Appeal decision

Appeal No. 2015-7094

USA
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The case of appeal against the examiner's decision of refusal Japanese Patent Application No. 2012-535317, entitled " Nonvisual Indication of an Unwanted Chemical in an Ingestible Substance" (International publication No. WO2011/050004 published on April 28, 2011, National Publication of International Patent Application No. 2013-508726 published on March 7, 2013) 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 originally filed on October 19, 2010 as an International Patent Application (the claim of priority under the Paris Convention was received by the foreign receiving office on October 19, 2009 in the US), reasons for refusal were noticed on December 26, 2013, and a written opinion was submitted along with a written amendment on July 7, 2014. However, a decision of refusal was made on

December 3, 2014, and an appeal against the examiner's decision of refusal and a written amendment were filed on April 15, 2015.

No. 2 Decision to dismiss the written amendment made on April 15, 2015

[Conclusion of Decision to Dismiss Amendment]

The written amendment dated April 15, 2015 (hereinafter, referred to as "the Amendment") shall be dismissed.

[Reason]

1 Details of the Amendment

The description in Claim 7 of the scope of claims for patent amended in the Amendment is as follows (the underlines indicate the amended portions.).

"A non-visual verification system, comprising:
a non-visual, sensing mechanism constructed to verify whether a target drug is present in an ingestible substance by producing a non-visual indicator that can be understood by a user, wherein the sensing mechanism is constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user by adding the non-visual indicator to the ingestible substance to produce interaction between the non-visual indicator and the target substance when the target drug is present in the ingestible substance."

2 Purpose of the Amendment

The above-described amendment is intended to limit "the sensing mechanism is constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user" to the sensing mechanism being constructed so as to produce a non-visual indicator "by adding the non-visual indicator to the ingestible substance to produce interaction between the non-visual indicator and the target substance when the target drug is present in the ingestible substance," and thus the Amendment includes an amendment that is not intended to change the field of industrial application and the problems to be solved.

Thus, the Amendment is intended to limit the necessary matter to specify the invention described in Claim 5 before amendment, and thus the Amendment includes an amendment that is not intended to change the field of industrial application and the

problems to be solved, which therefore falls under restriction of the scope of claims in accordance with Article 17-2(5)(ii) of the Patent Act.

3 Judgment on independent requirements for patentability

Then, we will examine whether or not the invention described in Claim 7 after the Amendment (hereinafter, referred to as the "Amended Invention") should fall under the provision of Article 126(7) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 17-2(6) of the Patent Act, or should be patented independently at the time of filing of the patent application as below.

(1) Article 36(4)(i) of the Patent Act (Enabling requirements)

The specification of the present application describes as follows about "the non-visual, sensing mechanism" "constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user" (the underlines are applied by the body).

A "[Description of Embodiments]
[0015]
The present invention includes systems and methods for performing a non-visual test to determine the presence of a target substance in an ingestible substance. In particular, the invention includes systems and methods for performing a non-visual test to determine the presence of a target substance in an ingestible substance, where the target substance may be indicated both non-visually and concealably."

B "[0018]
The disclosed methods may be performed using a non-visual verification system 26, as depicted schematically in Fig. 3. The non-visual verification system includes a sensing component 28, and an indicating component 32. The non-visual verification system optionally further includes a processor 30, as will be discussed below.
[0019]
The non-visual verification system may be used to test an ingestible substance, prior to consumption, for one or more specific target substances. That target substance(s) is typically an unwanted or undesired substance, such as a drug or a toxin. More particularly, the target substance may be a drug intended to confuse or sedate the consumer. Selected embodiments of the target substance include flunitrazepam,

gamma-hydroxybutyric, ketamine, clonazepam, alprazolam, temazepam, and midazolam, without limitation.

[0020]

The non-visual verification system is typically configured so that the ingestible substance may be tested for the target substance concealably. As used herein, the test is administered concealably where the ingestible substance may be tested for the target substance without alerting bystanders or companions that the test has been administered, or revealing the results of the test.

[0021]

The non-visual verification system includes a sensing component, where the selected ingestible substance interacts with the system. The sensing component may be as simple as a molecule or a molecular array that incorporates one or more binding sites that are complementary to the target substance, such that binding the target substance results directly or indirectly in a non-visual response.

