Appeal Decision

Appeal No. 2020-7606

Appellant James D. LEE

Patent Attorney YAMAO, Norihito

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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2016-536415, entitled "METHODS FOR IMPROVING RESPIRATORY SYSTEM HEALTH AND INCREASING THE CONCENTRATION OF HYPOTHIOCYANATE ION IN VERTEBRATE LUNGS" (International publication No. WO2015/026958 published on February 26, 2015, and National Publication of International Patent Application No. 2016-537144 published on December 1, 2016) has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The present application was filed as an international patent application on August 20, 2014 (priority claim under the Paris Convention received by the foreign receiving office on August 20, 2013 in the US) to which a written amendment was submitted on August 18, 2017, reasons for refusal were noticed on September 4, 2018, a written opinion and a written amendment were submitted on December 11, 2018, a notice of second reasons for refusal was issued on May 27, 2019, a written opinion and a written amendment were submitted on December 3, 2019, an examiner's decision of refusal based on the second reasons for refusal was issued on January 23, 2020, a written amendment was submitted on June 3, 2020 at the same time as an appeal against the examiner's decision of refusal was requested, a written amendment (formality) for amendment of the written request for trial was submitted on July 27, 2020, and a written statement was submitted on September 8, 2020.

No. 2 Statements in Claim 1 of the present application

The matters stated in Claims 1 to 12 in the scope of claims amended by the written amendment dated June 3, 2020 are the same as the matters stated in Claims 1 to 12 in the scope of claims amended by the written amendment dated December 3, 2019, which was the subject of the examiner's decision of refusal, and there is no change in the statements.

Furthermore, the inventions recited in Claims 1 to 15 of the present application are recognized as those specified by the matters stated in Claims 1 to 15 in the scope of claims amended by the written amendment dated June 3, 2020, in which Claim 1 states as follows:

"A composition comprising purified hydrogen peroxide gas (PHPG) for use in a method for treating a respiratory illness in a subject in need, wherein said method comprises the steps of:

providing a therapeutic enclosed space comprising a purified hydrogen peroxide gas (PHPG) that is substantially free of hydration and ozone at a final concentration of 0.01 to 1.0 parts per million (ppm), the PHPG being provided at a dose of at least 0.05 units; and

exposing said subject in need to said enclosed space for at least one period of time, wherein

said treatment comprises reducing the severity of a respiratory infection, reducing the duration of a respiratory infection, preventing transmission of a respiratory infection, reducing transmission of a respiratory infection in a population, or any combination thereof."

No. 3 Reasons for refusal stated in the examiner's decision

Among the reasons for refusal stated in the examiner's decision, the reasons for refusal of novelty and inventive step with respect to the invention recited in Claim 1 are as follows:

The invention recited in Claim 1 is the invention disclosed in Cited Document 1 stated below and falls under Article 29(1)(iii) of the Patent Act. Therefore, the Appellant should not be granted a patent for the invention.

In addition, the invention recited in Claim 1 could have been easily made by a person having ordinary skill in the art to which the invention belongs (hereinafter, referred to as "a person skilled in the art") prior to filing of the application on the basis of the invention disclosed in Cited Document 1. Therefore the Appellant should not be granted a patent for the invention under the provisions of Article 29(2) of the Patent Act.

Cited Document 1: Japanese Translation of PCT International Application No. 2010-535807

No. 4 Stated matters in the Cited Documents, etc.

1 Stated matters

Cited Document 1 cited for the reasons for refusal stated in the examiner's decision includes the following statements together with the drawings (underlines by the body, the same shall apply hereinafter).

(1a) "[Claim 1]

A method for microbial control and/or disinfection/remediation of an environment, the method comprising: (a) generating Purified Hydrogen Peroxide Gas (PHPG) that is substantially free of hydration, ozone, plasma species, and/or organic species; (b) directing the PHPG into the environment such that the hydrogen peroxide gas acts to provide microbial control and/or disinfection/remediation in the environment, both on surfaces and in the air.

...

[Claim 3]

The method of Claim 1, wherein the PHPG produced is between 0.005 ppm and 0.10 ppm in concentration.

[Claim 4]

The method of Claim 1, wherein said microbial control and/or disinfection/remediation of an environment includes indoor air treatment, water purifier, mold eliminator, bacteria eliminator, and virus eliminator."

