Patent Right	Date	February 9, 2022	Court	Intellectual Property High Court, Second Division
	Case number	2020 (Ne) 10059		
- A case in which, with regard to a request for an injunction against an infringing act, etc. filed based on a patent right for an invention titled "Equol-containing extract, method for production thereof, method for extraction of equol, and equol-containing food," the court presumed by applying Article 104 of the Patent Act that the Appellees' Material was produced by the method of the Invention, and determined that the presumption is not found to be rebutted.				

Case type: Injunction

Result: Reversal of prior instance judgment, granted

References: Article 104 and Article 39, paragraph (2) of the Patent Act

Related rights, etc.: Patent No. 6275313

Judgment of the prior instance: Tokyo District Court, 2018 (Wa) 18555, rendered on September 17, 2020

Summary of the Judgment

1. In this case, the Appellant, who is the patentee of a patent for an invention of a method for producing a product, titled "Equol-containing extract, method for production thereof, method for extraction of equol, and equol-containing food," (the "Patent") alleged that the method by which Appellee A produces the Appellees' Material (the Appellees' Method) falls within the technical scope of the patented invention in question, and that Appellee A's acts of producing and transferring the Appellees' Material and Appellee B's acts of producing the Appellees' Product by using the Appellees' Material purchased from Appellee A and transferring, etc. the Appellees' Product thus produced infringe the patent right relating to the Patent, and based on these allegations, the Appellant sought against the Appellees an injunction against production and transfer, etc. and the disposal of the Appellees' Material and the Appellees' Product, based on Article 100, paragraphs (1) and (2) of the Patent Act. The judgment in prior instance dismissed all of the Appellant's claims, holding as follows: in the Invention, it is regarded necessary for arginine to already be contained in the fermenting material, along with a daidzein compound at the stage of preparing the fermenting material, but in the Appellees' Method, arginine is not mixed in at the stage of preparing the fermenting material, but is mixed in for the first time in the subsequent fermentation process, and therefore the Appellees' Method is determined not to fall within the

technical scope of the Invention. After the judgment in prior instance, a decision by the Japan Patent Office upholding a request for correction of the Invention became final and binding. Therefore, in this judgment, the court only examined whether or not the Appellees' Method fulfills the constituent features of the Corrected Invention and the effectiveness of the Corrected Invention.

2. While a wide range of issues were involved in this case, the court reversed the judgment in prior instance, determining as follows, and upheld all of the Appellant's principal claims.

(1) Fulfilment of constituent features

The Corrected Invention is an invention for producing a product, and the produced product is "fermented powder containing ornithine and equol, wherein not less than 8 mg ornithine and not less than 1 mg equol are produced per gram by dry weight of said fermented substance, and which is used as a food material," which was not publicly known as of the priority date. Therefore, the presumption under Article 104 of the Patent Act applies, and the Appellees are to allege and prove that the product was not produced by the method of the Corrected Invention, in order to rebut the presumption, but it cannot be said that sufficient proof for rebutting the presumption has been produced in this case. Meanwhile, the judgment in prior instance determined that, because arginine is already contained in the fermenting material at the stage of preparing the fermenting material before the fermentation in the case of the Invention, the Appellees' Method (a method of mixing a treatment solution containing daidzein and a microorganism with a culture solution containing arginine to be fermented), in which arginine appears for the first time at the fermentation stage, does not fulfill the relevant constituent feature of the Invention. However, the patent claims and the description in question contain no statements suggesting any difference between a case of adding a microorganism after adding arginine to a daidzein compound and a case of mixing a daidzein compound, arginine, and a microorganism at the same time, and the description states that the fermenting material "containing daidzein compounds is not limited by other factors." It follows that the "culture solution containing arginine" of the Appellees' Method constitutes the "fermenting material containing arginine" of the Corrected Invention, and hence there is no proof that the Appellees' Method differs from the method of the Corrected Invention.

(2) Regarding novelty and inventive step

Although a lack of novelty and a lack of inventive step were alleged based on several cited inventions, none of the cited inventions contained a statement or suggestion concerning ornithine. Therefore, the cited inventions cannot be regarded to

be virtually identical to the Corrected Invention and a person skilled in the art could not have easily conceived of the Corrected Invention from the cited inventions.

(3) Regarding application of the second sentence of Article 39, paragraph (2) of the Patent Act

Generally, if patent applications are filed for two inventions on the same date, and if the difference of one of the inventions from the other is an addition, deletion, or replacement of well-known or commonly used art to the other and the invention does not produce any new effect, the two inventions constitute the "identical inventions" referred to in Article 39, paragraph (2) of the Patent Act. In this case, the Corrected Invention specifies that arginine is added to a daidzein compound, whereas Claim 4 of the Appellant's divisional application ("Divisional Invention 4") does not, and as stated in the description in question, the Corrected Invention produces a new effect in that arginine is converted into ornithine by the fermentation referred to in the Corrected Invention and therefore the amount of the ornithine produced can be increased by adding arginine. Accordingly, the Corrected Invention and Divisional Invention 4 cannot be regarded as identical inventions, and it cannot be said that the Corrected Invention becomes invalid pursuant to the second sentence of Article 39, paragraph (2) of the Patent Act.

(4) Regarding the need for a request for an injunction and disposal

Appellee B alleges that it has stopped producing the Appellees' Product and it also has no stock of the product. However, the only evidence produced as the basis of that allegation is a written statement prepared by Appellee B's employee, and there is no sufficient evidence to precisely find that no stock of the product exists at present. In addition, given that there is no change in the product name and in light of the situation of advertising, among other factors, one cannot go so far as to say that Appellee B is unlikely to produce and sell the Appellees' Product in the future. Consequently, the Appellant's request for an injunction and disposal is well-grounded.

Judgment rendered on February 9, 2022
2020 (Ne) 10059 Appeal case of seeking injunction against patent infringement
(Court of prior instance: Tokyo District Court, 2018 (Wa) 18555)
Date of conclusion of oral argument: December 2, 2021

Judgment

Appellant (first-instance Plaintiff): Otsuka Pharmaceutical Co., Ltd.

Appellee (first-instance Defendant): Advanced Medical Care Inc. (hereinafter referred to as "Appellee AMC")

Appellee (first-instance Defendant): Daicel Corporation (hereinafter referred to as "Appellee Daicel")

Main text

1. The part of the judgment in prior instance dismissing the Appellant's principal claims shall be rescinded.
2. Appellee AMC must not produce, transfer, lend out, offer to transfer or lend out, or export the product stated in the List of the Appellees' Product attached to this judgment.
3. Appellee AMC shall dispose of the product stated in the List of the Appellees' Product attached to this judgment.
4. Appellee Daicel must not produce the material stated in the List of the Appellees' Material attached to this judgment.
5. Appellee Daicel must not transfer, lend out, offer to transfer or lend out, or export the material stated in the List of the Appellees' Material attached to this judgment.
6. Appellee Daicel shall dispose of the material stated in the List of the Appellees' Material attached to this judgment.
7. The Appellees shall bear the court costs for the first and second instances.

8. This judgment may be provisionally executed as far as paragraphs 2, 4, and 5 of the main text are concerned.

Facts and reasons

Hereinafter, abbreviations of terms and meanings of the abbreviations follow those in the judgment in prior instance other than those defined in this judgment. The terms "Plaintiff," "Defendant AMC," "Defendant Daicel," "Defendants' Product," "Defendants' Material, " "Defendants' Method," and "Defendants" in the judgment in prior instance are deemed to be replaced with "Appellant," "Appellee AMC," "Appellee Daicel," "Appellees' Product," "Appellees' Material," "Appellees' Method," and "Appellees," respectively. In addition, the phrase "attached to this judgment" in all of the parts citing the judgment in prior instance is altered to "attached to the judgment in prior instance."

No. 1 Object of the claim

1. Same as paragraph 1 of the main text.

2. (Principal claim)

Same as paragraph 2 of the main text.

(Alternative claims)

(1) Appellee AMC must not use the material stated in the List of the Appellees' Material attached to this judgment produced by the method stated in the List of the Appellees' Method attached to the judgment in prior instance.

(2) Appellee AMC must not transfer, lend out, offer to transfer or lend out, or export the product stated in the List of the Appellees' Product attached to this judgment which uses the material stated in the List of the Appellees' Material attached to this judgment produced by the method stated in the List of the Appellees' Method attached to the judgment in prior instance.

3. (Principal claim)

Same as paragraph 3 of the main text.

(Alternative claim)

Appellee AMC shall dispose of the product stated in the List of the Appellees' Product attached to this judgment which uses the material stated in the List of the Appellees' Material attached to this judgment produced by the method stated in the List of the Appellees' Method attached to the judgment in prior instance.

4. (Principal claim)

Same as paragraph 4 of the main text.

(Alternative claim)

Appellee Daicel must not use the method stated in the List of the Appellees' Method attached to the judgment in prior instance.

5. (Principal claim)

Same as paragraph 5 of the main text.

(Alternative claim)

Appellee Daicel must not transfer, lend out, offer to transfer or lend out, or export the material stated in the List of the Appellees' Material attached to this judgment produced by the method stated in the List of the Appellees' Method attached to the judgment in prior instance.

6. (Principal claim)

Same as paragraph 6 of the main text.

(Alternative claim)

Appellee Daicel shall dispose of the material stated in the List of the Appellees' Material attached to this judgment produced by the method stated in the List of the Appellees' Method attached to the judgment in prior instance.

7. The Appellees shall bear the court costs for the first and second instances.

8. Declaration of provisional execution

No. 2 Outline of the case

1. In this case, the Appellant, who is the patentee of a patent for an invention of a method for producing a product, titled "Equol-containing extract, method for production thereof, method for extraction of equol, and equol-containing food" (the patent is hereinafter referred to as the "Patent" and the patent right under that patent is referred to as the "Patent Right"), alleges that, while the method stated in the List of the Appellees' Method attached to the judgment in prior instance (the Appellees' Method) carried out by Appellee Daicel falls within the technical scope of the patented invention relating to the Patent, [i] Appellee Daicel's acts of producing the material stated in the List of the Appellees' Material attached to this judgment (the Appellees' Material) by using the Appellees' Method and transferring or otherwise handling it infringe the Patent Right, and [ii] Appellee AMC's acts of producing the product stated in the List of the Appellees' Product attached to this judgment (hereinafter referred to as the "Appellees' Product") by using the Appellees' Material and transferring or otherwise handling the Appellees' Product containing the Appellees' Material infringe the Patent Right. Based on these allegations, the Appellant makes the following claims against the Appellees, based on Article 100, paragraphs (1) and (2) of the Patent Act.

(1) Against Appellee AMC

A. An injunction against production, transfer, lending out, offer to transfer or lend out, or export (hereinafter collectively referred to as "transfer, etc.") of the Appellees' Product

(principal claim) or an injunction against use of the Appellees' Material produced by the Appellees' Method (alternative claim) and an injunction against transfer, etc. of the Appellees' Product which uses the Appellees' Material produced by the Appellees' Method (alternative claim)
B. Disposal of the Appellees' Product (principal claim) or disposal of the Appellees' Product which uses the Appellees' Material produced by the Appellees' Method (alternative claim)
(2) Against Appellee Daicel
A. An injunction against production of the Appellees' Material (principal claim) or an injunction against use of the Appellees' Method (alternative claim)
B. An injunction against transfer, etc. of the Appellees' Material (principal claim) or an injunction against transfer, etc. of the Appellees' Material produced by the Appellees' Method (alternative claim)
C. Disposal of the Appellees' Material (principal claim) or disposal of the Appellees' Material produced by the Appellees' Method (alternative claim)
2. The judgment in prior instance dismissed all of the Appellant's claims by making determinations including the following: in the invention relating to Claim 1 in the claims of the Patent before the Correction (hereinafter referred to as the "Invention"), it is regarded as necessary for arginine to already be contained in the fermenting material, along with a daidzein compound at the stage of preparing the fermenting material, but in the Appellees' Method, arginine is not mixed in at the stage of preparing the fermenting material, but is mixed in for the first time in the subsequent fermentation process, and therefore the Appellees' Method is determined not to fall within the technical scope of the Invention. Against this judgment, the Appellant filed an appeal.

As mentioned in 3.(4) below, a decision by the Japan Patent Office (JPO) allowing the Correction became final and binding on May 20, 2021, after the filing of the appeal in question. Therefore, the Appellant only asserts claims based on the Corrected Invention as the statement of the claims in this instance.
3. Basic facts (the facts other than those for which evidence, etc. has been presented are not disputed among the parties concerned; documentary evidence with no indication of branch numbers includes those with branch numbers (the same applies hereinafter))

The basic facts are as described on page 4, line 1 through page 7, line 6 of the judgment in prior instance, except for making the following corrections, and therefore cited herein.
(1) The phrase "a patent right" on page 4, line 3 of the judgment in prior instance is altered to "the Patent Right" and the phrase "the patent relating to Claim 1 is hereinafter referred to as the 'Patent'" from line 4 to line 5 on that page is deleted.
(2) The sentence from "The plaintiff" in line 5 to "the establishment of a patent right was

registered on January 19, 2018" in line 6 on page 4 of the judgment in prior instance is altered to "The Appellant filed a patent application (Patent Application No. 2009-519326 (hereinafter referred to as the 'Original Application'), priority claim: June 13, 2007 (hereinafter referred to as the 'Priority Date'), Japan) for an invention titled 'Equol-containing extract, method for production thereof, method for extraction of equol, and equol-containing food' on June 13, 2008 (hereinafter referred to as the 'Original Filing Date'), after which it filed a divisional application for a part of the Original Application as Patent Application No. 2013-108439, then further filed a divisional application for a part thereof as Patent Application No. 2016-156372, and yet further filed a divisional application for a part thereof as Patent Application No. 2017-125880 (hereinafter referred to as the 'Application'), and the establishment of the Patent Right was registered as Patent No. 6275313 on January 19, 2018 (the description and drawings relating to the Patent Right (Exhibit Ko 2) are referred to as the 'Description,' and the paragraphs of the Description are simply referred to as [0001] or the like)."

(3) The part from line 8 through line 11 on page 4 of the judgment in prior instance is altered to "A. The statement of Claim 1 in the claims of the Patent before the Correction is as follows:".

(4) The phrase "that correction is referred to as the 'Correction')." on page 5, line 6 of the judgment in prior instance is altered to "that correction is referred to as the 'Correction'; the description and drawings were not corrected in the Correction)."

(5) The part from "Meanwhile," on page 5, line 8 of the judgment in prior instance through the end of line 12 on that page is altered as follows:

"Meanwhile, in the Invalidation Trial, the JPO rendered a decision allowing the Correction and holding that the request for the trial is groundless on July 19, 2019 (Exhibit Otsu B31; hereinafter referred to as the 'JPO Decision to Maintain the Patent'). Against this decision, Appellee Daicel filed a lawsuit to seek rescission of the JPO decision (Intellectual Property High Court; 2019 (Gyo Ke) 10112), and Appellee AMC made supporting intervention in the lawsuit, but a judgment dismissing Appellee Daicel's claims was rendered on October 21, 2020 (Exhibit Ko 41; hereinafter referred to as the 'Judgment to Maintain the Patent'). The Appellees filed petitions for the acceptance of a final appeal against this judgment, but a ruling not to accept a final appeal was rendered for both, and the judgment became final and binding on May 20, 2021. (Exhibits Ko 61 and 62)."

(6) The part from "in addition" on page 5, line 23 of the judgment in prior instance through "is referred to as Correction 4" in line 6 of that page is deleted.

(7) A new line is started following line 11 on page 6 of the judgment in prior instance, and the following sentence is added: "D. Appellee Daicel requested a trial for patent invalidation

for the Patent on November 19, 2019 (Invalidation Trial No. 2019-800098; hereinafter referred to as "Invalidation Trial 2"), and the Appellant filed a request for a correction with the same content as the Correction on February 7, 2020. The JPO rendered a decision allowing the correction and holding that the request for the trial for invalidation is groundless on November 25, 2020 (hereinafter referred to as the 'JPO Decision to Maintain Patent 2') (Exhibit Ko 55)."

(8) The part from line 15 through line 17 on page 6 of the judgment in prior instance is altered as follows:

"B. Appellee AMC was producing the product stated in the List of the Appellees' Product attached to this judgment by using the Appellees' Material purchased from Appellee Daicel and selling the product until July 26, 2021. (Exhibit Otsu A2)"

(9) The following is added at the end of line 26 on page 6 of the judgment in prior instance: "(however, the Appellant alleges that, if the claim interpretation of the Corrected Invention in the judgment in prior instance is to be applied, α3 of the Appellees' Method should be found in a more specific and detailed manner as described in α3-1 and α3-2 in 5.(1) (Appellant's claims) A. below)."

4. Issues

As mentioned in 2. and 3.(4) above, because the JPO decision allowing the Correction became final and binding, the Appellant decided to withdraw its claims based on the Invention and to only file claims based on the Corrected Invention, and cited the previous allegations relating to the Invention to support its arguments in this instance. Therefore, Issue 3 "whether the correction to the Invention can be asserted against the claim of invalidity" in the prior instance does not become an issue. In this instance, the Appellant added an allegation of infringement under the doctrine of equivalents, and the Appellees added Grounds for Invalidation 8 through 10 as invalidity defenses, but among the invalidity defenses, Grounds for Invalidation 9, which allege that the Correction violates the requirements for correction, lost the premise for the allegation. In addition, Appellee AMC added an assertion that there is no need for an injunction, etc. as it stopped producing and selling the Appellees' Product. Accordingly, the issues in this case are as follows:

(1) Whether the Appellees' Method falls within the technical scope of the Corrected Invention (Issue 1)

A. Whether the Appellees' Material is presumed to have been produced using the method of the Corrected Invention under Article 104 of the Patent Act (Issue 1-1)

B. Whether the "daidzein compound" "selected" in the Appellees' Method is daidzein glycosides (fulfillment of Constituent Features A', B'-1, and B'-2) (Issue 1-2)

C. Whether "at least one daidzein compound selected from the group consisting of daidzein

glycosides, daidzein, and dihydrodaidzein" in Constituent Feature A' is limited to soybean hypocotyl (fulfillment of Constituent Feature A') (Issue 1-3)

D. Whether the "microorganism" in Constituent Feature B'-2 is limited to a *Lactococcus* 20-92 strain (fulfillment of Constituent Feature B'-2) (Issue 1-4)

E. Whether the "microorganism" in Constituent Feature B'-2 is limited to a microorganism having the ability to cleave sugar (fulfillment of Constituent Feature B'-2) (Issue 1-5)

F. Whether the culture solution containing arginine in the Appellees' Method constitutes a "fermenting material containing arginine" (fulfillment of Constituent Feature B'-1) (Issue 1-6)

G. Whether infringement of the Corrected Invention under the doctrine of equivalents exists (Issue 1-7)

(2) Whether the Patent deserves to be invalidated in a trial for patent invalidation (Issue 2)

A. Whether Grounds for Invalidation 1 (lack of novelty based on Exhibit Otsu B3 on the premise that a priority claim cannot be made) exist (Issue 2-1)

B. Whether Grounds for Invalidation 2 (violation of the support requirement and the enablement requirement in relation to the "microorganism having the ability to produce ornithine and the ability to produce equol" in the Corrected Invention) exist (Issue 2-2)

C. Whether Grounds for Invalidation 3 (lack of novelty based on Exhibit Otsu B4 and lack of inventive step based on Exhibit Otsu B4 as the primary cited invention) exist (Issue 2-3)

D. Whether Grounds for Invalidation 4 (lack of novelty based on Exhibit Otsu B16 and lack of inventive step based on Exhibit Otsu B16 as the primary cited invention) exist (Issue 2-4)

E. Whether Grounds for Invalidation 5 (lack of novelty based on Exhibit Otsu B19-1 and lack of inventive step based on Exhibit Otsu B19-1 as the primary cited invention) exist (Issue 2-5)

F. Whether Grounds for Invalidation 6 (lack of novelty based on Exhibit Otsu B24 and lack of inventive step based on Exhibit Otsu B24 as the primary cited invention) exist (Issue 2-6)

G. Whether Grounds for Invalidation 7 (lack of novelty and inventive step based on Exhibit Otsu B2 on the premise that the patent application for the Patent violates the requirements for division of application) exist (Issue 2-7)

H. Whether Grounds for Invalidation 8 (the Description violating the requirement under the delegated ministerial order) exist (Issue 2-8)

I. Issue 2-9 is skipped (whether Ground for Invalidation 9 (the Correction violating the requirements for correction) exists)

J. Whether Grounds for Invalidation 10 (the second sentence of Article 39, paragraph (2) of

the Patent Act) exist (Issue 2-10)
(3) Issue 3 is skipped (whether the correction to the Invention can be asserted against the claim of invalidity)
(4) Whether it is necessary to seek an injunction and disposal against Appellee AMC (Issue 4)

(omitted)

No. 3 Summary of the court decision
1. Regarding the Corrected Invention
(1) The Description (Exhibit Ko 2) contains the following statements.
[Technical Field]
[0001]

The present invention relates to an equol-containing extract obtained by extracting effective components from an equol-containing fermented soybean hypocotyl and a production method thereof. The present invention also relates to a method for efficiently purifying an equol-containing substance to obtain a highly pure equol. The present invention further relates to an equol-containing food material and an equol-containing food.
[Background Art]
[0002]

The isoflavones (soybean isoflavones: daidzein, genistein, glycitein) contained in soybeans have structures similar to estradiol, and have anti-estrogen actions associated with binding to estrogen receptors (hereinafter referred to as ER) and estrogen-like actions. The ever conducted epidemiological studies and intervention studies of soybean isoflavones suggest that they have preventive effects due to their anti-estrogen actions on breast cancer, prostate cancer and other hormone-dependent cancers and improving effects due to their estrogen-like actions on menopausal disorders, postmenopausal osteoporosis and hyperlipidemia.
[0003]

Recently, it has been pointed out that the active component of the physiological effects of these soybean isoflavones may be a metabolite of daidzein, i.e., equol. More specifically, it has been reported that equol has an ability to bind to ER (especially to ERβ) greater than soybean isoflavones and that it has a remarkably high transition capability to target organs such as breast and prostate tissues (Non-Patent Documents 1 to 4). Moreover, a case-control study reports that there are significantly less patients who produce equol in the patients of breast cancer and prostate cancer. The effects of soybean isoflavones that improve bone

density and lipid metabolism were examined regarding postmenopausal women categorized into two groups: those who produce equol and those who do not. A significant improvement in those who produce equol was observed.

