Judgments of Tokyo District Court, 46th Civil Division
Date of Judgment: 2005.2.10
Case Number: 2003（Wa）No.19324

Title（Case）:

A case wherein X, the manufacturer and vendor of the generic drug product, with respect to Y, the owner of the patent for drug granules containing Branched Amino Acid and the process for producing the said product, petitioned for a confirmation of nonexistant rights to injunction of Y, whereby in regard to the manufacture of X's drug by X, the court did not recognize the non-exclusive license to be on the basis of prior use as it was not recognized that X was making preparations to set up a business to practice the invention in Japan（Patent Law Art. 79）at the time of Y's application for a patent.

The equivalent case wherein, notwithstanding that the patent owner Y sold the drug granules（Y's product）, the product through which the patent invention was practiced, it was extremely difficult to know, by the analytical technology normally available, that Y's product was the product through which the patent invention was practiced, and thus there were no grounds to revocation by the Patent Law Art. 29（1）(ii)（Public Practice）.

Summary of Judgment:

The pharmaceutical company Y is the owner of the patent of "a drug granules with an excellent content uniformity containing equal amounts of exactly three branched amino acids, i.e., isoleucine, leucine, and valine as the principal agents, including isoleucine and leucine granules whose grain sizes are 20－700?m, characterized by the fact that it is produced with the granulation ingredients with the ratio of the weight, isoleucine / leucine / valine = 1 / 1.9-2.2 / 1.1-1.3"（Patented product）and the process of producing this product, and manufactures and sells the drug granules（Y's product）, the product in which the patent invention was practiced. X is the pharmaceutical company that is planning to manufacture and sell the drug granules as a generic product（X' product）, whose arguments are as follows:

1） X's product does not fall within the technical scope of the patent invention.

Even if X's product did fall within the technical scope of the patent invention, X was preparing to manufacture his product before the patent application was filed; thereby X owns the right to be licensed based on the grounds of prior use according to Art. 79 of the Patent law.

2） Since Y sold Y's products, the products corresponding to which patent

invention was practiced, there are grounds for revocation based on the Article 29(1)(ii) of the Patent Law (Public use).

This court concluded that X's product was manufactured by the process of the patented invention and contained the structure of the patented invention described as follows, whereby it was found that X was not preparing to practice of the patent invention at the time the patent application was filed (10/26/2000), and thus the court rejected the argument of prior use by X.

To manufacture a drug as a business, a manufacturer has to perform a dissolution test, stability tests, and a bioequivalence test, and is required to obtain approval for manufacture from the Ministry of Health. To apply during "the preparation for business" to practice an invention as described in Article 79 of patent law, though it is not required that all of these steps be completed, at least the contents of the drug that would be the subject matter of those tests or manufacturing approval needs to be defined identically. In this case, in December of 2000, the manufacture partly altered the manufacturing process, and ordered Company A to manufacture the final drug for the tests and the sample for the stability tests, so it could not be recognized that the X had done "the preparation for the business," prior to December 23, at the time that manufacture of the final drug for the tests and the sample for the stability tests.

In addition to this, in regard to X's argument that there were grounds for the revocation of the patent invention based on Article 29(1)(ii) of the Patent Law, the court explained in the following terms, rejecting X's argument, and dismissing the petition for confirmation, because such grounds for revocation could not be made with the fact that Y had sold Y's products, corresponding through which the patent invention was practiced, prior to the filing of the patent application,

"'Public use' in Article 29 (1)(ii) requires the circumstances that the invention is known to general public through practice of the invention in the general public, simply saying that the product existed with a mechanism for practice cannot be a reason to prevent the inventor from obtaining a patent. In such case, where the patent invention is the invention of an object, it is not necessary for the product, in which the invention is practiced, to be in the situation where the product is produced completely. However, it should be required in the situation where it can be judged, by analyzing the product, in which the invention is practiced, given analytical technology is available, whether the product is applied to the object described in the specification of the patent request. And where such product is sold in the market, unless there is a special circumstance, it is usually possible to know the structure and the composition by analyzing such product.

"Applying these to this case, … the grain size of the branched amino acids contained in Y's product were approximately 50 ?m in the median diameter on the volume basis from the beginning, so the Y product, in which the patent invention was practiced, was produced in the process in this patented invention and sold before the patent application was filed. … however, according to the evidence, the process to produce Y's product was managed strictly as a trade secret. Although the composition of the contained components was public, other information was not published to the public, by the nature of the product that the product is kneaded with the branched amino acid ingredients and kneading ingredients, and granulated into granules, and coated, it is difficult to separate the individual grains such as isoleucine, leucine as the grain median before kneaded. It is extremely difficult for them by the analytical technology normally available for them to analyze the grain size of the branched amino acid contained in Y's product sold publicly and to know that Y's product had the composition of the patent invention at issue and was produced by the process in the patent invention at issue. … Therefore, it can be concluded that there were no grounds for the public use ruled in Art. 29(1)(ii) in the patent invention based on the fact that Y's product was sold in public."

