Appeal decision

Appeal No. 2012-20646

Taiwan

Appellant JEFFER MACHINERY CO. LTD.

Tokyo, Japan

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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2007-531272, entitled "Treatment of Diseases Using Nalmefene and Its Analog" (published internationally on March 16, 2006, WO2006/029167, and published nationally on April 24, 2008, National Publication of International Patent Application No. 2008-512462) has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The application was filed on September 6, 2005 as an international filing date (priority claim under the Paris Convention: September 8, 2004, US), a notice of reasons for refusal was issued on October 14, 2011, and despite submission of a written opinion and written amendment on April 25, 2012, an examiner's decision of refusal was issued on June 14, 2012, appeal against the examiner's decision of refusal was requested on October 19, 2012 and a written amendment was submitted on the same day, a written amendment (of formality) was submitted on December 5, 2012, and a reply was submitted on May 15, 2014 in response to an inquiry issued on December 13, 2013.

No. 2 Decision to Dismiss the written amendment submitted on October 19, 2012

[Conclusion of Decision to Dismiss Amendment]

The written amendment submitted on October 19, 2012 (hereinafter referred to as "the Amendment") shall be dismissed.

[Reason]

1 Details of the Amendment

The Amendment requests that Claim 1 before amendment

"[Claim 1]

A pharmaceutical composition for preventing or treating a condition selected from viral infections by Hepatitis B, organ damage being liver damage, lung damage, and kidney damage, and diseases associated with overproduction of superoxide anion radical, TNF-α or iNOS, selected from the group consisting of Crohn's disease, ulcerative colitis, and pulmonary fibrosis:

wherein,

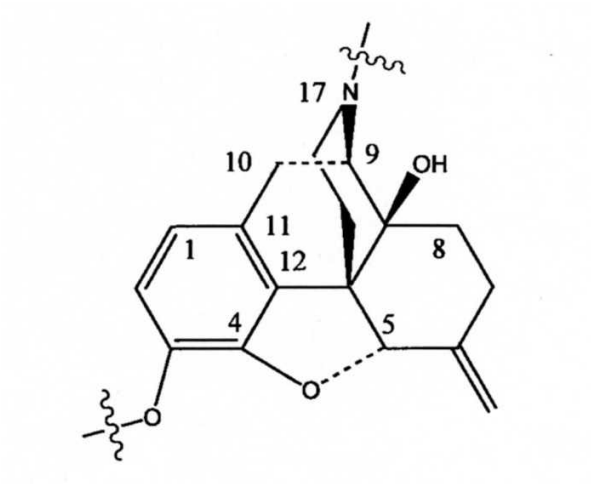
the pharmaceutical composition comprises a therapeutically effective amount of a compound according to the formula R-A-X and is administered to a human or animal in need thereof,

R is H, alkyl, allyl, phenyl, benzyl, or $(CH_2)_mR_4$, wherein m is from 0 to 6,

R_4 is a ring structure,

A is a structure selected from the group consisting of the following structures:

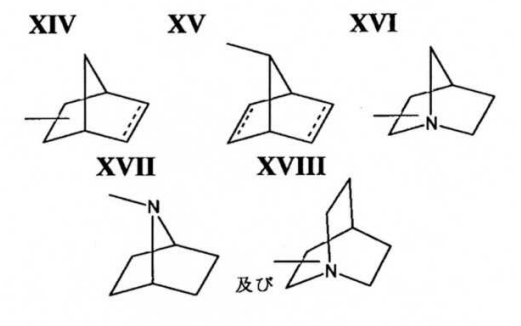
[Chem. 1]



wherein X is selected from the group consisting of hydrogen, allyl, cinnamoyl,

crotonyl, $(CH_2)C_6H_5$-4F, $(CH_2)_nC=CR_1R_2$, $(CH_2)_nC\equiv CR_3$, $(CH_2)_nR_5$, and $(CH_2)_mCHR_6R_7$, m is from 0 to 6, n is from 0 to 6, R_3 is H, alkyl, or the same as R_4, R_4 is described above and R_5 is alkyl, CN, COR_8, or structures selected from the group consisting of the following structures:

[Chem. 2]



wherein Y is O, R_6 and R_7 are each independently the same as R_4 as defined above, R_8 is alkyl, the same as R_4 as defined above, or the same as R_5 when R_5 is selected from the structures described above (IX to XVIII)."