[0004]

Equol is produced by metabolism of daidzein by enteric bacteria. The abilities to produce equol vary between individuals, and the percentage of Japanese who produce equol is reportedly about 50%. That is, about 50% of Japanese are not able to produce equol (non-equol-producing individuals). Such an individual cannot enjoy any useful physiological benefits based on the action of equol even if they ingest soybeans and processed soybean foods. Therefore, in order to attain useful physiological benefits based on the action of equol in a non-equol-producing individual, ingesting equol itself is thought to be effective.

[Problems to be Solved by the Invention]

[0006]

The present inventors have found that a fermented soybean hypocotyl obtained by fermenting a soybean hypocotyl with an equol-producing microorganism is usable as an equol-containing food material. The fermented soybean hypocotyl contains not only equol but also isoflavone, saponin and like useful soybean-derived components. The fermented soybean hypocotyl achieves such effective physiological effects attributable to these useful components, and therefore is usable as a functional material. The present inventors also found that the fermented soybean hypocotyl is useful as an allergen-reduced material, because the allergens attributable to the soybean hypocotyl therein are reduced. The fermented soybean hypocotyl found by the present inventors exhibits physiological effects attributable to the useful components, and is hypoallergenic, and therefore it is usable as a functional food material.

[0007]

In contrast, the content of the equol in the fermented soybean hypocotyl varies depending on the types of the soybean hypocotyl used for the production of the fermented soybean hypocotyl, types of the equol-producing microorganism, etc., but it is generally about 1 wt. %. If a material with an increased equol content can be provided, various types of equol-containing foods become easily available in response to the diversification of foods. However, the fermented soybean hypocotyl itself is not a known product, and the effective method for efficiently extracting useful component containing equol from the fermented soybean hypocotyl has not been found yet.

[0008]

The fermented soybean hypocotyl, which is an equol-containing substance obtained by the fermentation method describe above, is safer than that obtained by a chemical synthesis

method, and suitable for industrial production. However, equol-containing substances obtained by said fermentation method contain metabolites other than equol and various components derived from raw materials remaining therein. Depending on the type of raw material used for fermentation, the equol-containing substance obtained by a fermentation method may contain material that could become an allergen. Therefore, in order to use an equol as an additive for foods or drugs, a technique not only for producing an equol but also purifying the equol-containing substance so as to obtain a highly pure equol is required. However, as not many techniques for refining equol have been reported yet, there is a demand for establishing a technique, which is industrially applicable and by which an equol can be purified easily and efficiently.

[0010]

An object of the present invention is to provide an extract, which contains useful equol-containing components and which is derived from an equol-containing fermented soybean hypocotyl, and a method for producing such an extract. The present invention provides a method for purifying an equol-containing substance to effectively obtain a highly pure equol. Another object of the present invention is to provide a food material obtained by fermenting an equol-containing fermented soybean hypocotyl with an equol-producing microorganism or its extract, in which the flavor is improved. Still another object of the present invention is to provide a food product that contains an equol-containing fermented soybean hypocotyl and exhibits excellent flavor (in particular, baked confectioneries). Still another object of the present invention is to provide various forms of foods that contain an equol-containing fermented soybean hypocotyl or its extract.

[Effects of the Invention]

[0023]

The method for producing an equol-containing extract of the present invention can produce an equol-containing extract that is useful as a functional food material by effectively extracting useful components containing equol from an equol-containing fermented soybean hypocotyl. By sequentially subjecting an equol-containing fermented soybean hypocotyl to extraction using an ethanol aqueous solution and ethanol, an equol-containing extract that contains a high concentration of equol and glycitein, with a reduced amount of saponin that causes an unpleasant taste, is obtainable. Accordingly, the equol-containing extract can be added to foods without adversely affecting the taste.

[0024]

The purification method of the present invention makes it possible to readily and efficiently obtain a highly pure equol from the equol-containing substance. In particular, the purification method of the present invention makes it possible to obtain a highly pure equol

even when the equol-containing substance contains isoflavones, whose structure is similar to that of the equol, by removing these isoflavones. Accordingly, the purification method of the present invention can be suitably employed in obtaining equol from an equol-containing fermented material that contains a large proportion of isoflavones.

[0025]

Furthermore, the food material obtained by dispersing an equol-containing fermented soybean hypocotyl or its extract into cacao mass reduces bitterness and exhibits excellent flavor, although it contains an equol-containing fermented soybean hypocotyl or its extract. …

[0026]

The useful physiological benefits of the various forms of food of the present invention can be enjoyed based on the useful physiological activity of the equol-containing fermented soybean hypocotyl or its extract.

[Mode for Carrying Out the Invention]

[0029]

The following details the present invention.

1. Production Method for Equol-Containing Extract

… The following details an equol-containing fermented soybean hypocotyl used as a material of the method of the present invention, and describes in detail Production Methods I and II.

Equol-Containing Fermented Soybean Hypocotyl …

[0030]

An equol-containing fermented soybean hypocotyl is a kind of a fermented soybean hypocotyl produced by fermenting a soybean hypocotyl using an equol-producing microorganism.

[0031]

The equol-producing microorganism used for the production of the equol-containing fermented soybean hypocotyl is selected from microorganisms having the ability (metabolic activity) to produce equol by metabolizing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein. …

[0032]

The equol-producing microorganism is not limited and may be any microorganism having the foregoing ability and permissible in terms of food sanitation. For example, any publicly known microorganisms, or any microorganisms obtained by a general screening method, may be used. It is known that such equol-producing microorganisms exist in the microorganisms belonging to *Lactococcus*, such as *Lactococcus garvieae*; microorganisms

belonging to *Streptococcus*, such as *Streptococcus intermedius* or *Streptococcus constellatus*; or microorganisms belonging to *Bacteroides*, such as *Bacteroides ovatus*. Among various kinds of equol-producing microorganism, the present invention prefers lactic acid bacteria belonging to *Lactococcus* or *Streptococcus*, further prefers lactic acid bacteria belonging to *Lactococcus*, and in particular, lactic acid bacteria belonging to *Lactococcus garvieae*. The equol-producing microorganisms may be isolated from, for example, human feces, based on the index of the existence of an equol-producing property. The inventors of the present invention deposited some identified bacteria that had been isolated from human feces; namely, *Lactococcus* 20-92 (FERM BP-10036), *Streptococcus* E-23-17 (FERM BP-6436), *Streptococcus* A6G225 (FERM-6437), and *Bacteroides* E-23-15 (FERM BP-6435), that are available to be used as the equol-producing microorganisms. Among these, the present invention particularly prefers Lactococcus 20-92.

[0033]

The equol-containing fermented soybean hypocotyl is produced using a soybean hypocotyl as a fermenting material. The soybean hypocotyl is a part corresponding to the plumule or the radicle on the germination of soybean, and is known to contain a large amount of daidzein compounds such as daidzein glycosides or daidzein. The soybean hypocotyl used in the present invention is not limited by the producing district of soybean or whether processed or unprocessed, unless the daidzein compounds inside are significantly lost. For example, the equol-containing fermented soybean hypocotyl may be a raw hypocotyl, or may be one isolated from heated, dried or steam-boiled soybean, or one obtained by heating, drying or steam-boiling a hypocotyl that is isolated from unprocessed soybean. Further, the soybean hypocotyl may be processed by degreasing or deproteinization. The form of the soybean hypocotyl is not particularly limited, and may be in the form of powder, chunks, or pulverized or fragmentized grains. A powdery soybean hypocotyl is particularly preferable because of its efficient equol production.

[0034]

The fermentation of a soybean hypocotyl is carried out by first adjusting the water content of the soybean hypocotyl by adding an appropriate amount of water, and then inoculating the equol-producing microorganism to the hypocotyl.

[0036]

Further, if necessary, some additives may be added to the soybean hypocotyl as the raw material in the fermentation to improve the fermentation efficiency or flavor of the product. Examples of the additives include nitrogen sources such as a yeast extract, polypeptone, or a meat extract; carbon sources such as glucose or sucrose; inorganic salts such as phosphate, carbonate or hydrosulfate; vitamins; and nutritional components such as amino acid.

Particularly, when using an equol-producing microorganism for converting arginine into ornithine (hereinafter referred to as an "ornithine/equol-producing microorganism"), arginine is added to the soybean hypocotyl before fermentation so that the fermented substance contains ornithine. In this case, the amount of arginine is, for example, about 0.5 to 3 parts by weight, based on 100 parts by weight (dry weight) of the soybean hypocotyl. The ornithine/equol-producing microorganism may be obtained by a publicly-known screening method using an index of the equol-producing ability and the conversion ability from arginine into ornithine. The ornithine/equol-producing microorganism may be selected from the group of *Lactococcus garvieae*, typified by *Lactococcus* 20-92 (FERM BP-10036).

[0038]

Further, isoflavone containing the above-mentioned daidzein compounds may be added to the fermenting material (a soybean hypocotyl-containing substance). Such inclusion of isoflavone in the fermenting material increases the equol content of the fermented soybean hypocotyl, thereby improving the usability of the fermented soybean hypocotyl.

[0039]

The fermentation of the soybean hypocotyl is carried out under appropriate conditions according to the growing characteristic of the equol-producing microorganisms. For example, when the equol-producing microorganisms listed above are used, the fermentation of the soybean hypocotyl is carried out under anaerobic conditions.

[0040]

The fermentation temperature is not limited as long as it is within an appropriate range for the equol-producing microorganism to grow. The temperature is generally 20 to 40°C., preferably 35 to 40°C., and more preferably 36 to 38°C.

[0041]

The fermentation time is determined depending on the desired production amount of equol, the residual amount of daidzein compounds, the type of the equol-producing microorganism or the like. The fermentation time is generally 1 to 10 days, preferably 2 to 7 days, and more preferably 3 to 5 days.

[0042]

… The equol content in the fermented soybean hypocotyl varies depending on the type of the equol-producing microorganism or fermentation conditions. The equol content in the fermented soybean hypocotyl is generally 1 to 20 mg, preferably 2 to 12 mg, and more preferably 5 to 8 mg, per gram (dry weight) of the fermented soybean hypocotyl.

[0049]

The equol-containing fermented soybean hypocotyl also contains saponin derived from the soybean hypocotyl. The equol-containing fermented soybean hypocotyl generally

contains saponin in an amount of 10 to 80 mg, preferably 20 to 50 mg, and more preferably 30 to 40 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl.
[0050]

Further, as described above, ornithine is contained in the equol-containing fermented soybean hypocotyl produced from fermentation with an ornithine/equol-producing microorganism after adding arginine to a soybean hypocotyl. The ornithine content of the equol-containing fermented soybean hypocotyl is 5 to 20 mg, preferably 8 to 15 mg, and more preferably 9 to 12 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl.
[0089]

Equol-Containing Substance

In the purification method of the present invention, the equol-containing substance to be subjected to the purification process is not limited as long as it contains equol. For example, the equol-containing substance used for the method may be a reaction product containing equol generated by chemical synthesis, or an equol-containing fermented substance produced by fermentation. … an equol-containing fermented substance is suitable for an equol-containing substance for the purification method of the present invention.
[0090]

The following explains an equol-containing fermented substance.
[0091]

The equol-containing fermented substance was produced through a publicly-known fermentation method using an equol-producing microorganism. More specifically, a microorganism with the ability (metabolic activity) to produce equol by metabolizing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein, is inoculated in a fermenting material (material to be subjected to the fermentation) containing the daidzein. The sample is then fermented (cultured) under the conditions suitable to grow the microorganism. The resulting fermented substance contains equol.
[0092]

The equol-producing microorganism is selected from the list of "Equol-Containing Fermented Soybean Hypocotyl" in the section "1. Production Method for Equol-Containing Extract."
[0093]

The fermenting material containing daidzein compounds is not limited by other factors as long as it contains daidzein compounds; however, the material is preferably approved for its safety as a food material. Examples of the fermenting material containing daidzein

compounds include soybeans, a soybean hypocotyl, a soybean hypocotyl extract, tofu, deep-fried tofu, soy milk, fermented soybeans, soy sauce, bean paste, a tempeh, and a red clove or its extract, alfalfa or its extract. A suitable fermenting material containing daidzein compounds is a soybean hypocotyl because of its high daidzein content.

[0094]

Further, an isoflavone containing any of the above-described daidzein compounds may be added in advance to the fermenting material containing daidzein compounds. With this extra addition of isoflavone to the fermenting material, the equol content of the resulting fermented substance increases.

[0095]

Further, as required, some additives may be used in the fermenting material containing daidzein compounds to improve fermentation efficiency etc. Examples of the additives include nitrogen sources such as a yeast extract, poly peptone, or a meat extract; carbon sources such as glucose or sucrose; inorganic salts such as phosphate, carbonate or hydrosulfate; vitamins; and nutritional components such as amino acid.

[0096]

Various fermentation conditions including water content, time, temperature, and atmosphere in the production of an equol-containing fermented substance are determined depending on the type of the equol-producing microorganism, the type of the fermenting material, the production amount of equol, the residual daidzein compound amount, or the like.

[0097]

For the equol-containing substance used for the purification method of the present invention, the equol-containing fermented soybean hypocotyl … is particularly preferable.

[0142]

3. Food Material

The present invention further provides a food material in which the equol-containing fermented soybean hypocotyl or its extract is dispersed in cacao mass. The following describes the details, such as the ingredients, of the food material of the present invention.

[0144]

The equol-containing fermented soybean hypocotyl may be used for the food material of the present invention immediately after the fermentation, or after dried into a dry solid as required. … The air-dried equol-containing fermented soybean hypocotyl may be further processed into powder as required.

[0157]

Use of Food Material

The food material of the present invention may be incorporated into various kinds of foodstuffs, as a raw material of an equol-containing food, or as a food additive. The present invention also provides such equol-containing foods containing the above-described food material.

[0162]

The proportion of the food material of the present invention in the equol-containing food is not particularly limited, and is adjusted depending on the equol content in the food material of the present invention, the form of the equol-containing food or the like. The proportion of the food material of the present invention is generally 3 to 30 wt. %, preferably 5 to 20 wt. %, and more preferably 5 to 8 wt. %, based on the total amount of the materials of the equol-containing food. Further, the proportion of equol in the equol-containing food is generally 0.002 to 0.1 wt. %, preferably 0.004 to 0.05 wt. %, and more preferably 0.005 to 0.03 wt. %, based on the total amount of the materials of the equol-containing food. By ensuring this proportion of the food material of the present invention, the useful bioactivity derived from the equol-containing fermented soybean hypocotyl is expressed in the food, while maintaining the good flavor of the equol-containing food.

[0163]

The equol-containing food is produced by mixing the food material of the present invention with a predetermined amount of the other ingredients, and subjecting the mixture to forming, baking, cooling, etc. depending on the target form of the food product.

[0164]

The equol-containing food is made of an equol-containing fermented soybean hypocotyl, and contains various useful bioactivity materials including equol, thereby expressing various bioactivities or pharmacological activities. Therefore, the equol-containing food is useful not only as a general food but also as a food for specified health use, nutritional supplement, functional food, invalid food or the like. The food containing the fermented soybean hypocotyl of the present invention is particularly useful as a nutraceutical product.

[0165]

For example, the equol-containing food has an effect of preventing or treating various diseases or symptoms including menopausal disorders, osteoporosis, prostatic hypertrophy, and metabolic syndrome; or for blood cholesterol level reduction, skin-whitening, pimple treatment, intestinal control, improvement of obesity, and diuresis. Particularly, the equol-containing food is suitable for prevention or treatment of indefinite complaint or post-menopausal symptoms (e.g., osteoporosis, menopausal disorder) of middle-aged women.

[Examples]

[0221]

The following more specifically explains the present invention with reference to Reference Examples, Examples etc. The present invention is however not limited to these examples.

[0222]

Reference Examples 1-1 to 1-3 Production of Equol-Containing Fermented Soybean Hypocotyl

Soybean hypocotyl powder, arginine, and water were mixed to prepare a soybean hypocotyl solution (material) having a composition as shown in Table 1. A *Lactococcus* 20-92 strain (FERM BP-10036) was inoculated in this soybean hypocotyl solution of 5 ml, and the sample was subjected to stationary culture for 96 hours at 37°C. under anaerobic conditions. After that, the resulting fermentation solution (culture solution) was sterilized by heating for a minute at 100°C., followed by drying at 80°C. The dried product was processed into a powder using a homogenizer to obtain fermented soybean hypocotyl powder.

[0223]

Table 1 shows the viable cell count and pH of the culture solution after a 96-hour culture, the amount of fermented soybean hypocotyl powder collected and the equol concentration of the fermented soybean hypocotyl powder. …

[0224]

[Table 1]

		Ref. Ex. 1-1	Ref. Ex. 1-2	Ref. Ex. 1-3
Composition of Soybean Hypocotyl Solution (Material)	Soybean Hypocotyl Powder (dry wt.)	0.25 g	0.5 g	0.75 g
	Arginine	0.005 g	0.005 g	0.005 g
	Water	Appropriate Quantity	Appropriate Quantity	Appropriate Quantity
	Total Amount	5 ml	5 ml	5 ml
	PH	6.75 ± 0.03	6.54 ± 0.02	6.39 ± 0.03
Analytical Result of Fermented Liquid	Viable Bacterial Counts of Fermented Liquid (log cfu/ml)	7.9 ± 0.1	8.2 ± 0.1	8.3 ± 0.2
	PH of Fermented Liquid	7.00 ± 0.03	6.88 ± 0.01	6.76 ± 0.02
Analysis of	Equol	3.85 mg (-)	3.44 mg (-)	5.38 mg (48.9 wt.%)

Composition of Fermented Soybean Hypocotyl Powder in terms of Isoflavone	Daidzein Compounds	n.d. (-)	n.d. (-)	1.18 mg (10.7 wt.%)
	Genistein Compounds	n.d. (-)	n.d. (-)	1.45 mg (13.2 wt.%)
	Glycitein Compounds	n.d. (-)	n.d. (-)	3.00 mg (27.2 wt.%)

Each Example was performed using three lots of soybean hypocotyl powder (N=3). In the analysis of isoflavone composition in the table, the value on the left denotes a content (mg) of each isoflavone per gram of the fermented soybean hypocotyl, and the value in the bracket on the right denotes the ratio (wt. %) of each isoflavone to the gross isoflavone amount (100 wt. %) in the fermented soybean hypocotyl. "n.d." indicates that the measurement is not done, and "−" in the bracket indicates that the calculation is not done.

[0225]

Reference Example 1-4 Production of Equol-Containing Fermented Soybean Hypocotyl

A *Lactococcus* 20-92 strain (FERM BP-10036) was inoculated to a 5 ml soybean hypocotyl solution containing 10 wt. % of soybean hypocotyl powder and 0.1 wt. % of arginine, and the sample was subjected to fermentation by carrying out stationary culture for 96 hours at 37°C. under anaerobic conditions. After that, the resulting fermentation solution (culture solution) was sterilized by heating for a minute at 100°C., followed by drying at 80°C. The dried product was processed into powder using a homogenizer to obtain fermented soybean hypocotyl powder.

[0226]

The respective components of the soybean hypocotyl powder ("Pre-fermentation" in Table 2 and Table 3) and of the fermented soybean hypocotyl powder ("Post-fermentation" in Table 2 and Table 3) were analyzed. Table 2 shows an analysis regarding soybean isoflavones, and Table 3 shows an analysis regarding nutritional components. These tables show that the fermented soybean hypocotyl obtained by the fermentation of a soybean hypocotyl using a *Lactococcus* 20-92 strain has a high equol content. Further, oligosaccharide content for such oligosaccharides as raffinose or stachyose remains substantially the same after fermentation, which indicates that the fermentation did not influence the oligosaccharide content. Meanwhile, the tables show that arginine was converted into ornithine by the fermentation. Accordingly, by adding arginine to the soybean hypocotyl before fermentation using a *Lactococcus* 20-92 strain, the resulting fermented substance contains not only equol but also ornithine.

[0227]

[Table 2]

Soybean Isoflavones		Per 100 g
Component	Pre-fermentation	Post-fermentation
Equol	N.D.	632.0 mg
Daidzin	566.4 mg	29.7 mg
Malonyldaidzin	124.9 mg	N.D.
Acetyldaidzin	364.8 mg	25.4 mg
Daidzein	7.1 mg	24.4 mg
Dihydrodaidzein	N.D.	49.4 mg
Genistin	111.7 mg	3.2 mg
Malonylgenistin	35.1 mg	N.D.
Acetylgenistin	146.1 mg	3.7 mg
Genistein	0.9 mg	22.5 mg
Dihydrogenistein	N.D.	112.0 mg
Glycitin	331.7 mg	53.6 mg
Malonylglycitin	65.0 mg	N.D.
Acetylglycitin	169.2 mg	34.8 mg
Glycitein	19.1 mg	292.3 mg
Dihydroglycitein	N.D.	8.2 mg
Total Isoflavones	1942.0 mg	1291.2 mg

N.D. refers to "Not Detected."

