonableness from a chemical viewpoint. The statement "however, R1 and R2 may never be hydrogen atoms simultaneously" is not inconsistent with expression of the compounds according to General Formula 1 with the Proviso. Therefore, it should be understood that the Proviso is a statement that redundantly specifies the compounds and does not restrict the scope further.

Therefore, it cannot be understood that the existence of the Proviso creates with respect to compounds of General Formula 1 a room to accept combinations of other elements or substituents and the compounds of General Formula 1 become ambiguous.

Accordingly, with respect to the statements in Claim 1 before the correction of the case, "R2 is chlorine" and "however, R1 and R2 may never be hydrogen atoms simultaneously," the statement with respect to R2 does not literally cover hydrogen, it is not inconsistent with the above Proviso and it cannot be deemed that R2 is an ambiguous statement.

(b) Next, it is examined whether it is the original meaning that R1 is "hydrogen or fluorine" and R2 is "hydrogen or chlorine," but, as stated in above (a), judging from the statements in the claims, the statement, "R2 is chlorine" and the statement, "however, R1 and R2 may never be hydrogen atoms simultaneously" are not inconsistent with each other and cannot be deemed ambiguous statements, and, therefore, judging from the statement of this Proviso, it cannot be deemed that the substantially understood definition of R1 is "hydrogen or fluorine," and the substantially understood definition of R2 is "hydrogen or chlorine." In addition, the statement in the detailed description of the invention discloses that, as compounds of General Formula 1, "R1 and R2" are

"independently hydrogen atom, C1-C6 alkoxy, C1-C6 alkyl or halogen," and that "the designation halogen represents F, Cl, Br, or I (See paragraph [0009]), and, in Examples, since specific compounds in which both of R1 and R2 are independently "hydrogen, fluorine, chlorine, a methyl group, or a methoxy group" are disclosed, even if there is the statement of the Proviso, it cannot be deemed that the original meaning of R1 is "hydrogen or fluorine," and that the original meaning of R2 is "hydrogen or chlorine."

c Summary

As described above, the statement "R2 is chlorine" in Claim 1 before the correction of the case is clear. The statement cannot be said to be inconsistent with the Proviso and be ambiguous in relation to the statement, "however, R1 and R2 may never be hydrogen atoms simultaneously" since it does not include hydrogen literally.

Therefore, it cannot be said that R2 substantially understood means "hydrogen or chlorine." The assertion that hydrogen is added to the range of R2 in order to clarify the definition of R2 cannot be approved.

The assertion that hydrogen is deleted from R2, which is substantially regarded as "hydrogen or chlorine" cannot be approved either since the assertion that hydrogen is added to the range of R2 in order to clarify the definition of R2 cannot be approved.

Accordingly, Demandant's Assertion a that Correction B is for the purposes set forth in item iii of proviso to Article 126(1) of the Patent Act (clarification of ambiguous statement) and item i (restriction of the claims) cannot be approved.

(B) Assertion b

a As stated in above (A), b, (a) and (b), since the statement, "R2 is chlorine" and the statement, "however, R1 and R2 may never be hydrogen atoms simultaneously" are not inconsistent with each other, and, judging from the statement in the Proviso that does not cause any contradiction, it cannot be deemed that the substantially understood definition of R1 is "hydrogen or fluorine" and the substantially understood definition of R2 is "hydrogen or chlorine," Assertion b based on those assumptions cannot be approved.

As stated above, since Assertion a that is a premise for Assertion b cannot be approved, Assertion b cannot be approved, but, for the purpose of confirmation, Demandant's assertion that the combination of "fluorine" as R1 and "hydrogen" as R2 is a reasonable combination is examined below.