[0022]

The ingestible substance to be tested may be any solid, semi-solid, or liquid that is intended for ingestion. The ingestible substance may also be a food or beverage. In one aspect of the invention, the ingestible substance is a liquid or semi-liquid, to facilitate detection of the target substance by chemical or physical interaction. The ingestible substance may also include chewing gum, toothpaste, and other substances that may be placed in the mouth, but are not be intended to be swallowed.

[0023]

The non-visual verification system typically incorporates an indicating component capable of indicating the presence of the selected target substance via a non-visual indication. In one embodiment, the indicating component is directly coupled to the sensing component, such as via molecular recognition, where binding the target substance triggers a molecular modification that produces that desired non-visual indication, such as via a change in flavor, odor, or texture.

[0024]

In one particular embodiment, the non-visual verification system may correspond to an indicator substance that is selectively reactive toward the target substance (the sensing component), and produces an identifiable flavor compound in the presence of the target substance (the indicating component). Preferably, such substances react with the desired target substance with both selectivity and specificity, so as to avoid false positives. For example, the interaction between an indicator substance and the target substance may be similar to that of specific binding pairs. The

indicator substance may be designed so that binding the target substance triggers a molecular rearrangement of the indicator substance, creating a distinct flavor change. Alternatively, or in addition, binding the target substance may trigger the release of one or more small molecules that are then detectable by flavor or odor.

[0025]

Such an indicator substance may be utilized by placement in the user's mouth, or by placing a component of the non-visual verification system that includes the indicator substance in the user's mouth. Selected embodiments of the indicator substance may produce a bitter, or otherwise identifiable, taste to the user. The indicator substance may include more than one constituent element, and may correspond to any composition, element, material, reagent, or solution, or combination thereof, that is suitable for producing such an identifiable or bitter taste upon reaction with the target substance. In one embodiment, the non-visual verification system incorporates multiple indicator substances, each configured to react selectively with one or more target substances to produce a range of individually identifiable flavors. Such a multi-target system may be useful for the detection of multiple targets of interest simultaneously.

[0026]

Where the indicating component is intended to produce a non-visual indication that is a flavor, the indicating component may be present on a strip of paper, a dissolvable strip of material, a saliva-dissolvable material, or a chewing gum-type of material, which a user may put in his or her mouth prior to ingesting the ingestible substance. The substance may also be formulated as a liquid additive packaged in a small container with a dispenser such as a dropper/pipette so that the user can place a drop of the liquid additive in/on the beverage or food, respectively.

[0027]

An indicator substance configured to create an identifiable or bitter taste when in contact with target substance may be delivered to the user in any suitable form, such as through a pill, a readily-dissolvable tablet, or a liquid solution. The indicating substance can also be, or be impregnated in, any chewable or edible item that resembles a common beverage or food item, such as a stick or piece of gum, breath mint, mint, or candy, such as those candies sold under the federally registered trademark TIC TAC, etc. The substance can therefore be used openly in a manner that would not otherwise alert others that the user is performing a test for the presence of unwanted drugs in a beverage or food item. Alternatively, the substance may be added to the beverage or food itself to produce an identifiable and/or bitter taste.

[0028]

In some embodiments, the test may include a user placing a detector substance in his or her mouth, then drinking the beverage or eating the food in question. The detector substance may cause the user to have a pre-selected indicator taste. For example, a user may place a dissolvable strip of material in his or her mouth to moisten and/or dissolve the strip, thereby releasing the substance. The substance may then coat all or a portion of the interior of the user's mouth, including the taste buds, with the substance, so that the test may be performed by subsequently sipping, ingesting, or tasting a small portion of the suspected beverage or food. The results of the test are therefore fully concealed from others and only known to the taster.

[0029]

All of the compositions, substances, and methods disclosed herein can be made and executed without undue experimentation in light of the present disclosure. While the compositions, substances, and methods of this disclosure have been described in terms of preferred embodiments, it will be apparent to those of skill in the art that variations may be applied to the compositions/substances, and in the steps or in the sequence of steps of the method described herein without departing from the concept, spirit, and scope of the present disclosure. More specifically, it will be apparent that certain substances that are both chemically and physiologically related may be substituted for the substances described herein while the same or similar results would be achieved. All such similar substitutes and modifications apparent to those skilled in the art are deemed to be within the spirit, scope, and concept of the present disclosure."