[0228]

[Table 3]

Nutritional Components		Per 100 g
Component	Pre-fermentation	Post-fermentation
Moisture	3.2 g	6.2 g
Protein	38.1 g	38.3 g
Fat	13.0 g	14.5 g
Ash	4.3 g	4.0 g
Saccharide	30.9 g	26.8 g
Dietary Fiber	10.5 g	10.2 g
Energy	414 kcal	411 kcal
Sucrose	7.95 g	7.42 g
Raffinose	1.37 g	1.34 g
Stachyose	9.04 g	8.38 g

Trans Fatty Acids	N.D.	N.D.
Phospholipids (as stearo-oleo-lecithin)	3.33 g	2.92 g
Free Arginine	881 mg	12 mg
Free Ornithine	N.D.	1.06 g
Soyasapogenol A	N.D.	N.D.
Soyasapogenol B	N.D.	N.D.
Soybean Saponin	3.6 g	3.8 g

N.D. refers to "Not Detected."

[0229]

Reference Examples 1-5 to 1-11 Production of Equol-Containing Fermented Soybean Hypocotyl

In these examples, fermented soybean hypocotyl powder (Reference Examples 1-5 to 1-11) were produced in the same manner as in Reference Example 1-3 except that seven lots of soybean hypocotyl powder different from the three lots of Reference Example 1-3 were used. …

[0230]

[Table 4]

	Isoflavone Compositions			
	Equol	Daidzein Compounds	Genistein Compounds	Glycitein Compounds
Ref. Ex. 1-5	6.51 mg (62.2 wt. %)	0.71 mg (6.8 wt. %)	0.53 mg (5.1 wt. %)	2.71 mg (25.9 wt. %)
Ref. Ex. 1-6	6.25 mg (61.3 wt. %)	0.48 mg (4.7 wt. %)	0.35 mg (3.4 wt. %)	3.12 mg (30.6 wt. %)
Ref. Ex. 1-7	5.38 mg (48.9 wt. %)	1.18 mg (10.7 wt. %)	1.45 mg (13.2 wt. %)	3.00 mg (27.2 wt. %)
Ref. Ex. 1-8	6.43 mg (63.4 wt. %)	0.61 mg (6.0 wt. %)	0.48 mg (4.7 wt. %)	2.62 mg (25.8 wt. %)
Ref. Ex. 1-9	6.05 mg (64.2 wt. %)	0.51 mg (5.4 wt. %)	0.30 mg (3.2 wt. %)	2.57 mg (27.3 wt. %)
Ref. Ex. 1-10	6.11 mg (65.6 wt. %)	0.37 mg (4.0 wt. %)	0.10 mg (1.1 wt. %)	2.74 mg (29.4 wt. %)
Ref. Ex. 1-11	6.3 mg (60.9 wt. %)	0.49 mg (4.73 wt. %)	0.37 mg (3.6 wt. %)	3.19 mg (30.8 wt. %)

The value in the upper column denotes the content (mg) of each isoflavone per gram of the fermented soybean hypocotyl, and the value in the lower column denotes the ratio (wt. %) of each isoflavone to the gross isoflavone amount (100 wt. %) in the fermented soybean hypocotyl.

[0231]

Reference Experiment Example 1 Allergen Confirmation Test

A soybean hypocotyl is known to contain allergens including Gym4, Gm30K, Gm28K, 7S globulin mix (β-conglycine), oleosin, and trypsin inhibitors. The existence of allergens in the equol-containing fermented soybean hypocotyl produced in Reference Example 1-1 was examined using the following test.

[0233]

Figs. 1 to 3 show the result. Fig. 1 shows the result for the detection of total protein; Fig. 2 shows the result for the detection of Gym4, Gm30K, and Gm28K; and Fig. 3 shows the result for the detection of 7S globulin mix, oleosin, and trypsin inhibitors.

[0234]

These results show that the major allergen content of a soybean or a soybean hypocotyl is reduced in the equol-containing fermented soybean hypocotyl.

(2) Outline of the Corrected Invention

According to the Corrected Invention stated on page 5, lines 13 to 20 of the judgment in prior instance as cited in No. 2, 3. above and according to (1) above, the Corrected Invention is found to be as follows.

The Corrected Invention relates to a method for producing fermented powder, which is used as a food material containing ornithine and equol that has been suggested to have an effect of preventing menopausal disorders, etc. ([Claim 1] and paragraphs [0002] and [0003]). In this method, a fermenting material containing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein, to which arginine has been added, is fermented by using a microorganism having the ability to produce ornithine and the ability to produce equol, to produce fermented powder which contains not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight of the fermented substance, and which is used as a food material ([Claim 1] and paragraphs [0001], [0036], [0042], [0050], [0091] through [0096], [0222] through [0227], and [0229]).

The food containing equol and ornithine that is made by using the fermented substance produced according to the Corrected Invention as a food material expresses various bioactivities or pharmacological activities, including prevention or treatment of indefinite complaint or post-menopausal symptoms (e.g., osteoporosis, menopausal disorder) of

middle-aged women, and is useful not only as a general food but also as a food for specified health use, nutritional supplement, functional food, invalid food or the like (paragraphs [0144], [0157], and [0162] through [0165]).

2. Regarding Issue 1 (whether the Appellees' Method falls within the technical scope of the Corrected Invention)

(1) Regarding Issue 1-1 (whether the Appellees' Material is presumed to have been produced using the method of the Corrected Invention under Article 104 of the Patent Act)

A. Regarding application of Article 104 of the Patent Act

Article 104 of the Patent Act provides that, if a patent is granted for an invention that is a process for producing a product and the product was not publicly known in Japan prior to the filing of the patent application, any article identical to that product is presumed to have been produced using the patented process.

The Patent Claim states as follows: "A method of producing fermented powder containing ornithine and equol, comprising a step to add arginine to at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein, and a step to ferment a fermenting material containing said daidzein compound and said arginine by using a microorganism having the ability to produce ornithine and the ability to produce equol, wherein not less than 8 mg ornithine and not less than 1 mg equol are produced per gram by dry weight of said fermented substance as a result of the fermentation, and wherein said fermented powder is used as a food material." Therefore, the Patent constitutes a case in which a patent has been granted for a method of producing "fermented powder containing ornithine and equol, wherein not less than 8 mg ornithine and not less than 1 mg equol are produced per gram by dry weight of said fermented substance, and which is used as a food material" (the product of the Corrected Invention).

Here, the Appellees do not indicate approval or disapproval of the fact that the Appellees' Material constitutes the above product of the Corrected Invention, and do not make it clear that they deny the fact, so the Appellees are deemed to have admitted the fact that the Appellees' Material constitutes the above product of the Corrected Invention (Article 159, paragraph (1) of the Code of Civil Procedure). It follows that, if the product of the Corrected Invention was not publicly known in Japan prior to the filing of the patent application for the Patent, the Appellees' Material is presumed to have been produced using the method of the Corrected Invention. Moreover, the Appellees' Material is found to constitute the above product of the Corrected Invention also in light of the Appellees' Method, which the Appellees allege to be the production method of the Appellees' Material.

B. Next, examination will be made as to which specific date corresponds to the date of "the filing of the patent application for the Patent" under Article 104 of the Patent Act, with regard

to the Corrected Invention.

(A) The following statements are contained in the applications on which the priority claim for the Patent is based (Exhibits Otsu B1-1 through B1-3; the filing date: June 13, 2007; hereinafter, regarding the applications on which the priority claim is based and the documents for those applications, the application pertaining to Exhibit Otsu B1-1 is referred to as "Basic Application A," the application pertaining to Exhibit Otsu B1-2 is referred to as "Basic Application B," and the application pertaining to Exhibit Otsu B1-3 is referred to as "Basic Application C," and these are collectively referred to as the "Basic Applications").

a. Basic Application A (Exhibit Otsu B1-1)

[Title of the Invention] Food product that contains an equol-containing fermented soybean hypocotyl or its extract

[Claim 1] A beverage comprising an equol-containing fermented soybean hypocotyl obtained by fermenting a soybean hypocotyl with an equol-producing microorganism or its extract.

[Claim 3]

A creamy food comprising an equol-containing fermented soybean hypocotyl obtained by fermenting a soybean hypocotyl with an equol-producing microorganism or its extract.

[Technical Field]

[0001]

The present invention relates to various forms of foods that contain an equol-containing fermented soybean hypocotyl or its extract.

[Problems to be Solved by the Invention]

[0005]

The present inventors have found that a fermented soybean hypocotyl obtained by fermenting a soybean hypocotyl with an equol-producing microorganism is usable as an equol-containing food material. The fermented soybean hypocotyl contains not only equol but also isoflavone, saponin and like useful soybean-derived components. The fermented soybean hypocotyl achieves such effective physiological effects attributable to these useful components, and therefore is usable as a functional material. The present inventors also found that the fermented soybean hypocotyl is useful as an allergen-reduced material, because the allergens attributable to the soybean hypocotyl therein are reduced. …

[0006]

It is also known that an extract obtained through solvent extraction of useful components containing equol from an equol-containing fermented soybean hypocotyl is usable as a functional food material.

[0007]

Accordingly, an object of the present invention is to provide various forms of foods that contain an equol-containing fermented soybean hypocotyl or its extract.

[Best Mode for Carrying Out the Invention]

[0012]

Equol-Containing Fermented Soybean Hypocotyl

An equol-containing fermented soybean hypocotyl used for the food material of the present invention is a kind of a fermented soybean hypocotyl produced by fermenting a soybean hypocotyl using an equol-producing microorganism.

[0013]

The equol-producing microorganism used for the production of the equol-containing fermented soybean hypocotyl is selected from microorganisms having the ability (metabolic activity) to produce equol by metabolizing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein. Examples of the daidzein glycosides here include daidzin, malonyldaidzin, and acetyldaidzin.

[0014]

The equol-producing microorganism is not limited and may be any microorganism having the foregoing ability and permissible in terms of food sanitation. It is known that such equol-producing microorganisms exist in the microorganisms belonging to *Lactococcus*, such as *Lactococcus garvieae*; microorganisms belonging to *Streptococcus*, such as *Streptococcus intermedius* or *Streptococcus constellatus*; or microorganisms belonging to *Bacteroides*, such as *Bacteroides ovatus*. Among various kinds of equol-producing microorganism, the present invention prefers lactic acid bacteria belonging to *Lactococcus* or *Streptococcus*, further prefers lactic acid bacteria belonging to *Lactococcus*, and in particular, lactic acid bacteria belonging to *Lactococcus garvieae*. The equol-producing microorganisms may be isolated from, for example, human feces, based on the index of the existence of an equol-producing property. The inventors of the present invention deposited some identified bacteria that had been isolated from human feces; namely, *Lactococcus* 20-92 (FERM BP-10036), *Streptococcus* E-23-17 (FERM BP-6436), *Streptococcus* A6G225 (FERM-6437), and *Bacteroides* E-23-15 (FERM BP-6435), that are available to be used as the equol-producing microorganisms. Among these, the present invention particularly prefers Lactococcus 20-92.

[0015]

The equol-containing fermented soybean hypocotyl is produced using a soybean hypocotyl as a fermenting material. The soybean hypocotyl is a part corresponding to the plumule or the radicle on the germination of soybean, and is known to contain a large amount of daidzein compounds such as daidzein glycosides or daidzein. The soybean hypocotyl used

in the present invention is not limited by the producing district of soybean or whether processed or unprocessed, unless the daidzein compounds inside are significantly lost. For example, the equol-containing fermented soybean hypocotyl may be a raw hypocotyl, or may be one isolated from heated, dried or steam-boiled soybean, or one obtained by heating, drying or steam-boiling a hypocotyl that is isolated from unprocessed soybean. Further, the soybean hypocotyl may be processed by degreasing or deproteinization. The form of the soybean hypocotyl is not particularly limited, and may be in the form of powder, chunks, or pulverized or fragmentized grains. A powdery soybean hypocotyl is particularly preferable because of its efficient equol production.

[0016]

The fermentation of a soybean hypocotyl is carried out by first adjusting the water content of the soybean hypocotyl by adding an appropriate amount of water, and then inoculating the equol-producing microorganism to the hypocotyl.

[0017]

The amount of water added to the soybean hypocotyl is adjusted depending on the type of equol-producing microorganism or the type of fermenter. The ratio of water to the soybean hypocotyl in the beginning of fermentation is 400 to 4,000 parts by weight, preferably 500 to 2,000 parts by weight, more preferably 600 to 1,000 parts by weight, based on 100 parts by weight (dry weight) of the soybean hypocotyl.

[0018]

Further, if necessary, some additives may be added to the soybean hypocotyl as the raw material in the fermentation to improve the fermentation efficiency or flavor of the product. Examples of the additives include nitrogen sources such as a yeast extract, polypeptone, or a meat extract; carbon sources such as glucose or sucrose; inorganic salts such as phosphate, carbonate or hydrosulfate; vitamins; and nutritional components such as amino acid. Particularly, when using an equol-producing microorganism for converting arginine into ornithine (hereinafter referred to as an "ornithine/equol-producing microorganism"), arginine is added to the soybean hypocotyl before fermentation so that the fermented substance contains ornithine. In this case, the amount of arginine is, for example, about 0.5 to 3 parts by weight, based on 100 parts by weight (dry weight) of the soybean hypocotyl. Specifically, the equol-producing microorganism for converting arginine into ornithine may be selected from the group of *Lactococcus garvieae*, typified by *Lactococcus* 20-92 (FERM BP-10036).

[0019]

Further, the pH of the fermenting material (a soybean hypocotyl-containing substance) is not particularly limited within a range for the equol-producing microorganism to grow;

however, to secure excellent proliferation of the equol-producing microorganism, the pH of the fermenting material preferably falls within about 6 to 7, more preferably about 6.3 to 6.8.
[0020]

Further, isoflavone containing the above-mentioned daidzein compounds may be added to the fermenting material (a soybean hypocotyl-containing substance). Such inclusion of isoflavone in the fermenting material increases the equol content of the fermented soybean hypocotyl, thereby improving the usability of the fermented soybean hypocotyl.
[0024]

… The equol content in the fermented soybean hypocotyl varies depending on the type of the equol-producing microorganism or fermentation conditions. The equol content in the fermented soybean hypocotyl is generally 1 to 20 mg, preferably 2 to 12 mg, and more preferably 5 to 8 mg, per gram (dry weight) of the fermented soybean hypocotyl.
[0025]

Apart from equol, the equol-containing fermented soybean hypocotyl also contains various isoflavones such as daidzein compounds including daidzin, malonyldaidzin, acetyldaidzin, daidzein, or dihydrodaidzin (these components are referred to as "daidzein compounds," hereinafter); or genistein compounds including genistin, malonylgenistin, acetylgenistin, genistein, dihydrogenistein (these components are referred to as "genistein compounds," hereinafter). The isoflavones also express the useful physiologic activities. The content of each isoflavone (incl. equol) in the fermented soybean hypocotyl varies depending on the type of the equol-producing microorganism or fermentation conditions, but it is generally 5 to 20 mg, preferably 5 to 15 mg, and more preferably 8 to 15 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl.
[0031]

The equol-containing fermented soybean hypocotyl also contains saponin derived from the soybean hypocotyl. The equol-containing fermented soybean hypocotyl generally contains saponin in an amount of 10 to 80 mg, preferably 20 to 50 mg, and more preferably 30 to 40 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl.
[0032]

Further, as described above, ornithine is contained in the equol-containing fermented soybean hypocotyl produced from fermentation with an ornithine/equol-producing microorganism after adding arginine to a soybean hypocotyl. The ornithine content of the equol-containing fermented soybean hypocotyl is 5 to 20 mg, preferably 8 to 15 mg, and more preferably 9 to 12 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl.
[0100]

The following more specifically explains the present invention with reference to Reference Examples, Examples etc. The present invention is however not limited to these examples.

Reference Examples 1-1 to 1-3 Production of Equol-Containing Fermented Soybean Hypocotyl

Soybean hypocotyl powder, arginine, and water were mixed to prepare a soybean hypocotyl solution (material) having a composition as shown in Table 1. A *Lactococcus* 20-92 strain (FERM BP-10036) was inoculated in this soybean hypocotyl solution of 5 ml, and the sample was subjected to stationary culture for 96 hours at 37°C. under anaerobic conditions. After that, the resulting fermentation solution (culture solution) was sterilized by heating for a minute at 100°C., followed by drying at 80°C. The dried product was processed into a powder using a homogenizer to obtain fermented soybean hypocotyl powder.

[0101]

Table 1 shows the viable cell count and pH of the culture solution after a 96-hour culture, the amount of fermented soybean hypocotyl powder collected and the equol concentration of the fermented soybean hypocotyl powder. From the data, it is shown that fermentation of soybean hypocotyl powder using equol-producing bacteria produces equol with high efficiency.

[0102]

[Table 1]

		Ref. Ex. 1-1	Ref. Ex. 1-2	Ref. Ex. 1-3
Composition of Soybean Hypocotyl Solution (Material)	Soybean Hypocotyl Powder (dry wt.)	0.25 g	0.5 g	0.75 g
	Arginine	0.005 g	0.005 g	0.005 g
	Water	Appropriate Quantity	Appropriate Quantity	Appropriate Quantity
	Total Amount	5 ml	5 ml	5 ml
	PH	6.75 ± 0.03	6.54 ± 0.02	6.39 ± 0.03
Analytical Result of Fermented Liquid	Viable Bacterial Counts of Fermented Liquid (log cfu/ml)	7.9 ± 0.1	8.2 ± 0.1	8.3 ± 0.2
	PH of Fermented Liquid	7.00 ± 0.03	6.88 ± 0.01	6.76 ± 0.02
Analytical Result of Fermented	Equol Concentration of the Fermented Soybean Hypocotyl	385.6 ± 101.5	344.6 ± 62.1	417.5 ± 68.0

Soybean Hypocotyl Powder	Powder (mg/100 g)			

Each Example was performed using three lots of soybean hypocotyl powder (N=3). The analysis results in the table are presented in mean ± standard deviation.

[0103]

Reference Example 1-4 Production of Equol-Containing Fermented Soybean Hypocotyl

A *Lactococcus* 20-92 strain (FERM BP-10036) was inoculated to a 5 ml soybean hypocotyl solution containing 10 wt. % of soybean hypocotyl powder and 0.1 wt. % of arginine, and the sample was subjected to fermentation by carrying out stationary culture for 96 hours at 37°C. under anaerobic conditions. After that, the resulting fermentation solution (culture solution) was sterilized by heating for a minute at 100°C., followed by drying at 80°C. The dried product was processed into powder using a homogenizer to obtain fermented soybean hypocotyl powder.

[0104]

The respective components of the soybean hypocotyl powder ("Pre-fermentation" in Table 2 and Table 3) and of the fermented soybean hypocotyl powder ("Post-fermentation" in Table 2 and Table 3) were analyzed. Table 2 shows an analysis regarding soybean isoflavones, and Table 3 shows an analysis regarding nutritional components. These tables show that the fermented soybean hypocotyl obtained by the fermentation of a soybean hypocotyl using a *Lactococcus* 20-92 strain has a high equol content. … Meanwhile, the tables show that arginine was converted into ornithine by the fermentation. Accordingly, by adding arginine to the soybean hypocotyl before fermentation using a *Lactococcus* 20-92 strain, the resulting fermented substance contains not only equol but also ornithine.

[0105]

[Table 2]

Soybean Isoflavones — Per 100 g

Component	Pre-fermentation	Post-fermentation
Equol	N.D.	632.0 mg
Daidzin	566.4 mg	29.7 mg
Malonyldaidzin	124.9 mg	N.D.
Acetyldaidzin	364.8 mg	25.4 mg
Daidzein	7.1 mg	24.4 mg
Dihydrodaidzein	N.D.	49.4 mg
Genistin	111.7 mg	3.2 mg

Malonylgenistin	35.1 mg	N.D.
Acetylgenistin	146.1 mg	3.7 mg
Genistein	0.9 mg	22.5 mg
Dihydrogenistein	N.D.	112.0 mg
Glycitin	331.7 mg	53.6 mg
Malonylglycitin	65.0 mg	N.D.
Acetylglycitin	169.2 mg	34.8 mg
Glycitein	19.1 mg	292.3 mg
Dihydroglycitein	N.D.	8.2 mg
Total Isoflavones	1942.0 mg	1291.2 mg

N.D. refers to "Not Detected."

[0106]

[Table 3]

Nutritional Components Per 100 g

Component	Pre-fermentation	Post-fermentation
Moisture	3.2 g	6.2 g
Protein	38.1 g	38.3 g
Fat	13.0 g	14.5 g
Ash	4.3 g	4.0 g
Saccharide	30.9 g	26.8 g
Dietary Fiber	10.5 g	10.2 g
Energy	414 kcal	411 kcal
Sucrose	7.95 g	7.42 g
Raffinose	1.37 g	1.34 g
Stachyose	9.04 g	8.38 g
Trans Fatty Acids	N.D.	N.D.
Phospholipids (as stearo-oleo-lecithin)	3.33 g	2.92 g
Free Arginine	881 mg	12 mg
Free Ornithine	N.D.	1.06 g
Soyasapogenol A	N.D.	N.D.
Soyasapogenol B	N.D.	N.D.
Soybean Saponin	3.6 g	3.8 g

N.D. refers to "Not Detected."

b. Basic Application B (Exhibit Otsu B1-2)

Paragraphs [0015] through [0020], [0026], [0027], [0033], [0034], and [0070] through [0077] of the filing documents of Basic Application B contain statements corresponding to paragraphs [0013] through [0018], [0024], [0025], [0031], [0032], and [0100] through [0106] of the filing documents of Basic Application A. In addition, the filing documents of Basic Application B contain the following statements.

[Title of the Invention] Equol-containing food material, and food product using the same

[Claim 1]

(A) A food material obtained by dispersing an equol-containing fermented soybean hypocotyl, obtained by fermenting a soybean hypocotyl with an equol-producing microorganism or its extract, into (B) cacao mass.

c. Basic Application C (Exhibit Otsu B1-3)

Paragraphs [0014] through [0021], [0025], [0026], [0032], [0033], and [0056] through [0059] of the filing documents of Basic Application C contain statements corresponding to paragraphs [0013] through [0020], [0024], [0025], [0031], [0032], and [0100] through [0102] of Basic Application A. In addition, the filing documents of Basic Application C contain the following statements.

