Appeal Decision

Appeal No. 2020-9714

Appellant GLOBAL LIFE SCIENCES SOLUTIONS OPERATIONS UK LTD

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The case of appeal against the examiner's decision of Refusal for Japanese Patent Application No. 2017-530747, entitled "ANALYTE DETECTION ON SOLID SUPPORT BY NUCLEIC ACID AMPLIFICATION COUPLED TO IMMUNOASSAY" [international publication on June 23, 2016 (International Publication No. WO 2016/099999), national publication of PCT application on March 1, 2018 (National Publication of International Patent Application No. 2018-506020)] has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

I History of the procedures

The present application was filed on December 8, 2015 (priority claim under the Paris Convention: December 18, 2014, US) as an international patent, a Notice of Reasons for Refusal was issued on August 23, 2019, and the Written Opinion and the written amendment were submitted on November 20, 2019. However, a decision of refusal was issued on March 5, 2020. In response, an appeal against the examiner's decision of refusal was requested and the written amendment was filed on July 10, 2020.

II Decision to dismiss amendment of the written amendment made on July 10, 2020

[Conclusion of decision to dismiss the amendment]

The written amendment (hereinafter, referred to as the "amendment") made on July 10,

2020, shall be dismissed.

[Reasons]

1 The Amendment

(1) Description of the scope of claims after the amendment

The description of Claims 1 and 21 in the scope of claims prior to amendment was amended as follows by in the present amendment. (It should be noted that the original Claim 21 prior to the present amendment was changed to Claim 20 in the present amendment, and the underlined portion is the amended portion.)

A "[Claim 1]

A method for detection of at least one analyte derived from a sample, the method comprising the step of:

a) depositing the sample on a surface of a solid support;

b) transferring at least a portion of the solid support to a receptacle suitable for performing a specific binding assay for one or more analytes;

c) optionally washing the portion;

d) adding a single specific binding partner for each analyte of interest to the receptacle, the binding partner being labelled with an oligonucleotide sequence;

e) mixing the portion with nucleic acid amplification reagents;

f) amplifying the oligonucleotide sequence; and

g) detecting amplified nucleic acid, wherein

the solid support surface is impregnated with a <u>chaotrope</u>."

B: "[Claim 20]

A kit comprising a solid support; a specific binding partner for each analyte of interest labelled with an oligonucleotide sequence; reagents for amplifying the oligonucleotide sequence; and a user instruction manual, wherein

<u>the solid support surface is impregnated with a chaotrope</u>."

(2) Scope of claims prior to the present amendment

The description of Claims 1 and 21 in the scope of claims amended by the written amendment made on November 20, 2019, prior to the present amendment is as follows.

A "[Claim 1]

A method for detection at least one analyte derived from a sample, the method comprising the step of:

a) depositing the sample on a surface of a solid support;

b) transferring at least a portion of the solid support to a receptacle suitable for performing a specific binding assay for one or more analytes;

c) optionally washing the portion;

d) adding a single specific binding partner for each analyte of interest to the receptacle, the binding partner being labelled with an oligonucleotide sequence;

e) mixing the portion with nucleic acid amplification reagents;

f) amplifying the oligonucleotide sequence; and

g) detecting amplified nucleic acid, wherein

the solid support surface is impregnated with chemicals, such as a weak base, a chelating agent, an anionic surfactant, and optionally an anti-oxidant."

B: "[Claim 21]

A kit comprising a solid support; a specific binding partner for each analyte to interest labelled with an oligonucleotide sequence; reagents for amplifying the oligonucleotide sequence; and a user instruction manual."