b Assertion b-1

Demandant's Assertion b-1 asserts that, in the statement in the claims, the substantially understood definition of R1 is "hydrogen or fluorine," and the substantially understood definition of R2 is "hydrogen or chlorine," and that three alternatives are conceivable for the combination of R1 and R2, but, it is as described in above (A), b, (b) that, from the statement in the claims, it cannot be deemed that the substantially understood definition of R1 is "hydrogen or fluorine," and the substantially understood definition of R1 is "hydrogen or fluorine," and the substantially understood definition of R1 is "hydrogen or fluorine," and the substantially understood definition of R2 is "hydrogen or chlorine," and, therefore, it cannot be deemed that there are three alternatives for the combination of R1 and R2. In addition, the detailed description of the invention discloses for compounds of General Formula 1 that "R1 and R2" are "independently a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen,"

and that "the designation halogen represents F, Cl, Br, or I" (See [0009]), and, in addition, judging from the fact that Examples disclose various specific combinations as combinations of alternatives of "R1" and "R2," right from the start, it cannot be interpreted that combinations of R1 and R2 are limited to the above three alternatives.

Furthermore, with respect to the combination of R1 and R2, the facts that no specific compound for the combination of a) is disclosed in Examples, that it has been pointed out for the combination of c) that specific compounds disclosed in examples do not deliver any prominent effect, and that the combination of b) delivers a prominent effect have nothing to do with whether, with respect to compounds of General Formula 1 disclosed in the patented claims, any room to include combinations of other substituents including hydrogen in combination of substituents that are clearly specified as "R1 is fluorine" and "R2 is chlorine" is created and the compounds of General Formula 1 become ambiguous, and it cannot be deemed that the combination of "R1 is fluorine" and "R2 is hydrogen" is a reasonable alternative.

Accordingly, existence or nonexistence of Examples and the degree of effects in Examples cannot be any ground for assertion that the fact that "R1 is fluorine" and "R2 is hydrogen" clarifies the original meaning.

c Assertion b-2

As stated in above (A), b, (b), it cannot be deemed to indicate that there are three alternatives for the combination of R1 and R2. In addition, Demandant's assertion b-2 regarding the combination of R1 and R2 merely points out that a specific compound shown in Examples in which R1 is "fluorine" and R2 is "fluorine" does not deliver any prominent effect. Moreover, this has nothing to do with whether, with respect to compounds of General Formula 1 disclosed in the patented claims,

any room to include combinations of other substituents including hydrogen in combination of substituents that is clearly specified as "R1 is fluorine" and "R2 is chlorine" is created, and the compounds of General Formula 1 become ambiguous, and the fact that compounds in which R1 is fluorine and R2 is fluorine do not deliver any prominent effect does not prove that the combination of "R1 is fluorine" and "R2 is hydrogen" is a reasonable alternative, and cannot be any ground for assertion that the fact that "R1 is fluorine" and "R2 is hydrogen" clarifies the original meaning.

d Summary

As described above, Assertion b that asserts that the combination of "fluorine" as R1 and "hydrogen" as R2 is a reasonable alternative cannot be approved.

(C) Assertion c

In short, Demandant's assertions point out that no specific example of the combination of "fluorine" as R1 and "chlorine" as R2 disclosed in the patented claims has been disclosed in Examples in the Detailed Description of the Invention.

However, right from the start, the Patent Act provides that "In claims ..., the patent applicant must state all matters that the applicant finds to be necessary for defining the invention for which the patent in sought, ..." (Article 36(5)), and it is not necessary to be described in the detailed description of the invention as an "example" in order to be described in the claims. In addition, it has been already described that compounds of General Formula 1 has nothing unreasonable as compounds even without

the Proviso and are compatible with the Proviso. Furthermore, it is also described in the patented specification as "R1 and R2" are "independently, a hydrogen atom, a C1-C6 alkoxy, a C1-C6 alkyl, or a halogen" and "the designation halogen represents F, Cl, Br, or I" (See paragraph [0009]). In addition, a specific example of a compound in which R1 is fluorine, and a specific example of a compound in which R2 is chlorine are described, and there is no unreasonable point for stating in the claims that R1 is "fluorine" and R2 is "chlorine."

Therefore, Assertion c cannot be approved.

(D) Assertion d

Demandant asserts that, taking into consideration history of the case including communications with the local attorney after the decision to grant a patent for the application recorded in Evidence A, No. 1 (Statement dated January 27, 2012) by a patent attorney, Mr. Nobuo Ogawa, who was the attorney for the application of the case, compounds of General Formula 1 described in the claims before correction do not include any compound that delivers prominent effect and the invention according to Claim 1 is ambiguous, and it is obvious that the case in which R2 is hydrogen should be covered, but this Assertion d cannot be approved due to reasons stated in above (A) and (B).