[Title of the Invention] Equol-containing extract, and method for production thereof

[Claim 1]

A method for producing an equol-containing extract, comprising Step 1 of extracting an equol-containing fermented soybean hypocotyl by using an ethanol aqueous solution as an extraction solvent, and collecting the extracted liquid.

(B) Statements added in the Original Application (Exhibit Otsu B2)

Statements corresponding to paragraph [0093] of the Description, which clearly indicates that a "material containing daidzein compounds" other than a "soybean hypocotyl" is used as a fermenting material, and statements corresponding to paragraph [0095] of the Description, which clearly indicates that appropriate nutritional components are added to the "daidzein compounds" did not exist in the Basic Applications, and were added for the first time in the Original Application (paragraphs [0091] and [0093] of the Original Application).

In addition, statements corresponding to paragraph [0032] of the Description concerning a publicly-known screening method and statements in paragraph [0036] concerning obtainment of an "ornithine/equol-producing microorganism" by "a publicly-known screening method using an index of the equol-producing ability and the conversion ability from arginine into ornithine" also did not exist in the Basic Applications, and were added for the first time in the Original Application (paragraphs [0030] and [0034] of the Original Application).

(C) Regarding whether a priority claim can be made

As mentioned in (A) and (B) above, the only substance clearly indicated as a fermenting material in the Basic Applications is a "soybean hypocotyl," and a statement clearly indicating that a substance other than a "soybean hypocotyl" can be used as a fermenting material was added in the Original Application and in later applications.

However, the Basic Applications state that the invention uses a microorganism having the ability to produce equol by metabolizing "daidzein compounds," and that the *Lactococcus* 20-92 strain used in examples of the Basic Applications is one example of such microorganism (paragraphs [0013] and [0014] of Basic Application A, paragraphs [0015] and [0016] of Basic Application B, and paragraphs [0014] and [0015] of Basic Application C). Meanwhile, the Basic Applications state, "… if necessary, some additives may be added to the soybean hypocotyl as the raw material in the fermentation to improve the fermentation efficiency or flavor of the product. Examples of the additives include … and nutritional components ..." (paragraph [0018] of Basic Application A, paragraph [0020] of Basic Application B, and paragraph [0019] of Basic Application C), and therefore the Basic Applications do not exclude addition of nutritional components other than "water" and "arginine." Moreover, the Basic Applications state "Further, isoflavone containing the above-mentioned daidzein compounds may be added to the fermenting material (a soybean hypocotyl-containing substance)" (paragraph [0020] of Basic Application A, paragraph [0022] of Basic Application B, and paragraph [0021] of Basic Application C), and it can be said that they assume using isoflavone containing "daidzein compounds" as a fermenting material.

As mentioned in (A)a. and b. above, examples in Basic Applications A and B state, along with specific experiment results, that by adding arginine to a "soybean hypocotyl" and fermenting it by using a *Lactococcus* 20-92 strain, equol is produced through metabolism of daidzin contained in the "soybean hypocotyl," and fermented powder is obtained as a result of the strain converting arginine into ornithine (paragraphs [0103] through [0106] of Basic Application A and paragraphs [0074] through [0077] of Basic Application B). In addition, the Basic Applications state "The equol content in the fermented soybean hypocotyl is generally 1 to 20 mg, preferably 2 to 12 mg, and more preferably 5 to 8 mg, per gram (dry weight) of the fermented soybean hypocotyl" and "The ornithine content of the equol-containing fermented soybean hypocotyl is 5 to 20 mg, preferably 8 to 15 mg, and more preferably 9 to 12 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl" (paragraphs [0024] and [0032] of Basic Application A, paragraphs [0026] and [0034] of Basic Application B, and paragraphs [0025] and [0033] of Basic Application C), indicating that the fermented substance generally contains 1 to 20 mg of equol and should

preferably contain 8 to 15 mg of ornithine per gram (dry weight) of the fermented substance. Therefore, it can be said that these lower limits are specified in the Corrected Invention. Moreover, it is clear from the claim statements in Basic Applications A and B that the fermented substance obtained by the inventions of these basic applications is a food material.

Meanwhile, according to evidence (Exhibit Otsu B4 (*Journal of Bioscience and Bioengineering*, Vol. 102, No. 3, 247-250. 2006) and Exhibit Otsu B16 (International Publication No. 2005/000042)), it is found to have been common general technical knowledge as of the Priority Date that equol is produced from daidzein, that a *Lactococcus* 20-92 strain produces equol by metabolizing a daidzein compound, including daidzein glycosides (e.g., daidzin), daidzein, and dihydrodaidzein, and that, in the case of daidzin, daidzin is metabolized to liberate daidzein, and the liberated daidzein is further metabolized to dihydrodaidzein to finally produce equol. It follows that a person skilled in the art is found to have recognized that, in the Basic Applications, the substance that is metabolized in effect is a "daidzein compound" such as daidzin contained in the "soybean hypocotyl."

For the reasons mentioned above, it should be said that a person skilled in the art who read the abovementioned statements of Basic Applications A and B could have recognized the following, by also taking into account the abovementioned common general technical knowledge as of the Priority Date: even in the case of using a "material containing daidzein compounds" other than a "soybean hypocotyl" as a fermenting material, if a microorganism having the ability to produce equol and ornithine, such as a *Lactococcus* 20-92 strain, is used to cause the "daidzein compounds" in the fermenting material to be metabolized together with arginine, it is possible to produce fermented powder which contains not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight of the fermented substance, and which is used as a food material. Therefore, a person skilled in the art is found to have been able to understand the Corrected Invention from the statements in Basic Applications A and B.

Consequently, the Corrected Invention is at least found to be an invention stated or equivalent to have been stated in Basic Applications A and B, and should be regarded to be able to enjoy the effect of the priority claim based on Basic Applications A and B.

It follows that, with regard to application of the provisions of Article 104 of the Patent Act, the patent application for the Patent is deemed to have been filed on June 13, 2007, which is the Priority Date. Accordingly, when examining whether the product of the Corrected Invention was "not publicly known" in Japan prior to the filing of the patent application as referred to in that Article, Exhibit Otsu B3 (International Publication No. 2007/066655; the international publication date: June 14, 2007), which was published after the Priority Date, cannot be taken into consideration.

C. Whether the product was "not publicly known"

In order for a product to have been "publicly known" as referred to in Article 104 of the Patent Act, there should at least be a fact that was sufficiently known to enable a person skilled in the art to acquire clues for producing that product as of the reference date. However, it cannot be said that the product of the Corrected Invention was stated in Exhibit Otsu B16 and Exhibit Otsu B24, which were publicly known as of the Priority Date, and hence a person skilled in the art could not have easily conceived of the Corrected Invention from Exhibit Otsu B16 or Exhibit Otsu B24 as mentioned in 3.(4) and (6) below. It follows that a person skilled in the art who read Exhibit Otsu B16 or Exhibit Otsu B24 could not have been able to acquire clues for producing the product of the Corrected Invention as of the Priority Date.

The Appellees allege that the product of the Corrected Invention was "publicly known," as it is merely a product made by adding "8 mg" of ornithine of "97.48%" purity, which is a nutrition enhancing additive, (International Publication (WO2006/051940) of Exhibit Otsu B67) to "992 mg" of fermented substance wherein "1 mg to 3 mg of equol is produced per gram by dry weight" as referred to in "Example 1" of Exhibit Otsu B16. However, as mentioned in A. above, the product of the Corrected Invention is "fermented powder containing ornithine and equol, wherein not less than 8 mg ornithine and not less than 1 mg equol are produced per gram by dry weight of said fermented substance, and which is used as a food material." Thus, even if Exhibit Otsu B16 is combined with Exhibit Otsu B67, the product of the Corrected Invention does not constitute a product "wherein not less than 8 mg ornithine and not less than 1 mg equol are produced per gram by dry weight of said fermented substance," and hence the Appellees' allegations mentioned above are unacceptable.

As the Appellees alleged that the product of the Invention constitutes a publicly known product based on Exhibit Otsu B4, this point was examined to make certain. As a result of the examination, it cannot be said that the Corrected Invention was stated in Exhibit Otsu B4, and that a person skilled in the art could have easily conceived of the Corrected Invention from Exhibit Otsu B4, as mentioned in 3.(3) below, and it also cannot be said that a person skilled in the art could have acquired clues for producing the product of the Corrected Invention from Exhibit Otsu B4.

Consequently, it is determined that the product of the Corrected Invention was "not publicly known" as of the Priority Date.

D. Regarding the constitution of the Appellees' Method

The Appellees allege that the presumption under Article 104 of the Patent Act does not apply because their admission has been established regarding the fact that the method for producing the Appellees' Material is the Appellees' Method stated in the "List of the Defendants' Method" attached to the judgment in prior instance. On the fourth date for

preparatory proceedings in the prior instance on June 7, 2019, both parties stated that the constitution of the Appellees' Method is as stated in the "List of the Defendants' Method" attached to the judgment in prior instance (a fact evident to this court).

The difference between the Appellees' Method that was found to be not disputed among the parties concerned in the prior instance and the Appellees' Method alleged by the Appellant in this instance is that the constituent portion "α3 a treatment solution containing daidzein obtained through said enzyme treatment process and [redacted] are mixed with a culture solution containing arginine to be fermented," in the former method is changed to the following constitution in the latter method: "α3-1 daidzein obtained through said enzyme treatment process is mixed with other components including arginine to form a medium, and this is sterilized to form a sterilized medium," and "α3-2 [redacted] is inoculated in this sterilized medium to be fermented." The contents of these α3-1 and α3-2 are intended to make the contents of α3 more specific and detailed, and the Appellant asserts that if the claim interpretation of the Corrected Invention in the judgment in prior instance is to be applied, the constitution of the Appellees' Method should be regarded as α3-1 and α3-2. Therefore, first, the constitution of the Appellees' Method that was found to be not disputed among the parties concerned in the prior instance (the method according to α1 through α6, which has not changed α3 to α3-1 and α3-2) will be examined.

E. Regarding rebuttal of presumption

The Appellees are regarded to be making allegations and presenting evidence to the effect that they are not using the method of the Corrected Invention, on the basis that the method for producing the Appellees' Material is the Appellees' Method, which differs from the method of the Corrected Invention. Accordingly, the question of whether the Appellees' Method (first of all, the method according to α1 through α6, which has not changed α3 to α3-1 and α3-2) differs from the method of the Corrected Invention is examined below.

(A) Regarding addition of arginine

a. The Appellees allege that, in the Appellees' Method, the daidzein compound selected in Constituent Feature A' is the "daidzein glycosides" referred to in Constitution α1, and the method does not have a step to add arginine to the daidzein glycosides, and therefore it is proven that the method does not fulfill Constituent Features A', B'-1, and B'-2.

b. While the Appellees allege that the Appellees' Method does not have a step to add arginine, the Appellees' Method has a step wherein a treatment solution containing daidzein and [redacted] are mixed with a culture solution containing arginine to be fermented in Constitution α3. Therefore, the question is whether this step can be regarded as constituting "addition of arginine" (Constituent Feature

A').

Constituent Feature A' in the claim statement has a step to "add arginine to at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein," whereas Constitution α3 of the Appellees' Method has a step to mix a treatment solution containing daidzein with a culture solution containing arginine, and this can be regarded as a step to add arginine to daidzein. The Appellees allege that, while the "daidzein glycosides" of Constitution α1 corresponds to "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" of Constituent Feature A', the Appellees' Method does not add arginine to daidzein glycosides, and hence it does not fulfill the step to "add arginine" in Constituent Feature A'. However, as mentioned above, the claim states that arginine is added to "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein," and provides no reason to limit the daidzein compound to daidzein glycosides. In Constitution α3, a treatment solution containing "daidzein," which is one of the abovementioned daidzein compounds, and a culture solution containing "arginine" are mixed. Therefore, it should be said that arginine is added to daidzein, which is a daidzein compound, in the Appellees' Method. It follows that the Appellees' Method fulfills Constituent Feature A'.

c. The judgment in prior instance determined that the "culture solution containing arginine" in Constitution α3 does not constitute the "fermenting material containing arginine" in Constituent Features A-2 and A-3 of the Invention, and therefore the Appellees' Method does not fulfill Constituent Features A-2 and A-3 of the Invention. However, since there is also a "fermenting material containing arginine" in Constituent Feature B'-1 of the Corrected Invention, the question of whether the "culture solution containing arginine" in α3 constitutes the "fermenting material containing arginine" in Constituent Feature B'-1 is examined below.

While Constituent Feature B'-1 reads "a fermenting material containing said daidzein compound and said arginine," it is natural to construe that this refers to the substance resulting from adding arginine to a daidzein compound in Constituent Feature A'. As mentioned in b. above, in Constitution α3 of the Appellees' Method, a treatment solution containing "daidzein" and a culture solution containing "arginine" are mixed with ●●● ●●●●●●●●●●●●●●●●●●●●●●●● to be fermented, and the mixture of the treatment solution containing "daidzein" and the culture solution containing "arginine" is "fermented" by using ●●●●●●●●●●●●●●●●●●●●●●●●●●●●●, which is a "microorganism having the ability to produce ornithine and the ability to produce equol"; thus, it should be said that the abovementioned mixture constitutes a fermenting material. It follows that the mixture constitutes "a fermenting material containing said

daidzein compound and said arginine," and therefore, even if the Appellees' Method alleged by the Appellees is premised, the method for producing the Appellees' Material fulfills Constituent Feature B'-1 of the Corrected Invention, and also fulfills Constituent Feature B'-2, which is a step to ferment the fermenting material of Constituent Feature B'-1 by using a microorganism.

In this regard, the judgment in prior instance construed, with regard to the Invention, that arginine is contained in the fermenting material at the stage of preparing the fermenting material before the fermentation, and that the "treatment solution containing daidzein" of Constitution α3 constitutes a fermenting material, whereas the "culture solution containing arginine" constitutes not a fermenting material, but a nutritional component aimed at improving the fermentation efficiency, etc. On such basis, the judgment determined that the Appellees' Method does not fulfill the relevant constituent feature of the Invention, as arginine appears for the first time at the fermentation stage.

However, the Patent Claim and the Description contain no statements suggesting any difference between a case of adding a microorganism after adding arginine to a daidzein compound and a case of mixing a daidzein compound, arginine, and a microorganism at the same time. Meanwhile, looking at the Description, paragraph [0091] states "a fermenting material (material to be subjected to the fermentation)," but paragraph [0093] states that the fermenting material "containing daidzein compounds is not limited by other factors," indicating that there are no particular limitations concerning the fermenting material, and there are no other statements defining the fermenting material. As mentioned in 1.(2) above, the substances subjected to the fermentation using a microorganism having the ability to produce ornithine and the ability to produce equol in the Corrected Invention are a "daidzein compound" and "arginine," and regardless of whether a microorganism is added after adding arginine to a daidzein compound or arginine and a microorganism are added to a daidzein compound at the same time, there is no difference in that arginine is subjected to fermentation. It follows that there are no grounds for regarding that the arginine in the Appellees' Method is not a fermenting material.

The judgment in prior instance found that a nutritional component aimed at improving the fermentation efficiency, etc. is treated as a component different from a fermenting material, because paragraph [0033] of the Description states "The equol-containing fermented soybean hypocotyl is produced using a soybean hypocotyl as a fermenting material," and paragraph [0036] states that "if necessary, some additives may be added to the soybean hypocotyl as the raw material in the fermentation to improve the fermentation efficiency or flavor of the product. Examples of the additives include nitrogen sources such as a yeast extract, polypeptone, or a meat extract; carbon sources such as glucose or sucrose;

inorganic salts such as phosphate, carbonate or hydrosulfate; vitamins; and nutritional components such as amino acid. Particularly, when using an equol-producing microorganism for converting arginine into ornithine (omitted), arginine is added to the soybean hypocotyl before fermentation so that the fermented substance contains ornithine. In this case, the amount of arginine is, for example, about 0.5 to 3 parts by weight, based on 100 parts by weight (dry weight) of the soybean hypocotyl," indicating that a nutritional component aimed at improving the fermentation efficiency, etc. may be added to the soybean hypocotyl to be used as a fermenting material, if necessary. However, there is no contradiction between a fact that a "soybean hypocotyl" containing a daidzein compound constitutes a fermenting material and a fact that a treatment solution containing a daidzein compound and a culture solution containing arginine both constitute a fermenting material. Moreover, the statement in paragraph [0036] is also not contradictory to deeming a substance resulting from adding arginine to a soybean hypocotyl as a fermenting material. Consequently, it must be said that the determination by the judgment in prior instance contains an error.

Then, it is reasonable to find that the "culture solution containing arginine" in α3 constitutes the "fermenting material containing arginine" in Constituent Feature B'-1, and hence the allegation that the Appellees' Method does not fulfill Constituent Feature A', B'-1, and B'-2 is not proven.

(B) Regarding the type of the microorganism

a. Constituent Feature B'-2 reads "comprising a step to ferment … by using a microorganism having the ability to produce ornithine and the ability to produce equol. The "microorganism" needs to have "the ability to produce ornithine and the ability to produce equol," but it is not limited to a specific microorganism. When looking at the statements in the detailed description of the invention in the Description, only a *Lactococcus* 20-92 strain is mentioned as the "microorganism" in the [Examples] section, but on the other hand, paragraph [0032] states that some microorganisms having the ability to produce equol were known as of the time of the filing of the patent application for the Patent, and paragraph [0036] states that a microorganism having the ability to produce ornithine can be obtained from among those microorganisms by a publicly-known screening method.

Then, it should be regarded that a person skilled in the art who read the statements of the Patent Claim and the detailed description of the invention in the Description could have been able to also find a microorganism having "the ability to produce ornithine and the ability to produce equol" other than a *Lactococcus* 20-92 strain, within a general extent of trial and error, by using a publicly-known screening method. Therefore, it should be said that the "microorganism" in Constituent Feature B'-2 is not limited to a *Lactococcus* 20-92 strain, and that the enteric bacterium (●●●●●●●●●●●●●●●●●●●●●●●●●

● ● ●) used in the Appellees' Method fulfills the abovementioned wording, "microorganism."

b. The Appellees allege that the "microorganism" in Constituent Feature B'-2 should be interpreted to be limited to a *Lactococcus* 20-92 strain, by indicating matters including the following: although "comprising a step to ferment … by using a microorganism having the ability to produce ornithine and the ability to produce equol" in Constituent Feature B'-2 is a statement that covers a wide range of microorganisms as a so-called functional claim, the Description states that the basic technical idea of the invention lies in the discovery of a *Lactococcus* 20-92 strain being an appropriate microorganism, and it has no statement indicating that all types of microorganisms are covered; given this fact and the information available on the Appellant's website (Exhibit Otsu B11), it should be said that excessive trial and error would have been required for a person skilled in the art to find the abovementioned microorganism other than a *Lactococcus* 20-92 strain.

However, there are no reasonable grounds to find that the wording of a microorganism having "the ability to produce ornithine and the ability to produce equol" in Constituent Feature B'-2 covers a wide range of microorganisms, and as explained in a. above, it should be regarded that a person skilled in the art who read the statements of the Description, etc. could have been able to also find a microorganism having "the ability to produce ornithine and the ability to produce equol" other than a *Lactococcus* 20-92 strain, within a general extent of trial and error, by using a publicly-known screening method. Therefore, the Description cannot be regarded to be stating that the basic technical idea of the invention lies solely in the discovery of a *Lactococcus* 20-92 strain being an appropriate microorganism. Moreover, even if it may be difficult to find a microorganism that is excellent enough to be actually commercialized by looking at the information available on the Appellant's website (Exhibit Otsu B11), the "microorganism" in Constituent Feature B'-2 does not need to be a microorganism that is excellent enough to be actually commercialized, but a microorganism having "the ability to produce ornithine and the ability to produce equol" to a certain extent would suffice, in light of the statements of the Patent Claim and the detailed description of the invention in the Description, and finding such microorganism would not impose excessive trial and error on a person skilled in the art.

In addition, the "daidzein compound" in Constituent Feature A' of the Corrected Invention only needs to be at least one daidzein compound selected from three types of daidzein compounds, "daidzein glycosides, daidzein, or dihydrodaidzein," and it does not necessarily have to be "daidzein glycosides." While the "microorganism" in Constituent Feature B'-2 needs to be one having "the ability to produce ornithine and the ability to produce equol," the claim and the Description contain no statements indicating that the

abovementioned "microorganism" needs to be one having the ability to cleave sugar. Although only a *Lactococcus* 20-92 strain, which is a microorganism having the ability to cleave sugar, is mentioned as the "microorganism" in the [Examples] section of the Description, the "microorganism" in Constituent Feature B'-2 is not limited to a *Lactococcus* 20-92 strain. It follows that the "microorganism" in Constituent Feature B'-2 does not need to be one having the ability to cleave sugar.

According to the above, it is reasonable to find that "[redacted]" in α3 constitutes the "microorganism" in Constituent Feature B'-2, and hence the allegation that the Appellees' Method does not fulfill Constituent Feature B'-2 is not proven.

(C) As described above, the allegation that the method of the Corrected Invention is not used for production of the Appellees' Material is not proven. Therefore, the presumption under Article 104 of the Patent Act cannot be found to have been rebutted.

(2) Conclusion regarding Issue 1

As mentioned in (1) above, the Appellees' Material is presumed to have been produced using the method of the Corrected Invention. Accordingly, the Appellees' Method is determined to fall within the technical scope of the Corrected Invention, without having to determine other points.

