Trial decision

Invalidation No. 2018-800122

Demandant	DAICEL CORPORATION
Patent Attorney	YOSHIZAWA, Takao
Patent Attorney	KONNO, Akio
Patent Attorney	INAMI, Minoru
Patent Attorney	KAWADA, Atsushi
Demandee	OTSUKA PHARMACEUTICAL CO. LTD.
Patent Attorney	SHIROYAMA, Yasufumi
Attorney	YAMANOUCHI, Masayuki
Attorney	OIDE, Megumi
Patent Attorney	ONO, Makoto
Patent Attorney	SHIGEMORI, Kazuki

The case of trial regarding the invalidation of Japanese Patent No. 6275313, entitled "EQUOL-CONTAINING EXTRACT, METHOD FOR PRODUCTION THEREOF, METHOD FOR EXTRACTION OF EQUOL, AND EQUOL-CONTAINING FOOD" between the above parties has resulted in the following trial decision:

Conclusion

The correction of the scope of claims of Japanese Patent No. 6275313 shall be approved as the Corrected Scope of Claims attached to the Written Request for Correction.

The demand for trial of the case was groundless.

The costs in connection with the trial shall be borne by the Demandant.

Reason

No. 1 History of the procedures

Application for Japanese Patent No. 6275313 is a new patent application arising from the division of Japanese Patent Application No. 2016-156372 under the provision of Article 44(1) of the Patent Act, which is a divisional application of Japanese Patent Application No. 2013-108439 under the same provision, which is a divisional application of Japanese Patent Application No. 2009-519326 (PCT/JP 2008/060913) under the same provision, filed on June 13, 2008 as an international filing date (based on three patent applications with priority claim under the Paris Convention on June 13, 2007). The outline of the history of the procedures of the case after the registration of establishment of the patent right is as follows:

January 19, 2018	Registration of establishment of the patent right
October 12, 2018	Demand for Trial for Patent Invalidation
January 24, 2019	Written Reply and Written Request for Correction
April 8, 2019	Oral Proceedings Statement Brief (Demandant)
April 8, 2019	Oral Proceedings Statement Brief (Demandee)
April 15, 2019	Written Statement (Demandant)
April 22, 2019	Oral proceeding
May 7, 2019	Written Statement (Demandee)
May 31, 2019	Written Statement (Demandant)

No. 2 Suitability of request for correction

1. Contents of correction

The contents of the correction in the request for correction dated January 24, 2019 (hereinafter, referred to as "the request for correction of the case") are read as the following (1) to (4):

(1) Correction A

"A fermenting raw material containing at least one daidzein compounds and arginine," recited in Claim 1 of the scope of claims is corrected to "adding arginine to at least one daidzein compounds ... and ... a fermenting raw material containing the daidzein compound and the arginine."

(2) Correction B

"A method for producing a fermented product containing ornithine and equol," recited in Claim 1 of the scope of claims is corrected to "a method for producing a powdery fermented product containing ornithine and equol,"

(3) Correction C

"... Wherein the fermentation produces 8 mg or more of ornithine and 1 mg or more of equol per 1 g dry weight of the fermented product," is added in Claim 1 of the scope of claims for further specifying the specific values of amount of production of ornithine and equol.

(4) Correction D

"And the fermented product is used as a food material" is added in Claim 1 of the scope of claims for further specifying the use of the fermented product as a food material.

2. Suitability of purpose of correction, presence or absence of addition of new matter, and existence or absence of substantial enlargement or alteration of the scope of claims

(1) Regarding Correction A

The invention according to Claim 1 after the correction by Correction A specifies that the method for producing a fermented product comprises the step of adding arginine to a daidzein compound. This specified matter restricts the method for producing a fermented product in Claim 1 before the correction.

Therefore, Correction A is intended for restriction of the scope of claims prescribed in item (i) of the proviso to Article 134-2(1) of the Patent Act.

In addition, it is described in paragraphs [0036], [0050], [0222], [0226], and so on of the Description attached to the Application for the Patent (hereinafter referred to as "the Patent Description") that the fermentation is performed by the addition of arginine to a daidzein compound. Thus, it does not correspond to the addition of new matter, and does not substantially enlarge or alter the scope of claims.

Therefore, Correction A complies with the provisions of Article 126(5) and (6) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 134-2(9) of the Patent Act.

(2) Regarding Correction B

The invention according to Claim 1 after the correction by Correction B specifies that the fermented product is in powder form. This specified matter restricts the

method for producing a fermented product in Claim 1 before the correction.

Therefore, Correction B is intended for restriction of the scope of claims prescribed in item (i) of the proviso to Article 134-2(1) of the Patent Act.

In addition, it is described in paragraphs [0144], [0222], [0225], [0229], and so on of the Patent Description that the fermented product is powdered. Thus, it does not correspond to the addition of new matter, and does not substantially enlarge or alter the scope of claims.

Therefore, Correction B complies with the provisions of Article 126(5) and (6) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 134-2(9) of the Patent Act.

(3) Regarding Correction C

The invention according to Claim 1 after the correction by Correction C specifies that the fermentation produces 8 mg or more of ornithine and 1 mg or more of equol per 1 g dry weight of the fermented product. This specified matter restricts the method for producing a fermented product in Claim 1 before the correction.

Therefore, Correction C is intended for restriction of the scope of claims prescribed in item (i) of the proviso to Article 134-2(1) of the Patent Act.

In the Patent Description, furthermore, it is described that the fermented product prepared with soybean hypocotyl containing arginine as a fermenting material allows for the production of ornithine in an amount corresponding to "8 mg or more per 1 g dry weight of the fermented product" in paragraph [0050] and that the fermented product allows for the production of equol in amount corresponding to "1 mg or more per 1 g dry weight of the fermented product" in paragraph [0042]. The same is also applied to the production amounts of equol and ornithine in the case in which the daidzein compound including arginine is used as a fermenting material. In paragraphs [0042] and [0226] of the Patent Description, ornithine and equol are described as those produced by fermentation.