Note that, in this case, X petitioned for confirmation that Y did not have rights to claim injunction for the patent involving the patented invention to adjust the temperature of kneading substance when to produce the drug granules with extrusion granulation device. As to this patent, the X's product did not fall within the technical scope of this patent, so the court recognized the petition.

Judgment rendered on February 10,2005

2003 (Wa) 19324 Case of Seeking Declaratory Judgment of Absence of Right to Seek Injunction Against Patent Right Infringement

Date of conclusion of oral argument: September 3, 2004

Judgment

Plaintiff: Nihon Pharmaceutical Co., Ltd.

Defendant: Ajinomoto, Co., Inc.

Main text

1. The court confirms that the defendant does not have the right to seek an injunction based on the patent right granted for Patent No. 3341771 against the plaintiff's act of manufacturing the "BRANUTE GRANULES" stated in the attached "List of the Plaintiff's Preparation" by using the method stated in the attached "List of the Plaintiff's Manufacturing Process."

2. The plaintiff's other claims shall be dismissed.

3. The court costs shall be divided into two, and each one shall be borne by the plaintiff and the defendant, respectively.

Facts and reasons

No. 1 The Plaintiff's claims

1. Same as paragraph (1) of the main text

2. The court will declare that the defendant does not have the right to seek an injunction based on the patent right granted for Patent No. 3211824 against the plaintiff's acts of manufacturing and selling the "BRANUTE GRANULES" stated in the attached "List of the Plaintiff's Preparation."

No. 2 Outline of the case

1. The plaintiff is engaged in the manufacture and sale of the "BRANUTE GRANULES" stated in the attached "List of the Plaintiff's Preparation" (hereinafter referred to as "Plaintiff's Preparation") by using the method stated in the attached "List of the Plaintiff's Manufacturing Process" (hereinafter referred to as "Plaintiff's Manufacturing Process"). The defendant, who holds a patent right for a granular drug preparation containing branched-chain amino acids and the manufacturing process thereof (the "First Patent Right" as mentioned below) and a patent right for the granulation process of granules (the "Second Patent Right" as mentioned below), claimed against the plaintiff discontinuation of the manufacture and sale based on an allegation that the Plaintiff's Preparation and the Plaintiff's Manufacturing Process infringe the patent rights mentioned above.

In this case, the plaintiff sought a declaratory judgment that the defendant does not have the

right to seek an injunction against the plaintiff's acts of manufacturing the Plaintiff's Preparation by the Plaintiff's Manufacturing Process and selling the Plaintiff's Preparation manufactured by the Plaintiff's Manufacturing Process, based on the patent rights mentioned above. The defendant contests the plaintiff's claims for a declaratory judgment mentioned above, alleging that the Plaintiff's Preparation and the Plaintiff's Manufacturing Process fall within the technical scope of the patented invention stated in Claims 1 and 3 of the First Patent Right and the patented invention stated in Claims 1 and 2 of the Second Patent Right, respectively.

2. Facts on which the decision is premised (Undisputed facts and facts that can be easily found based on evidence stated at the end of the relevant part, respectively)

(1) The plaintiff is a stock company engaged in the manufacture and sale, etc. of drugs and quasi-drugs in the course of trade.

The defendant is a stock company engaged in the business of manufacture, processing, sale, import and export and research and development of products including seasoning and drugs as well as the raw materials, by-products, and related products thereof, in the course of trade.

(2) The defendant obtained approval for manufacture under the Pharmaceutical Affairs Act with respect to a branched-chain amino acid preparation "LIVACT Granules" as new prescription combination preparations on January 31, 1996 and started the sale thereof from May of the same year (hereinafter referred to as "Defendant's Preparation"; Exhibit Ko 6).

The re-examination period for the Defendant's Preparation was set to be six years, ending January 30, 2002.

(3) The defendant filed a patent application with respect to the following patents on October 26, 2000 and January 30, 2002, respectively, and received registration as a patentee.

A. Patent No. 3211824 (hereinafter referred to as "First Patent Right"; the invention covered by said patent right shall be referred to as "First Patented Invention"; the description concerning said patented invention shall be referred to as "First Patent Description"; and the bulletin publishing the First Patent Right (Exhibit Ko 1) shall be referred to as "First Bulletin"; Exhibits Ko 1 and 2).