3. Regarding Issue 2 (whether the Patent deserves to be invalidated in a trial for patent invalidation)

(1) Issue 2-1 (whether Grounds for Invalidation 1 (lack of novelty based on Exhibit Otsu B3 on the premise that a priority claim cannot be made) exist)

As mentioned in 2.(1)B.(C) above, the Corrected Invention is able to enjoy the effect of the priority claim based on Basic Applications A and B.

Consequently, the Appellees' assertion of Grounds for Invalidation 1 lacks a premise, and is groundless.

(2) Issue 2-2 (whether Grounds for Invalidation 2 (violation of the support requirement and the enablement requirement in relation to the "microorganism having the ability to produce ornithine and the ability to produce equol" in the Corrected Invention) exist)

A. Regarding the support requirement

(A) Whether the claim statement satisfies the support requirement concerning the description should be determined by comparing the claim statement and the statements in the detailed description of the invention, and examining whether the invention stated in the claim is the invention stated in the detailed description of the invention, and whether the extent of disclosure is such that a person skilled in the art can recognize that the problem to be solved by the invention can be solved based on the statements in the detailed description of the

invention, and whether the extent of disclosure is such that a person skilled in the art can recognize that the problem to be solved by the invention can be solved, even without the relevant statements or suggestions, in light of the common general technical knowledge as of the time of the filing of the patent application.
(B) The Description (Exhibit Ko 2) mentions several microorganisms having the ability to produce equol by metabolizing "daidzein compounds" and states that an ornithine/equol-producing microorganism can be obtained by a publicly-known screening method using an index of the equol-producing ability and the conversion ability from arginine into ornithine (paragraphs [0032] and [0036]). In addition, the Description states that a "material containing daidzein compounds" other than a "soybean hypocotyl," such as a soybean hypocotyl extract, etc., can be used as a fermenting material (paragraph [0093]) and that the fermented substance of a "soybean hypocotyl," which is an example of a "material containing daidzein compounds," can be used as a food material in the form of powder (paragraph [0144]). The Description also states an example of producing fermented soybean hypocotyl powder containing equol and ornithine in the amounts specified in the Corrected Invention by using a substance obtained by adding arginine to a "soybean hypocotyl," which is an example of a "material containing daidzein compounds," as a fermenting material and also using a *Lactococcus* 20-92 strain (paragraphs [0225] through [0228]), as well as various examples of food products using that fermented substance (paragraphs [0271] through [0616]).

Comprehensively taking into account the statements of the Description and the fact that it was common general technical knowledge as of the Original Filing Date to produce equol by fermenting a "daidzein compound" or a "material containing daidzein compounds" other than a "soybean hypocotyl" by using an equol-producing microorganism, as mentioned in 2.(1)B.(C) above, it can be said that not only the "soybean hypocotyl" but also the "material containing daidzein compounds" stated in the claim are supported by the Description. Accordingly, the Appellees' allegation that only the "soybean hypocotyl" is being supported is unacceptable.
(C) Next, examination is made as to whether an ornithine/equol-producing microorganism other than the *Lactococcus* 20-92 strain, which is stated in the examples, is supported in terms of the screening method.
a. According to evidence (Exhibits Otsu B4, B10, and B24), it is found that several equol-producing microorganisms, such as the do03 strain, SNU-Julong strain, *Bacteroides* E-23-15, *Streptococcus* E-23-17, and *Streptococcus* A6G-225, had been isolated and identified from human feces, rat cecal content, etc. by the Priority Date. It follows that, because several microorganisms having the ability to produce equol other than the *Lactococcus* 20-92 strain

had been discovered by the Original Filing Date, it would have been possible to obtain an ornithine/equol-producing microorganism also by a method of examining whether these known microorganisms having the ability to produce equol had the ability to produce ornithine. It can be said that there is no particular difficulty in obtaining an ornithine/equol-producing microorganism from among known equol-producing microorganisms by using an index of the ornithine-producing ability in such manner.

b. Next, examination is made regarding ornithine/equol-producing microorganisms that were undiscovered as of the Original Filing Date. Paragraph [0036] of the Description states that an ornithine/equol-producing microorganism may be obtained by "a publicly-known screening method." According to evidence (Exhibit Ko 16 (FUKUI Saburo, supervising ed., *Baiotekunorojī shirīzu: Sukurīningu gijutsu—Biseibutsu no senzai kinō o saguru* (Biotechnology series: Screening technology—Exploring the potential functions of microorganisms), Kodansha, 1985), Exhibit Ko 17 (ARAI Mamoru et al., "Biseibutsu no sukurīningu hō I" (Microorganism screening method I), *Kagaku to seibutsu* (Chemistry and biology), vol. 5, no. 5, pp. 294–303, 1967)), it is found that a general technique of searching a microorganism of specific nature by screening was common general technical knowledge as of the Original Filing Date. In addition, according to evidence (Exhibit Ko 19 (the gazette of Unexamined Patent Application Publication No. 2006-242602), Exhibit Ko 20 (the gazette of Unexamined Patent Application Publication No. 2008-61584), Exhibit Otsu B10 (*Journal of intestinal microbiology*, vol. 21, no. 3, pp. 217–220, 2007)), it is found that a method of screening an equol-producing microorganism was known as of the Original Filing Date and that this method was not particularly different from the abovementioned general technique of searching a microorganism of specific nature by screening.

c. While paragraphs [0224] and [0225] of the Description (Exhibit Ko 2) and evidence (Exhibits Ko 19 and 20, and Exhibits Otsu B4, B10, B16, and B24) state the culture conditions of various equol-producing microorganisms including a *Lactococcus* 20-92 strain and a do03 strain, these culture conditions are not found to have been set specifically for each strain, and hence it would not have been difficult to set the culture conditions. Moreover, a person skilled in the art is found to have been able to implement the abovementioned screening by using the culture conditions stated in the evidence above as clues.

Thus, it cannot be said that the search for an equol-producing microorganism would have required excessive trial and error.

d. As a result of the examination above, it cannot be said that the Corrected Invention lacks support by statements in the Description merely because the examples do not disclose the specific screening method and the like for ornithine/equol-producing microorganisms that were undiscovered as of the Original Filing Date.

Consequently, it should be said that the Corrected Invention is supported also in terms of the screening method for an ornithine/equol-producing microorganism other than a *Lactococcus* 20-92 strain.

(D) Further, the amounts of equol and ornithine in the Corrected Invention are examined.

a. With regard to the amount of equol, paragraphs [0036], [0038], and [0094] through [0096] of the Description (Exhibit Ko 2) state that an isoflavone which serves as a fermenting material may be added or nutritional components may be added, as appropriate, so as to increase the equol content or to improve the fermentation efficiency, and that the fermentation conditions should be determined, as appropriate, according to the type of the microorganism and the like. Also, paragraph [0224] [Table 1] of the Description shows that the production amount of equol increased when the amount of the "soybean hypocotyl" was tripled under the same conditions.

Thus, it can be said that, even if a person skilled in the art uses a strain other than the *Lactococcus* 20-92 strain referred to in the examples, the person would recognize that the amount of equol specified in the Corrected Invention can be obtained by increasing the amount of the "daidzein compound," adding nutritional components, or adjusting the fermentation conditions as appropriate based on the abovementioned statements of the Description and common general technical knowledge concerning fermentation.

b. With regard to ornithine as well, it would not have been so difficult as to require special ingenuity or creativity for a person skilled in the art to produce ornithine in the amount specified by the Corrected Invention by increasing the amount of arginine that is used as a raw material or adjusting the fermentation conditions as appropriate. Also, this fact would not be affected by the absence of an upper limit for the ornithine in the Corrected Invention. Consequently, a person skilled in the art would have recognized that ornithine can be obtained in the amount specified by the Corrected Invention even in the case of using a microorganism other than a *Lactococcus* 20-92 strain.

c. Considering that paragraphs [0042] and [0050] of the Description state the production amounts of ornithine and equol from the viewpoint that they are components having useful physiological effects, it also cannot be said that there is a problem in specifying only the lower limits of their production amounts in the Corrected Invention.

(E) As a result of the examination above, the Corrected Invention is found not to be in violation of the support requirement.

B. Regarding the enablement requirement

According to the examination in A. above, it can be said that a person skilled in the art could have obtained fermented powder that can be used as a food material containing equol and ornithine in the amounts specified by the Corrected Invention by using a "material

containing daidzein compounds," other than a "soybean hypocotyl," to which arginine is added as a fermenting material, and also using a strain other than a *Lactococcus* 20-92 strain, without requiring excessive trial and error. Accordingly, the Corrected Invention is found not to be in violation of the enablement requirement.

The Appellees allege that some microorganisms in the Corrected Invention do not have the ability to produce equol in the specified amount from daidzin contained in a "soybean hypocotyl," and therefore a part of the invention fails to satisfy the enablement requirement in relation to daidzin.

However, the Description states that the *Lactococcus* 20-92 strain is a strain that can produce equol from daidzin (paragraph [0227] [Table 2]). In addition, as the "daidzein compound" in the Corrected Invention also includes daidzein and dihydrodaidzein, a microorganism that can produce specified amounts of equol and ornithine from such "daidzein compound" other than daidzin and arginine also constitutes the microorganism in the Corrected Invention, and it cannot be said that a microorganism other than a *Lactococcus* 20-92 strain would violate the enablement requirement unless it also has the ability to produce equol from daidzin without fail. Accordingly, the Appellees' abovementioned allegation is unacceptable.

C. Conclusion regarding Grounds for Invalidation 2

Due to the above, Grounds for Invalidation 2 alleged by the Appellees are groundless.

(3) Issue 2-3 (whether Grounds for Invalidation 3 (lack of novelty based on Exhibit Otsu B4 and lack of inventive step based on Exhibit Otsu B4 as the primary cited invention) exist)

A. Regarding Exhibit Otsu B4 Invention

(A) Exhibit Otsu B4 contains the following statements.

"After isolating an equol-producing bacterium, a [precultured GAM broth containing 1% L-arginine at 37°C for 28 h was added to an equol-assay medium for quantitative determination containing 59 g of GAM broth and daidzein (final concentration: 200 μM) per liter of distilled water. Then, the medium was incubated anaerobically at 37°C, extracted and analyzed by HPLC as described below."(page 248, left column, lines 23 to 29)

"An anaerobic gram-positive rod-shaped strain capable of producing equol was isolated from a rat cecal content. This strain is referred to as the Gram-positive bacterium do03 (AB266102)." (p. 248, right column, lines 8 to 11)

"The strain do03 converted 200 μM daidzein to equol … for 4 d at 37°C anaerobically." (p. 248, right column, lines 25 to 26)

"In the medium containing arginine, the equol ratio increased to 0.67±0.01 with increases in OD_{600} and culture broth pH." (p. 248, right column, lines 38 to 40)

"Moreover, for the growth of some bacteria such as *E. lentum*, arginine is required

because they obtain energy for growth using the arginine dihydrolase pathway (19). The bacterial metabolism of arginine produces NH_3, which caused the increase in culture broth pH. Arginine supplementation increased OD_{600}; thus, the strain do03 uses arginine for growth. Therefore, the increase in equol ratio may be attributed to an increase in the number of do03 cells. The supplementation of butyric acid and arginine decreased the equol ratio by approximately 10%. Because culture broth pH increased more than that of the control, the strain do03 seemed to use arginine; however, OD_{600} did not increase. Butyric acid supplementation caused a decrease in OD_{600}. The mechanism of equol production stimulated by butyric acid supplementation has not yet been reported. Antagonist action seemed to occur by the supplementation of butyric acid and arginine." (p. 248, right column, lines 45 to 60 and p. 250, line 1)

(B) Finding of Exhibit Otsu B4 Invention

As mentioned in (A) above, Exhibit Otsu B4 contains statements about the production of equol from daidzein by a do03 strain, but contains no statements about obtaining not less than 1 mg equol per gram of the fermented substance, about processing the fermented substance into powder, and about using it as a food material, and also contains no statement at all about ornithine.

Therefore, the following Exhibit Otsu B4 Invention is found to be stated in Exhibit Otsu B4.

"A method for obtaining equol from daidzein by adding a gram-positive do03 strain, which is a microorganism having the ability to produce equol, and arginine to a medium containing daidzein, and culturing the strain."

B. Comparison between the Corrected Invention and Exhibit Otsu B4 Invention

When the Corrected Invention stated on p. 5, lines 13 to 20 of the judgment in prior instance cited in No. 2, 3. above and Exhibit Otsu B4 Invention referred to in A.(B) above are compared, the Corrected Invention and Exhibit Otsu B4 Invention are found to differ in the following respects.

(Difference 1) In the Corrected Invention, the microorganism is a "microorganism having the ability to produce ornithine and the ability to produce equol," while "not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight of the fermented substance" are produced by fermenting a fermenting material by using a microorganism, and the fermented substance is a substance "containing ornithine and equol," whereas in Exhibit Otsu B4 Invention, the microorganism is a "microorganism having the ability to produce equol" and the fermented substance is a substance "containing equol."

(Difference 2) In the Corrected Invention, the obtained substance is fermented powder that is used as a food material, whereas in Exhibit Otsu B4, no such specification is made.

C. Regarding Difference 1

(A) As mentioned in A.(B) above, Exhibit Otsu B4 contains no statements about the amount of equol in the fermented substance, and also contains no statements about ornithine.

Exhibit Otsu B5 cited in Exhibit Otsu B4 as a reference document states that *E. lentum* converts arginine into ornithine by using the arginine dihydrolase pathway, and produces NH_3 and ATP, and Exhibit Otsu B4 states that a do03 strain, similarly to *E. lentum*, metabolized arginine and produced NH_3.

However, Exhibit Otsu B4 does not disclose a detailed analysis of the arginine metabolic pathway of the do03 strain. In addition, Professor B, one of the authors of Exhibit Otsu B4, states in a written opinion (Exhibit Ko 32) that Professor B does not remember paying attention to production and accumulation of ornithine regarding the do03 strain, and also does not remember talking about it with the other authors of Exhibit Otsu B4. Likewise, Professor C, another author of Exhibit Otsu B4, states in a written statement (Exhibits Otsu B34 and B52) that, although Professor C does not know the amount of accumulation of ornithine in the do03 strain (Exhibit Otsu B34), the production amount of ornithine by a microorganism tends to be unstable (Exhibit Otsu B52). These statements coincide with each other in that the amount of accumulation of ornithine is unknown in Exhibit Otsu B4.

(B) Appellee Daicel alleges that it conducted reproduction experiments of Exhibit Otsu B4, and submitted the results (Exhibits Otsu B6, B29, and B64). However, one cannot go so far as to say that these are experiments that have accurately reproduced the experiment conditions of Exhibit Otsu B4.

(C) According to the above, one cannot go so far as to say that Exhibit Otsu B4 Invention discloses a fact that it produces not less than 8 mg ornithine per gram by dry weight of the fermented substance. It follows that at least Difference 1 can be considered to be a substantive difference, and therefore the Corrected Invention is not regarded to lack novelty in relation to Exhibit Otsu B4 Invention.

(D) Further, as Exhibit Otsu B4 contains no statements or suggestions about producing "not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight of the fermented substance," it cannot be said that Difference 1 would have been easily conceived of by a person skilled in the art.

D. Regarding Difference 2

When Difference 2 is examined, Exhibit Otsu B4 merely states a method for obtaining equol and contains no statements or suggestions about processing the culture product containing equol and ornithine into fermented powder and using it as a food material, and hence the Corrected Invention is not regarded to lack novelty in relation to Exhibit Otsu B4, and it cannot be said that the invention would have been easily conceived of by a person

skilled in the art.

E. Conclusion regarding Grounds for Invalidation 3

Due to the above, Grounds for Invalidation 3 alleged by the Appellees are groundless.

(4) Regarding Issue 2-4 (whether Grounds for Invalidation 4 (lack of novelty based on Exhibit Otsu B16 and lack of inventive step based on Exhibit Otsu B16 as the primary cited invention) exist)

A. Regarding Exhibit Otsu B16 Invention

(A) The description and drawings of Exhibit Otsu B16 contain the following statements (the page numbers are those in the description of Exhibit Otsu B16).

"Field of the Invention

The present invention relates to equol-producing lactic acid bacterial strain, a composition comprising said lactic acid bacterial strain, and a method for producing equol by utilizing said lactic acid bacterial strain." (page 1, lines 3 to 5)

"Background of the Invention" (page 1, line 6)

"Based on the above idea, the inventors had conducted intensive investigations and isolated from human stools novel 3 strains of microorganisms and identified them: namely *Bacterioides* E-23-15 (FERM BP-6435), *Streptococcus* E-23-17 (FERM BP-6436), and *Streptococcus* A6G225 (FERM BP-6437), as equol producing-bacteria suitable for the expression of said antiestrogen and estrogenic-like effects, among other effects, and applied for a patent claiming inventions concerning these equol-producing strains of microorganisms and utilization of the microorganisms (WO99/07392).

Disclosure of Invention

The inventors conducted further studies and succeeded in the isolation and characterization of a lactic acid bacterial strain belonging to the genus *Lactococcus* which is capable of utilizing daidzein glycoside, daidzein, or dihydrodaidzein to produce equol as a novel strain of microorganism which is fundamentally different from the previously isolated and identified microorganisms. The present invention has been developed on the basis of the above isolation and identification of this novel strain of lactic acid bacterium." (page 2, lines 13 to 24)

"The present invention subsumes the following inventions summarized in paragraphs 1-13.

Item 1. An equol-producing lactic acid bacteria-containing composition comprising, as an essential component thereof, a lactic acid bacterial strain belonging to the genus *Lactococcus* having an ability to utilize at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol." (page 2, lines 25 to 29)

"Item 9. A method for producing equol comprising the step to let a lactic acid bacterial strain belonging to the genus *Lactococcus* having an ability to utilize a daidzein compound to produce equol act on at least one member selected from the group consisting of daidzein compounds and daidzein compound-containing ingredients.
Item 10. The method according to Item 9, wherein said lactic acid bacterial strain belonging to the genus *Lactococcus* is *Lactococcus garvieae*." (page 3, lines 11 to 15)
"II. Biochemical characteristics
…
(13) Arginine dihydrolase: +" (page 4, lines 7 to 20)
"(2) Daidzein compounds and daidzein compound-containing ingredients

Daidzein compounds, which are utilized by the present strain *Lactococcus* 20-92, include a daidzein glycoside, daidzein, and dihydrodaidzein. A specific example of said daidzein glycoside is daidzin. Daidzin is an isoflavone glycoside having daidzein as the aglycone (daidzein glycoside). Referring to daidzin, it is utilized by said strain of microorganism to liberate daidzein which is further utilized by the strain to give dihydrodaidzein, from which equol is finally produced.

In the present invention, said daidzein compound is used as the substrate. The substrate includes not only daidzein compounds but also various materials or ingredients containing the same. As a representative example of said material or ingredient containing said daidzein compounds (referred to as daidzein compound-containing ingredient), soybean isoflavone can be mentioned. Soybean isoflavone is already available from commercial sources and, in the present invention, such commercial products, for example "Fujiflavone P10" (registered trademark) from Fujicco Co., Ltd., can be used. Moreover, said daidzein compound-containing ingredient includes not only soybean isoflavone but also plant tissues as such, e.g. kudzu (= *Pueraria thurbergiana* Benth) and root of kudzu (arrowroot), red clove, alfalfa, etc., and isoflavone derivatives originating therefrom.

Further examples of said daidzein compound-containing ingredient include not only the above-mentioned food materials such as soybean, kudzu, root of kudzu, red clove, alfalfa, etc. but also processed products thereof, such as soybean meal (soybean flour), boiled soybeans, tofu (soybean curd), fried bean curd, soy milk, soybean hypocotyl extract, etc., fermentation products thereof, such as natto (fermented soybeans), soy sauce, miso, tempeh, and fermented soy beverages. These materials invariably contain daidzein compounds. Moreover, these not only contain daidzein compounds but also estrogenic isoflavones, such as genistein and its glycosides (genistin etc.); glycitein and its glycosides (glycitin etc.); biochain A and formononetin which are partially methylated daidzein and genistein precursors and can be used with advantage in the present invention." (page 9, lines 3 to 28)

"(3-1) An equol-producing lactic acid bacteria-containing composition" (page 10, line 1)

All that is necessary for the composition of the invention is that it contains the bacteria (cells or equivalent) as said active component but, if desired, the composition may be supplemented with nutrients suited for the maintenance (or growth) of the microorganism as said active component. The nutrients mentioned above may for example be the nutrient media for culture of the respective microorganisms, such as BHI, EG, BL and GAM, as mentioned hereinbefore.

(omitted)

The above composition of the invention, when taken orally, expresses the desired equol-producing activity in the recipient's body." (page 10, lines 16 to 26)

"(3-3) Equol-containing composition of the invention

The composition of the invention may further contain equol.

(omitted)

A preferred specific example of the equol-containing composition of the invention is the fermentation product obtained by a process which comprises adding soybean isoflavone or a food material containing it to a suitable medium and culturing the microorganism of the invention, preferably *Lactococcus* 20-92, therein to cause fermentation. More particularly, such fermentation can be effected by the procedure which comprises adding a predetermined amount of the microorganism of the invention to a mixture of a sterilized substrate solution and a nutrient medium favorable for growth of the microorganism, such as BHI, EG, BL or GAM, or to cow's milk, soy milk, or a vegetable juice which can be used as food, and carrying out an anaerobic or aerobic fermentation reaction at 37°C under stationary conditions for about 48-96 hours (where necessary, a pH control agent and a reducing agent (e.g. a yeast extract, vitamin K_1, or the like) may be added). In the above procedure, the amount of the substrate may be about 0.01-0.5 mg/ml and the inoculum size of the microorganism can be selected from the range of about 1% to about 5%.

(omitted)

The presence of equol in the product composition of the invention can be confirmed by the method described hereinafter in Test Example 1." (page 11, line 25 to page 13, line 1)

"Example 1

(1) Production of a fermented soy milk beverage

The following ingredients were taken according to the formula and blended to prepare the composition of the invention in the form of a fermented soy milk beverage.