be amended to

"[Claim 1]

A pharmaceutical composition for preventing or treating a condition selected from viral infections by Hepatitis B, organ damage of non-venous ischemia/hypoperfusion including liver damage, lung damage, and kidney damage, and diseases associated with overproduction of TNF-α, selected from the group consisting of Crohn's disease, ulcerative colitis, and pulmonary fibrosis:

wherein,

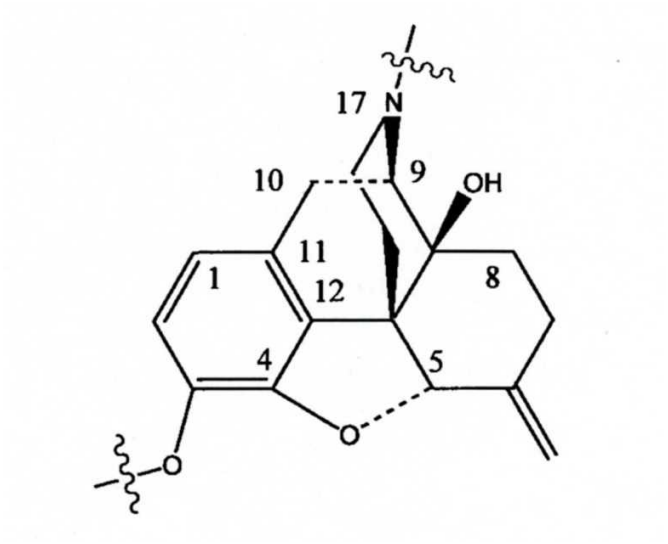
the pharmaceutical composition comprises a therapeutically effective amount of a compound according to the formula R-A-X and is administered to a human or animal in need thereof,

R is H, alkyl, allyl, phenyl, benzyl, or $(CH_2)_mR_4$, wherein m is from 0 to 6,

R_4 is a ring structure,

A is a structure selected from the group consisting of the following structures:

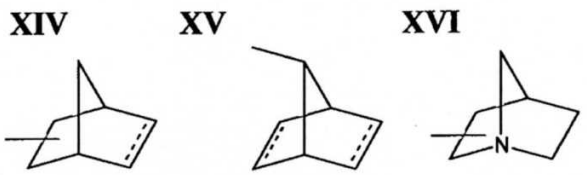
[Chem. 1]



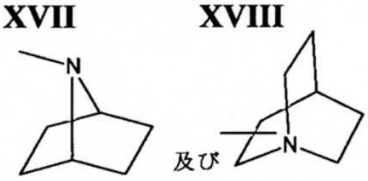
wherein X is selected from the group consisting of hydrogen, allyl, cinnamoyl, crotonyl, $(CH_2)C_6H_5$-4F, $(CH_2)_nC=CR_1R_2$, $(CH_2)_nC\equiv CR_3$, $(CH_2)_nR_5$, and $(CH_2)_mCHR_6R_7$, m is from 0 to 6, n is from 0 to 6, R_3 is H, alkyl, or the same as R_4, R_4 is described above and R_5 is alkyl, CN, COR_8, or structures selected from the group consisting of the following structures:

[Chem. 2]

XIV XV XVI



XVII XVIII



wherein R_6 and R_7 are each independently the same as R_4 as defined above, R_8 is alkyl, the same as R_4 as defined above, or the same as R_5 when R_5 is selected from the structures described above (IX to XVIII)." (Underlines indicate amended portions.)

Comparing the matters specifying the invention before and after amendment, it is acknowledged that

(1) "organ damage" is limited to "organ damage of non-venous ischemia/hypoperfusion,"

(2) "diseases associated with overproduction of superoxide anion radical, TNF-α or iNOS" are limited to "diseases associated with overproduction of TNF-α," and

(3) "Y is O" defining the formula is deleted.

In addition, the Amendment requests that Claim 4 before amendment

"[Claim 4]

A pharmaceutical composition of Claim 3, wherein the organ damage is liver damage."

be amended to

"[Claim 4]

A pharmaceutical composition of Claim 3, wherein the organ damage is liver damage, and

the prevention or treatment is to measure at least one enzyme of SGPT and SGOP in a patient to be treated whether the enzyme level is reduced." (Underlines indicate amended portions.)

Comparing the matters specifying the invention before and after amendment, it is acknowledged that

(4) "Prevention or treatment" is limited by adding the matter "the prevention or treatment is to measure at least one enzyme of SGPT and SGOP in a patient to be treated to determine whether the enzyme level is reduced."