According to the above description, it can be understood that "the non-visual, sensing mechanism" "constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user" in the "Amended Invention" may correspond to an indicator substance that binds the target substance to trigger a molecular modification or a molecular rearrangement of the indicator substance, and produces that desired non-visual indication, such as via a change in flavor such as a bitter taste, or odor, and such an indicator substance may correspond to any composition, element, material, reagent, or solution, or combination thereof, that is suitable for producing such an identifiable sensation upon reaction with the target substance.

However, since the description that binding the target substance triggers a molecular modification or a molecular rearrangement of the indicator substance, and produces that desired non-visual indication, such as via a change in flavor such as a bitter taste, or odor only explains abstractly or functionally the concept of the "indicator

substance" that may correspond to the Amended Invention, it is unknown how binding the target substance specifically triggers a molecular modification or a molecular rearrangement of the indicator substance, and produces that desired non-visual indication.

In addition, the only description about a specific indicator substance is that of an indicator substance that may correspond to any composition, element, material, reagent, or solution, or combination thereof, that is suitable for producing such an identifiable thing upon reaction with the target substance. For example, it is unknown what indicator substances bind to flunitrazepam, gamma-hydroxybutyric, ketamine, clonazepam, alprazolam, temazepam, and midazolam, respectively, which are target substances, and trigger a desired molecular modification or a desired molecular rearrangement of the indicator substances to produce non-visual indicators.

It is normal that those skilled in the art cannot conceive specific embodiments of indicator substances to meet these conditions in technical fields in which it is difficult to expect the effects of the inventions if verifications are not made by experiments or the like.

In view of the above, since the detailed description of the invention is not clear and sufficient enough to enable a person of ordinary skill in the art to carry out the Amended Invention, the present application does not meet the requirements stipulated in Article 36 (4) (i) of the Patent Act.

(2) Article 36(6)(i) of the Patent Act (requirements for support)

According to paragraph [0009] of the specification, the problem to be solved by the Amended Invention is understood to provide "a test system that can verify the presence or absence of a target drug in a food or beverage without requiring a visual evaluation, so that a person suspected of tampering with the food or beverage need never know that he or she is under suspicion".

However, as discussed in (1) above, while it can be understood "the non-visual, sensing mechanism " "constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user" in the "Amended Invention" may correspond to an indicator substance that binds the target substance to trigger a molecular modification or a molecular rearrangement of the indicator substance, and produces that desired non-visual indication, such as via a change in flavor such as a bitter taste, or odor, and such an indicator substance may correspond to any composition, element, material, reagent, or solution, or combination thereof, that is suitable for producing such an identifiable sensation upon reaction with

the target substance, there is no indication in the detailed description of the invention about what substance specifically constitutes the "indicator substance" that may correspond to "the non-visual, sensing mechanism" "constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user" in the Amended Invention.

Thus, a person skilled in the art cannot recognize that the problems of the Amended Invention can be solved by "the non-visual, sensing mechanism" "constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user" in the Amended Invention.

Therefore, the Amended Invention is not within "the matters described in the detailed description of the invention so that a person skilled in the art can recognize the problems of the invention can be solved."

As described above, the Amended Invention does not meet the requirement stipulated in Article 36(6)(i) of the Patent Act.

(3) Demandant's allegation

The demandant alleges, in the written demand for trial, that a person skilled in the art would be usually conversant with particular types of flavor receptors and odor receptors that cause the individual odors and flavors to be acknowledged, would know the types, shapes, and the like of molecules that interact with these receptors, and would be further conversant with a method for subjecting small molecules to a screening in order to cause the small molecules to interact with a particular target receptor. In addition, the demandant alleges, indicating an example in Kurtz et al., that the change in shape and/or structure of molecules has an influence on a substance flavor, and that once a receptor ligand that is suitable for inducing a desirable odor or flavor is subjected to a screening to be selected, the ligand needs to be released in the presence of the target substance, which can simply define a structure that binding the target substance replaces a desired receptor ligand, or define a problem of producing a ligand that causes release of the receptor ligand instead, and a benzodiazepine that defines a target substance interacts with a receptor to a neural transmitter substance gamma-aminobutyric acid (GABA), and the binding type and the binding strength between the compound and the GABA receptor have been widely studied, so that a screening analysis for designing to adjust a molecule analogue of the GABA receptor as an indicator substance is a normal aspect of a biotechnological study or a biomedical study, which requires no excessive experiments, while the demandant submitted a plurality of documents indicating that the Amended Invention may be practiced.