Fermentative culture of water-soluble soy protein	100 ml
Vitamins & minerals	q.s.

Flavoring	q.s.
Water	q.s.
Total	150 ml

The above fermentative culture of water-soluble soy protein was obtained by dissolving 13 g of water-soluble soy protein in 100 ml of water, adding 10^8-10^9 cells of *Lactococcus* 20-92 (FERM BP-10036), and carrying out fermentation at 37°C for 24-48 hours. The water-soluble soy protein used contained about 1-2 mg, calculated as daidzein, of daidzein compounds in each one gram.

(2) Production of a fermented milk

The following ingredients were taken according to the formula and blended to prepare the composition of the invention in a fermented milk form.

Lactococcus 20-92 fermented milk	100 ml
Vitamins & minerals	q.s.
Flavoring	q.s.
Water	q.s.
Total	150 ml

The *Lactococcus* 20-92 fermented milk was obtained by adding 10^8-10^9 cells of *Lactococcus* 20-92 (FERM BP-10036) to 1 L of cow's milk (having a nonfat milk solids content of 8.5% or greater and a milk fat content of 3.8% or greater) and carrying out fermentation at 37°C for 24-48 hours.

(3) Production of a freeze-dried powder of fermented soy milk

Using about 10^9 cells of *Lactococcus* 20-92 (FERM BP-10036) and 100 g of soy milk (soy solids 10%, daidzein compound content 10-15 mg calculated as daidzein), lactic acid fermentation was carried out at 37°C for 72-96 hours for the production of equol. This fermentation product was freeze-dried to prepare a powder. The equol content of the powder as determined by HPLC was 0.1-0.3 wt. %.

The powder obtained above and various other ingredients were weighed out according to the following formula and blended to prepare the composition of the invention in the powder form (food form and pharmaceutical product form).

Freeze-dried powder of fermented soy milk (equol content 0.005 g)	2.2g
Excipient (corn starch)	17 g

Vitamins & minerals	q.s.
Flavoring	q.s.
Total	20 g"

(page 21, line 14 to page 22, line 20)

"Test Example 1

Test for growth performance, equol-producing ability (activity), and equol output

(1) Test protocol

Lactococcus 20-92 strain (10^7-10^9 cells/g) was incubated in 5 ml of BHI broth (a liquid medium for growth (basal medium)) anaerobically at 37°C for 24 hours and the culture was diluted to 10^2 and 10^4 cells with the basal medium.

The culture obtained at completion of incubation and its dilutions prepared above were respectively taken, 0.2 ml each, and blended with 5 ml each of daidzein-supplemented basal medium (daidzein added to BHI broth at a final concentration of 10 μg/ml), cow's milk and soy milk, respectively, and cultured anaerobically at 37°C. The incubation time was set to 8, 24, 48, 72, and 96 hours in the case of 10 μg/ml daidzein-supplemented basal medium and soy milk, and 8, 24 and 48 hours in the case of cow's milk.

Before the start of incubation and at the end of each incubation period, 0.1 ml and 0.2 ml portions of the culture were sampled and respectively subjected to the counting of cells and assay of equol-producing ability (activity). Furthermore, for 10 μg/ml daidzein-containing basal medium and soy milk, 0.5 ml of each culture was sampled before the start of incubation and at the end of each incubation period and the amount of equol produced in each sample was determined.

The number of bacteria was determined in the following manner. Each 0.1 ml sample was diluted with PBS(-) solution (product of Nissui Co.) to prepare 10^4, 10^5, 10^6 and 10^7-fold dilutions and 0.1 ml each of these dilutions were respectively coated on GAM agar medium and incubated aerobically at 37°C for 24 hours. The colonies formed on the medium were counted for use as the number of bacteria.

The equol-producing ability (activity) was assayed as follows. Each 0.2 ml sample was blended with 5 ml of daidzein-supplemented basal medium (each in triplicate) and incubated anaerobically at 37°C for 96 hours. At completion of incubation, 0.5 ml samples of the respective cultures were taken and respectively extracted twice with 5 ml portions of ethyl acetate and the daidzein, dihydrodaidzein (intermediate), and equol in the extract were quantitated by HPLC. Moreover, based on the total amount, the percentage of equol was calculated. The results were scored on the following 5-point scale and the average score of 3 samples was used as an index of equol-producing ability (activity).

4: Equol (90% or greater)
3: Equol produced, with daidzein diminishing to less than 50% (formation of intermediate)
2: Equol produced, with residual daidzein (50% or greater) (formation of intermediate)
1: Intermediate formed, equol not produced
0: Neither intermediate formed nor equol produced, with daidzein not diminishing

The amount of equol produced was determined as follows. Each 0.5 ml sample was extracted twice with 5 ml portions of ethyl acetate and the amounts of daidzein, dihydrodaidzein (intermediate), and equol in the extract were quantitated by HPLC. Then, the respective concentrations were used to calculate the amount of equol produced.

(2) Test Results

(2-1) The results of counting of the cells (growth performance) are presented in Fig. 1.

In Fig. 1, (1) represents the result obtained in the case where the daidzein-supplemented basal medium was used, (2) represents the result obtained in the case where soy milk was used, and (3) represents the result obtained when cow's milk was used. In each diagram, the horizontal axis represents incubation time (hr) and the vertical axis represents viable cell count (Log CFU/ml).

It can be seen from the respective diagrams, the growth performance of the strain of the invention is good and, regardless of the inoculum size used, the stationary phase of growth was invariably attained in 8 hours of incubation in all the daidzein-supplemented basal medium, soy milk and cow's milk. The viable cell count was found to be steady at $10^{9.1\text{-}9.4}$ CFU/ml in the daidzein-supplemented basal medium, $10^{8.5\text{-}8.7}$ CFU/ml in soy milk, and $10^{8.0\text{-}8.4}$ CFU/ml in cow's milk.

(2-2) The equol-producing ability (activity) values found are presented in Fig. 2.

In Fig. 2, (1) represents the result obtained in the case where the daidzein-supplemented basal medium was used, (2) represents the result obtained in the case where soy milk was used, and (3) represents the result obtained in the case where cow's milk was used. In each diagram, the horizontal axis represents incubation time (hr) and the vertical axis represents activity score.

It is obvious from the results presented in Fig. 2 that the equol-producing ability (activity) tends to increase with time in any of the daidzein-supplemented basal medium, soy milk, and cow's milk. It could also be confirmed that even in the cases where cow's milk and soy milk were used, the equol-producing ability (activity) of the strain of the invention is sustained.

(2-3) Results of determination of the amount of equol produced

The quantities of equol produced in the daidzein-supplemented basal medium and soy milk (about 80 μg/ml calculated as daidzein) were as shown in Fig. 3.

In Fig. 3, (1) represents the result obtained in the case where the daidzein-supplemented basal medium was used and (2) represents the result obtained in the case where soy milk was used. In each diagram, the horizontal axis represents incubation time (hr) and the vertical axis represents equol concentration (μg/ml).

In both media, the production of equol began to be noticed at hour-48 following the start of incubation. In the case where soy milk was used, the amount of equol produced varied with inoculum size and particularly at the inoculation level of 4.00%, and the production of equol was as large as 57.0 μg/ml at hour-96 of incubation.

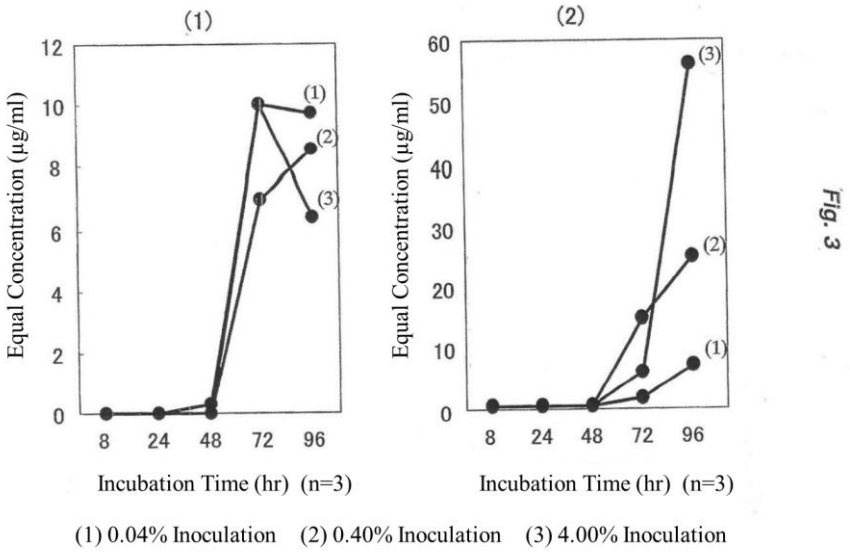
Although, in soy milk, not less than 90% of daidzein serving as the precursor of equol is present in the form of glycoside (in the form of glucose attached), the peak corresponding to the glycoside was no longer observed on the post-incubation chromatogram and this fact suggests that the strain of the invention decomposes the glycoside (β-glucosidase activity) to produce daidzein and further metabolizes this daidzein to equol." (page 23, line 22 to page 25, last line)

"Brief Description of the Drawings

(omitted)

Fig. 3 is a diagrammatic representation showing the relationship of incubation time to equol output as determined by the test protocol described in Test Example 1." (p. 20, line 24 to page 21, line 1)

[Fig. 3]



(1) 0.04% Inoculation (2) 0.40% Inoculation (3) 4.00% Inoculation

Fig. 3

(B) Finding of Exhibit Otsu B16 Invention

As mentioned in (A) above, Exhibit Otsu B16 discloses a method for producing equol comprising the step to let a lactic acid bacterial strain belonging to the genus *Lactococcus* having an ability to utilize a daidzein compound to produce equol act on at least one member selected from the group consisting of daidzein compounds and daidzein compound-containing ingredients as Example 1, and indicates *Lactococcus* 20-92 (FERM BP-10036) as a specific example of that lactic acid bacterial strain. Further, as Test Example 1, it states that equol was produced as shown in [Fig. 3] as a result of blending *Lactococcus* 20-92 (FERM BP-10036) with a daidzein-supplemented basal medium, soy milk, and so on, and culturing them.

Therefore, the following Exhibit Otsu B16 Invention is found to be stated in Exhibit Otsu B16.

"A method for producing a fermented substance containing equol, comprising the step to ferment a fermenting material containing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein (such as soy milk or daidzein-supplemented basal medium) by using *Lactococcus* 20-92 (FERM BP-10036), which is a microorganism having the ability to produce equol."

B. Comparison between the Corrected Invention and Exhibit Otsu B16 Invention

When the Corrected Invention stated on p. 5, lines 13 to 20 of the judgment in prior instance cited in No. 2, 3. above and Exhibit Otsu B16 Invention referred to in A.(B) above are compared, the Corrected Invention and Exhibit Otsu B16 Invention are found to have commonalities in that they are "a method for producing a fermented substance containing equol, comprising the step to ferment a fermenting material containing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein by using a microorganism having the ability to produce equol," and differ in the following respects.

(Difference A1) The Corrected Invention specifies that the microorganism "has the ability to produce ornithine," whereas Exhibit Otsu B16 Invention specifies that the microorganism is "*Lactococcus* 20-92 (FERM BP-10036)," but does not specify that it "has the ability to produce ornithine."

(Difference A2) The Corrected Invention specifies that arginine is added to "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" and that the fermenting material containing the daidzein compound and arginine is fermented, whereas Exhibit Otsu B16 Invention specifies that the fermenting material is soy milk, a daidzein-supplemented basal medium, or the like, but does not specify that the fermenting material contains arginine as a result of adding arginine to the daidzein

compound.
(Difference A3) The Corrected Invention specifies that a fermented substance containing ornithine is produced, whereas Exhibit Otsu B16 Invention does not specify this point.
(Difference A4) The Corrected Invention specifies that not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight are produced by fermentation, whereas Exhibit Otsu B16 Invention does not specify this point.
(Difference A5) The Corrected Invention specifies that the fermented substance produced is powder and that it is used as a food material, whereas Exhibit Otsu B16 Invention does not specify this point.
C. Regarding Difference A4

In light of the counsel's arguments, Difference A4 (the Corrected Invention specifies that not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight are produced by fermentation, whereas Exhibit Otsu B16 Invention does not specify this point) is examined below.
(A) Regarding novelty

As mentioned in A. above, the description of Exhibit Otsu B16 (page 22) contains the following statements concerning Example 1: "Using about 10^9 cells of *Lactococcus* 20-92 (FERM BP-10036) and 100 g of soy milk (soy solids 10%, daidzein compound content 10-15 mg calculated as daidzein), lactic acid fermentation was carried out at 37°C for 72-96 hours for the production of equol. This fermentation product was freeze-dried to prepare a powder. The equol content of the powder as determined by HPLC was 0.1-0.3 wt. %." According to this, in Exhibit Otsu B16 Invention, soy milk was fermented by using *Lactococcus* 20-92 (FERM BP-10036) to produce equol, which was then freeze-dried to obtain a powder, and the equol content of the powder was 0.1-0.3 wt. %. This means that "1-3 mg equol per gram by dry weight was produced by fermentation."

However, Exhibit Otsu B16 does not state that ornithine is produced by fermentation, and contains no statement on the amount of ornithine produced by Example 1. In addition, while 100 g of soy milk is used in Example 1, according to Exhibit Otsu B17-1 ("Studies on Quality Index of Aseptic Soymilk on Preservation," *Nippon Shokuhin Kogyo Gakkaishi* (Journal of food science and technology), 1985, vol. 32, no. 7, pp. 457-462, Table 4), the amount of free arginine in 1 ml of soy milk is less than 0.7 μmol. Therefore, even if all arginine contained in soy milk was converted into ornithine, only ornithine in an amount less than 0.1 mg per 1 ml of soy milk (0,7 μmol × 132.16 (the molecular weight of ornithine) ≒ 0.09 mg) would be produced. Accordingly, even by considering the fact that the amount of soy solids in the soy milk is 10% and the fact that the fermentation product is dried to prepare a powder after the fermentation, as mentioned in the statements of Exhibit Otsu B16,

Example 1 cannot be found to produce not less than 8 mg ornithine per gram by dry weight.

In addition, Exhibit Otsu B16, including the statements in A. above, contains no suggestions concerning production of ornithine even in its test examples. Also, according to the results of experiments (Exhibit Ko 15) conducted according to the conditions of Test Example 1 of Exhibit Otsu B16 by using *Lactococcus* 20-92 (FERM BP-10036) and using soy milk as a fermenting material, the production amount of ornithine was less than 8 mg per gram by dry weight.

Therefore, it cannot be said that Difference A4 is an equivalent of descriptions in Exhibit Otsu B16.

(C) Regarding inventive step

When the remaining statements in Exhibit Otsu B16 are examined, they also do not contain statements suggesting that not less than 8 mg ornithine per gram by dry weight is produced by fermenting a fermenting material containing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein (such as soy milk or daidzein-supplemented basal medium) by using *Lactococcus* 20-92 (FERM BP-10036).

Exhibit Otsu B16 contains no statement at all concerning "ornithine" in the first place. Thus, it also cannot be said that Exhibit Otsu B16 Invention would have motivated a person skilled in the art to determine the composition of the fermenting material or the culture conditions and the like for securing more than a specific production amount of ornithine.

Therefore, it cannot be said that a person skilled in the art could have easily conceived of Difference A4 based on Exhibit Otsu B16 Invention.

(D) Regarding the Appellees' allegations

a. The Appellees allege that the amount of ornithine produced in Test Example 1 of Exhibit Otsu B16 is calculated to be 11.4 mg per gram by dry weight of the fermented substance.

The Appellees' allegation is based on the premise that the conversion rate from arginine to ornithine is far higher than 100% (conversion rate: approx. 159%) in [Table 3] of the Description. However, [Table 3] of the Description shows the results of inoculating *Lactococcus* 20-92 strain (FERM BP-10036) to 5 ml of soybean hypocotyl solution containing 10 wt. % of soybean hypocotyl powder and 0.1wt. % of L-arginine, and incubating it anaerobically at 37°C for 96 hours under stationary conditions to be fermented (paragraph [0225] of the Description), whereas in the test example of Exhibit Otsu B16, *Lactococcus* 20-92 (10^7-10^9 cells/g) was incubated in 5 ml of BHI broth (a liquid medium for growth (basal medium)) anaerobically at 37°C for 24 hours and the culture was diluted with the basal medium, after which it was blended with 5 ml each of daidzein-supplemented basal medium (daidzein added to BHI broth at a final concentration of 10 μg/ml), cow's milk

and soy milk and cultured. Therefore, their fermenting material and the fermentation conditions differ. As the dry weight of the fermented substance could vary substantially depending on the fermenting material and the content of solid component in the medium, the amount of ornithine per gram by dry weight would also vary if the fermenting material changes. Therefore, the amount of ornithine produced per gram by dry weight of the fermented substance could vary substantially between a case of using a soybean hypocotyl solution and a case of using soy milk as the fermenting material. In addition, if the culture conditions differ, the conversion rate from arginine to ornithine could also differ.

Accordingly, it cannot be said that it is reasonable to use [Table 3] of the Description as a premise in presuming the amount of ornithine produced in the test example of Exhibit Otsu B16.

b. The Appellees also allege that, in a reproduction experiment of Figure 3(1) of Exhibit Otsu B16 (Exhibit Otsu B56-1), the amount of ornithine produced was 13.7 mg per gram by dry weight of the fermented substance in the case of using "10 mg/L of daidzein," and therefore the amount of ornithine produced in Exhibit Otsu B16 Invention is not less than 8 mg per gram by dry weight of the fermented substance. However, in a reproduction experiment conducted by the Appellant (Exhibit Ko 15), the amount of ornithine produced was less than 8 mg per gram by dry weight of the fermented substance. As this difference may partly be owed to the difference in the amounts of arginine and ornithine contained in the medium before culturing between the two experiments, and as it is not the case where only one of the two experiments has a circumstance that makes the reliability of the experiment doubtful, it can only be said that not less than 8 mg ornithine per gram by dry weight of the fermented substance is not necessarily produced in Exhibit Otsu B16 Invention, as long as the composition of the BHI broth used as a medium is not specified in the test example of Exhibit Otsu B16.

Accordingly, it cannot be said that Exhibit Otsu B16 Invention "produces not less than 8 mg ornithine per gram by dry weight of the fermented substance."

c. The Appellees further allege that it was a well-known fact for a person skilled in the art from before the Priority Date that, when using a lactic acid bacterial strain, a decrease in pH should be prevented by adding arginine so that the growth of the strain would not be hindered, among other reasons. According to evidence (Exhibit Otsu B83), preventing a decrease in pH through adding arginine is found to be based on a mechanism that a lactic acid bacterial strain liberates ornithine and ammonia from arginine, and that the liberation of ammonia increases pH. However, according to evidence (Table 5 of Exhibit Ko 56 ("Classification and Pathogenicity of the Genus *Streptococcus*," *Gyobyō kenkyū* (Fish Pathology), 17(1), 1982, pp. 1-10) and Table 2 of Exhibit Ko 57 (*FEMS Microbiology Letters*, 144, 1996, pp.

135-140)), it cannot be said that a lactic acid bacterial strain always has arginine dihydrolase activity (ADH), in other words, that a lactic acid bacterial strain always liberates ornithine and ammonia from arginine, and hence preventing growth hindrance due to a decrease in pH by adding arginine to a lactic acid bacterial strain generally cannot be found to be common general technical knowledge.

d. The Appellees also allege that there is no need to go so far as to grant an exclusive right to give an incentive for creating a product or method that will sooner or later become available for use by the general public, even if the intentions for its exploitation vary, and therefore there is no need for a person skilled in the art to have been motivated to conceive of exactly the same technical idea as the Corrected Invention, and it is sufficient for a person skilled in the art to have been motivated to conceive of a technology that is objectively regarded to be the same in terms of the product or method.

In the case of determining whether the present invention could have been easily made by applying the secondary cited invention to the primary cited invention, it is reasonable to [i] determine whether there is a motivation to apply the secondary cited invention to the primary cited invention and arrive at the present invention by comprehensively considering the suggestions in the primary cited invention or the secondary cited invention, the relevance in technical field, and the commonality in problem, effect, and function, and [ii] also consider the presence or the absence of factors inhibiting the application as well as the presence or the absence of unexpected significant effects in making the determination (see Intellectual Property High Court, 2016 (Gyo-Ke) 10182, 10184, rendered on April 13, 2018). This principle is also applicable to a case of determining whether the present invention could have been easily made by applying well-known art to a cited invention. On such basis, the involvement of inventive step should be determined based on whether the invention could have been easily conceived of by a person skilled in the art as of the reference date, and when examining the presence or absence of motivation, it cannot be regarded that an uncertain circumstance irrelevant to the technical contents of the invention, such as whether it will sooner or later become available for use by the general public, should affect the determination on whether to protect the invention by granting a patent right.

In addition, even if the Appellees' allegation were to be premised, in the present case where Exhibit Otsu B16 contains no statements or suggestions on ornithine in the first place, it must be said that it also provides no motivation for conceiving of a technology that is objectively regarded to be the same in terms of the product or method. This does not affect the determination that a person skilled in the art could not have easily conceived of Difference A4.

D. Conclusion regarding Grounds for Invalidation 4

Consequently, without having to examine other differences, the Corrected Invention is not found to be an equivalent of descriptions in Exhibit Otsu B16, and a person skilled in the art is also not found to have been able to easily conceive of the Corrected Invention based on Exhibit Otsu B16 Invention.

Due to the above, Grounds for Invalidation 4 alleged by the Appellees are groundless.