(A) Title of the Invention: Granular drug preparations containing branched-chain amino acids and process for manufacturing the same

(B) Application Date: October 26, 2000

(C) Application Number: Patent Application No. 2000-326513

(D) Registration Date: July 19, 2001

(E) The statements of the scope of claims in the First Patent Description are as follows.

(Hereinafter, the invention stated in each claim shall be referred to as "Claim 1 of the First Patented Invention" and likewise.)

[Claim 1] A process for manufacturing a granular drug preparation with good content uniformity

that is characterized by using the particles of three kinds of branched amino acids consisting of isoleucine, leucine, and valine, which contain isoleucine particles and leucine particles whose particle size is adjusted to 20 to 700μm as the only principal agents and granulizing the raw material to be granulated wherein isoleucine, leucine, and valine are contained in a weight ratio of isleucine/leucine/valine=1/1.9 to 2.2/1.1 to 1.3.

[Claim 2] A process for manufacturing a granular drug preparation with good content uniformity stated in Claim 1 that is characterized by the abovementioned isoleucine particles and leucine particles with a particle size of 50 to 500μm.

[Claim 3] A granular drug preparation with good content uniformity that is characterized by being manufactured with the use of the particles of three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine, which contain isoleucine particles and leucine particles with a particle size of 20 to 700μm as the only principal agents and raw materials granulated to contain isoleucine, leucine, and valine in a weight ratio of isoleucine/leucine/valine=1/1.9 to 2.2/1.1 to 1.3.

[Claim 4] A granular drug preparation with good content uniformity stated in Claim 3 that is characterized by the abovementioned isoleucine particles and leucine particles with a particle size of 50 to 500μm.

B. Patent No. 3341771 (hereinafter referred to as "Second Patent Right"; the invention covered by said patent right shall be referred to as "Second Patented Invention"; the description of said patented invention shall be referred to as "Second Patent Description"; and the bulletin publishing the Second Patent Right (Exhibit Ko 3) shall be referred to as "Second Bulletin"; Exhibits Ko 3 and 4).

(A) Title of the Invention: Granulation process of granules

(B) Priority Claim: September 28, 2001

(C) Priority Claim Number: Patent Application No. 2001-299210

(D) Application Date: January 30, 2002

(E) Application Number: Patent Application No. 2002-22157

(F) Registration Date: August 23, 2002

(G) The statements of the scope of claims in the Second Patent Description are as follows.

(Hereinafter the invention stated in each claim shall be referred to as "Claim 1 of the Second Patented Invention" and likewise.)

[Claim 1] A process for manufacturing a granular drug containing only three kinds of branched amino acids consisting of isoleucine, leucine, and valine as active ingredients that is characterized by the fact that when a particle mixture containing three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine is kneaded with kneading water and then subjected to extrusion granulation with an extrusion granulator, the temperature of the

kneaded material to be supplied to the extrusion granulator is controlled to fall within the range of 30 to 0°C.

[Claim 2] A process for manufacturing a granular drug containing only three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine as active ingredients stated in Claim 1 that is characterized by controlling the temperature of the kneading water mentioned above to fall within the range of temperature mentioned above by controlling the temperature of the kneading water to be used for kneading.

[Claim 3] A process for manufacturing a granular drug containing only three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine as active ingredients stated in Claim 1 or 2 that is characterized by controlling and maintaining the temperature of the kneaded material to fall within the range of 30 to 0°C inside the extrusion granulator mentioned above.

[Claim 4] A process for manufacturing a granular drug containing only three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine as active ingredients stated in Claim 1, 2, or 3 that is characterized by the fact that the particle mixture and/or kneading water contains a binder for granulation.

[Claim 5] A process for manufacturing a granular drug containing only three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine as active ingredients that is characterized by the fact that when a particle mixture containing three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine is kneaded with kneading water and then subjected to extrusion granulation with an extrusion granulator, the temperature of the kneaded material is controlled to fall within the range of 30 to 0°C inside the extrusion granulator.

(4) On March 12, 2003, the plaintiff received approval for manufacture of the branched-chain amino acid preparation named "BRANUTE GRANULES" as a generic version of the Defendant's Preparation under the Pharmaceutical Affairs Act (the "Plaintiff's Preparation"; Exhibit Ko 8).

The composition of the Plaintiff's Preparation is as stated in the attached "List of the Plaintiff's Preparation," while the method of manufacturing the Plaintiff's Preparation is as stated in the attached "List of the Plaintiff's Manufacturing Process" (Exhibits Ko 14-1 and 14-2).