2 Suitability of the Amendment

(1) Regarding amendment to Claim 1 prior to the present amendment

In the present amendment, the amendment to Claim 1 prior to the amendment changed the configuration that "the solid support surface is impregnated with chemicals, such as a weak base, a chelating agent, an anionic surfactant, and optionally an anti-oxidant", which is a matter necessary for specifying the invention described in Claim 1 prior to the present amendment, to the configuration that "the solid support surface is impregnated with a "chaotrope", the "chaotrope" does not limit "chemicals, such as a weak base, a chelating agent, an anionic surfactant, and optionally an anti-oxidant", and therefore, the amendment is not deletion of the claims, restriction of the scope of claims, or correction of errors, and further, is not clarification of an ambiguous statement. Therefore, the amendment is not intended for any item of Article 17-2(5) of the Patent Act.

(2) Regarding amendment to Claim 21 prior to the present amendment

In the present amendment, the amendment to Claim 21 prior to the present amendment is one that adds a limitation that "the solid support surface is impregnated with a chaotrope." The industrial applicability and the problem to be solved of the invention described in Claim 21 prior to the present amendment and the invention

described in Claim 20 after the present amendment are the same, and therefore, the present amendment falls into one that aims at "restriction of the scope of claims" defined in Article 17-2(5)(ii) of the Patent Act.

Therefore, whether the invention described in Claim 20 after the present amendment (hereinafter referred to as the "Amended Invention") complies with the provision of Article 126(7) of the Patent Act as applied mutatis mutandis under Article 126(6) of the Patent Act (whether the invention could have been patented independently at the time of filing of the patent application) will be discussed below.

A Amended Invention

The Amended Invention is as described in the above 1(1)A.

B Cited Documents

(A) Cited Document 1

a JP 2009-124990A (hereinafter referred to as "Cited Document 1"), which has been cited in the Reason for Refusal in the original decision and has been distributed before the priority date of the present application or made available to the public through electric telecommunication lines, has the following description together with the drawings.

(1a) "[0013]

(9) A kit for detecting an antigen in blood, wherein the kit includes a fiber; and an oligonucleotide-conjugated antibody containing an oligonucleotide chain and an antibody specifically binding to each antigen, and in which the oligonucleotide-conjugated antibody has a cleavage site configured to release the oligonucleotide chain.

[0014]

(10) The kit according to (9), wherein the fiber is a filter paper"

(1b): "[0039]

(1-1) Synthesis of Oligonucleotides

First, a first 131-mer oligonucleotide was synthesized by PCR using a primer 1 (SEQ ID NO: 1) having biotin bound to a 3' end as a 5' primer, a primer 2 (SEQ ID NO: 2) as a 3' primer, and a template 1 (SEQ ID NO: 3). A second 136-mer oligonucleotide was synthesized in the same manner using the primer 1 (SEQ ID NO: 1) having biotin bound to the 3' end as the 5' primer, the primer 2 (SEQ ID NO: 2) as the 3' primer, and the template 2 (SEQ ID NO: 4). A third 161-mer oligonucleotide was synthesized in the same manner using the primer 1 (SEQ ID NO: 1) having biotin bound to the 3' end as the 5'

primer, the primer 2 (SEQ ID NO: 2) as the 3' primer, and the template 3 (SEQ ID NO: 5). Each amplified product after PCR was purified using MinElute PCR Purification spin column (manufactured by Qiagen) or Miniprep column (manufactured by Invitrogen). Sequences and reaction conditions of the primers are shown below.

Primer 1: CTTACTGGCTTATCGAAA (SEQ ID NO: 1)

Primer 2: GGCAAGCCACGTTTGGTG (SEQ ID NO: 2)

Template 1:

CATCGTCTAGCTAGCTAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAG
AGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGA
GAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAGAG
AGAGAGAGAGAGTTGCC (SEQ ID NO: 3)

Template 2:

CACTGCTTACTGGCTTATCGAAATGGAATTCTGCATGCATCTAGAGGGCCCT
ATTCTATAGCATAGTGTCACCTAAATGCTAGGCAATCAGCCTCGACTGTGCC
TTCgcaGCAtgGCACACCAAACGTGGCTTGCC (SEQ ID NO: 4)

Template 3:

CACTGCTTACTGGCTTATCGAAATGGAATTCTGCATGCATCTAGAGGGCCCT
ATTCTATAGCATAGTGTCACCTAAATGCTAGGCAACCGACAATTGCATGAA
GAAcTCGCACATTGACGTCAATAATGACGTATGTTCCCAcCACCAAACGTGG
CTTGCC (SEQ ID NO: 5)

Reaction Conditions:

<Reaction Solution Composition>

Template DNA (100 μg/μL): 1 μL Taq polymerase: 2.5u

Primers (20 μM each): 2 μL x 2 dNTPs (2.5 mM each): 8 μL 10 x Buffer: 10 μL

Sterilized water: 77 μL (100 μL in total)

<Conditions>

"30 cycles, one cycle being "95°C for 1 minute → 55°C for 1 minute → 72°C for 30 seconds"."

(1c): "[0045]

(3) Preparation of Sample for Calibration Curve

Proteins of α-Gal (FABRAZYME), GCR (CEREZYME), and GAA (all manufactured by Genzyme) were mixed with PBS containing 1% BSA so as to be 1.2 μg/mL, 3 μg/mL, and 60 μg/mL, respectively, and then 5-fold diluted in seven stages. A filter paper impregnated with mouse blood is cut into φ3 mm, and each mixed protein solution was dropped at 1 μL/paper onto the filter paper. The filter paper was put into a

1.5 mL microtube and dried as it was for 60 minutes in a state in which a lid was opened. 5 mM Tris-HCl (pH 7.4) containing 0.05% Tween 20 was added to the tube at 60 μL/tube, and the tube was allowed to stand at room temperature for 60 minutes to elute proteins from the filter paper. The eluate was used as an antigen for a calibration curve.
[0046]
(4) Preparation of Sample

Blood collected from a healthy person was dropped onto the filter paper, and the filter paper was completely dried. A part of the filter paper into which the blood had permeated was punched and cut into φ3 mm, and put into the 1.5 mL tube, and the 5 mM Tris-HCl (pH 7.4) containing 0.05% Tween 20 was added to the tube at 60 μL/tube. The tube was allowed to stand at room temperature for 60 minutes to extract an antigen from the filter paper, and then the solution was collected as a sample.

Next, the antigen for a calibration curve and the sample were added to the plate prepared in (2) at 50 μL/well, and the plate was allowed to stand overnight at 4°C, and then the well was washed three times."

(1d): "[0048]
(6) Detection of Oligonucleotides

The washing buffer solution was removed from the well, and EcoR I was added at 0.3 units/30 μL/well. The plate seal was attached and left to stand at 37°C for 15 minutes to separate the oligonucleotide from the antigen-antibody complex, and a solution containing the oligonucleotide was recovered as a sample for Real-Time PCR. The following primers (Forward: TGCATCTAGAGGGCCCTATTCTATA: SEQ ID NO: 6) (Reverse: GGCAAGCCACGTTTGGTG: SEQ ID NO: 7) are used to perform Real-Time PCR (the condition was 35 cycles, one cycle being 95°C for 15 minutes and then 95°C to 60°C) on 3 μL of this solution, and a fluorescence intensity (Ct) was measured by the DNA Intercarator method or the TaqMan method. A calibration curve was prepared using measurement values for the sample for a calibration curve, and an amount of antigen was calculated for a sample of a subject."

b From the above (1a), Cited Document 1 describes the following invention (hereinafter referred to as the "Cited Invention").

"A kit for detecting an antigen in blood, wherein the kit includes a fiber as a filter paper; and an oligonucleotide-conjugated antibody containing an oligonucleotide chain and an antibody specifically binding to each antigen, in which the oligonucleotide-conjugated

antibody has a cleavage site configured to release the oligonucleotide chain."