However, what the demandant explains in the written demand for trial while referring to the description of Kurtz et al., is only that an artificial sweetener such as aspartame turns bitter or tasteless by substitution of functional groups; that is, by a molecular modification or a molecular rearrangement, and thus the demandant does not explain the relation between the GABA receptor and the molecule analogue. In addition, in any of the documents submitted in the written demand for trial in support of demandant's allegation, there is no description that would lead the reader to believe that no excessive experiment is required of a screening analysis for designing to adjust a molecule analogue of the GABA receptor. In the technical field relating to chemical substances, verification by many experiments should be required of a screening analysis for designing to adjust a molecule analogue of the GABA receptor as an indicator substance, considering that it is often difficult to predict the function and effect based on the structures of chemical substances.

Therefore, the allegation of the demandant alleging that the Amended Invention may be practiced cannot be accepted.

(4) Summary

As described above, the Amended Invention does not meet the requirements stipulated in Article 36(4)(i) and Article 36(6)(i) of the Patent Act, and the Amended Invention should not be granted a patent for it independently at the time of patent application.

4 Summary

Therefore, the Amendment violates the provisions of Article 126(7) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 17-2(6) of the Patent Act, and shall be accordingly 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

1 Acknowledgment of the Invention

Since it was decided that the written amendment dated April 15, 2015 would be dismissed as described above, the invention relating to Claim 5 of the present application (hereinafter, referred to as "the Invention") is acknowledged as follows, as

specified by the matters described in Claim 5 according to the scope of claims for patent amended by the written amendment dated July 7, 2014:

"A non-visual verification system, comprising:
a non-visual, sensing mechanism constructed to verify whether a target drug is present in an ingestible substance by producing a non-visual indicator that can be understood by a user, wherein the sensing mechanism is constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user."

2 Gist of reasons for refusal of the examiner's decision

Described in the detailed description of the invention is merely a concept about "the target substance may be indicated both non-visually and concealably," and there is no description about a specific device mechanism thereof.

For example, while a concept of the non-visual verification system is described in paragraphs [0023] to [0024] in the specification of the present application, there is no description about how binding the target substance specifically triggers a molecular modification or a molecular rearrangement, or how binding the target substance is specifically designed so as to create a distinct flavor change. It is common general technical knowledge that a specific form to meet these conditions cannot be conceived immediately by a person skilled in the art.

In view of the above, the present application does not meet the requirements for support and the enabling requirements, and accordingly does not meet the requirements stipulated in Article 36(4)(i) and Article 36(6)(i) of the Patent Act.

3 Judgment by the body

In the Invention, concerning "the sensing mechanism is constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user," the limitation of being constructed so as to produce a non-visual indicator "by adding the non-visual indicator to the ingestible substance to produce interaction between the non-visual indicator and the target substance when the target drug is present in the ingestible substance" is omitted.

In view of the above, as discussed above in item 3 of No. 2, the Amended Invention concerning "the sensing mechanism is constructed so as to produce a non-visual indicator that is selected from the group consisting of a taste indicator and a smell indicator to the user" does not meet the requirements stipulated in Article 36(4)(i)

(enabling requirements) and Article 36(6)(i) of the Patent Act (requirements for support), and accordingly the Invention of the present application also does not meet the requirements stipulated in Article 36(4)(i) (enabling requirements) and Article 36(6)(i) of the Patent Act (requirements for support).

No. 4 Closing

As described above, since the Invention of the present application does not meet the requirements stipulated in Article 36(4)(i) and Article 36(6)(i) of the Patent Act, the demandant 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.

May 9, 2016

Chief administrative judge:	OZAKI, Atsushi
Administrative judge:	FUJITA, Toshihiko
Administrative judge:	IZUMI, Takuya