In addition, the Amendment requests that Claim 5 before amendment

"[Claim 5]

A pharmaceutical composition of Claim 3, wherein the organ damage is kidney damage."

be amended to

"[Claim 5]

A pharmaceutical composition of Claim 3, wherein the organ damage is kidney damage, and

the prevention or treatment is to measure at least one level of blood urea nitrogen and creatinine in a patient to be treated to determine whether the level is reduced." (Underlines indicate amended portions.)

Comparing the matters specifying the invention before and after amendment, it is acknowledged that

(5) "Prevention or treatment" is limited by adding the matter "the prevention or treatment is to measure at least one level of blood urea nitrogen and creatinine in a patient to be treated to determine whether the level is reduced."

2 Propriety of amendment

Since written amendment regarding the Amendment is submitted at the same time when appeal against the examiner's decision of refusal provided for Article 121(1) of the Patent Act pursuant to the provisions of Article 17-2(1)(iv) is requested, the Amendment shall meet the requirements stipulated in (i) Article 17-2(3) that "when the amendment is to amend the scope of claims, except in the case where the amendment is made through the submission of a statement of correction of an incorrect translation, any amendment of the description, scope of claims, or drawings shall be made within the scope of the matters described in the description, scope of claims or drawings originally attached to the application (in the case of a foreign language written application under Article 36-2(2), the translation of the foreign language documents as provided in Article 36-2(2) that is deemed to be the description, scope of claims, and drawings under Article 36-2(4) (in the case where the amendment to the description, scope of claims, or drawings has been made through the submission of the statement of correction of an incorrect translation, said translation or the amended description, scope of claims, or drawings)) (hereinafter referred to as "originally attached description, etc."), and (ii) Article 17-2(5) that "the amendment is to amend the scope of claims in the case listed in Article 17-2(1)(iv) of the Patent Act, the amendment shall be limited to those for the following purposes under Article 17-2(5)(i) to (iv): deletion of claim(s), restriction of the scope of claims, correction of errors, and clarification of an ambiguous statement, and the amendment will be examined as to whether the amendment meets the requirements.

There is no description of (1) "organ damage of non-venous ischemia/hypoperfusion" and "non-venous ischemia/hypoperfusion" in the originally attached description, etc.

In addition, there is no description of (4) "to measure at least one enzyme of SGPT and SGOP in a patient to be treated to determine whether the enzyme level is reduced" and (5) "to measure at least one level of blood urea nitrogen and creatinine in a patient to be treated whether the level is reduced" in the originally attached description, etc., and these matters are not obvious from matters described in originally attached description, etc.

Thus, the Amendment including the amendment regarding the above (1), (4), and (5) introduces new technical matters and matters that are not described in the originally attached description, etc.

Meanwhile, the amendment regarding the above (2) is to limit the matter specifying the invention according to Claim 1 before amendment "diseases associated with overproduction of superoxide anion radical, TNF-α or iNOS" to "diseases associated with overproduction of TNF-α" and is to restrict the scope of claims under Article 17-2(5)(ii) of the Patent Act, and the amendment regarding the above (3) is to delete the definition of Y not present in the formula and is to correct errors under Article 17-2(5)(iii) of the Patent Act.

3 Closing

Therefore, since the Amendment violates the provisions of Article 17-2(3) of the Patent Act before revision by the Act No. 55 of 2006, of which the provisions then in force shall remain applicable according to revision supplement Article 3(1) of the Act No. 55 of 2006, the Amendment shall be dismissed under the provisions of Article 53(1) of the Patent Act applied mutatis mutandis by replacing certain terms pursuant to Article 159(1) of the Patent Act.

No. 3 The Invention

It is acknowledged that the inventions according to Claims 1 to 13 of the application are specified by the matters described in Claims 1 to 13 amended by written amendment submitted on April 25, 2012.

The invention according to Claim 1 (hereinafter referred to as "the Invention") is the invention specified by the following matters.