(E) Summary

As described above, none of Demandant's assertions can be approved.

G Summary of purposes of the correction

As described above, Correction B is not for any purpose set forth in each item of proviso to Article 126(1) of the Patent Act.

(2) Whether or not the claims are substantially expanded or changed

A Judgment

It is judged that correction substantially changes the scope of the claims when the scope of the claims is changed by correcting a statement in the claims

As for Correction B, it corrects "R2 is chlorine" in Claim 1 before the correction of the case to "R2 is hydrogen." That means, a group of compounds according to the Claim 1 after the correction has hydrogen as a substituent of compound 1 of "R2" while a group of compounds before the correction has chlorine as "R2."

Then, since Correction B changes a group of compounds disclosed in the claims before the correction of the case to a different group of compounds after the correction of the case, it can be deemed obvious that Correction B substantially changes the claims.

B Demandant's allegation

Demandant asserts that describing hydrogen as the definition of R2 in Correction B is to merely clarify literally the definition substantially understood since the definition of R2 substantially understood in Claim 1 before the correction means chlorine and hydrogen. Demandant also asserts that Correction B does not change any of category, object, or purpose, and does not fall under any correction that substantially expands or changes the claims, and complies with Article 126(6) of the Patent Act (Written

Demand for Trial, page 7, line 22 to page 8, line 6; Written Opinion, page 7, lines 15 to 26) since deletion of chlorine by Correction B is deletion of only one of alternatives for R2.

C Consideration to Demandant's allegation

As stated in above, (1), F, (A), b, (a), compounds of General Formula 1 before the correction of the case does not have any unreasonable point as compounds from a chemical point of view and are clear even without the statement of the Proviso, and, since the specification, "however, R1 and R2 may never be hydrogen atoms simultaneously" is not contradictory as an expression of the structure of the compounds of General Formula 1 that is specified by the description preceding the Proviso, it should be understood that the statement of the Proviso specifies the compound redundantly and is not any description that anew restrict the scope, and it cannot be understood that this generates a room to accept combinations of other elements or substituents and the compounds of General Formula 1 become ambiguous.

Therefore, these statements cannot be deemed ambiguous, and, an assertion based on such premise that compounds in which R1 and R2 are hydrogen is also covered; namely, any assertion based on such definition as a premise that it is substantially understood that R2 before the correction is defined as chlorine and hydrogen cannot be approved.

Accordingly, as far as R2 is defined chlorine, there is no other way but to understand that any correction to correct the definition of R2 to hydrogen is a substantial change of the claims. Therefore, Demandant's assertion that the corrections of the case do not substantially expand or change the claims cannot be approved.

D Summary

Accordingly, Correction B does not comply with requirements set forth in Article 126(6) of the Patent Act.

(3) Summary

As described above, Correction B with respect to Claim 1 cannot be approved since Correction B is not made for any purpose as set forth in each item in proviso to Article 126 (1) of the Patent Act and does not comply with the requirements set forth in Article 126(6) of the Patent Act.

3. Corrections A, C to M

As stated in above "II, 1," Corrections A, and C to I are corrections with respect to Claim 1, and Corrections J to M are corrections with respect to Claims 2 to 5. As stated in above 1, Claims 1 to 8 form a group of claims.

As stated in above 2, (3), Corrections A, and C to M with respect to Claims 1 to 5, which form a group of claims, cannot be approved since Correction B with respect to Claim 1 cannot be approved.

No. 4 Closing

As described above, the corrections of the case cannot be approved since the corrections of the case are not made for any purposes as set forth in items of proviso to Article 126(1) of the Patent Act and do not comply with the requirements set forth in

Article 126(6) of the Patent Act.

Therefore, the trial decision shall be made as described in the conclusion.

May 8, 2018

Chief administrative judge: SERA, Satoki Administrative judge: SATO, Takefumi Administrative judge: TOMINAGA, Tamotsu