(B) Matters described in Reference Documents

As a document showing a technique regarding matters added by the amendment, the following reference documents are shown.

a Matters described in the description of United States Patent Application Publication No. 2013/0338351 (hereinafter referred to as "Reference Document 1")

(R1a) "[0002] The invention relates to solid substrates and methods for ambient extraction and stabilization of nucleic acids from a biological sample in a dry format. Methods for collecting, extracting, preserving, and recovering nucleic acids from the dry solid substrates are also described."

(R1b) "[0029] The term "extraction" refers to any method for separating or isolating the nucleic acids from a sample, more particularly from a biological sample. Nucleic acids such as RNA and DNA may be released, for example, by cell-lysis. In one embodiment, nucleic acids may be released during evaporative cell-lysis. In another embodiment, the cells are lysed upon contact with the matrix comprising cell lysis reagents. Contacting a biological sample comprising cells to the matrix results in cell lysis which releases nucleic acids, for example by using FTATM Elute cellulose papers.
[0030] The solid matrix may be porous. In one embodiment, the solid matrix is a porous cellulose paper, such as a cellulose matrix from WhatmanTM. In one example, the cellulose matrix from WhatmanTM comprises 903-cellulose, FTATM or FTATM Elute.
[0031] In one or more examples, the extraction matrix is impregnated with one or more reagents. As noted, in an example embodiment, the matrix comprises one or more protein denaturants impregnated in a dry state. In one embodiment, the matrix further comprises one or more acids or acid-titrated buffer reagents. In another embodiment, the matrix further comprises one or more reducing agents. In some embodiments, the impregnated reagents comprise lytic reagents, nucleic acid-stabilizing reagents, nucleic acid storage chemicals and combinations thereof.
[0032] In some embodiments, the dried reagents impregnated in the matrix are hydrated by adding a buffer, water or a sample. In one embodiment, the impregnated dried reagents are hydrated by a sample, more specifically a biological sample, which is disposed on the matrix for extraction or storage of nucleic acids. In some other embodiments, in addition of a sample, water or buffer is added to hydrate the matrix and reconstitute or activate the

reagents embedded in the matrix. In some embodiments, the hydration of the matrix generates an acidic pH on the matrix. In some embodiments, the hydration further results in reconstituting the reagents, such as protein denaturant, acid or acid titrated buffer reagents that are present in a dried form in the matrix.

[0033] In one or more embodiments, the matrix comprises a protein denaturant. The protein denaturant may comprise a chaotropic agent or detergent. Without intending to be limited to a particular denaturant, protein denaturants may be categorized as either weak denaturants or strong denaturants depending on their biophysical properties and ability to completely inhibit biological enzyme activity (e.g. RNases). In some embodiments, weak protein denaturants (e.g. detergent) may be used for lysing cells and disrupting protein-protein interactions without denaturing nucleic acids. In further embodiments, use of strong protein denaturants (e.g. chaotropic salts) may also denature nucleic acid secondary structure in addition to denaturing cells and proteins. Numerous protein denaturants are known in the art and may be selected for use in the compositions and methods described herein. Without intending to be limited to a particular protein denaturant, exemplary protein denaturants include guanidinium thiocyanate, guanidinium hydrochloride, sodium thiocyanate, potassium thiocyanate, arginine, sodium dodecyl sulfate (SDS), urea or a combination thereof. Exemplary detergents may be categorized as ionic detergents, non-ionic detergents, or zwitterionic detergents. The ionic detergent may comprise anionic detergent such as, sodium dodecylsulphate (SDS) or cationic detergent, such as ethyl trimethyl ammonium bromide. Non-limiting examples of non-ionic detergent for cell lysis include TritonX-100, NP-40, Brij 35, Tween 20, Octyl glucoside, Octyl thioglucoside or digitonin. Some zwitterionic detergents may comprise 3-[(3-Cholamidopropyl)dimethylammonio]-1-propanesulfonate (CHAPS) and 3-[3-Cholamidopropyl)dimethylammonio]-2-hydroxy-1-propanesulfonate (CHAPS 0)."

b The description of United States Patent No. 5939259 (hereinafter referred to as "Reference Document 2") describes the following matters.