"[Claim 1]

A pharmaceutical composition for preventing or treating a condition selected from viral infections by Hepatitis B, organ damage being liver damage, lung damage, and kidney damage, and diseases associated with overproduction of superoxide anion radical, TNF-α or iNOS, selected from the group consisting of Crohn's disease, ulcerative colitis, and pulmonary fibrosis:

wherein,

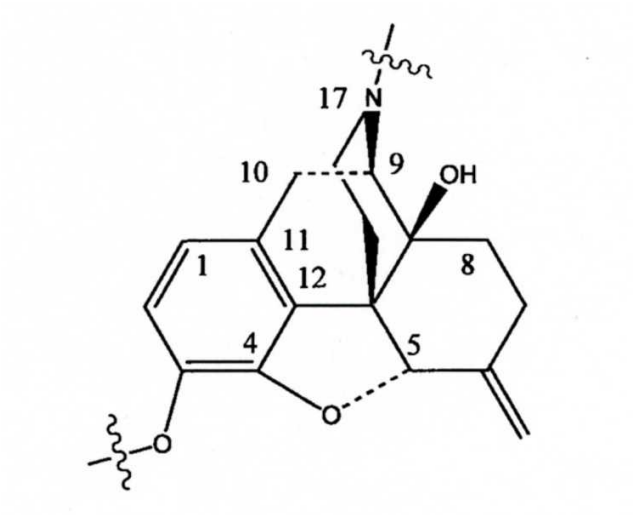
the pharmaceutical composition comprising a therapeutically effective amount of a compound according to the formula R-A-X is administered to a human or animal in need thereof,

R is H, alkyl, allyl, phenyl, benzyl, or $(CH_2)_mR_4$, wherein m is from 0 to 6,

R_4 is a ring structure,

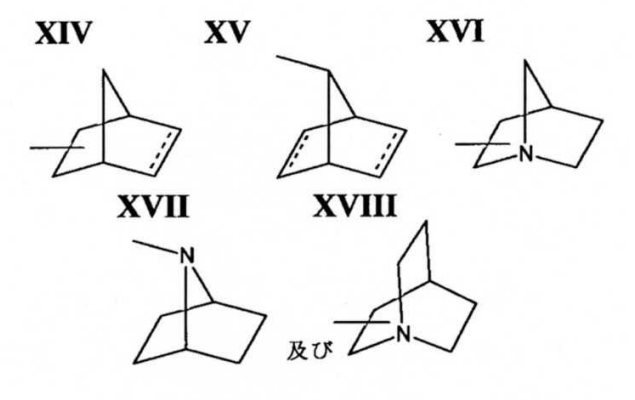
A is a structure selected from the group consisting of the following structures:

[Chem. 1]



wherein X is selected from the group consisting of hydrogen, allyl, cinnamoyl, crotonyl, $(CH_2)C_6H_5$-4F, $(CH_2)_nC=CR_1R_2$, $(CH_2)_nC\equiv CR_3$, $(CH_2)_nR_5$, and $(CH_2)_mCHR_6R_7$, m is from 0 to 6, n is from 0 to 6, R_3 is H, alkyl, or the same as R_4, R_4 is described above, and R_5 is alkyl, CN, COR_8, or structures selected from the group consisting of the following structures:

[Chem. 2]



wherein Y is O, R_6 and R_7 are each independently the same as R_4 as defined above, R_8 is alkyl, the same as R_4 as defined above, or the same as R_5 when R_5 is selected from the

structures described above (IX to XVIII)."

1. Novelty (Violation of Article 29(1) (iii) of the Patent Act)

(1) Cited publication and the described matters

Matters described in International Publication No. WO92/18126, Publication 1 which is the cited document of reasons for refusal stated in the examiner's decision (Cited Document 4 of the examiner's decision) and had been distributed before the priority date of the application, are as follows.

Additionally, the underlines are applied by the body

(Publication 1-1)

"8. A method of treating a patient suffering from ischemia or hypoperfusion in an internal organ as a result of trauma, insult, or hemorrhagic shock comprising the intravenous administration to the patient of about 10 to about 3000 μg/kg, based on patient body weight, of nalmefene in an injectable vehicle subsequent to the onset of ischemia or hypoperfusion in the organ. ...

14. A method according to Claim 8 wherein the internal organ is a kidney, small intestine, liver, or lung." (Claims 8 to 14)

(Publication 1-2)

"EXAMPLE 1

Hepatic (Splanchnic) Ischemia

Sprague-Dawley rats (ten per dosage group) weighing 250-300 grams, were subjected to 40 minutes of warm ischemia after cross-clamping of the hepatic hilum (hepatic artery and portal vein, respectively). Each animal received an intravenous injection of a vehicle (for control), naloxone or nalmefene, immediately after release of the vascular clamps. Intravenous fluids based on Ringer's lactate (15 ml/kg) were given. The animals were followed for 24 hours and their survival evaluated. The 24-hour survival data for each dosage group is set forth in Table 1 below. Survival of animals at 48 and 72 hours post ischemia was identical to 24-hour results; i.e., no additional animals died.