Thus, Correction C does not correspond to the addition of new matter, and does not substantially enlarge or alter the scope of claims.

Therefore, Correction C complies with the provisions of Article 126(5) and (6) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 134-2(9) of the Patent Act.

(4) Regarding Correction D

The invention according to Claim 1 after the correction by Correction D

specifies the use of the fermented product produced by the production method as a food material. This specified matter restricts the method for producing a fermented product in Claim 1 before the correction.

Therefore, Correction D is intended for restriction of the scope of claims prescribed in item (i) of the proviso to Article 134-2(1) of the Patent Act.

In addition, it is described in paragraphs [0144] and so on of the Patent Description that the use of the fermented product is a food material. Thus, it does not correspond to the addition of new matter, and does not substantially enlarge or alter the scope of claims.

Therefore, Correction D complies with the provisions of Article 126(5) and (6) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 134-2(9) of the Patent Act.

(5) Summary

As stated above, the corrections by the request for correction of the case are intended for the matters listed in item (i) of the proviso to Article 134-2(1) of the Patent Act and fall under the provisions of Article 126(5) and (6) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 134-2(9) of the Patent Act.

Therefore, the correction of the scope of claims shall be approved as the Corrected Scope of Claims attached to the Written Request for Correction.

No. 3 The Patent Invention

The invention according to Claims 1 of Japanese Patent No. 6275313 (hereinafter, referred to as "the Patent Invention) is one stated in Claim 1 of the scope of claims corrected by the request for correction of the case and read as follows:

"A method for producing a powdery fermented product containing ornithine and equol, the method comprising:

adding arginine to at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein; and

fermenting a fermenting raw material containing the daidzein compound and the arginine with a microorganism having ornithine-producing ability and equol-producing ability, wherein

the fermentation produces 8 mg or more of ornithine and 1 mg or more of equol are produced per 1 g dry weight of the fermented product, and

the fermented product is used as a food material."

No. 4 Overview of the parties' allegations

1. The Demandant's allegation

The Demandant demands the trial decision, "The demand for the invalidation trial of the case was groundless. The costs in connection with the trial shall be borne by the Demandee." The Demandant alleges as follows:

Regarding Invalidation Reason 1

The invention according to Claim 1 of the case is the invention disclosed in Evidence A No. 1 or the invention that could have been easily invented by a person of ordinary skill in the art of the invention based on the invention disclosed in Evidence A No. 1, so that the invention falls under Article 29(1)(iii) of the Patent Act, or a patent should not have been granted for the invention in accordance with the provision of Article 29(2) of the Patent Act.

Regarding Invalidation Reason 2

The invention according to Claim 1 of the case does not comply with the so-called Support Requirement and Enablement Requirement and thus does not satisfy the requirements under the provisions of Article 36(6)(i) and (4)(i) of the Patent Act.

Regarding Invalidation Reason 3

The invention according to Claim 1 of the case is the invention disclosed in Evidence A No. 6 or the invention that could have been easily invented by a person of ordinary skill in the art of the invention based on the invention disclosed in Evidence A No. 6, so that the invention falls under Article 29(1)(iii) of the Patent Act, or a patent should not have been granted for the invention in accordance with the provision of Article 29(2) of the Patent Act.

For the above reasons, the Patent for the invention according to Claim 1 of the case falls under Article 123(1)(ii) and (iv) of the Patent Act and should be invalidated.

Means of proof submitted by the Demandant are as follows:

(Those attached to the Written Demand for Trial)

Evidence A No. 1: International Publication No. WO 2007/066655

Evidence A No. 2-1: Priority certificate (Japanese Patent Application No. 2007-156822)

Evidence A No. 2-2: Priority certificate (Japanese Patent Application No. 2007-156825)

Evidence A No. 2-3: Priority certificate (Japanese Patent Application No. 2007-156833)

Evidence A No. 3: Domestic Re-Publication of PCT International Publication No. WO 2008/153158 (published on August 26, 2010)

Evidence A No. 4: Japanese Patent No. 5946489

Evidence A No. 5-1: Written Amendment dated June 18, 2015 for Japanese Patent Application No. 2014-83507
Evidence A No. 5-2: Notice of Reasons for Rejection dated October 21, 2015 for Japanese Patent Application No. 2014-83507
Evidence A No. 5-3: Written Amendment dated December 16, 2015 for Japanese Patent Application No. 2014-83507
Evidence A No. 6: JOURNAL OF BIOSCIENCE AND BIOENGINEERING, Vol. 102, No. 3, pp. 247-250, 2006,
Evidence A No. 7: JOURNAL OF BACTERIOLOGY, Vol. 127, No. 2, p. 780-784, 1976
Evidence A No. 8: "The Japanese Biochemical Society, Ed., Biochemical Experiment Lecture 11, Amino Acid Metabolism and Biological Amine (volume 2)", published by Tokyo Kagaku Dojin Co., Ltd., pp. 532-535, November 28, 1976
Evidence A No. 9: Original by R. Y. Stanier, etc., translated by Hajime Takahashi, "Microbiology (volume 1)", published by BAIFUKAN Co., Ltd., pp. 380-383, September 10, 1981
Evidence A No. 10: "The Japanese Society for Microbiology, Ed., Dictionary of Microbiology", published by GIHODO SHUPPAN Co., Ltd., pp. 40-41, August 23, 1989
Evidence A No. 11: Experiment Report prepared by Hiroaki Yamamoto, Daicel Co., Ltd. employee, on June 12, 2018