(1b) "[0034]

In certain embodiments, with reference to the microbial control and/or disinfection/remediation of air and related environments (including surfaces therein), the amount of PHPG may vary from about 0.005 ppm to about 0.10 ppm, more particularly, from about 0.02 ppm to about 0.05 ppm, in the environment to be disinfected. Such amounts have been proven effective against, e.g., the Feline Calicivirus (an EPA approved surrogate for Norovirus), Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomyacin Resistant Enterococcus Faecal (VRE), Clostridium Difficile (C-Diff), Geobacillus Stearothermophilus, and Aspergillus Niger. Such amounts of PHPG are safe to use in areas occupied by persons (including, but not

limited to, schools, hospitals, offices, homes, and other common areas), disinfect surface contaminating microbes, kill airborne pathogens, and provide microbial control, e.g., for preventing the spread of Pandemic Flu, controlling nosocomial infections, and reducing the transmission of common illnesses."

(1c) [Table 3] is as follows:

試験生命体	暴露時間(時間)	暴露後に観察されたウイルスの平均感染力	ウイルス制御零時間の時と比較した減少%	自然死滅と比較した減少%
ネコカリシウイルス（ノロウイルス代替）	2	4.3 $\log_{10}$	99.5%	96.8%
	6	2.3 $\log_{10}$	99.995%	99.8%
	24	≤0.6 $\log_{10}$(唯一のレプリカにウイルス検出)	≥99.9999%	99.8%

試験生命体	Test Organism
ネコカリシウイルス（ノロウイルス代替）	Feline Calicivirus (Norovirus substitute)
暴露時間（時間）	Exposure Time (hrs.)
暴露後に観察されたウイルスの平均感染力	Average Virus Infectivity Observed After Exposure
（唯一のレプリカにウイルス検出）	(virus detected in only one replicate)
ウイルス制御零時間の時と比較した減少%	Percent Reduction as compared to Time Zero Virus Control %
自然死滅と比較した減少%	Percent Reduction Compared to Corresponding Natural Die-off %

試験生命体	時刻	平均CFU/試験担体（生存ウイルス）	ウイルス制御零時間の時と比較した減少%	自然死滅と比較した減少%
MRSA (ATCC 33592)	2 時間	<1（生存なし）	>99.9999%	>99.9999%
	6 時間	<1（生存なし）	>99.9999%	>99.9999%
	24 時間	<1（生存なし）	>99.9999%	>99.9999%
VRE (ATCC 51575)	2 時間	<1（生存なし）	>99.9999%	>99.999%
	6 時間	<1（生存なし）	>99.9999%	>99.99%
	24 時間	<1（生存なし）	>99.9999%	>99.9%
C.difficile (ATCC 700792)	2 時間	2.18×10^{5}CFU/担体	27.3%	9.2%
	6 時間	1.1×10^{5}CFU/担体	63.3%	60.6%
	24 時間	7.3×10^{4}CFU/担体	75.7%	70.4%
A.niger (ATCC 16404)	2 時間	1.9×10^{5}CFU/担体	19.1%	13.6%
	6 時間	4.67×10^{4}CFU/担体	80.1%	81.3%
	24 時間	1.2×10^{4}CFU/担体	94.9%	90.8%

試験生命体　Test Organism
時刻　Time point
2 時間　2 hours
6 時間　6 hours
24 時間　24 hours
平均ＣＦＵ／試験担体（生存ウイルス）　Average CFU/Test carrier (Survivors in the test)
（生存なし）　(no survivors)
担体　Carrier
ウイルス制御零時間の時と比較した減少％　Percent Reduction as compared to Time Zero Virus Control %
自然死滅と比較した減少％　Percent Reduction Compared to Corresponding Natural Die-off %

2 Matters recognized

Any composition comprising "Purified Hydrogen Peroxide Gas (PHPG)" "to be discharged on the surface and into the air in the environment" (see Claim 1 in indication (1a)) can be said to be a composition for use in "a method for microbial control and/or disinfection/remediation of an environment" "including indoor air treatment," "mold eliminator, bacteria eliminator, and virus eliminator" (see Claims 1 and 4 in indication (1a)).

3 Cited Invention

From the above "1" and "2," Cited Document 1 is recognized to disclose the following invention (hereinafter, referred to as "Cited Invention").