(R2a) "The present invention relates to devices and methods for the collection, storage, and purification of nucleic acids, such as DNA or RNA, from fluid samples for subsequent genetic characterization, primarily by conventional amplification methods." (Column 1, lines 5-9)

(R2b) "A poster disclosure at the annual American Association of Clinical Chemistry in 1995 by Dr. Michael A. Harvey et alia revealed that chaotropic salts can be used to

prepare DNA from dried and untreated whole blood spots for PCR amplification. Hemoglobin present in dried untreated whole blood spots was known to cause an inhibition of PCR reactions. A cellulosic paper treated with a chaotropic salt was found to overcome the problem of hemoglobin inhibition in untreated whole blood spots." (Column 2, lines 36-44)

(R2c) "For example, the present invention can be used to detect pathogens such as bacteria or viruses that can be found in the circulatory system. More importantly, these nucleic acids can be released after collection or storage in a manner that enables them to be amplified by conventional techniques such as polymerase chain reaction. The release of amplifiable nucleic acids is substantially more than in the presence of the inhibitory composition alone. In particular, an absorbent material that does not bind nucleic acids irreversibly is impregnated with a chaotropic salt. A biological source sample is contacted with the impregnated absorbent material and dried. Any nucleic acids present in the biological source can be either eluted or re-solubilized off the absorbent material. The present device can collect nucleic acids not only from point sources such as humans or animals, but also can be used to collect widely disseminated sources such as fungal spores, viruses, or bacterial spores, or bodily fluids present at crime scenes." (Column 2, line 62 - column 3, line 14)

(R2d) "Preferred embodiments of the present invention use cellulosics, in particular, flat sheet paper as an absorbent material. The shape or configuration of the absorbent material can vary. One can choose from flat sheets or spherical shapes. For example, FIG. 1 shows a flat sheet device (10) having a ready made perforation lines (12). One can simply contact the sheet with a biological source fluid or tissue and break off a piece of the absorbent material at the perforation. (Alternatively, FIG. 2 shows a ovoid dip device (20), shaped much like a match stick.) The device comprises three elements. The first is a handle means (22) that has a distal end (24) and a proximal end (26). The distal end is easily separable manually from the handle end. This can be achieved either by a perforation or a scribing (28) that weakens the connection to the handle. Absorbent material (30) that does not bind to nucleic acids is disposed about the distal end of the handle means. Finally, a chaotropic salt is impregnated about the absorbent material by dipping the absorbent material into a solution containing from 0.5M to 2.0M chaotropic salt, such as guanidine (iso)thiocyanate. The absorbent material is then dried. In use, one holds the proximal end (26) and contacts the distal absorbent head (24) with the biological source." (Column 4, lines 15-37)

c Well-known Technique

(a) Reference Document 1 describes that, in the "method for collecting, extracting, storing, and recovering nucleic acids", "the solid matrix" is "a porous cellulose paper", "the extraction matrix is impregnated with one or more reagents", "the matrix comprises one or more protein denaturants impregnated in a dry state", "the protein denaturant includes a chaotropic agent or detergent", "the protein denaturants completely inhibit their biophysical properties and biological enzyme activities", and "use of the chaotropic salts may also denature a nucleic acid secondary structure in addition to denaturing cells and proteins".

Since the "nucleic acid" is an oligonucleotide sequence, it can be recognized that the "extraction matrix" of Reference Document 1 is for collecting, extracting, storing, and recovering the oligonucleotide sequence. The "solid matrix", the "extraction matrix", and the "matrix" described in Reference Document 1 are the same and correspond to the "solid support" of the Amended Invention. Further, it is obvious that when "the extraction matrix is impregnated with one or more reagents", the surface of the "extraction matrix" is impregnated with "one or more reagents". The "chaotropic agent" described above corresponds to the "chaotropic" of the Amended Invention.