TABLE 1

	% Survival (24 hr post ischemia		
DOSE (μg/kg)	100	50	10
Control	50	50	30
Naloxone	60	50	10
Nalmefene	80*	80*	30

*p < 0.05

"(Table 1 of Example 1 on page 6)

(Publication 1-3)

"EXAMPLE 3

Renal Ischemia

The methodology of Example 1 was followed, but the animals were subjected to 60 minutes of warm ischemia after clamping of the renal artery and vein. Ten animals per dosage group subsequently received either 50, 100, or 200 μg/kg of a vehicle, naloxone or nalmefene. The survival rates, evaluated 72 hours after reperfusion, are set forth in Table 4.

TABLE 4

DOSE (μg/kg)	50	100	200
Control	30	40	50
Naloxone	30	40	50
Nalmefene	50	70*	80*

*Significant relative to control (p <0.05)

"(Table 4 of Example 3 on page 8)

(2) Invention described in Publication 1

Regarding Claim 8 of Publication 1 as an invention of a product used in "a method of treating," in addition of specifying "the internal organ" of Claim 14 (Publication 1-1), it is acknowledged that the following invention is described in the Publication 1.

"An agent for intravenously administering about 10 to 3000 μg/kg, based on patient body weight, of nalmefene in an injectable vehicle subsequent to the onset of ischemia or hypoperfusion in the organ, for treating the patient suffering from ischemia or hypoperfusion in an internal organ of kidney, small intestine, liver, or lung as a result of trauma, insult, or hemorrhagic shock." (hereinafter referred to as "Cited Invention")

(3) Comparison

A Regarding "condition"

Regarding "organ damage being liver damage, lung damage, and kidney damage" (in a case where "organ damage" is selected from "viral infections by Hepatitis B, organ damage being liver damage, lung damage, and kidney damage, and diseases associated with overproduction of superoxide anion radical, TNF-α or iNOS, selected from the group consisting of Crohn's disease, ulcerative colitis, and pulmonary fibrosis"), which is one of

"conditions" of the Invention, the Invention and the Cited Invention will be compared.

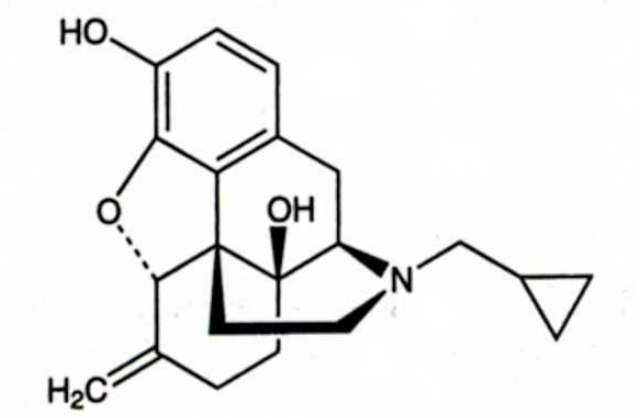
Regarding "organ damage" of the Invention, it is described in the description of the Invention that "[0073] In particular embodiments, organ damage includes, but is not limited to, liver damage, kidney damage, and lung damage. Such damage may arise from causes that include, but are not limited to, alcohol abuse, cirrhosis, hepatitis, and septic shock such as sepsis arising from bacterial infections or environmental toxins such as carbon tetrachloride"; however, the cause and condition are not defined.

Further, "ischemia or hypoperfusion in an internal organ of kidney, small intestine, liver, or lung as a result of trauma, insult, or hemorrhagic shock" is a condition that "kidney, small intestine, liver, or lung" receives "trauma, insult, or hemorrhagic shock," and "ischemia or hypoperfusion" is developed.

Thus, "ischemia or hypoperfusion in an internal organ of kidney, small intestine, liver, or lung as a result of trauma, insult, or hemorrhagic shock" of the Cited Invention is common with "organ damage being liver damage, lung damage, or kidney damage" in "a condition" including "kidney, small intestine, liver, or lung."