"A composition comprising Purified Hydrogen Peroxide Gas (PHPG) for use in a method for microbial control and/or disinfection/remediation of an environment, including indoor air treatment, mold eliminator, bacteria eliminator, and virus eliminator, the method comprising: (a) generating a gas comprising Purified Hydrogen Peroxide Gas (PHPG) that is substantially free of hydration, ozone, plasma species, and/or organic species; and (b) directing the PHPG into the environment such that the hydrogen peroxide gas acts to provide microbial control and/or disinfection/remediation in the environment, both on surfaces and in the air,

wherein the PHPG produced is between 0.005 ppm and 0.10 ppm in concentration.

and is safe to use in areas occupied by persons including schools, hospitals, offices, homes, and other common areas, to disinfect surface contaminating microbes, and kill airborne pathogens, e.g., for preventing the spread of Pandemic Flu."

No. 5 Comparison / Judgment

1 Regarding the invention (part 1)

(1) Comparison

The invention recited in Claim 1 of the application is an invention of "a composition comprising purified hydrogen peroxide gas (PHPG) for use in a method for treating a respiratory illness in a subject in need."

Then, among the matters stated in Claim 1 of the application, the matter of "said method" "comprising providing a therapeutic enclosed space comprising a purified hydrogen peroxide gas (PHPG), the PHPG being provided at a dose of at least 0.05 units; and exposing said subject in need to said enclosed space for at least one period of time" are matters relating to the treating method and cannot be said to be matters specifying the "composition" itself.

As stated above, the invention recited in Claim 1 of the application is invention of the "composition", and thus the above matters for the treating method which are stated in Claim 1 cannot be said to be those specifying the invention recited in Claim 1 of the application. Therefore, the invention recited in Claim 1 of the application, which is invention of the "composition" (hereinafter referred to as "the invention (part 1)," can be reorganized as follows:

"A composition comprising purified hydrogen peroxide gas (PHPG) for use in a method for treating a respiratory illness in a subject in need, wherein

the composition is substantially free of hydration and ozone at a final concentration of 0.01 to 1.0 parts per million (ppm), and
said treatment comprises reducing the severity of a respiratory infection, reducing the duration of a respiratory infection, preventing transmission of a respiratory infection, reducing transmission of a respiratory infection in a population, or any combination thereof."

Based on the above, the invention (part 1) is compared with the Cited Invention.
A The "purified hydrogen peroxide gas (PHPG)" and "PHPG" in the latter correspond to the "purified hydrogen peroxide gas (PHPG)" and "PHPG" in the former, respectively. Similarly, "hydration" and "ozone" in the latter correspond to the "hydration" and "ozone," respectively.

B Comparing the latter's statement that "(a) generating Purified Hydrogen Peroxide Gas (PHPG) that is substantially free of hydration, ozone, plasma species, and/or organic species; (b) directing the PHPG into the environment such that the hydrogen peroxide gas acts to provide microbial control and/or disinfection/remediation in the environment, both on surfaces and in the air, wherein the PHPG produced is between 0.005 ppm and 0.10 ppm in concentration" with the former's statement that "substantially free of hydration and ozone at a final concentration of 0.01 to 1.0 parts per million (ppm)," it can be said that these statements are common in "substantially free of hydration and ozone."

C The "treatment" in the former "comprises reducing the severity of a respiratory infection, reducing the duration of a respiratory infection, preventing transmission of a respiratory infection, reducing transmission of a respiratory infection in a population, or any combination thereof" and thus the "treatment" includes the cases of "preventing transmission of a respiratory infection" and " reducing transmission of a respiratory infection in a population."

Furthermore, the "Flu" in the latter is a type of respiratory infection and is easily transmitted within the population by inhaling the virus. The disease also develops symptoms of respiratory infections. Therefore, "preventing the spread of Pandemic Flu" can be said to prevent the transmission of influenza or reduce the transmission of influenza within a population. Further, the "treatment" in the former includes the cases of "preventing transmission of a respiratory infection" and "reducing transmission of a respiratory infection in a population." Based on such a premise, therefore, the

"person" in the latter can be said to correspond to the "subject" in the former.

Then, it can be said that "is safe to use in areas occupied by persons including schools, hospitals, offices, homes, and other common areas and disinfect surface contaminating microbes, kill airborne pathogens, e.g., for preventing the spread of Pandemic Flu" and "a composition comprising Purified Hydrogen Peroxide Gas (PHPG) for use in a method for microbial control and/or disinfection/remediation of an environment including indoor air treatment, mold eliminator, bacteria eliminator, and virus eliminator" of the latter correspond to "said treatment comprises reducing the severity of a respiratory infection, reducing the duration of a respiratory infection, preventing transmission of a respiratory infection, reducing transmission of a respiratory infection in a population, or any combination thereof" and "a composition comprising purified hydrogen peroxide gas (PHPG) for use in a method for treating a respiratory illness in a subject in need," of the former respectively.