(5) Prior to engaging in the sale of the Plaintiff's Preparation, the plaintiff requested the defendant to confirm that the Plaintiff's Preparation does not infringe the patent rights held by the defendant. However, the defendant presented its opinion that the Plaintiff's Preparation constitutes infringement of the First and Second Patent Rights.

(6) The plaintiff is tentatively engaged in the manufacture and sale of the Plaintiff's Preparation

whose particle sizes of the isoleucine and leucine powders are changed (Exhibit Ko 9).

3. Issues

(1) Whether the term "particle size" used in the scope of claims of Claims 1 and 3 of the First Patented Invention refers to the "particle diameter of each particle" or "volumetric basis median size" (Issue 1).

(2) Whether the plaintiff holds a non-exclusive license based on prior use with respect to Claims 1 and 3 of the First Patented Invention (Issue 2).

(3) Whether or not the defendant's act of exercising the right based on the First Patent Right by alleging that the Plaintiff's Preparation and the manufacturing process thereof fall within the technical scope of Claims 1 and 3 of the First Patented Invention is an abuse of right.

A. Whether or not it is obvious that there are grounds for invalidation of Claims 1 and 3 of the First Patented Invention for being patented in violation of Article 29, paragraph (1), item (ii) of the Patent Act (Issue 3).

B. Whether or not the defendant's act of receiving a patent for Claims 1 and 3 of the First Patented Invention is an act of receiving a patent by an act of fraud as prescribed in Article 197 of the Patent Act. If so, whether or not the act of exercising the right based on the First Patent Right (Claims 1 and 3), with respect to which a patent was obtained by such act of fraud, is an abuse of right (Issue 4).

(4) Whether or not the Plaintiff's Manufacturing Process falls within the technical scope of Claims 1 and 2 of the Second Patented Invention (Issue 5).

(5) Whether or not the plaintiff holds a non-exclusive license based on prior use with respect to Claims 1 and 2 of the Second Patented Invention (Issue 6).

(6) Whether it is obvious that there are grounds for invalidation of Claims 1 and 2 of the Second Patented Invention and the act of exercising the right based on the Second Patent Right is an abuse of right.

A. Whether or not it is obvious that there are grounds for invalidation of Claims 1 and 2 of the Second Patented Invention for being patented in violation of Article 29, paragraph (2) of the Patent Act (Issue 7).

B. Whether or not it is obvious that there are grounds for invalidation of Claims 1 and 2 of the Second Patented Invention for being patented in violation of the proviso to Article 29, paragraph (1) of the Patent Act (Issue 8).

(omitted)

No. 4 Court decision

1. Regarding Issue 1 (Whether the term "particle size" used in the scope of claims of Claims 1

and 3 of the First Patented Invention refers to the "particle diameter of each particle" or "volumetric basis median size")

(1) Interpretation of "particle size"

A. Regarding the statements in the scope of claims

The technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application (Article 70, paragraph (1) of the Patent Act). As such, Claims 1 and 3 of the First Patented Invention contain the term "particle size."

According to Exhibit Ko 18 (*Terminology Dictionary of Powder Technology*, 2nd Edition, edited by The Society of Powder Technology, Japan , and published by Nikkan Kogyou Shimbun, Ltd. in 2000) and Exhibit Otsu 2 (*Kagaku Kogaku Taiyo* (Synopsis of Chemical Engineering) multi-authored by Koichi Iinoya and others, Volume 2, published by Yokendo Co., Ltd. in 1970), the term "particle size" generally refers to the size of particles, which can be expressed in various ways using their weight, volume, surface area, or sedimentation velocity. There are documents stating that recently, the "particle size" is often indicated by being converted into the particle diameter. Yet, even if the particle size were to be converted into the particle diameter, the particle diameter of each particle in the particle group is usually not uniform, and thus the particle size of powders is indicated by the average particle size, which is obtained by averaging each particle diameter. Moreover, there are plenty of ways to mathematically define the method of averaging the particle diameter, and the major method that will be practically used includes number length mean diameter, surface mean diameter, volume mean diameter, volume surface diameter, median diameter, and mode diameter. Therefore, there are also various ways to indicate the "particle size" when converting it to the particle diameter.

Accordingly, the term "particle size" is ambiguous and its meaning is not unambiguously clarified from the statements in the scope of claims.

B. Regarding the statements in the First Patent Description

When the technical scope of a patented invention cannot be unambiguously clarified from the statements in the scope of claims alone, the meaning of each term used in the scope of claims shall be interpreted in consideration of the statements in the description and drawings attached to the application (Article 70, paragraph (2) of the Patent Act).