B Regarding "compound according to the formula R-A-X"

According to THE MERCK INDEX 13TH EDITION (see "6386. Nalmefene," MERCK CO., INC., published in 2001), "nalmefene" of the Cited Invention is a compound represented by the following formula,



corresponding to the description of Claim 1, in the formula R-A-X,

R is H,

X is $(CH_2)_nR_5$,

n is 1,

R_5 is cyclopropyl,

and R is bonded to an oxygen atom of A and X is bound to a nitrogen atom of A.

It is not obvious from the formula whether bonding of A is bound to R or X in "the compound according to the formula of R-A-X" of the Invention; however, it is described in [0027] of the description of the Invention that "The invention relates to use of a compound according to the formula for treatment of various diseases or conditions, or production of pharmaceutical compositions for treatment of such condition, and in the formula, R is bound to an oxygen atom and X is bound to a nitrogen atom," and it is also described in [0041] of the description of the Invention that "The term "alkyl" as used herein refers to C_1-C_{20} inclusive, linear, branched, or cyclic, saturated, or unsaturated hydrocarbon chains, including for example, methyl, ethyl, propyl, isopropyl, ...," and thus a saturated three-membered ring compound in which R_5 is cyclic (namely nalmefene) corresponds to "the

compound according to the formula of R-A-X."

Additionally, it is described in [0033] of the description of the Invention that "It is preferable that the compound is a compound in which X is cyclopropylmethyl and R is hydrogen, namely nalmefene," and this description matches the correspondence.

C Regarding "therapeutically effective amount"

It can be said that "about 10 to 3000 μg/kg, based on patient body weight, of nalmefene in an injectable vehicle" of the Cited Invention is an amount based on patient body weight "for treating the patient suffering from ischemia or hypoperfusion" and this amount is "a therapeutically effect amount," and it can also be said that the Cited Invention uses "a therapeutically effect amount" of nalmefene being an active ingredient.

Further, as described in the above B, nalmefene of the Cited Invention corresponds to "the compound according to the formula R-A-X."

Thus, "about 10 to 3000μg/kg, based on patient body weight, of nalmefene in an injectable vehicle" of the Cited Invention corresponds to "a therapeutically effective amount of the compound according to the formula R-A-X."

D Regarding "a pharmaceutical composition for preventing of treating a condition"

Since "an agent for intravenously administering about 10 to 3000 μg/kg, based on patient body weight, of nalmefene in an injectable vehicle subsequent to the onset of ischemia or hypoperfusion in the organ" of the Cited Invention is to treat the patient suffering from ischemia or hypoperfusion with nalmefene, this agent corresponds to "a pharmaceutical composition for preventing or treating a condition" of the Invention and includes "administering to a human or animal in need thereof."

Thus, the two inventions are common in "a pharmaceutical composition for

preventing or treating a condition including kidney damage, small intestine damage, liver damage, or lung damage, wherein a therapeutically effective amount of a compound according to the formula R-A-X is administered to a human or animal in need thereof," and are different in the following features.

<The different feature 1>

Regarding "a condition" including "kidney damage, small intestine damage, liver damage, or lung damage," in the Invention, the condition is "organ damage being liver damage, lung damage, or kidney damage," and on the other hand, in the Cited Invention, the condition is "ischemia or hypoperfusion in an internal organ of kidney, small intestine, liver, or lung as a result of trauma, insult, or hemorrhagic shock."

(4) Judgment

The different feature will be examined. Additionally, the underlines are applied by the body.

As described in Publication 1-2, as the embodiment, "ischemia or hypoperfusion in an internal organ of kidney, small bowel, liver, or lung as a result of trauma, insult, or hemorrhagic shock" of the Cited Invention induces ischemia as "hepatic ischemia" by clamping artery and vein, "renal ischemia" in Publication 1-3 is the same as in Publication 1-2, and thus ischemia includes at least "ischemia in liver by damage" and "ischemia in kidney by damage."

On the other hand, as described in the above "(3)A", "organ damage" of the Invention is not defined, and "ischemia" in organ "by damage" is not excluded.

Further, taking "organ damage being liver damage, lung damage, or kidney damage" of the Invention word for word, this phrase means damages of liver damage, lung damage, and kidney damage, it is described in [0073] of the description of the Invention

that "In particular embodiments, organ damage includes, but is not limited to, liver damage, kidney damage, and lung damage," and thus it is reasonable that this phrase means "organ damage being "liver damage, lung damage, or kidney damage."