(Evidences attached to the Oral Proceedings Statement Brief)
Evidence A No. 12: Chemistry Dictionary Editing Committee, Ed., "Chemistry Dictionary 5", published by Kyoritsu Publishing Co., Ltd., pp. 924-925, published on September 20, 1997
Evidence A No. 13-1: Written Opinion dated April 3, 2006 for Japanese Patent Application No. 2005-511140
Evidence A No. 13-2: Written Opinion dated September 25, 2007 for Japanese Patent Application No. 2006-173789
Evidence A No. 14: Websites "Otsuka Pharmaceutical's official mail order Otsuka Plus One," "EQUELLE Birth Secret Story I" to " EQUELLE Birth Secret Story III"
Evidence A No. 15-1: Journal of the Brewing Society of Japan, vol. 62, No. 4, pp. 366-373, 1967
Evidence A No. 15-2: "Report of the Food Research Institute, volume 19," pp. 120-127, March, 1965

Evidence A No. 15-3: Bull. Eur. Ass. Fish Pathol., Vol. 21, No. 4, P.136-144, 2001
Evidence A No. 16-1: Mitsuo Kamewada, etc., Ed., "Basics and Applications of Dried Foods", published by SAIWAI SHOBO Co., Ltd.
Evidence A No. 16-2: Journal of the Japanese Society for Food Science and Technology, vol. 51, No 9, pp. 441-448, September 2004
Evidence A No. 17: Experiment report prepared by Hiroaki Yamamoto, Daicel Co., Ltd. employee, on March 8, 2019
Evidence A No. 18: International Publication No. WO 99/07392
Evidence A No. 19: International Publication No. WO 2005/000042

2. The Demandee's allegation

The Demandee alleges that the Patent Invention cannot be invalidated by the reasons alleged by the Demandant and the evidences submitted thereby, and demands the decision, "The demand for trial of the case was groundless, and the costs in connection with the trial shall be borne by the Demandant."

Means of proof submitted by the Demandee are as follows:

(Those attached to the Written Reply)
Evidence B No. 1: Akiyoshi Hosono, Ed., "Science of Fermented Milk, Function of Lactic Acid Bacteria and Their Impact on Human Health", published by IK-Publishing Co., Ltd., pp. 120-135, November 10, 2002
Evidence B No. 2-1: Japanese Patent No. 6391956
Evidence B No. 2-2: Japanese Patent No. 4743114
Evidence B No. 2-3: Japanese Patent No. 4490361
Evidence B No. 3: Journal of Fermentation Technology, Vol. 55, No 2, pp. 68-74, 1977
Evidence B No. 4: Soil Microorganisms, No. 38, pp. 45-60, 1991
Evidence B No. 5: Written Opinion dated April 22, 2016 for Japanese Patent Application No. 2012-202388

(Those attached to the Oral Proceedings Statement Brief)
Evidence B No. 6-1: Saburo Fukui supervised, "Screening Technology - Searching for Potential Functions of Microorganisms", published by Kodansha Co., Ltd., pp. 1-3, April 20, 1985
Evidence B No. 6-2: KAGAKU TO SEIBUTSU, Vol. 5, No. 5, pp. 294-303
Evidence B No. 7: Japanese Patent Application No. 2006-242602
Evidence B No. 8: Journal of Intestinal Microbiology, Vol. 21, No. 3, pp. 217-220,

2007
Evidence B No. 9: Japanese Unexamined Patent Application Publication No. 2008-61584
Evidence B No. 10: JOURNAL OF THE JAPANESE SOCIETY FOR FOOD SCIENCE AND TECHNOLOGY, Vol. 62, No. 7, pp. 356-363, July 2015
Evidence B No. 11: International Publication No. WO 99/07392
Evidence B No. 12: Japanese Unexamined Patent Application Publication No. 2006-204296
Evidence B No. 13: National Publication of International Patent Publication No. 2006-504409
Evidence B No. 14: Japanese Unexamined Patent Application Publication No. 2008-61584
Evidence B No. 15: Experiment report prepared by Naruto Uchiyama, Otsuka Pharmaceutical Co., Ltd. employee, on April 5, 2019

No. 5 Described matters in Evidences A and B
1. Evidence A No. 1

The following matters are described in Evidence A No. 1 (hereinafter, abbreviated as "A1," and the same is also applied to other evidences).

(1-1) "[0021] Further, in the fermentation of soybean hypocotyl, if necessary, some additives may be added to the soybean hypocotyl used as the fermenting raw material in order to improve the fermentation efficiency, flavor and taste of the fermented product, etc. Examples of the additives include nitrogen sources such as yeast extracts, polypeptones or meat extracts; carbon sources such as glucose or sucrose; mineral salts such as phosphate, carbonate or sulfate; vitamins; and nutritional components such as amino acids; etc. In particular, when using a microorganism having an ability to convert arginine into ornithine (hereinafter referred to as "ornithine/equol-producing microorganism") as an equol-producing microorganism, it is possible to obtain a fermented product containing ornithine by adding arginine to soybean hypocotyls and then performing fermentation. In such a case, the amount of added arginine may be, for example, about 0.5 to about 3 parts by weight per 100 parts by weight of soybean hypocotyls (on a dry weight basis). The equol-producing microorganisms having an ability to convert arginine into ornithine can be selected from Lactococcus garvieae strains, and specific examples include Lactococcus 20-92 (FERM BP-10036)."

(1-2) "[0050] Example 4

Lactococcus strain 20-92 (FERM BP-10036) was inoculated into 5 ml of a soybean hypocotyl solution containing 10 wt.% of powdered soybean hypocotyls and 0.1 wt.% of L-arginine, and subjected to static cultivation at 37°C for 96 hours under anaerobic conditions. After cultivation, the resulting fermented liquid (culture solution) was sterilized by heating at 100°C for one minute, then dried at 80°C, and further powdered using a homogenizer, thereby obtaining a powdered fermented soybean hypocotyl product.