In relation to this, the First Patent Description contains the following statements (Exhibit Ko 1).

(A) Line 23 to line 28 in column 3 of the First Bulletin

"This invention uses the basic means to carry out granulation by adjusting the particle size of the isoleucine particles and leucine particles, which are used for the manufacture of a granular preparation containing the particles of three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine, to be larger than the particle size of the particles

that are usually used for the granulation of a preparation […]."

(B) Line 4 to line 6 in column 4 of the First Bulletin

"The granular drug preparation of this invention refers to the granules and powders stated in the Japanese Pharmacopoeia, and the particle size thereof falls within the scope prescribed in the Japanese Pharmacopoeia."

(C) Line 22 to line 28 in column 4 of the First Bulletin

"Since there is no particular restriction on the method to adjust the particle size of the particles of the three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine that will be used for granulation, an ordinary grinding technique will be adopted. Examples of grinding mills that may be used for grinding include impact (high-speed rotating) grinding mills, such as hammer mills, tumbler (media) grinding mills, such as ball mills, and hydraulic (air) grinding mills, such as jet mills."

(D) Line 3 to line 16 of column 6 of the First Bulletin

"Next, this invention will be explained more specifically by showing working examples […]. Table 1 below shows the kind and particle diameter of the branched-chain amino acids used in each working example, and the particle size is a figure measured by the following method. […] The average particle diameter was indicated by using the volumetric basis median diameter."

(E) Table 1 in column 6 of the First Bulletin

BCAA	Volumetric basis median diameter
L-leucine	411μm 267μm 59μm 23μm
L-isoleucine	51μm 28μm
L-valine	179μm 45μm 22μm

According to the abovementioned statements in the First Patent Description, it is appropriate to construe that the term "particle size" stated in Claims 1 and 3 of the First Patented Invention means the volumetric basis median diameter, i.e., the diameter of the particle when the integrated volume has reached half the total volume of all particles, which is calculated by adding up the volume of the particles in the particle group from the particle with the smallest particle diameter in an ascending order.

C. (A) In this regard, the plaintiff alleges that, in the pharmaceutical field, when the particle size is indicated within a certain numerical value range, it is normal to interpret that, in general, the upper limit and lower limit of each particle diameter is indicated, based on the statements in the Japanese Pharmacopoeia and the statements in the technical documents.

However, the statements in the Japanese Pharmacopoeia cited by the plaintiff lead merely to a finding that the term "particle size" means the "particle diameter" when powders and fine granules are to be defined. Moreover, the statements in the other technical documents cited by the plaintiff are insufficient to find that, in the pharmaceutical field, a person ordinarily skilled in the art would generally interpret that, when the particle size is indicated within a certain numerical value range, the upper limit and lower limit of each particle diameter is indicated.

Rather, according to Exhibits Otsu 4 through 6, it is found that Sawai Pharmaceutical Co., Ltd., which is a person ordinarily skilled in the art, interprets the term "particle size" to mean "volumetric basis median diameter" based on the statements in Claims 1 and 3 of the First Patented Invention and the First Patent Description.

(B) The plaintiff further alleges that even if the volumetric basis median diameter were limited to a certain range, the particle diameter of each particle would not be limited, and thus if the term "particle size" stated in Claims 1 and 3 of the First Patented Invention were interpreted to mean the volumetric basis median diameter, the structures stated in the scope of claims would not necessarily achieve the function and effect of "improving the taste by eliminating particles with small particle diameters."

However, when an ordinary grinding method is used to grind branched-chain amino acids such as isoleucine and leucine and the grinding is conducted by having the volumetric basis median diameter of all the particles after the grinding fall within the range of 20 to 700μm, i.e., larger than the conventional diameter, the particle diameter of each particle will be larger than in the past as a whole, and thus, the function and effect of Claims 1 and 3 of the First Patented Invention to make the taste better than in the past will be achieved.

The plaintiff cites as an example a group of particles wherein the volumetric basis median diameter is adjusted to 50μm by adding 8 grains of particles with a particle size of 50μm to 1,000 grains of uniform particles with a particle size of 10μm. However, when drugs containing branched-chain amino acids are to be manufactured, the particles of each branched-chain amino acid will by no means have the abovementioned structure unless the particle diameter of each particle is intentionally made smaller and a grinding method different from ordinary grinding methods is used for the purpose of enlarging the volumetric basis median diameter. Moreover, the plaintiff alleges that the taste of the Plaintiff's Preparation would not have been improved because [i] the proportion of isoleucine and leucine with a particle diameter of 20μm or smaller to the volume is approximately 20 to 30% in the Plaintiff's Preparation; and [ii] the proportion

of such isoleucine and leucine to the number of particles is approximately 92 to 97%. Therefore, the plaintiff alleges that even if the volumetric basis median diameter were to fall within the technical scope of the First Patent, a preparation with unimproved taste (Plaintiff's Preparation) would actually exist. However, it cannot be found that the taste of the Plaintiff's Preparation has not been improved from the fact that the Plaintiff's Preparation wherein the volumetric basis median diameter of isoleucine and leucine is 57.7μm and 38.7μm, respectively, has the abovementioned structure as alleged by the plaintiff, and thus, the plaintiff's allegation lacks its basis.