Thus, "ischemia or hypoperfusion in an internal organ of kidney, small intestine, liver, or lung as a result of trauma, insult, or hemorrhagic shock" in the Cited Invention is not substantially different from conditions of "organ damage being liver damage, lung damage and kidney damage" of the Invention.

Additionally, the appellant alleges in the response submitted on May 15, 2014 that "ischemia damage" in Publication 1 (indicated as "Cited Document 4" in reply) "deals with symptoms," and on the other hand, regarding the application, "organ damage is treatable and reversible, completely different from irreversible ischemia damage"; however, since such matter is not limited in the Invention and this allegation is not based on the description of the application, this allegation does not affect the judgment.

(5) Closing of novelty

As described above, it is acknowledged that the Invention is the invention described in Publication 1 which had been obviously distributed before the priority date of the application, and thus the appellant should not be granted a patent for the Invention in accordance with the provisions of Article 29(1)(iii) of the Patent Act.

2. Improper statement

(1) Reasons for refusal stated in the examiner's decision

Reasons 4 and 5 for refusal stated in the examiner's decision are that the description of the detailed description of the invention does not meet the requirement stipulated in Article 36(4)(i) of the Patent Act, and the description of the scope of claims does not meet the requirement stipulated in Article 36(6)(i) of the Patent Act, and the following matters

are pointed out in the reasons.

Regarding the result of the pharmacological test of compounds of the medicinal invention, all of the following should be made sufficiently clear: which compounds are applied to what sort of the pharmacological test, what sort of result is obtained, and what sort of relationship the pharmacological test has with the medicinal use of the medicinal invention of claims.

However, there is no description of the result of the pharmacological test of a compound of the Invention in the detailed description of the Invention, and technical common sense supporting relationship between the compound and medicinal use is not obvious.

(2) Description of the Invention

Regarding "for preventing or treating viral infections," the following matters are described in the description of the Invention. Additionally, the underlines are applied by the body.

A "[Best Mode for Carrying Out the Invention]

[0034]

Treatments and pharmaceutical compositions produced according to the invention include treatments and pharmaceutical compositions for preventing or treating viral infections by Hepatitis B and Hepatitis C and conditions such as septic shock, organ damage, neurological disorders, cancer, and diseases associated with overproduction of superoxide anion radical, TNF-α or iNOS.

[0035]

According to other embodiments of the invention, the invention relates to methods

for preventing or treating viral infections by Hepatitis B and Hepatitis C and conditions such as viral infections by Hepatitis B and Hepatitis C, septic shock, organ damage, neurological disorders, cancer, and diseases associated with overproduction of superoxide anion radical, TNF-α or iNOS, wherein a pharmaceutical composition comprising a therapeutically effective amount of one or more desired compounds is administered to a subject in need thereof."

B "[0054]

Active compounds of the invention can be administered alone or in combination with other therapeutic agents. For example, active compounds of the invention can be coadministered with compounds now known, or later identified, to be useful for the prevention and/or treatment of viral infections and/or conditions such as septic shock, inflammation, organ damage, neurological disorders, neurodegenerative diseases, cancer, and cardiac disorders, and diseases associated with overproduction of superoxide anion radical, TNF-α, and iNOS. Exemplary compounds include, but are not limited to, analgesics, anesthetics, antifungals, antibiotics, antiinflammatories, anthelmintics, antidotes, antiemetics, antihistamines, antihypertensives, antimalarials, antimicrobials, antipsychotics, antipyretics, antiseptics, antiarthritics, antituberculotics, antitussives, antivirals, cardioactive drugs, cathartics, chemotherapeutic agents, corticoids (steroids), antidepressants, depressants, diagnostic aids, diuretics, enzymes, expectorants, hormones, hypnotics, minerals, nutritional supplements, parasympathomimetics, potassium supplements, sedatives, sulfonamides, stimulants, sympathomimetics, tranquilizers, urinary antiinfectives, vasoconstrictors, vasodilators, vitamins, xanthine derivatives, and the like."

C "[0072]

Methods of Use

In addition to the compounds of the formulas described herein, the present invention also provides useful therapeutic methods. For example, the invention provides a method of treating viral infections and septic shock, inflammation, organ damage, neurological disorders, neurodegenerative diseases, cancer, cardiac disorders, and diseases associated

with overproduction of superoxide anion radical, TNF-α, and iNOS. In some embodiments, viral infections include, but are not limited to, infections by Hepatitis B virus and Hepatitis C virus.