(5) Regarding Issue 2-5 (whether Grounds for Invalidation 5 (lack of novelty based on Exhibit Otsu B19-1 and lack of inventive step based on Exhibit Otsu B19-1 as the primary cited invention) exist)

A. Regarding Exhibit Otsu B19 Invention

(A) Exhibit Otsu B19-1 contains the following statements (the Japanese translation is based on Exhibit Otsu B19-2, which can be deemed to be a translation of Exhibit Otsu B19-1; hereinafter, Exhibit Otsu B19-1 as expressed by the statements in Exhibit Otsu B19-2 is simply referred to as "Exhibit Otsu B19").

[0001]

This invention relates to the making and isolating of enantiomeric equol compounds, namely S-equol and R-equol, and foods and medicaments containing enantiomeric equol compounds for treating of disease and conditions in mammals and humans.

[0065]

Biological production of S-equol

S-equol can be produced in bulk, and can be produced in situ in a variety of food products, using conventional food technology. A base solution media, food product or plant extract can be provided that comprises daidzein or another related isoflavone from which daidzein can be derived. The daidzein or other isoflavone can be converted to S-equol by a standard bacterial or enzyme fermentation process, to provide a bulk solution, food product or plant extract that comprises S-equol.

[0066]

The production of S-equol in a food product can be achieved by utilizing the metabolic activity of bacteria growing on the food that contains a satisfactory starting material, such as daidzin, daidzein, formononetin or peurarin, or a conjugate or mixture thereof. As shown in Figure 2, the conversion of daidzein to equol involves three major steps: 1) hydrolysis of any glucoside conjugate group, 2) conversion of the isoflavone aglycons to a dihydro-intermediate, and 3) conversion of the dihydro-intermediate to equol. The metabolic pathway and enzymes for each of the three steps required/ may not necessarily be present in one bacterium. Anecdotal evidence from human studies suggests that there may be one or more bacteria that act in conjunction to perform these reactions, as evidenced from the fact that often dihydrodaidzein can be present in significant amounts in plasma and urine yet equol

may be low or barely detectable. Although equol may be produced from daidzein by a single organism it is believed that better or more efficient conversion can be achieved when using a mixture of bacterial species, each with its own metabolic profile. Important conditions for effective conversion to S-equol include the selection of the bacterial organism or mixture of organisms, the temperature of incubation, and the amount of oxygen available to the organisms. These conditions can be optimized by techniques well known to persons skilled in this art. The organisms used to effect this change can be inactivated by standard techniques used in the food industry or, alternately, allowed to remain in an active state in the product.
[0067]

Bacteria useful in a fermentation process to convert daidzein and/or other structurally related isoflavones, or an intermediate compound, to S-equol, can include a bacterial strain or bacterial strains found to colonize the intestinal tract of a human, horse, rodent, or other mammal that is an 'equol producer'. Since intestinal bacteria in mammals are found in feces, the equol-producing bacteria can also be found in the feces of 'equol producing' mammals.
[0068]

Typical bacteria useful in a fermentation process should demonstrate an optimized conversion rate and extent of conversion that makes the biological production of equol efficient.
[0069]

Typically, one or more bacterial strains are required to convert the daidzein (or other related isoflavone) through intermediate products to S-equol, which generally involves one or more of the three major reactions: the conversion of isoflavone glycone to aglycon isoflavone; the conversion of aglycon isoflavone to dihydro isoflavone; and the conversion of dihydro isoflavone to the product, equol. For example, a mixed culture of organisms isolated from equine feces and a mixed culture of organisms derived from the gastrointestinal tract of a person known to [be] an 'equol producer' can convert, as they do in vivo, the glycone daidzein to the final product, S-equol.
[0070]

Typical bacterial strains that can convert a glycone to an aglycon (such as daidzin to daidzein) include *Enterococcus faecalis*, *Lactobacillus plantarum*, *Listeria welshimeri*, a mixed culture of organisms isolated from the intestinal tract of an 'equol producing' mammal, *Bacteriodes fragilis*, *Bifidobacterium lactis*, *Eubactria limosum*, *Lactobacillus casei*, *Lactobacillus acidophilous*, *Lactobacillus delbrueckii*, *Lactobacillus paracasei*, *Listeria monocytogenes*, *Micrococcus luteus*, *Proprionobacterium freudenreichii* and *Sacharomyces boulardii*, and mixtures thereof.
[0071]

Typical bacterial strains that can convert an aglycon to equol (such as daidzein to S-equol) include *Proprionobacteria freundenreichii*, a mixed culture containing: [*sic*] *Bifidobacterium lactis*, *Lactobacillus acidophilus*, *Lactococcus lactis*, *Enterococcus faecium*, *Lactobacillus casei* and *Lactobacillus salivarius*; and a mixed culture of organisms isolated from the intestinal tract of an 'equol producing' mammal.

[Example 5]

[0152]

Bacterial Conversion of Daidzein to Equol in Food

In an experiment to discover bacteria, or combinations of bacteria, that can metabolise daidzein in a reducing environment, samples of a daidzein-enriched soy milk containing approximately 20 mg/L of daidzein were inoculated with different bacteria either in pure culture or as a combination of several organisms. The inoculated soy milks were incubated anaerobically at 37°C for up to 42 hours[.] Samples were withdrawn at intervals throughout the time period of the experiment and analyzed for isoflavone content, in particular the daidzein content. Conversion of daidzein to equol would be accompanied by lowering of the level of daidzein in the product over time, with the hydrogenated product, equol, taking its place. No significant changes in isoflavone content, outside of the daidzein level, were found in any of the inoculated products, which effectively demonstrates the stability of isoflavones (including daidzein when suitable metabolizing bacteria are absent or inactive). The results are shown in Table D. Of seven different innocula studied, four showed no change in daidzein content during the full incubation period. Three of the inoculated samples demonstrated substantial lowering of the level of daidzein with corresponding conversion to the hydrogenated compound. The organisms effecting this change were *Proprionobacteria freundenreichii*, a mixed culture containing: *Bifidobacterium lactis*, *Lactobacillus acidophilus*, *Lactococcus lactis*, *Enterococcus faecium*, *Lactobacillus casei* and *Lactobacillus salivarius*; and a mixed culture isolated from equine feces. Daidzein loss to approximately 50% of the initial level occurred in less than 15 hours with the equine feces mixed culture and took up to 25 hours with the other two cultures[.]

[0153]

[Table 4]

Table D

Conversion of Daidzein During Growth of
Various Microorganisms in a Food Base
(Incubation at 37°C under Anaerobic Conditions)

Bacterial species / strain	Time required to

	metabolize 50% of the daidzein present
Uninoculated Food medium	Not metabolized
Propionobacterium acnes	Not metabolized
Propionobacterium freundenreichii	25 hours
Lactobacillus fermentum	Not metabolized
Mixed culture from equine feces	15 hours
Mixed culture containing: *Bifidobacterium lactis*, *Lactobacillus acidophilus*, *Lactococcus lactis*, *Enterococcus faecium*, *Lactobacillus casei* and *Lactobacillus salivarius*	25 hours
Lactobacillus salivarius	Not metabolized
Bacterioides vulgatus	Not metabolized

(B) Finding of Exhibit Otsu B19 Invention

As mentioned in (A) above, [Example 5] in Exhibit Otsu B19 states that equol was produced as a result of inoculating "a daidzein-enriched soy milk containing daidzein" with "a mixed culture containing: *Bifidobacterium lactis*, *Lactobacillus acidophilus*, *Lactococcus lactis*, *Enterococcus faecium*, *Lactobacillus casei* and *Lactobacillus salivarius*" and incubating it.

Therefore, the following Exhibit Otsu B19 Invention is found to be stated in Exhibit Otsu B19.

"A method for producing a fermented substance containing equol, comprising the step to ferment a daidzein-enriched soy milk containing daidzein by using a "mixed culture" containing *Bifidobacterium lactis*, *Lactobacillus acidophilus*, *Lactococcus lactis*, *Enterococcus faecium*, *Lactobacillus casei* and *Lactobacillus salivarius*," which are microorganisms having the ability to produce equol."

B. Comparison between the Corrected Invention and Exhibit Otsu B19 Invention

When the Corrected Invention stated on p. 5, lines 13 to 20 of the judgment in prior instance cited in No. 2, 3. above and Exhibit Otsu B19 Invention referred to in A.(B) above are compared, the Corrected Invention and Exhibit Otsu B19 Invention are found to have commonalities in that they are "a method for producing a fermented substance containing equol, comprising the step to ferment a fermenting material containing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein by using a microorganism having the ability to produce equol," and differ in the following respects.

(Difference B1) The Corrected Invention specifies that the microorganism "has the ability to produce ornithine," whereas Exhibit Otsu B19 Invention specifies that the microorganism includes "*Lactococcus lactis*," but does not specify that the microorganism "has the ability to produce ornithine."
(Difference B2) The Corrected Invention specifies that arginine is added to "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" and that the fermenting material containing the daidzein compound and arginine is fermented, whereas Exhibit Otsu B19 Invention specifies that the fermenting material is a daidzein-supplemented basal medium or the like, including soy milk, but does not specify that the fermenting material contains arginine as a result of adding arginine to the daidzein compound.
(Difference B3) The Corrected Invention specified that a fermented substance containing ornithine is produced, whereas Exhibit Otsu B19 Invention does not specify this point.
(Difference B4) The Corrected Invention specifies that not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight are produced by fermentation, whereas Exhibit Otsu B19 Invention does not specify this point.
(Difference B5) The Corrected Invention specifies that the fermented substance produced is powder and that it is used as a food material, whereas Exhibit Otsu B19 Invention does not specify this point.
C. Regarding Difference B1

Difference B1 (the Corrected Invention specifies that the microorganism "has the ability to produce ornithine," whereas Exhibit Otsu B19 Invention specifies that the microorganism includes "*Lactococcus lactis*," but does not specify that the microorganism "has the ability to produce ornithine") is examined below.
(A) Exhibit Otsu B19 discloses a "mixed culture" of "*Bifidobacterium lactis*, *Lactobacillus acidophilus*, *Lactococcus lactis*, *Enterococcus faecium*, *Lactobacillus casei* and *Lactobacillus salivarius*" as microorganisms having "the ability to produce equol," but it does not state that any of these microorganisms has the ability to produce ornithine.

Regarding this point, the Appellees allege that it was common general technical knowledge that "*Lactococcus lactis*" has "the ability to produce ornithine" whereby it produces ornithine by metabolizing arginine via the arginine deiminase pathway. While *Lactococcus lactis* used to be called *Streptococcus lactis* (or *lactis*) in the past (Exhibit Otsu B21), Exhibit Otsu B20 (*Journal of Bacteriology*, vol. 150, no.3, 1982, pp. 1024-1032) states "*Streptococcus lactis* metabolizes arginine via the arginine deiminase pathway, producing ornithine, ammonia, carbon dioxide, and ATP." Meanwhile, Exhibit Otsu B78 (*Journal of Daily Research*, vol.65, 1998, pp.101-107) states "Increased activity of the arginine

deiminase pathway during late log phase was inferred from increased utilization of Arg and liberation of citrulline and ornithine."

However, as shown in Table 5 of Exhibit Ko 56, *Streptococcus lactis* includes strains that have the arginine deiminase pathway activity and those that do not (YIT-2003 is ADH+, but M-29C is ADH−). Therefore, a *Streptococcus lactis* strain is not immediately found to have the ability to produce ornithine.

Accordingly, it must be said that whether *Lactococcus lactis* in Exhibit Otsu B19 is a microorganism having the ability to produce ornithine is unclear. With regard to the other microorganisms in Exhibit Otsu B19 Invention as well, Exhibit Otsu B19 does not state that they have the ability to produce ornithine, and there is no sufficient evidence to find that there was such common general technical knowledge as of the Priority Date.

Consequently, it cannot be said that Difference B1 is an equivalent of descriptions in Exhibit Otsu B19.

(B) As mentioned in (A) above, while Difference B1 is a substantive difference, a person skilled in the art, as of the Priority Date, would have been unable to derive from statements in Exhibit Otsu B19 that any of the microorganisms stated in Exhibit Otsu B19 has the ability to produce ornithine.

Moreover, Exhibit Otsu B19 Invention is an invention relating to the making and isolating of enantiomeric equol compounds, namely S-equol and R-equol, and foods and medicaments containing enantiomeric equol compounds for treating of disease and conditions in mammals and humans (paragraph [0001] of Exhibit Otsu B19), and Exhibit Otsu B19 contains no statement at all about ornithine, and also contains no statements suggesting production of ornithine, such as obtaining a fermented substance containing equol and ornithine by using a microorganism having the ability to produce ornithine and the ability to produce equol.

Accordingly, it cannot be said that a person skilled in the art could have easily conceived of Difference B1 from Exhibit Otsu B19 Invention as of the Priority Date.

D. Conclusion regarding Grounds for Invalidation 5

Consequently, without having to examine other differences, a person skilled in the art is also not found to have been able to easily conceive of the Corrected Invention based on Exhibit Otsu B19 Invention, and hence a person skilled in the art is not found to have been able to easily make the Corrected Invention based on the invention stated in Exhibit Otsu B19 and well-known art.

Due to the above, Grounds for Invalidation 5 alleged by the Appellees are groundless.

(6) Regarding Issue 2-6 (whether Grounds for Invalidation 6 (lack of novelty based on Exhibit Otsu B24 and lack of inventive step based on Exhibit Otsu B24 as the primary cited

invention) exist)

A. Regarding Exhibit Otsu B24 Invention

(A) The description of Exhibit Otsu B24 (the third sheet onward of Exhibit Otsu B24; hereinafter referred to as "Exhibit Otsu B24 Description") contains the following statements.

"Based on the above findings the inventors did further research and, as a result, succeeded in the development of a novel composition which comprises a strain of microorganism having the ability (metabolic activity) to elaborate equol by metabolizing daidzein and either daidzein or a suitable substance containing daidzein in combination, and a novel composition which comprises equol obtained by causing said strain of microorganism to metabolize daidzein. The inventors then discovered that the intake of whichever of the above compositions is effective in the prevention and alleviation of unidentified clinical syndrome in middle-aged and older women and have accordingly developed the instant invention." (page 6, line 18 to page 7, line 4)

"The present invention in a second aspect provides a composition, in the form of a food or a pharmaceutical product, which comprises equol which is obtained by causing a strain of microorganism capable of metabolizing daidzein to equol to act upon a daidzein-containing substance (this composition will hereinafter be referred to as 'equol-containing composition')." (page 7, lines 11 to 15)

"(3) *Streptococcus* A6G-225 (FERM BP-6437)

I. Cultural Characteristics

(omitted)

II. Physiological Characteristics

(omitted)

The above morphological and biochemical characteristics, sugar fermentation test and organic acid production spectrum suggest that this strain belongs to the gram-positive *Streptococcus intermedius* but the strain differentiates itself from the type culture strain of *S. intermedius* in the ability to utilize L-rhamnose and D-trehalose. Therefore, the inventors named the strain *Streptococcus* A6G-225 and deposited it with National Institute of Bioscience and Human Technology (NIBH, Higashi 1-1-3, Tsukuba-shi, Ibaraki, Japan) as of July 7, 1997, with the accession number of FERM P-16314 assigned. This deposit was subsequently converted to a Budapest deposit as of July 22, 1998 and assigned with the accession number of FERM BP-6437." (page 19, line 7 to page 23, line 5)

"The equol-containing composition of the invention can be produced by culturing said strain of microorganism according to conventional fermentation technology utilizing said daidzein-containing substance, preferably soybean isoflavone or a food material containing it, as the substrate.

More particularly, the technology comprises sterilizing the substrate in solution form, adding the predetermined strain of microorganism thereto, and incubating the mixture at 37°C either under anaerobic conditions or under aerobic stationary conditions for about 48-96 hours to let fermentation proceed. (Where necessary, a pH control agent, a reducing substance (e.g. a yeast extract, vitamin K_1) can be added.)

Taking *Streptococcus intermedius* as an example, the above cultural process can be more preferably carried out as follows. First, daidzein is dissolved in the range of 0.01-0.5 mg/ml in Modified GAM (Modified Gifu Anaerobic Medium) for culture of anaerobic bacteria. A seed culture prepared by growing the microorganism in Modified GAM for about 14 hours is then inoculated into the above daidzein-containing Modified GAM. The inoculum size may be 1/100 by volume of the medium. The incubated medium is incubated aerobically at 37°C under stationary conditions for 48-96 hours.

The present invention further provides a method for producing equol utilizing such a strain of microorganism.

In the above fermentation system, there may be incorporated a nutrient which is particularly suited for the maintenance and growth of the microorganism. The nutrient includes oligosaccharides such as galactosyl-sucrose, soybean-oligosaccharide, lactulose, lactitol, fructo-oligosaccharide, and galacto-oligosaccharide. The amount of said nutrient is not particularly restricted but is preferably selected from the range of generally about 1-3 wt. % based on the total composition of the invention.

The desired equol-containing culture broth can thus be obtained." (page 27, line 21 to page 29, line 7)

"The equol-containing composition of the invention can be produced, in a suitable food form or pharmaceutical dosage form, by formulating the equol-containing culture broth prepared as above or equol isolated therefrom with other optional food materials.

The food form includes drinks, milk products, fermented milk, bars, granules, powders, capsules, and tablets." (page 29, lines 13 to 19)

"Example 3 Preparation of a Fermented Soy Milk Lyophilizate

Using 1 ml of a suspension of about 10^7 cells/ml of *Streptococcus* A6G-225 (FERM BP-6437), 100 g of soy milk was caused to undergo lactic acid fermentation at 37°C for 24 hours to provide equol. This product was lyophilized. The equol content of this freeze-dried powder was 0.1-0.3 wt. %.

The above powder and other ingredients according to the following recipe were weighed and blended to provide the composition of the invention in the form of a fermented soy milk lyophilizate.

Fermented soy milk lyophilizate	2.2 g
Excipient	q.s.
Vitamins & minerals	q.s.
Flavor	q.s.
Total	20 g

As the excipient, 17 g of corn starch was used." (page 32, lines 7 to 20)

(B) Finding of Exhibit Otsu B24 Invention

As mentioned in (A) above, Exhibit Otsu B24 states the following: the invention "provides a composition, in the form of a food or a pharmaceutical product, which comprises equol which is obtained by causing a strain of microorganism capable of metabolizing daidzein to equol to act upon a daidzein-containing substance (this composition will hereinafter be referred to as 'equol-containing composition')" (page 7, lines 11 to 15 of Exhibit Otsu B24 Description); the abovementioned microorganism is preferably cultured by using "Modified GAM" (page 27, line 21 to page 29, line 7); the food form includes "drinks, milk products, fermented milk, bars, granules, powders, capsules, and tablets" (page 29, lines 13 to 19); and in Example 3, when "soy milk" was caused to undergo lactic acid fermentation by using "*Streptococcus* A6G-225 (FERM BP-6437)" to "provide equol," and the product "was lyophilized," "the equol content of this freeze-dried powder was 0.1-0.3 wt. %," that is, 1-3 mg per gram by dry weight (page 32, lines 7 to 20).

According to the statements above, the following Exhibit Otsu B24 Invention is found to be stated in Exhibit Otsu B24.

"A method for producing a fermented powder containing equol, comprising the step to ferment a fermenting material containing daidzein, such as soy milk, as the substrate in Modified GAM by using *Streptococcus intermedius*, particularly *Streptococcus* A6G-225 (FERM BP-6437), which is a microorganism having the ability to produce equol, wherein 1-3 mg equol is produced per gram by dry weight of the fermented powder, and said fermented substance is used in a food form including drinks, milk products, fermented milk, bars, granules, powders, capsules, and tablets."

B. Comparison between the Corrected Invention and Exhibit Otsu B24 Invention

When the Corrected Invention stated on p. 5, lines 13 to 20 of the judgment in prior instance cited in No. 2, 3. above and Exhibit Otsu B24 Invention referred to in A.(B) above are compared, the Corrected Invention and Exhibit Otsu B24 Invention are found to have commonalities in that they are "a method for producing a fermented powder containing equol, comprising the step to ferment a fermenting material containing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and

dihydrodaidzein by using a microorganism having the ability to produce equol, wherein said fermented substance is used as a food material," and differ in the following respects.
(Difference C1) The Corrected Invention specifies that the microorganism "has the ability to produce ornithine," whereas Exhibit Otsu B24 Invention specifies that the microorganism is "*Streptococcus intermedius*, particularly *Streptococcus* A6G-225 (FERM BP-6437)," but does not specify that the microorganism "has the ability to produce ornithine."
(Difference C2) The Corrected Invention specifies that arginine is added to "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" and that the fermenting material containing the daidzein compound and arginine is fermented, whereas Exhibit Otsu B24 Invention specifies that the fermentation is carried out in Modified GAM, but does not specify that the fermenting material contains arginine as a result of adding arginine to the daidzein compound.
(Difference C3) The Corrected Invention specifies that a fermented substance containing ornithine is produced, whereas Exhibit Otsu B24 Invention does not specify this point.
(Difference C4) The Corrected Invention specifies that not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight are produced by fermentation, whereas Exhibit Otsu B24 Invention does not specify this point.
C. Regarding Difference C4

In light of the counsel's arguments, Difference C4 (the Corrected Invention specifies that not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight are produced by fermentation, whereas Exhibit Otsu B24 Invention does not specify this point) is examined below.
(A) Regarding novelty

Exhibit Otsu B24 Invention uses *Streptococcus* A6G-225 (FERM BP-6437), which is a microorganism stated in paragraph [0032] of the Description, but Exhibit Otsu B24 contains no statements about the fact that ornithine can be obtained by fermentation using that microorganism and the amount of the ornithine produced.