D Summarizing the above, it is recognized that the corresponding feature and the different feature between the invention (part 1) and the Cited Invention are as follows:

[Corresponding Feature 1]

"A composition comprising purified hydrogen peroxide gas (PHPG) for use in a method for treating a respiratory illness in a subject in need, wherein

the composition is substantially free of hydration and ozone, and

said treatment comprises reducing the severity of a respiratory infection, reducing the duration of a respiratory infection, preventing transmission of a respiratory infection, reducing transmission of a respiratory infection in a population, or any combination thereof."

[Different Feature 1]

The concentration of "purified hydrogen peroxide gas (PHPG)" is "a final concentration of 0.01 to 1.0 parts per million (ppm)" in the invention (part 1), but "between 0.005 ppm and 0.10 ppm" in the Cited Invention.

(2) Judgment

Consideration is given to the above Different Feature 1.

It is obvious that "the PHPG produced is between 0.005 ppm and 0.10 ppm in concentration" in the Cited Invention is the final concentration in consideration of the statement of "the amount of PHPG may vary from about 0.005 ppm to about 0.10 ppm in the environment to be disinfected" in indication (1b).

Regarding the final concentration, the invention (part 1) and the Cited Invention are common in the range of at least "0.01 to 0.10 parts per million (ppm)." In this sense, the final concentration in the above Different Feature 1 cannot be said to be a substantial difference.

In addition, a specific final concentration should be appropriately set by a person skilled in the art in consideration of a desired bactericidal effect, safety to the human body, and the like. Therefore, a person skilled in the art could appropriately set a range outside the numerical range of the Cited Invention as desired.

Then, it can be said that the effects of such a configuration are not beyond the scope that a person skilled in the art could predict.

Therefore, the invention (part 1) is the Cited Invention itself or could have been easily invented by a person skilled in the art on the basis of the Cited Invention.

2 Regarding the invention (part 2)

The invention recited in Claim 1 of the application for "a composition comprising purified hydrogen peroxide gas (PHPG) for use in a method for treating a respiratory illness in a subject in need" is as stated in the above "1." Here, consideration is given to the invention by assuming that the matter of "said method" "comprising providing a therapeutic enclosed space comprising a purified hydrogen peroxide gas (PHPG), the PHPG being provided at a dose of at least 0.05 units; and

exposing said subject in need to said enclosed space for at least one period of time" is a matter specifying the "composition", and the matter specified by the statements in Claim 1 of the application (see, the above "No. 2") is the invention recited in Claim 1 of the application (hereinafter, referred to as "the invention (part 2)"), as follows.

(1) Comparison

The invention (part 2) is now compared with the Cited Invention.

A The matters in the invention (part 2) common to the matters in the invention (part 1) and the comparison with the Cited Invention are as stated in the above "1 (1)."

B From the above, it is recognized that the corresponding feature and the different features between the invention (part 2) and the Cited Invention are as follows:

[Corresponding Feature 2]

A composition comprising purified hydrogen peroxide gas (PHPG) for use in a method for treating a respiratory illness in a subject in need, wherein

the composition is substantially free of hydration and ozone, and

said treatment comprises reducing the severity of a respiratory infection, reducing the duration of a respiratory infection, preventing transmission of a respiratory infection, reducing transmission of a respiratory infection in a population, or any combination thereof."

[Different Feature 2]

The concentration of "purified hydrogen peroxide gas (PHPG)" is "a final concentration of 0.01 to 1.0 parts per million (ppm)" in the invention (part 2), but "between 0.005 ppm and 0.10 ppm" in the Cited Invention.

[Different Feature 3]

Regarding the method, the invention (part 2) includes the matter of "said method" "comprising providing a therapeutic enclosed space comprising a purified hydrogen peroxide gas (PHPG), the PHPG being provided at a dose of at least 0.05 units and exposing said subject in need to said enclosed space for at least one period of time," whereas the Cited Invention does not specify such a matter.

(2) Judgment

A Regarding Different Feature 2

First, the above Different Feature 2 will be examined. The content of Different Feature 2 is the same as that of Different Feature 1, and the judgment is also as shown in the above "1 (2)."

B Regarding Different Feature 3

Next, the above Different Feature 3 will be examined.