[0073]

In particular embodiments, organ damage includes, but is not limited to, liver damage, kidney damage, and lung damage. Such damage may arise from causes that include, but are not limited to, alcohol abuse, cirrhosis, hepatitis, and septic shock such as sepsis arising from bacterial infections or environmental toxins such as carbon tetrachloride."

(3) Judgment by the body

(3-1) Article 36(1)(i) of the Patent Act

Determination of Article 36(6)(i) of the Patent Act is to examine whether or not the invention according to claims exceeds the extent of disclosure in the description to which a person skilled in the art would recognize that a problem to be solved by the invention would be actually solved. When it is determined that the invention according to claims exceeds the extent of disclosure in the description, it cannot be said that the invention according to claims is substantially described in the detailed description of the invention, and thus the description of claims violates Article 36(6)(i) of the Patent Act.

Applying these examination guidelines to the Invention, the Invention includes "a pharmaceutical composition for preventing or treating viral infections by Hepatitis," wherein "a therapeutically effect amount of a compound according to the formula R-A-X," including nalmefene, "is administered to a human or animal in need thereof," and the problem of the invention is to provide "the compound according to the formula R-A-X" as "the pharmaceutical composition for preventing or treating viral infections by Hepatitis."

To have a person skilled in the art understand that a problem to be solved by the

invention would be actually solved, the Invention needs to be understood such that "the compound according to R-A-X" is useful in medicinal use "for preventing or treating viral infections by Hepatitis."

"The compound according to R-A-X" is a publicly known compound, including nalmefene (see 1.(3)B).

However, taking each indicated matter in (1) into account, there is no description that the compound is used "for preventing or treating viral infections by Hepatitis." In addition, there is description of viral infections in the indicated matters A to C; however, the description is only the list of conditions to be prevented or treated, and is not description based on objective evidence that "the compound according to R-A-X" can be used as "the pharmaceutical composition for preventing or treating viral infections by Hepatitis."

Thus, it cannot be said that in the description of the detailed description of the invention, the Invention, namely "a pharmaceutical composition for preventing or treating viral infections by Hepatitis," wherein "a therapeutically effective amount of a compound according to the formula R-A-X," including nalmefene, "is administered to a human or animal in need thereof," is described, and thus it cannot be said that the Invention is described in the detailed description of the invention.

(3-2) Article 36(4)(i) of the Patent Act

As described in the above (3-1), only conditions to be prevented or treated are listed, there is no specific example of whether "viral infections by Hepatitis" are prevented or treated by using "the compound according to R-A-X" is actually confirmed. In addition, it is not acknowledged that theoretical description instead of examples indicates whether "viral infections by Hepatitis" are prevented or treated by using "the compound according to R-A-X."

Further, in the technical fields, it cannot be acknowledged at the time of the priority date of the application that technical common sense that "viral infections by Hepatitis" had

been obviously related to "the compound according to R-A-X."

For these reasons, it cannot be said that the detailed description of the Invention describes that the Invention can be used as the expected pharmaceutical composition.

Thus, regarding the Invention, it cannot be said that the detailed explanation of the Invention is clear and sufficient in such a manner as to enable a person skilled in the art to work the invention.

(4) Closing regarding improper statement

Therefore, regarding the application according the Invention, the description of the scope of claims does not meet the requirement stipulated in Article 36(6)(i) of the Patent Act, the description of the detailed description of the invention does not meet the requirement stipulated in Article 36(4)(i) of the Patent Act.

3. Closing

As described above, regarding the present application, the invention according to Claim 1 is the invention described in Publication 1 which had been distributed before the priority date of the present application, and thus the appellant should not be granted a patent for the Invention in accordance with the provisions of Article 29(1)(iii) of the Patent Act. Further, the description of Claim 1 does not meet the requirement stipulated in Article 36(6)(i) of the Patent Act, and the description of the detailed description of the invention does not meet the requirement stipulated in Article 36(4)(i) of the Patent Act, and thus the appellant should not be granted a patent for the Invention.

Thus, the present application should be rejected without examining other claims.

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

October 27, 2014

Chief administrative judge: UCHIDA, Junko

Administrative judge: ANDO, Michiyo

Administrative judge: FUCHINO, Ruka