[0051] The powdered soybean hypocotyls used as starting materials (referred to as "pre-fermentation" in Tables 2 and 3) and the obtained powdered fermented soybean hypocotyl product (referred to as "post-fermentation" in Tables 2 and 3) were analyzed for compositional components. Table 2 shows the analytical results for soybean isoflavones, and Table 3 shows the analytical results for nutritional components. These results also established that fermented soybean hypocotyl products containing high levels of equol can be produced by fermenting soybean hypocotyls with Lactococcus strain 20-92. The results further revealed that the contents of oligosaccharides such as raffinose, stachyose, and the like after the fermentation remain almost the same as before, indicating that they are hardly influenced by fermentation. However, it was found that arginine is converted to ornithine by fermentation. Consequently, it was established that when arginine-added soybean hypocotyls are fermented with Lactococcus strain 20-92, not only equol but also ornithine can be produced."

2. Evidence A No. 6

The following matters are described in A6. Note that A6 is written in English and thus the submitted translation of Exhibit A6 is shown.

(2-1) "After isolating of equol-producing bacterium, a precultured GAM broth containing 1% L-arginine at 37°C for 28 hours 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)

(2-2) "An anaerobic gram-positive rod-shaped strain capable of producing equol was isolated from a rat cecal contents. This strain is referred to as gram-positive bacterium do03 (AB266102)." (page 248, right column, lines 8 to 11)

(2-3) "The strain do03 converted 200 μM daidzein to equol for 4 d at 37°C anaerobically." (page 248, right column, lines 25 to 26)

(2-4) "In the medium containing arginine, the equol ratio increased to 0.67 ± 0.01 with increases in OD_{600} and culture broth pH." (page 248, right column, lines 38 to 40)

(2-5) "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." (page 248, right column, lines 45 to 51)

3.Evidence B No. 10
B10, Table 1 (page 358)

表 1　エクオール産生菌単離・同定に関する報告例

発見/報告年	報告者	所属（国）	菌名（株名）	分離源
1997 年	Uchiyama et al.	大塚製薬（日本）	バクテロイデス属（E-15 株）	ヒト腸内
1997 年	Uchiyama et al.	大塚製薬（日本）	ルミノコッカス属（E-17 株）	ヒト腸内
1997 年	Uchiyama et al.	大塚製薬（日本）	ストレプトコッカス属（A6G-225 株）#1	ヒト腸内
2002 年	Uchiyama et al.	大塚製薬（日本）	ラクトコッカス属（20-92 株）#1	ヒト腸内
2005 年	Wang et al.	ソウル大（韓国）	エゲレセラ属（Julong 732 株）#2	ヒト腸内
2005 年	Decros et al.	ゲント大（ベルギー）	4 種混合菌（EPC4）	ヒト腸内
2006 年	Minamida et al.	北大（日本）	アサッカロバクター属（do3 株）	ラット盲腸内
2006 年	Tamura et al.	食総研（日本）	スラッキア属（TM-30 株）	ヒト腸内
2006 年	Jin et al.	富山大・理研（日本）	スラッキア属（DZE 株）	ヒト腸内
2008 年	Yu et al.	南京農大（中国）	ユウバクテリウム（D1, D2 株）	ブタ糞便内
2008 年	Maruo et al.	フジッコ・理研（日本）	アドラークロイチア属（FJC-B9 株）	ヒト腸内
2008 年	Yokoyama et al.	岐阜県生物工学研（日本）	エゲレセラ属（YY7918 株）	ヒト腸内
2008 年	Motira et al.	麻布大（日本）	シェーピア属（ST18 株）	ウマ腸内
2009 年	Clavel et al.	ミュンヘン工科大（ドイツ）	エンテロラブダス属（Mt1B8 株）	マウス腸内
2009 年	Matthies et al.	ドイツ栄養研（ドイツ）	スラッキア属（HE8 株）	ヒト腸内
2010 年	Tsuji et al.	ヤクルト・筑波大（日本）	スラッキア属（NATTS 株）	ヒト腸内

#1：乳酸球菌
#2：ジハイドロダイゼインからエクオールを産生（その他の菌株は全てダイゼインからエクオールを産生）

表１　エクオール産生菌単離・同定に関する報告例　Table 1 Examples of reports on isolation and identification of equol-producing bacteria

発見／報告年	Discovery/reporting year
報告者	Reporter
所属（国）	Affiliation (country)
菌名（株名）	Bacterial name (strain name)
分離源	Separation source
１９９７年	1997

２００２年	2002
大塚製薬（日本）	Otsuka Pharmaceutical (Japan)
バクテロイデス属（Ｅ－１５株）	Bacteroides (strain E-15)
ルミノコッカス属（Ｅ－１７株）	Ruminococcus (strain E-17)
ストレプトコッカス属（Ａ６Ｇ－２２５株）	Streptococcus (strain A6G-225)
ラクトコッカス属（２０－９２株）	Lactococcus (strain 20-92)
ヒト腸内	Human intestinal
２００５年	2005
２００６年	2006
２００８年	2008
２００９年	2009
２０１０年	2010
ソウル大（韓国）	Seoul University (Korea)
ゲント大（ベルギー）	Ghent University (Belgium)
北大（日本）	Hokkaido University (Japan)
食総研（日本）	National Food Research Institute (Japan)
富山大・理研（日本）	University of Toyama - RIKEN (Japan)
南京農大（中国）	Nanjing Agricultural University (China)
フジッコ・理研（日本）	Fujicco/RIKEN (Japan)
岐阜県生物工学研（日本）	Gifu Prefectural Institute of Biotechnology (Japan)
麻布大（日本）	Azabu University (Japan)
ミュンヘン工科大（ドイツ）	Technical University of Munich (Germany)
ドイツ栄養研（ドイツ）	German Institute of Nutrition (Germany)
ヤクルト・筑波大（日本）	Yakult/University of Tsukuba (Japan)
エゲレセラ属（Ｊｕｌｏｎｇ　７３２株）	Eggerthella (Julong 732 strain)
４種混合菌（ＥＰＣ４）	DPT-IPV bacteria (EPC4)
アサッカロバクター属（ｄｏ３株）	Genus Asaccharobacter (strain do3)
スラッキア属（ＴＭ－３０株）	Genus Slackia (strain TM-30)
スラッキア属（ＤＺＥ株）	Genus Slackia (strain DZE)
ユウバクテリウム（Ｄ１，Ｄ２株）	Eubacterium (strains D1, D2)
アドラークロイチア属（ＦＪＣ－Ｂ９株）	Genus Adlercreutzia (strain FJC-B9)
エゲレセラ属（ＹＹ７９１８株）	Genus Eggerthella (strain YY7918)
シェーピア属（ＳＴ１８株）	Genus Sharpie (strain ST18)