(A) It is clear that "areas occupied by persons including schools, hospitals, offices, homes, and other common areas" in the Cited Invention are substantially enclosed spaces, in consideration of the statement of "the amount of PHPG may vary from about 0.005 ppm to about 0.10 ppm" in indication (1b) (the concentration cannot be maintained outdoors, and the concentration cannot be maintained in an open space even indoors). Thus, it can be said that the Cited Invention also has a step of providing an enclosed space including purified hydrogen peroxide gas (PHPG). It is also clear that a "person" stays in such an "area" for a predetermined period of time. Furthermore, it can be said that the Cited Invention also has a step of exposing a "person" to the "area." The matters that the enclosed space is "therapeutic" and the person is the "subject" are

the same as those stated in the above "1 (1) C."

(B) Then, the "dose" will be examined below based on the statement in paragraph [0093] of the description for the application, "As used herein, a dose may be defined in 'units' of PHPG equivalent to the concentration of PHPG in ppm multiplied by the number of hours a subject is exposed to the PHPG containing environment."

In the "schools" of the Cited Invention, it is quite possible that students and school staffs, such teachers, will stay for about 5 hours or more. The same can be said with inpatients and hospital staff members, such as doctors, in the "hospitals," employees in the "offices," and family members in the "homes."

Then, in the judgment about Different Feature 2 above, the range of "0.01 to 0.10 parts per million (ppm)" (see also "1 (2)" above) in which the final concentration of "purified hydrogen peroxide gas (PHPG)" is common between the invention (part 2) and the Cited Invention is examined. Even the lowest concentration of 0.01 million per million (ppm) in the range of the Cited Invention is 0.05 units or more if the person stays 5 hours or more. Therefore, it can be said that the Cited Invention also substantially includes the matter of "providing PHPG at a dose of at least 0.05 units."

(C) Summarizing the above, it can be said that the Cited Invention substantially includes the matter of "said method" of the Invention (part 2) relating to Different Feature 3 "comprising providing an enclosed space comprising a purified hydrogen peroxide gas (PHPG), the PHPG being provided at a dose of at least 0.05 units; and exposing said subject in need to said enclosed space for at least one period of time."

(D) Alternatively, even if the above (A) to (C) cannot be said, it is obvious that a bactericidal effect can be expected even in the Cited Invention by exposing a person to purified hydrogen peroxide gas (PHPG) for a certain period of time (also see, [Table 3] (Indication (1c)), which represents experimental results, in Cited Document 1). A person skilled in the art could easily conceive of the method including the matter of the Invention (part 2) relating to Different Feature 3 by allowing the Cited Invention to include "providing PHPG at a dose of at least 0.05 units" as well as include "providing a therapeutic enclosed space comprising a purified hydrogen peroxide gas," as "an area occupied by persons" and "exposing the subject in need to the enclosed space for at least one period of time."

Then, it can be said that the effects of such a configuration are not beyond the

scope that a person skilled in the art could predict.

The invention (part 2) is the Cited Invention itself or could have been easily invented by a person skilled in the art on the basis of the Cited Invention.

No. 6 Appellant's allegation

Regarding the reasons for novelty, in the written request for trial amended by the written amendment (formality) dated July 27, 2020 (4, (2)) and the written statement dated September 8, 2020 (4, (2)), the Appellant alleges as follows: "Regarding the invention of the application, we consider that Cited Document 1 does not state any required illnesses, such as respiratory illnesses, in the subjects. Therefore, we consider that the invention of the application is a different invention from the invention stated in Cited Document 1."

However, in the invention recited in Claim 1 of the application, the "treatment" includes "preventing transmission of a respiratory infection" and "reducing transmission of a respiratory infection in a population," and the Cited Invention includes the matter of "preventing the spread of Pandemic Flu." This matter corresponds to "preventing transmission of a respiratory infection" and "reducing transmission of a respiratory infection in a population" as stated in the above "No. 5 1 (1) C." Therefore, the allegation of the Appellant stated above cannot be accepted.

No. 7 Closing

As stated above, the invention cited in Claim 1 of the application is the invention disclosed in Cited Document 1 and falls under Article 29(1)(iii) of the Patent Act. Thus, it should not be granted a patent under the provision of Article 29(1) of the Patent Act. Alternatively, the invention could be easily made by a person skilled in the art based on the invention disclosed in Cited Document 1. Thus, it should not be granted a patent under the provision of Article 29(2) of the Patent Act.

As stated above, the present application should be rejected even without examining the inventions recited in the other claims.

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

March 4, 2021

Chief administrative judge: UJIHARA, Yasuhiro

Administrative judge: ICHINOSE, Satoru

Administrative judge: DEGUCHI, Masaya