The Appellees allege that Difference C4 is an equivalent of descriptions in Exhibit Otsu B24, as the amount of ornithine per gram by dry weight of the fermented substance obtained by performing a culture by using *Streptococcus* A6G-225 (FERM BP-6437) disclosed in Exhibit Otsu B24 and Modified GAM is 25.4 mg. However, the Appellees have calculated the above amount of ornithine on the premise that the main culture is performed by using daidzein as the fermenting material and also using Modified GAM, and that 100% of the arginine in the medium is converted into ornithine, whereas in Exhibit Otsu B24, a culture using *Streptococcus* A6G-225 (FERM BP-6437) is stated as Example 3, on which Exhibit Otsu B24 Invention is premised (page 32, lines 7 to 20 of the description of Exhibit Otsu

B24). In this example, using 1 ml of a suspension of about 10^7 cells/ml of *Streptococcus* A6G-225 (FERM BP-6437), 100 g of soy milk was caused to undergo lactic acid fermentation at 37°C for 24 hours to provide equol, which was then lyophilized to obtain a powder. As the example does not use daidzein as a fermenting material, and also does not use Modified GAM for the main culture, the Appellees' calculation above is premised on conditions that differ from those of the example. Even if it is supposed that, in the example, Modified GAM was used for the culture, 1 ml of *Streptococcus* A6G-225 including the Modified GAM and 100g of soy milk were fermented, and arginine contained in the Modified GAM used for the culture was converted to produce ornithine, considering the small amount of ornithine derived from the Modified GAM used for the culture as compared to the amount of soy milk, and the amount of the soy milk-derived solid matter contained in the dried powder, it cannot be found, based on the Appellees' calculation above which premises conditions, including the fermenting material and the medium, that differ from those of the example, that not less than 8 mg of ornithine per gram by dry weight of the fermented substance would be produced in the example.

According to the results of the experiment allegedly conducted by the Appellant based on Example 3 of Exhibit Otsu B24 (the experiment report of Exhibit Ko 60; however, the experiment uses a mixture of soy milk and Modified GAM broth for the main culture, so the medium for the main culture differs from that of Example 3), ornithine was found to be produced, but as the production amount was approximately 0.15-0.16 mg per gram by dry weight, it cannot be found that not less than 8 mg ornithine is produced per gram by dry weight in Example 3.

Exhibit Otsu B24 also contains statements that, using *Streptococcus intermedius*, daidzein is dissolved in the range of 0.01-0.5 mg/ml in Modified GAM, and a seed culture prepared by growing the microorganism in Modified GAM for about 14 hours is then inoculated into the daidzein-containing Modified GAM to be incubated aerobically at 37°C under stationary conditions for 48-96 hours (page 27, line 21 to page 29, line 7), but in this culture method, the conversion rate from arginine to ornithine and the specific culture conditions are not necessarily clear, and the conditions cannot be regarded to comply with the conditions premised in the Appellees' calculation above. Therefore, it cannot be said, based on these statements, that Exhibit Otsu B24 contains a statement that not less than 8 mg ornithine is produced per gram by dry weight by this culture method.

Accordingly, it cannot be said that Difference C4 is an equivalent of descriptions in Exhibit Otsu B24.

(B) Regarding inventive step

According to (A) above, Exhibit Otsu B24 contains no descriptions (or equivalents of

descriptions) that not less than 8 mg ornithine is produced per gram by dry weight by fermentation. Also, given that Exhibit Otsu B24 Invention provides a composition which comprises equol which is obtained by causing a strain of microorganism capable of metabolizing daidzein to equol to act upon a daidzein-containing substance (page 7, lines 11 to 15 of Exhibit Otsu B24 Description) and that Exhibit Otsu B24 contains no statement at all and no suggestions about ornithine, it cannot be said that a person skilled in the art could have conceived of changing the culture conditions, etc. in Exhibit Otsu B24 Invention so as to produce not less than 8 mg ornithine per gram by dry weight of the fermented substance.

Accordingly, it cannot be said that a person skilled in the art could have easily conceived of Difference C4 based on Exhibit Otsu B24 Invention.

D. Conclusion regarding Grounds for Invalidation 6

Consequently, without having to examine other differences, the Corrected Invention is not found to be an equivalent of descriptions in Exhibit Otsu B24, and a person skilled in the art is also not found to have been able to easily conceive of the Corrected Invention based on Exhibit Otsu B24 Invention.

Due to the above, Grounds for Invalidation 6 alleged by the Appellees are groundless.

(7) Regarding Issue 2-7 (whether Grounds for Invalidation 7 (lack of novelty and inventive step based on Exhibit Otsu B2 on the premise that the patent application for the Patent violates the requirements for division of application) exist)

A. The Appellees allege that none of [1] the composition of using "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" as a fermenting material, [2] the composition of "adding arginine," and [3] the composition of producing "not less than 8 mg ornithine per gram by dry weight of the fermented substance" adopted in the Corrected Invention is stated in the Original Description, which is the description, etc. originally attached to the application immediately before filing the divisional application, and that therefore the requirement to "divide a patent application containing two or more inventions into one or more new patent application" under Article 44, paragraph (1) of the Patent Act is not satisfied. Therefore, whether the compositions [1] through [3] of the Corrected Invention fall within the scope of the matters stated in the Original Description is examined below.

B. The Original Description (Exhibit Otsu B47) contains the following statements.

[0036]

Further, if necessary, some additives may be added to the soybean hypocotyl as the raw material in the fermentation to improve the fermentation efficiency or flavor of the product. Examples of the additives include nitrogen sources such as a yeast extract, polypeptone, or a meat extract; carbon sources such as glucose or sucrose; inorganic salts such as phosphate,

carbonate or hydrosulfate; vitamins; and nutritional components such as amino acid. Particularly, when using an equol-producing microorganism for converting arginine into ornithine (hereinafter referred to as an "ornithine/equol-producing microorganism"), arginine is added to the soybean hypocotyl before fermentation so that the fermented substance contains ornithine. In this case, the amount of arginine is, for example, about 0.5 to 3 parts by weight, based on 100 parts by weight (dry weight) of the soybean hypocotyl. The ornithine/equol-producing microorganism may be obtained by a publicly-known screening method using an index of the equol-producing ability and the conversion ability from arginine into ornithine. The ornithine/equol-producing microorganism may be selected from the group of *Lactococcus garvieae*, typified by *Lactococcus* 20-92 (FERM BP-10036).
[0050]

Further, as described above, ornithine is contained in the equol-containing fermented soybean hypocotyl produced from fermentation with an ornithine/equol-producing microorganism after adding arginine to a soybean hypocotyl. The ornithine content of the equol-containing fermented soybean hypocotyl is 5 to 20 mg, preferably 8 to 15 mg, and more preferably 9 to 12 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl.
[0091]

The equol-containing fermented substance was produced through a publicly-known fermentation method using an equol-producing microorganism. More specifically, a microorganism with the ability (metabolic activity) to produce equol by metabolizing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein, is inoculated in a fermenting material (material to be subjected to the fermentation) containing the daidzein. The sample is then fermented (cultured) under the conditions suitable to grow the microorganism. The resulting fermented substance contains equol.
[0093]

The fermenting material containing daidzein compounds is not limited by other factors as long as it contains daidzein compounds; however, the material is preferably approved for its safety as a food material. Examples of the fermenting material containing daidzein compounds include soybeans, a soybean hypocotyl, a soybean hypocotyl extract, tofu, deep-fried tofu, soy milk, fermented soybeans, soy sauce, bean paste, a tempeh, and a red clove or its extract, alfalfa or its extract. A suitable fermenting material containing daidzein compounds is a soybean hypocotyl because of its high daidzein content.
[0226]

The respective components of the soybean hypocotyl powder ("Pre-fermentation" in

Table 2 and Table 3) and of the fermented soybean hypocotyl powder ("Post-fermentation" in Table 2 and Table 3) were analyzed. Table 2 shows an analysis regarding soybean isoflavones, and Table 3 shows an analysis regarding nutritional components. These tables show that the fermented soybean hypocotyl obtained by the fermentation of a soybean hypocotyl using a *Lactococcus* 20-92 strain has a high equol content. Further, oligosaccharide content for such oligosaccharides as raffinose or stachyose remains substantially the same after fermentation, which indicates that the fermentation did not influence the oligosaccharide content. Meanwhile, the tables show that arginine was converted into ornithine by the fermentation. Accordingly, by adding arginine to the soybean hypocotyl before fermentation using a *Lactococcus* 20-92 strain, the resulting fermented substance contains not only equol but also ornithine.

[0228]

[Table 3]

Nutritional Components — Per 100 g

Component	Pre-fermentation	Post-fermentation
Moisture	3.2 g	6.2 g
Protein	38.1 g	38.3 g
Fat	13.0 g	14.5 g
Ash	4.3 g	4.0 g
Saccharide	30.9 g	26.8 g
Dietary Fiber	10.5 g	10.2 g
Energy	414 kcal	411 kcal
Sucrose	7.95 g	7.42 g
Raffinose	1.37 g	1.34 g
Stachyose	9.04 g	8.38 g
Trans Fatty Acids	N.D.	N.D.
Phospholipids (as stearo-oleo-lecithin)	3.33 g	2.92 g
Free Arginine	881 mg	12 mg
Free Ornithine	N.D.	1.06 g
Soyasapogenol A	N.D.	N.D.
Soyasapogenol B	N.D.	N.D.
Soybean Saponin	3.6 g	3.8 g

N.D. refers to "Not Detected."

C. With regard to [1] the composition of using "at least one daidzein compound selected

from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" as a fermenting material, as mentioned in B. above, paragraph [0091] of the Original Description states "a microorganism with the ability (metabolic activity) to produce equol by metabolizing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein," and paragraph [0093] of the description states "The fermenting material containing daidzein compounds is not limited by other factors as long as it contains daidzein compounds." Therefore, the composition of using "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" as a fermenting material is regarded to be stated in the Original Description. Accordingly, the composition [1] above is found to fall within the scope of the matters stated in the Original Description.

D. Regarding [2] the composition of "adding arginine"

As mentioned in B. above, paragraph [0036] of the Original Description states "Particularly, when using an equol-producing microorganism for converting arginine into ornithine (hereinafter referred to as an "ornithine/equol-producing microorganism"), arginine is added to the soybean hypocotyl before fermentation so that the fermented substance contains ornithine," and paragraph [0226] of the description states "by adding arginine to the soybean hypocotyl before fermentation using a *Lactococcus* 20-92 strain, the resulting fermented substance contains not only equol but also ornithine." Based on these statements, it can be said that a step to add arginine to the fermenting material is stated in the Original Description. Accordingly, the composition [2] above is found to fall within the scope of the matters stated in the Original Description.

E. Regarding [3] the composition of producing "not less than 8 mg ornithine per gram by dry weight of the fermented substance"

As mentioned in B. above, paragraph [0050] of the Original Description states "The ornithine content of the equol-containing fermented soybean hypocotyl is 5 to 20 mg, preferably 8 to 15 mg, and more preferably 9 to 12 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl," indicating that 8 to 15 mg ornithine per gram by dry weight of the fermented substance should preferably be contained, and the composition [3] above can be regarded to have been specified by the lower limit value of "8 to 15 mg" that was given as an example in the Original Description.

Furthermore, paragraph [0093] of the Original Description states "The fermenting material containing daidzein compounds is not limited by other factors as long as it contains daidzein compounds; however, the material is preferably approved for its safety as a food material" and "A suitable fermenting material containing daidzein compounds is a soybean hypocotyl because of its high daidzein content." While a soybean hypocotyl is found to

constitute an example of a "material containing daidzein compounds" based on these statements, paragraph [0050] above is construed to state the ornithine content in the case of using a "soybean hypocotyl," which is an example of a "material containing daidzein compounds."

Accordingly, it can be said that the composition [3] above falls within the scope of the matters stated in the Original Description.

F. Conclusion regarding Grounds for Invalidation 7

Consequently, all of the compositions [1] through [3] fall within the matters stated in the Original Description. As the statements in B. above all coincide with the respective statements in paragraphs [0034], [0048], [0089], [0091], [0224] and [0226], and [Table 3] of [detailed description of the invention] in the domestic re-publication of PCT international publication for the Original Application (Exhibit Otsu B2), the compositions [1] through [3] are regarded to fall within the scope of the matters stated in the description, etc. of the Original Application, and further, they are presumed to fall within the scope of the matters stated in the respective descriptions of Patent Application No. 2013-108439 filed as a divisional application for a part of the Original Application, and Patent Application No. 2016-156372 further filed as a divisional application for a part thereof. As the Application is found to have been lawfully filed as a divisional application, it is deemed to have been filed on June 13, 2008, which is the filing date the Original Application.

Meanwhile, Exhibit Otsu B2 is a document that was internationally published on December 18, 2008, which is after the abovementioned filing date. Therefore, the Corrected Invention cannot be held to be in violation of the novelty and inventive step requirements based on Exhibit Otsu B2.

Due to the above, Grounds for Invalidation 7 alleged by the Appellees are groundless.

(8) Regarding Issue 2-8 (whether Grounds for Invalidation 8 (the Description violating the requirement under the delegated ministerial order) exist)

A. Regarding the requirement under the delegated ministerial order

While Article 24-2 of the Regulation for Enforcement of the Patent Act as delegated by Article 36, paragraph (4), item (i) of the Patent Act provides that statements in the detailed description of the invention "must be made by stating the matters necessary for a person with ordinary skill in the art of the invention to understand the technical meaning of the invention, such as the problem to be solved by the invention and the means for solving the problem," the Appellees allege that the Corrected Invention violates this requirement under the delegated ministerial order on the basis that it is unclear from the Description what kind of problem was solved by the Corrected Invention using ornithine and how, and that the problems and effects for overcoming the numerical limitation of "not less than 8 mg

ornithine" "per gram by dry weight of the fermented substance" are not stated in the Description, and hence a person skilled in the art could not have recognized the problem to be solved by the Corrected Invention and the means for solving the problem.

B. Regarding statements in the Description

As mentioned in 1.(1) above, paragraph [0226] of the Description states that analysis results "show that arginine was converted into ornithine by the fermentation. Accordingly, by adding arginine to the soybean hypocotyl before fermentation using a *Lactococcus* 20-92 strain, the resulting fermented substance contains not only equol but also ornithine." In addition, paragraph [0228] and [Table 3] also indicate that ornithine is produced from arginine by fermentation. Moreover, paragraph [0050] states that, in the case of using a "soybean hypocotyl," which is an example of a "material containing daidzein compounds," the ornithine content is "5 to 20 mg, preferably 8 to 15 mg, and more preferably 9 to 12 mg, per gram (dry weight) of the equol-containing fermented soybean hypocotyl." Thus, a person skilled in the art could have understood that the Corrected Invention adopted the lower limit of this preferable amount range.

According to the above, a person skilled in the art could have understood that the technical meaning of the Corrected Invention was in clarifying that not only equol, but also ornithine can be produced by performing fermentation by using a *Lactococcus* 20-92 strain and in providing a method for producing a fermented substance containing equol and ornithine (the ornithine content is not less than 8 mg per gram by dry weight), and that the Corrected Invention solved these by performing fermentation. Therefore, it can be said that the detailed description of the invention of the Description states the matters necessary for a person skilled in the art to understand the technical meaning of the invention.

C. Regarding the Appellees' allegation

The Appellees indicate that paragraph [0010] of [Problem to be Solved by the Invention] in the Description contains no statement about ornithine. However, because Article 24-2 of the Regulation for Enforcement of the Patent Act is a provision concerning "statements in the detailed description of the invention" as mentioned above, it is sufficient for a person skilled in the art to be able to understand the technical meaning of the invention from the entire statements of the Description, and the matters necessary for understanding the technical meaning of the invention do not necessarily need to be stated in the "problem to be solved by the invention" section.

D. Conclusion regarding Grounds for Invalidation 8

Accordingly, it can be said that the Description satisfies the requirement under the Order of the Ministry of Economy, Trade and Industry as delegated under Article 36, paragraph (4), item (i) of the Patent Act (Article 24-2 of the Regulation for Enforcement of the Patent Act).

Due to the above, Grounds for Invalidation 8 alleged by the Appellees are groundless.

(9) Regarding Issue 2-10 (whether Grounds for Invalidation 10 (the second sentence of Article 39, paragraph (2) of the Patent Act) exist)

A. Regarding Divisional Inventions 1 and 4

The Appellant filed a divisional application from Patent Application No. 2018-147514 on March 8, 2021 (Patent Application No. 2021-36323; the Basic Applications on which the priority claim is based are the same as those of the Patent), and the application was registered as Patent No. 6892972 (the number of claims: 6) on June 1, 2021. Claims 1 and 4 of the claims of that patent contain the following statements. (Exhibit Otsu B88)

[Claim 1]

A method for producing a fermented substance containing ornithine and equol,

comprising a step to ferment daidzein compounds and arginine by using a microorganism having the ability to produce ornithine and the ability to produce equol,

wherein said fermented substance contains not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight thereof,

and wherein said daidzein compounds comprise at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein.

[Claim 4]

The production method stated in any of Claims 1 through 3, wherein said fermented substance is used as a food material.

B. Comparison between the Corrected Invention and Divisional Invention 4

When the Corrected Invention and the invention stated in Claim 4 of the claims of the abovementioned patent (Divisional Invention 4) are compared, they are found to have commonalities in that they are "a method for producing a fermented substance containing ornithine and equol, comprising the step to ferment a fermenting material containing at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein and arginine by using a microorganism having the ability to produce ornithine and the ability to produce equol, wherein not less than 8 mg ornithine and not less than 1 mg equol per gram by dry weight are produced by the fermentation and said fermented substance is used as a food material," and differ in the following respects.

(Difference E1) The Corrected Invention specifies a step to "add arginine to at least one daidzein compound," whereas Divisional Invention 4 has no such specification.

(Difference E2) The Corrected Invention specifies the product to be "fermented powder," whereas Divisional Invention 4 has no such specification.

C. Regarding Difference E1

Generally, if applications are respectively filed for two inventions on the same date, and

if the difference of either invention from the other constitutes an addition, deletion, or replacement of well-known or commonly used art to prior art, and it does not produce any new effect, the two inventions constitute the "identical inventions" referred to in Article 39, paragraph (2) of the Patent Act.

When this point is examined for the present case, while the Corrected Invention specifies that arginine is added to a daidzein compound, arginine is converted into ornithine by the fermentation in the Corrected Invention as mentioned in paragraph [0226] of the Description, and it can be said that addition of arginine produces a new effect of increasing the production amount of ornithine.

It follows that, without having to examine other points, the Corrected Invention and Divisional Invention 4 cannot be regarded as identical inventions. In addition, as Divisional Invention 1 also has Difference E1, without having to examine other points, the Corrected Invention and Divisional Invention 1 cannot be regarded as identical inventions.

D. Conclusion regarding Grounds for Invalidation 10

Due to the above, Grounds for Invalidation 10 alleged by the Appellees are groundless.

The Appellant alleges that Appellee Daicel's allegation of Grounds for Invalidation 10 and offer of Exhibit Otsu B88 as evidence should be dismissed as belated allegation and evidence. However, as the allegation and offer of evidence by Appellee Daicel are not found to delay the conclusion of the lawsuit in light of the progress of the proceedings, the Appellant's abovementioned allegation concerning belated allegation and evidence is unacceptable.

4 Regarding Issue 4 (whether it is necessary to seek an injunction and disposal against Appellee AMC)

Appellee AMC alleges that the Appellant's claims against Appellee AMC should be dismissed, because the Appellees' Product which uses the Appellees' Material has all been sold off, including those in stock, and there is no likelihood of producing and selling the product in the future.

However, the only evidence submitted by Appellee AMC as the basis for the above allegation is a written statement prepared by the Appellee AMC's employee (Exhibit Otsu A2), and there is no sufficient evidence to precisely find that no stock of the product exists at present. In addition, in light of the fact that there is no dispute among the parties concerned that Appellee AMC was producing and selling the Appellees' Product at least in or until July 2021, there is no sufficient evidence to find that Appellee AMC has no possession at all of the Appellees' Product. Furthermore, given that Appellee AMC has not changed the product name and the contents of advertisements (a fact not disputed between the Appellant and Appellee AMC), and considering other factors, one cannot go so far as to say that Appellee

AMC is unlikely to produce and sell the Appellees' Product in the future.

Consequently, the claims for an injunction and disposal, which are the principal claims against Appellee AMC, are regarded to be well-grounded.

Meanwhile, the Appellant alleges that Appellee AMC's allegations in the Appellees' Brief No. 1 and offer of Exhibit Otsu A1 and Exhibit Otsu A2 as evidence should be dismissed as belated allegation and evidence. However, as the allegations and offer of evidence by Appellee AMC are not found to delay the conclusion of the lawsuit, the Appellant's abovementioned allegation concerning belated allegations and evidence is unacceptable.

5. Conclusion

Due to the reasons above, while all of the Appellant's principal claims are well-grounded and should be upheld, the part of the judgment in prior instance dismissing the principal claims is inappropriate, and therefore the present appeal is well-grounded. Accordingly, the part of the judgment in prior instance dismissing the Appellant's principal claims is rescinded and all of the principal claims are upheld. With regard to the declaration of provisional execution, it is not reasonable to apply this declaration to disposal of the Appellees' Product, and hence the declaration is applied to the extent of transfer, etc. of the Appellees' Product. Consequently, the judgment is rendered as indicated in the main text.

Intellectual Property High Court, Second Division
Presiding Judge: HONDA Tomonari
Judge: ASAI Ken
Judge: KATSUMATA Kumiko

(Attachment)

List of the Appellees' Product

Food product containing fermented soy germ extract
Product name: Equol + Lactobionate

Only those for which the best-before date indicated on the package is April 2023 or earlier or those for which "Energy 4.98 kcal, Protein 0.34 g, Fat 0.03 g, Carbohydrate 0.84 g, Sodium chloride equivalent 0.004 g" is indicated as the nutritional components.

End

(Attachment)

List of the Appellees' Material

Fermented soy germ extract

Product name: FlavoCel EQ-5

End