(C) The plaintiff further alleges as follows: If the term "particle size" stated in the scope of claims of Claims 1 and 3 of the First Patented Invention were interpreted to mean volumetric basis median diameter, preparations with a volumetric basis median diameter of 700μm would be allowed. However, such preparations would include particles with a particle diameter of 1,700μm, which is excluded by the definition of granular preparation in the Japanese Pharmacopoeia, and thus inconsistency would occur. Yet, based on the fact that it is stated in the First Patent Description that "The granular drug preparation of this invention refers to the granules and powders stated in the Japanese Pharmacopoeia and the particle size thereof falls within the scope prescribed in the Japanese Pharmacopoeia" (line 4 to line 6 in column 4 of the First Bulletin), manufacture and sale should inevitably be conducted within the range prescribed in the Japanese Pharmacopoeia by preparing the drugs by excluding particles that have a particle diameter larger than 1,700μm, and thus no inconsistency will occur.

D. Based on the abovementioned findings, the term "particle size" stated in the scope of claims of Claims 1 and 3 of the First Patented Invention should be interpreted to mean the volumetric basis median diameter.

(2) Whether or not the Plaintiff's Preparation and the manufacturing process thereof fall within the technical scope of Claims 1 and 3 of the First Patented Invention

As mentioned above, since the term "particle size" means the volumetric basis median diameter, if the volumetric basis median diameter of each branched-chain amino acid contained in the Plaintiff's Preparation were to fall within the range of 20 to 700μm, the Plaintiff's Preparation would fall within the technical scope of Claim 3 of the First Patented Invention and the manufacturing process thereof would fall within the technical scope of Claim 1 of the First Patented Invention. (It is obvious that the Plaintiff's Preparation satisfies the requirements other than the "particle size" based on the statements in the attached "List of the Plaintiff's Preparation" and there are no disputes between the parties.)

The volumetric basis median diameter of the particles of each branched-chain amino acid contained in the Plaintiff's Preparation is as stated in the attached "List of the Plaintiff's Preparation," i.e., 57.7μm for isoleucine and 38.7μm for leucine, and thus the Plaintiff's

Preparation and the manufacturing process thereof fall within the technical scope of Claims 1 and 3 of the First Patented Invention.

(omitted)

3. Issue 3 (Whether or not it is obvious that there are grounds for invalidation of Claims 1 and 3 of the First Patented Invention for being patented in violation of Article 29, paragraph (1), item (ii) of the Patent Act)

(1) According to the evidence (Exhibits Ko 1, 2, 5, 6, 12, 13, 20, 32, 34 (the branch numbers are omitted)) and the entire import of the oral argument, the following facts are found.

A. The defendant obtained approval for manufacture of the Defendant's Preparation as a new prescription combination preparation on January 31, 1996, and started the sale thereof from May 1996 (Exhibit Ko 6).

The defendant kept tight control over the manufacture of the Defendant's Preparation as trade secret, and has made public the composition of the component (Exhibit Ko 6) but has not externally disclosed other information. The Defendant's Preparation is manufactured by kneading and granulating the branched-chain amino acid raw material and kneading agent and further applying coating thereto.

B. On October 26, 2000, the defendant filed a patent application for the First Patented Invention and received registration of a patent (Exhibits Ko 1 and 2).

C. On December 27, 2000, the defendant submitted to the Commissioner of the Japan Patent Office an explanation of circumstances concerning accelerated examination of the First Patented Invention ("Explanation of Circumstances"). The document contains the following statements with respect to the composition of the Defendant's Preparation (Exhibit Ko 20).