エンテロラブダス属（Ｍｔ１Ｂ８株）	Enterorhabdus (strain Mt1B8)
スラッキア属（ＨＥ８株）	Genus Slackia (strain HE8)
スラッキア属（ＮＡＴＴＳ株）	Genus Slackia (strain NATTS)
ラット盲腸内	In rat cecum
ブタ糞便内	In pig feces
ウマ腸内	In horse intestine
マウス腸内	In mouse intestine
＃１：乳酸球菌	#1: Lactococcus
＃２：ジハイドロダイゼインからエクオールを産生（その他の菌株は全てダイゼインからエクオールを産生）	#2 Produces equol from dihydro daidzein (all other strains produce equol from daidzein)

No. 6 Judgment by the body

1. Regarding Invalidation Reason 1

(1) Regarding the priority of the present application

A Japanese Patent Application No. 2009-519326, which is the original application of the divisional application of the case, is an international patent application PCT/JP 2008/060913 transferred into the national phase in Japan and claiming domestic priority based on Japanese Patent Application No. 2007-156822 (filing date: June 13, 2007), Japanese Patent Application No. 2007-156825 (filing date: June 13, 2007) and Japanese Patent Application No. 2007-156833 (filing date: June 13, 2007).

B The Patent Invention specifies as "a fermenting raw material" one in which arginine is added to "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" thereby "containing the daidzein compound and the arginine."

C Against this, the following matters are described in the priority document (A2-1) for the priority basic application (Japanese Patent Application No. 2007-156822) claiming priority of the original application from which the divisional application of the case is made. Note that the underlines are applied by the body.

"[0012]

Equol- Containing Fermented Soybean Hypocotyl Product

An equol-containing fermented soybean hypocotyl product used as a food material according to the present invention is a kind of a fermented soybean hypocotyl product 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 product is a microorganism 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. Here, concrete examples of the daidzein glycosides include daidzin, malonyldaidzin, and acetyldaidzin.

[0014]

The equol-producing microorganism is not particularly limited as long as it is acceptable for food hygiene and have the above ability. For example, it is known that such microorganisms having the above ability 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 the equol-producing microorganisms, preferable microorganisms include lactic acid bacteria belonging to Lactococcus and Streptococcus, and further preferable lactic acid bacteria are those belonging to Lactococcus, and in particular 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. As the equol-producing microorganisms, the inventors of the present invention deposited some identified bacterium that had been isolated from human feces; namely, Lactococcus 20-92 (FERM BP-10036), Streptococcus E-23-17 (FERM BP-6436), Streptococcus A6G225 (FERM BP-6437), and Bacteroides E-23-15 (FERM BP-6435). In the present invention, these deposited bacteria can be used. Among these, Lactococcus 20-92 is particularly preferably used.

[0015]

The equol-containing fermented soybean hypocotyl product is produced using soybean hypocotyl as a fermenting raw material. The soybean hypocotyl designates a part corresponding to the plumule or the radicle on the germination of soybean, and is known to contain a large amount of daidzein compound 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 not significantly lost. For example, the equol-containing fermented soybean hypocotyl product 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 hypocotyl that is isolated from unprocessed soybean. Further, the soybean hypocotyl used may be processed by degreasing or deproteinization. The form of the soybean hypocotyl used is not particularly limited, and may be in the form of powder, chunks, or pulverized or fragmentized grains. From the viewpoint of producing equol more efficiently, it is desirable to use powdery soybean hypocotyl.

[0016]

The fermentation of 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, further preferably 600 to 1,000 parts by weight, based on 100 parts by weight (dry weight) of the soybean hypocotyl.

[0018]

Further, in the fermentation of soybean hypocotyl, if necessary, some additives may be added to the soybean hypocotyl used as the fermenting raw material in order to improve the fermentation efficiency, flavor and taste of the fermented product, etc. Examples of the additives include nitrogen sources such as yeast extract, polypeptone, or 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. In particular, when using an equol-producing microorganism having an ability to convert arginine into ornithine (hereinafter referred to as an "ornithine/equol-producing microorganism") as an equol-producing microorganism, it is possible to obtain a fermented product containing ornithine by adding arginine to the soybean hypocotyl and then performing fermentation. In such a case, the amount of added arginine may be, for example, about 0.5 to 3 parts by weight, based on 100 parts by weight of the soybean hypocotyl (on a dry weight basis). The equol-producing microorganism having an ability to convert arginine into ornithine can be selected from Lactococcus garvieae strains, and specific examples include 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 to within about 6 to 7, more preferably about 6.3 to 6.8.
[0020]

Further, to the fermenting material (a soybean hypocotyl containing substance) to be used, isoflavone containing the above-mentioned daidzein compounds may be added in advance. Such addition of isoflavone to the fermenting material separately may increase the equol content of the fermented soybean hypocotyl product, thereby improving the usability of the fermented soybean hypocotyl product."

Furthermore, similar matters are described in the Paragraphs [0014] to [0022] of Japanese Patent Application No. 2007-156825 (A2-2) and in the Paragraphs [0012] to [0021] of Japanese Patent Application No. 2007-156833(A2-3), which are priority documents of the original application of the divisional application of the case.