Thus, it can be recognized that Reference Document 1 describes that the surface of the "solid support" for collecting, extracting, storing, and recovering the oligonucleotide sequence is impregnated with the "chaotrope".

(b) Reference Document 2 "relates to a device and a method for collecting, storing, and purifying nucleic acids, such as DNA or RNA", and describes that "chaotropic salts can be used to prepare DNA from dried and untreated whole blood spots for PCR amplification" and "a cellulosic paper treated with a chaotropic salt overcomes the problem of hemoglobin inhibition in untreated whole blood spots", and thus, "in the detection of amplifiable nucleic acids", "an absorbent material is impregnated with a chaotropic salt", "a biological sample is adsorbed to the impregnated absorbent material and dried", and "the chaotropic salt is impregnated around the absorbent material by immersing the absorbent material in a solution containing the chaotropic salt". The "absorbent material" and the "chaotropic salt" of Reference Document 2 correspond to the "solid support" and the "chaotrope" of the Amended Invention, respectively, and the "DNA", the "RNA", and the "nucleic acid" are the "oligonucleotide sequence". Further, since the "chaotropic salt" of Reference Document 2 is "impregnated around the absorbent material by immersing the absorbent material in a solution containing the chaotropic salt", it can be recognized that the surface of the "absorbent material" of

Reference Document 2 is impregnated with the "chaotropic salt".

Thus, it can be recognized that Reference Document 2 describes that the surface of the "solid support" for collecting, storing, and purifying the oligonucleotide sequence is impregnated with the "chaotrope".

(c) From the above (a) and (b), both Reference Documents 1 and 2 describe that the surface of the "solid support" for collecting and storing the oligonucleotide sequence is impregnated with the "chaotrope", and thus the "technique in which the surface of the solid support for collecting and storing the oligonucleotide sequence is impregnated with the chaotrope" can be recognized to be a well-known technique.

C Comparison with Cited Invention

(A) The Amended Invention is compared with the cited invention.

a Since (1c) describes that "blood collected from a healthy person" was "dropped onto the filter paper, and the filter paper was completely dried", the "fiber made of filter paper" of the cited invention corresponds to the "solid support" of the Amended Invention.

b The "oligonucleotide-conjugated antibody containing an oligonucleotide chain and an antibody specifically binding to each antigen" of the Amended Invention corresponds to the "specific binding partner for each analyte labelled with an oligonucleotide sequence" of the Amended Invention.

(B) From the above, the similarities and the differences between the Amended Invention and the cited invention are as follows.

(Similarities) "A kit comprising a solid support; and a specific binding partner for each analyte labelled with an oligonucleotide sequence."

(Difference 1) The kit of the Amended Invention comprises "reagents for amplifying the oligonucleotide sequence; and a user instruction manual", whereas the cited invention does not have such a specification.

(Difference 2) The solid support of the Amended Invention is one whose "solid support surface is impregnated with a chaotrope", whereas the cited invention does not have such a specification.

D Judgment
Hereinafter, the differences will be discussed.

(A) Difference 1

According to the descriptions of the above (1b) and (1d), the "kit for detecting an antigen in blood" of the cited invention amplifies an oligonucleotide sequence by PCR, and in this case, a reagent containing a primer or the like is usually used. It is merely a common means to previously contain a reagent to be used in the subsequent treatment in the kit.

In addition, it is also common practice to include a user instruction manual in the kit.

Thus, it can be said that a person skilled in the art could have easily conceived that the "kit for detecting an antigen in blood" of the cited invention includes a reagent for amplifying an oligonucleotide sequence by PCR and a user instruction manual, and therefore, it can be said that a person skilled in the art could have easily conceived of the configuration according to the difference 1 based on the cited invention.

(B Difference 2

As discussed in the above 2(2)B(B)c, the "technique in which the surface of the solid support for collecting and storing the oligonucleotide sequence is impregnated with the chaotrope" is a well-known technique. The "fiber made of filter paper" of the cited invention is also for detecting an oligonucleotide sequence. In order to detect the oligonucleotide sequence, the oligonucleotide sequence needs to be collected and stored in the "fiber made of filter paper" of the cited invention, and therefore, the "fiber made of filter paper" of the cited invention can be recognized to be the "solid support for collecting and storing an oligonucleotide sequence".