"Isoleucine and leucine, which are branched-chain amino acids used as raw materials for the granular preparation 'LIVACT,' had the disadvantage of being extremely difficult to dose due to their strong bitterness and specific bad taste. Thus, the dosability was improved by adding sweeteners and flavors to the granules or implementing flavoring coating, but such effort was insufficient. In light of these circumstances, the inventors of this invention conducted further intensive research on reducing the bitterness and improving the taste of the preparation. As a result, they found that, surprisingly, the particle size of isoleucine and leucine used as raw materials has a correlation with the bitterness and taste of the granular preparation product, and eventually created this invention. Specifically, as stated in the description in question, it had been found that the bitterness and bad taste of the granular preparation product, which was the problem, can be substantially reduced by making the particle size of the amino acid used as raw material larger than the particle size of the base powder of ordinary drugs (which is

approximately 10μm or smaller), i.e., 20 to 700μm and preferably 50 to 500μm. As this technology is extremely useful for solving the problem of granular preparation containing branched-chain amino acids, it is planned to be introduced for the manufacture of granular preparation products, such as 'LIVACT'."

D. The defendant failed to report the changes made to the composition of the Defendant's Preparation to the Ministry of Health, Labour and Welfare after the First Patented Invention was registered but continued the manufacture and sale of the Defendant's Preparation under the approval obtained prior to filing a patent application for the First Patented Invention.

E. The defendant submitted a document dated April 18, 2003 stating the following contents regarding the composition of the Defendant's Preparation titled "Regarding the negotiation with the company manufacturing a generic version of the branched-chain amino acid preparation 'LIVACT Granules'" to the Director of the Economic Affairs Division of the Health Policy Bureau of the Ministry of Health, Labour and Welfare in relation to the plaintiff's policy to sell, for the time being, temporary products wherein the particle size of the branched-chain amino acid used in the Plaintiff's Preparation was changed, after obtaining approval for the Plaintiff's Preparation (Exhibit Ko 32).

"Although the investigational new drug was manufactured by a process that is likely to conflict with the patent of our company, in this negotiation, we received an answer that, in the actual production, the relevant drug is planned to be manufactured by a process avoiding any conflict with our company's patent or any conflict will be avoided. In particular, the basic experiment conducted by our company (examination of blood concentration in dogs) has suggested that it is highly likely for the preparation manufactured by adjusting the particle size of the branched chain amino acid used as raw materials to fall within the range of 20 to 700μm (for LIVACT Granules, branched amino acid with a particle size of approximately 50μm is used) and the granular preparation manufactured by using raw materials pulverized to 20μm or smaller for the purpose of avoiding any conflict with our company's patent to have different bioequivalence (AUC and Cmax of all of the three kinds of amino acids that are active ingredients). In other words, it is highly likely that the actual product will have a different BE (bioequivalence) with the original drug. Under the current inspection conducted for permission in Japan, unlike in the United States and other countries, it is not necessarily clarified to check the pharmaceutical equivalence between the investigational new drug and the actual product. However, […] the possibility of any difference in the efficacy expression has the risk of causing confusion to the site of treatment. We therefore request that you take this point into consideration when conducting hearings with companies producing generic drugs and to confirm that the BE of the actual product in addition to the investigational new drug is absolutely pharmaceutically equivalent to that of the original drug and to further give necessary

instructions."

F. The plaintiff stated its objections against the defendant with respect to the defendant's act of submitting the abovementioned document to the Ministry of Health, Labour and Welfare in a document dated June 13, 2003 (Exhibit Ko 33).

The contents of the plaintiff's objections can be basically summarized into the following four points: [i] Although the plaintiff has not acknowledged that the Plaintiff's Preparation falls within the technical scope of the First Patented Invention, the defendant has stated as if the plaintiff has acknowledged it; [ii] Although the defendant entered into a confidentiality agreement with the plaintiff in the process of the negotiation, the defendant leaked the particle size of the branched-chain amino acids used in the Plaintiff's Preparation; [iii] If the bioequivalence differs according to the particle size, the initial particle size of the Defendant's Preparation at the time when the manufacture and sale thereof started (10μm or smaller) has changed after the patent application was filed for the First Patented Invention (approximately 50μm) and thus it would result in lack of bioequivalence; and [iv] If the defendant had made no changes to the granule size of the Defendant's Preparation, the First Patented Invention has been publicly worked prior to filing a patent application therefor and thus there will be grounds for invalidation of the First Patented Invention.

G. The defendant responded to the plaintiff's document mentioned above in a document dated July 2 of the same year. In this document, the defendant responded as follows with respect to the objection mentioned in F[iii] above: "It seems that you have doubts that the particle size of our company's product at the time when we obtained approval for manufacture differs from the particle size of our company's product that is now manufactured, but there are no such facts." (Exhibit Ko 34).