D As stated in the above C, "soybean hypocotyl" is explicitly stated as a "fermenting raw material" in the priority document of the original application of the divisional application of the case. On the other hand, the priority document describes as follows: "in the fermentation of soybean hypocotyl, if necessary, some additives may be added to the soybean hypocotyl used as the fermenting raw material in order to improve the fermentation efficiency, flavor and taste of the fermented product, etc. Examples of the additives include nitrogen sources such as yeast extracts, polypeptones or meat extracts; carbon sources such as glucose or sucrose; inorganic salts such as phosphate, carbonate or sulfate; vitamins; and nutritional components such as amino acids; etc." and "to the fermenting material (a soybean hypocotyl containing substance) to be used, isoflavone containing the above-mentioned daidzein compounds may be added in advance. Such addition of isoflavone to the fermenting material separately may increase the equol content of the fermented soybean hypocotyl product, thereby improving the usability of the fermented soybean hypocotyl product." In other words, it indicates the addition of ingredients other than soybean hypocotyl to the fermenting raw material. In addition, the priority document also describes that "the soybean hypocotyl designates 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." It is recognized that soybean hypocotyl is described as being used as a material containing a large amount of daidzein compounds, such as daidzein glycoside and daidzein.

Furthermore, the priority document also describes that "the equol-producing microorganism used ... 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." In other words, it is recognized that there is described that a microorganism, which ferments a fermenting raw material, metabolizes "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" contained in the fermenting material to produce equol.

Thus, it is obvious from the description of the priority document of the original application on which the application of the case is based, that one containing "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein" assimilated by microorganism is to be used as a "fermenting raw material."

E Therefore, it is acknowledged that providing as a "fermenting raw material" one containing "at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein," which is specified in the Patent Invention, is as a matter equal to one described in the priority document of the original application on which the application of the case is based.

Hence, the reference date for determining the novelty and inventive step of the Patent Invention is June 13, 2007, which is the priority date where priority is claimed.

(2) Violation of novelty and inventive step over A1 as a main cited document

Since A1 is a publication distributed after the priority date of the application for the Patent, the lack of novelty and inventive step of the Patent Invention cannot be determined using A1 as an evidence.

Therefore, Invalidation Reason 1 is groundless.

2. Regarding Invalidation Reason 2

(1) Problem to be solved by the Patent Invention

In view of the wording of Claim 1, a problem to be solved by the Patent Invention is recognized to provide "a method capable of producing a powdery fermented product containing ornithine and equol by subjecting a fermenting raw material containing a daidzein compound and arginine to fermentation with a microorganism having ornithine-producing ability and equol-producing ability."

(2) Description of the Patent Description

The Patent Description describes the following matters. Note that the

underlines are applied by the body.

A "[Description of Embodiments]

[0029]

The following details the present invention.

1. Production Method for Equol-containing Extract

The present invention provides a method for producing an equol-containing extract using an equol-containing fermented soybean hypocotyl product as a raw material. The production method for the equol-containing extract of the present invention is divided into the following Production Methods I and II. The following details an equol-containing fermented soybean hypocotyl product used as a material of the production method of the present invention, and describes in detail Production Methods I and II.

Equol-Containing Fermented Soybean Hypocotyl Product

In the production method for the equol-containing extract according to the present invention, an equol-containing fermented soybean hypocotyl product is used as a raw material. The following describes an equol-containing fermented soybean hypocotyl product.

[0030]

An equol-containing fermented soybean hypocotyl product is a kind of a fermented soybean hypocotyl product 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 product is a microorganism 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. Here, concrete examples of the daidzein glycosides include daidzin, malonyldaidzin, and acetyldaidzin.

[0032]

The equol-producing microorganism is not particularly limited as long as it is acceptable for food hygiene and have the above ability, and one conventionally known or screened by a general method can be used. For example, it is known that such microorganisms capable of producing equol 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 the

equol-producing microorganisms, preferable microorganisms include lactic acid bacteria belonging to Lactococcus and Streptococcus, and further preferable lactic acid bacteria are those belonging to Lactococcus, and in particular 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. As the equol-producing microorganisms, the inventors of the present invention deposited some identified bacterium that had been isolated from human feces; namely, Lactococcus 20-92 (FERM BP-10036), Streptococcus E-23-17 (FERM BP-6436), Streptococcus A6G225 (FERM BP-6437), and Bacteroides E-23-15 (FERM BP-6435). In the present invention, these deposited bacteria can be used. Among these, Lactococcus 20-92 is particularly preferably used.

[0033]

The equol-containing fermented soybean hypocotyl product is produced using soybean hypocotyl as a fermenting raw material. The soybean hypocotyl designates 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 not significantly lost. For example, the equol-containing fermented soybean hypocotyl product 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 hypocotyl that is isolated from unprocessed soybean. Further, the soybean hypocotyl used may be processed by degreasing or deproteinization. The form of the soybean hypocotyl used is not particularly limited, and may be in the form of powder, chunks, or pulverized or fragmentized grains. From the viewpoint of producing equol more efficiently, it is desirable to use powdery soybean hypocotyl.

[0034]

The fermentation of 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.

[0035]

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, further preferably 600 to 1,000 parts by weight, based on 100 parts by weight (dry weight) of the soybean hypocotyl.

[0036]

Further, in the fermentation of soybean hypocotyl, if necessary, some additives may be added to the soybean hypocotyl used as the fermenting raw material in order to improve the fermentation efficiency, flavor and taste of the fermented product, etc. 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. In particular, when using an equol-producing microorganism having an ability to convert arginine into ornithine (hereinafter referred to as an "ornithine/equol-producing microorganism") as an equol-producing microorganism, it is possible to obtain a fermented product containing ornithine by adding arginine to the soybean hypocotyl and then performing fermentation. In such a case, the amount of added arginine may be, for example, about 0.5 to 3 parts by weight, based on 100 parts by weight of the soybean hypocotyl (on a dry weight basis). 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 can be selected from Lactococcus garvieae strains, and specific examples include Lactococcus 20-92 (FERM BP-10036)."

B "[0090]

The following explains an equol-containing fermented product.