Thus, it can be said that it is preferable that the surface of the "fiber made of the filter paper" of the cited invention, which is the "solid support for collecting and storing an oligonucleotide sequence", is impregnated with the chaotrope, and therefore, it can be said that a person skilled in the art could have easily conceived that the surface of the "fiber made of filter paper" of the cited invention is impregnated with the chaotrope.

(C) Effects

The operation and effect of the Amended Invention are merely within a range predicted from the operation and effect of the technique described in Cited Document 1 and the well-known techniques described in Reference Documents 1 and 2, and cannot be said to be particularly remarkable.

3 Conclusion regarding the Amendment

Therefore, in the amendment, the amendment to Claim 1 prior to the present amendment violates the requirement as provided in 17-2(5) of the Patent Act, and in the amendment, the amendment to Claim 21 prior to the present amendment violates the provision of Article 126(7) of the Patent Act as applied mutatis mutandis under Article 17-2(6) of the Patent Act, and thus should be rejected under the provision of Article 53(1) of the Patent Act that shall be applied mutatis mutandis upon reading the specified terms in accordance with Article 159(1) of the Patent Act.

Therefore, the decision is made as described in the conclusion of decision to dismiss the amendment.

No. 3 Regarding the present invention

1 Present Invention

Since the written amendment made on July 10, 2020 was rejected as described above, the inventions according to Claims 1 to 23 of the present application are specified by the matters described in Claims 1 to 23 in the scope of claims amended by the written amendment made on November 20, 2019, and the invention according to Claim 21 (hereinafter referred to as the "present invention") is specified by the matter described in Claim 21 and is as described in the above No. 2[Reasons]1(2)B.

2 Reason for Refusal in the Original Decision

The Reason for Refusal in the original decision is that the inventions according to Claims 21 to 23 of the present application shall not be granted a patent under the provision of Patent Act Article 29(2) for the reason that the claimed inventions could have easily been made by persons who have common knowledge in the technical field to which the claimed inventions pertain prior to the filing of the patent application, on the basis of the invention described in the distributed Cited Document 1 and the matters described in the distributed Cited Documents 2 and 3 listed below or made available to the public through electric telecommunication lines before the priority claim date of the present application.

Cited Document 1: JP 2009-124990A

Cited Document 2: Kaori Homma et al., Study of Pregnant Anti-HIV Antibody Screening Using Dried Blood Spots, Annual Report of Sapporo City Public Health Research Institute, 1999, 26, 35-38 (a document showing a well-known technique)

Cited Document 3: JP H07-501149A (a document showing a well-known technique)

3 Cited Document

Cited Document 1 cited in the Reason for Refusal in the original decision and the matters described therein are as described in the above No. 2[Reasons]2(2)B(A).

4 Comparison and Judgment

The present invention is made by deleting the limitation that "the solid support surface is impregnated with a chaotrope" from the Amended Invention discussed in the above No. 2[Reasons]2(2).

Thus, when the present invention is compared with the cited invention, only the difference 1 is different among the differences discussed in the above No. 2[Reasons]2(2)C. As described in the above No. 2[Reasons]2(2)D(A), it can be said that the configuration according to the difference 1 has been easily conceived by a person skilled in the art based on the cited invention, and therefore, the present invention could also have been easily invented by a person skilled in the art based on the cited invention.

No. 4 Conclusion

As described above, since the present invention shall not be granted a patent under the provision of the Patent Act Article 29(2), the present application should be rejected without examining the inventions according to the remaining claims.

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

March 10, 2021

Chief administrative judge: MISAKI, Hitoshi
Administrative judge: FUKUSHIMA, Koji
Administrative judge: ITO, Yoshihito