[0091]

The equol-containing fermented product 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 compound. The sample is then fermented (cultured) under the conditions suitable to grow the microorganism. The resulting fermented product contains equol.

[0092]

As the above equol-producing microorganism, an equol-producing microorganism used is from the list of "Equol-containing fermented soybean hypocotyl product" in the section "1. Production Method for equol-containing extract."

[0093]

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

C "[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 product

Powdered soybean hypocotyl, 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 a powdered fermented soybean hypocotyl product."

(3) Judgment

The Patent Invention specifies the production of "a powdery fermented product containing ornithine and equol" by fermenting "a fermenting raw material containing a daidzein compound and arginine" with "a microorganism having ornithine-producing ability and equol-producing ability."

In addition, the Patent Description describes that the "daidzein compound" in the fermenting raw material is "at least one selected from a group consisting of daidzein glycosides, daidzin, and dihydrodaidzein" and the "daidzein glycosides" include "daidzin, malonyldaidzin, acetyldaidzin, and so on." These substances and arginine are recognized to be available for a person skilled in the art.

Furthermore, regarding the "microorganism having ornithine-producing ability and equol-producing ability" used for the fermentation, the example in the Patent Description describes Lactococcus strain 20-92 (FERM BP-10036). It can be therefore said that the use of Lactococcus strain 20-92 allows production of a powdery fermented product containing ornithine and equol from a fermenting raw material containing a daidzein compound and arginine.

On the other hand, regarding the "microorganism having ornithine-producing ability and equol-producing ability" other than Lactococcus strain 20-92, paragraph [0036] describes that "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 can be selected from Lactococcus garvieae strains, and specific examples include Lactococcus 20-92 (FERM BP-10036)," but describes no microorganism other than Lactococcus strain 20-92 or specific microorganism obtained by actual screening as a "microorganism having ornithine-producing ability and equol-producing ability."

However, paragraph [0032] describes as follows: "For example, it is known that such microorganisms capable of producing equol 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 the equol-producing microorganisms, preferable microorganisms include lactic acid bacteria belonging to Lactococcus and Streptococcus, and further preferable lactic acid bacteria are those belonging to Lactococcus, and in particular Lactococcus garvieae" and "The inventors of the present invention deposited some identified bacterium that had been isolated from human feces; namely, Lactococcus 20-92 (FERM BP-10036), Streptococcus E-23-17 (FERM BP-6436), Streptococcus A6G225 (FERM BP-6437), and Bacteroides E-23-15 (FERM BP-6435), that are available to be used as the equol-producing microorganisms. In the present invention, these deposited bacteria can be used." It is therefore recognized that those known as equol-producing microorganisms at the time of the original filing date of the present application as described here can be obtained by using the conversion ability from arginine into ornithine as an index to produce ornithine.

Further, a method for obtaining a microorganism that produces ornithine using the conversion ability of arginine into ornithine as an index is a well-known technique in the art. In addition, from the description in Table 1 of B10, it is recognized that

some equol-producing microorganisms were known at the time of June 13, 2008, which is the international filing date of the original filing date of the present application. Thus, it can be said that targeting such microorganisms and using the conversion ability from arginine into ornithine as an index allow a person skilled in the art to obtain "a microorganism having ornithine-producing ability and equol-producing ability." This is supported by the description in the B15 Experimental Report, which experimentally confirmed that "Streptococcus A6G225 (FERM BP-6437)" and "Bacteroides E-23-15 (FERM BP-6435)" shown as equol-producing microorganisms in paragraph [0032] of the Patent Description have the ability to produce ornithine.

Furthermore, in paragraphs[0144], [0222], [0225], [0229], and so on of the Patent Description, there is described that drying and powdering makes the fermented product into a powder form.

Then, the description of the Patent Description will allow a person skilled in the art to recognize that a powdery fermented product containing ornithine and equol can be produced by preparing a fermenting material containing a daidzein compound and arginine, subjecting it to fermentation with a microorganism having ornithine-producing ability and equol-producing ability to give a fermented product, and drying and powderizing the fermented product, or to recognize that the above problem of the Patent Invention can be solved.

Therefore, it can be said that the Patent Invention is described in the Detailed Description of the Invention so that a person skilled in the art can recognize that the problem of the invention can be solved, and satisfies the so-called Support Requirement.

It can be also said that a person skilled in the art can carry out the Patent Invention from the description of the Patent Description and common general technical knowledge. Therefore, the Patent Description satisfies the Enablement Requirement.

(4) The Demandant's allegation

In the Written Statement dated April 15, 2019 and the Written Statement dated May 31, 2019, the Demandant substantially alleges as follows:

A Other than Lactococcus strain 20-92, it is difficult to find safe microorganisms that can be used for food.

B When microorganisms other than Lactococcus strain 20-92 are used, it cannot be said that the equol and ornithine can be produced in predetermined amount or more as specified in the Patent Invention. Moreover, only lower limit on production amount is specified, and the upper limit is not specified.

C Support and Enablement Requirements are not satisfied, because the range of objects to be screened and the method for screening are not specified.

Regarding the above A

According to the description of B8, Lactococcus strain 20-92 is recognized as a safe microorganism available in food. Here, it is recognized that the safe microorganisms that can be used for food are microorganisms that can ingest fermented products without modification, including live microorganisms.

On the other hand, the specified matter "the fermented product is used as a food material" in the Patent Invention is a matter specifying that the product obtained by fermentation is used as a food material and is recognized to also include some kind of processing that can be carried out when a fermented product is processed into a food material. However, the specified matter is not recognized as one only meaning that the fermented product containing live microorganisms is ingested as food as it is.

Then, as stated in the above (3), it is therefore recognized that the subject is microorganisms, which were known as equol-producing microorganisms at the time of the original filing date of the present application. Using the conversion ability from arginine into ornithine as an index, "a microorganism having ornithine-producing ability and equol-producing ability" can be obtained. Microorganisms isolated from the intestines of humans and animals as shown in Table 1 of B10 are considered to be highly likely to be safe for humans and animals. If the safety is not enough, the microorganisms are prevented from remaining in the fermented product by sterilizing the microorganisms in the fermented product and devising the fermentation method to make it possible to increase safety. In addition, when a microorganism produces some harmful by-product, it is possible to treat it so as not to contain the by-product. Furthermore, it can be said that a microorganism previously confirmed to be pathogenic is not subject to screening for ornithine production in the first place.

It can be thus said that a person skilled in the art can discover a microorganism, which is capable of using the fermented product as a food material, other than Lactococcus strain 20-92. Therefore, the Demandant's allegation cannot be adopted.

Regarding the above B

From the description of the Patent Description, it is understood that Lactococcus strain 20-92 produces certain amounts or more of equol and ornithine as specified in the Patent Invention. It is recognized that Table 1 shows an increase in amount of equal produced with an increase in amount of daidzein compound, such as soybean hypocotyl,

in the fermenting material, and Tables 2 and 3 show that equol is produced from daidzein glycosides, such as daidzin, malonyl daidzin, and acetyldaidzin, in the fermenting material, and ornithine is produced from arginine. From these descriptions, it is also recognized that the production amounts of equol and ornithine can be adjusted by adjusting the amounts of daidzein glycosides and arginine in the fermenting material.

Similarly, furthermore, it is considered that when a microorganism other than Lactococcus strain 20-92 is used, it is recognized that the production amounts of equol and ornithine can be adjusted by adjusting the ratio of each component in the fermenting raw material.

The Demandant also alleges that no upper limit on production amount is specified.

However, equol and ornithine are produced as metabolites of microorganisms. In the light of the common technical knowledge that microorganisms produce the required amount of metabolites under ordinary circumstances, the fact that the upper limit is not specified in the Patent Invention does not mean that the specifying the production amount includes the case where the production amount far exceeds the lower limit.

Therefore, it cannot be said that the Patent Invention does not comply with the Support Requirement and the Patent Description does not comply with the Enablement Requirement.

Regarding the above C

As stated in the above (3), subjects to be screened include those known as equol-producing microorganisms at the time of the original filing date of the application of the case. In addition, it is recognized that a well-known method (such as one in B6-1 and B6-2) can be adopted in which a microorganism that produces ornithine is obtained by screening with the ability of conversion from arginine into ornithine as an index.

Therefore, the Demandant's allegation cannot be accepted.

3. Regarding Invalidation Reason 3

(1) Invention disclosed in A6

It is recognized that A6 discloses the invention (hereinafter, referred to as "A6 Invention") as follows:

"A method for converting daidzein into equol by culturing gram-positive bacterium do03, which is a bacterium capable of producing equol, in a culture medium containing arginine and daidzein."

(2) Comparison

Comparing the Patent Invention with the A6 Invention, they differ in at least the following point:

In the Patent Invention, a microorganism is "a microorganism having ornithine-producing ability and equol-producing ability" and the microorganism is employed in fermentation of a fermenting raw material to produce "8 mg or more of ornithine and 1 mg or more of equol per 1 g dry weight of the fermented product," where the fermented product is one "containing ornithine and equol." In A6, on the other hand, a microorganism is "a bacterium capable of producing equol" and a fermented product is one "containing equol."

Specifically, A6 does not describe that gram-positive bacteria do03 has the ability of producing ornithine, culturing the bacteria causes the production of at least 8 mg of ornithine per gram of dry weight of a fermented product, and ornithine is obtained as a useful product.

(3) Judgment

A6 describes that the medium is fermented to obtain equol, but does not describe about obtaining 8 mg or more of ornithine per gram dry weight of fermented product.

Since the Patent Invention and A6 Invention differ in the above point, it cannot be said that the Patent Invention is the invention disclosed in A6.

Furthermore, although the medium of A6 Invention contains arginine, the addition of arginine is described in Exhibit A6 as "use the arginine dihydrolase pathway to gain energy for growth." It cannot be said that A6 suggests that ornithine is generated from arginine and that ornithine is obtained as a useful product in a high proportion, such as "8 mg or more per 1 g dry weight of the fermented product."

Therefore, it cannot be said that a person skilled in the art could have easily invented the Patent Invention based on the A6 Invention.

Furthermore, it cannot be said that a person skilled in the art could have easily invented the Patent Invention by taking into consideration the other evidence presented by the Appellant.

(4) The Demandant's allegation

In the Oral Proceedings Statement Brief dated April 8, 2019, the Demandant generally alleges the following point:

In the method described in A6, "the arginine dihydrolase pathway" produces

ornithine from arginine. The production of ornithine was confirmed in the reproductive experiment (A11 and A17) for A6. Since ornithine is well known as an excellent bioactive ingredient, a person skilled in the art should have conducted a confirmation test for A6.

Considering the above allegation, as stated in the above (3), A6 ferments the medium and obtains energy from arginine using the arginine dihydrolase pathway but does not give ornithine as a useful product. Even if the excellent physiological activity of ornithine was well known in the art, it cannot be said that a skilled in the art could have easily conceived of obtaining ornithine by the culture method described in A6. Even if a person skilled in the art would conduct a follow-up test for A6, there is no motivation to confirm the production or amount of ornithine.

Therefore, the allegation of the Demandant cannot be accepted.

No 7 Closing

The judgment by the body on the reasons for invalidation alleged by the Demandant is as stated above. Therefore, the Demandant's allegation and the means of proof of the Demandant cannot invalidate the Patent.

The costs in connection with the trial shall be borne by the Demandant under the provisions of Article 61 of the Code of Civil Procedure which is applied mutatis mutandis in the provisions of Article 169(2) of the Patent Act.

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

July 19, 2019

Chief administrative judge: TAMURA, Kiyoko
Administrative judge: NAKAJIMA, Yoko
Administrative judge: KOGURE, Michiaki