(2) As stated above, the defendant has stated that "for LIVACT Granules, branched amino acid with a particle size of approximately 50μm is used" in a document submitted to the Ministry of Health, Labour and Welfare in April 2003, and has further stated in a document submitted to the plaintiff in July of the same year that "It seems that you have doubts that the particle size of our company's product at the time when we obtained approval for manufacture differs from the particle size of our company's product that is now manufactured, but there are no such facts." In light of these statements, it should be found that the particle size of the branched-chain amino acids contained in the Defendant's Preparation, which had been manufactured and sold since around 1996 until the filing of a patent application for the First Patented Invention, was approximately 50μm.

The defendant has stated as follows in the Explanation of Circumstances prepared in December 2000: [i] "Isoleucine and leucine, which are branched-chain amino acids used as raw materials for the granular preparation 'LIVACT,' had the disadvantage of being extremely

difficult to dose due to their strong bitterness and specific bad taste."; [ii] "the inventors of this invention conducted further intensive research for reduction of the bitterness and improvement of the taste of the preparation. As a result, they found that, surprisingly, the particle size of isoleucine and leucine used as raw materials has a correlation with the bitterness and taste of the granular preparation product and eventually created this invention."; and [iii] "it is planned to be introduced for the manufacture of granular preparation products, such as 'LIVACT'." The abovementioned statements may lead to an understanding that prior to filing a patent application of the First Patented Invention, the particle size of the branched-chain amino acids contained in the Defendant's Preparation was 20μm or smaller and the Defendant's Preparation had a bad taste. However, putting together the following facts and the entire import of the oral argument, it is appropriate to find that the volumetric basis median diameter of each branched-chain amino acid used in the Defendant's Preparation was approximately 50μm from the beginning of its sale in 1996 as stated above: [i] it is not stated that "'LIVACT' has a bitterness" but is instead stated that "Isoleucine and leucine, which are branched-chain amino acids used as raw materials for the granular preparation 'LIVACT,' […] had […] strong bitterness"; and [ii] the defendant has prepared a document stating that the particle size of the branched-chain amino acids contained in the Defendant's Preparation is approximately 50μm in April and July of 2003 after preparing the Explanation of Circumstances, as stated above.

(3) As such, based on the premise that the particle size of the branched-chain amino acids contained in the Defendant's Preparation is approximately 50μm, this court will examine whether or not the sale of the Defendant's Preparation at the market may serve as the grounds for finding that the inventions stated in Claims 1 and 3 of the First Patented Invention were publicly worked as prescribed in Article 29, paragraph (1), item (ii) of the Patent Act in the following parts.

Under the patent system, an exclusive right is granted in compensation for disclosure of a new technical idea to society. Thus, it is unnecessary to grant an exclusive right to technical means that is already socially known. Moreover, granting an exclusive right to such technical means would rather hinder the free development of technology.

The Patent Act has prescribed that a patent cannot be obtained for the inventions prescribed in the items of Article 29, paragraph (1) of said Act based on the abovementioned idea. As such, with respect to the requirement of being "publicly worked" prescribed in item (ii) of said paragraph, it is appropriate to construe that the contents of the relevant invention must have become known to many and unspecified persons as a result of working it in front of them and that the mere existence of the product based on the invention does not inhibit the relevant inventor from obtaining a patent for the relevant invention. In this case, it is appropriate to construe that, if the relevant invention were an invention of a product, the product based on the

relevant invention would not be required to be in a state where a person ordinarily skilled in the art could analyze to completely reproduce the relevant product but rather it would be required to be in a state where a person ordinarily skilled in the art could determine whether or not the product were the product stated in the scope of claims by analyzing the relevant product based on the invention with the use of available analysis techniques.

If the product based on the relevant invention were sold in the market, unless there were special circumstances, a person ordinarily skilled in the art would know the structure or composition of the relevant product by analyzing it.

In this case, as stated above, with respect to the particle size of the branched-chain amino acids contained in the Defendant's Preparation, it is found that the volumetric basis median diameter was approximately 50μm from the beginning of its sale. As such, it may be found that the Defendant's Preparation manufactured by the method stated in Claim 1 of the First Patented Invention, which is a product based on the invention stated in Claim 3 of the First Patented Invention, had been sold prior to filing a patent application for the First Patented Invention (it is found from Exhibit Ko 6 that the Defendant's Preparation satisfies the requirements other than the particle size of the branched-chain amino acids). However, according to the evidence (Exhibit Ko 6 and Exhibits Otsu 1 and 2), the manufacturing process of the Defendant's Preparation was tightly controlled as a trade secret, and although the composition of the component thereof was made public, other information was not externally disclosed. In addition, based on the nature of a preparation, which has been manufactured by kneading and granulating branched-chain amino acids and kneading material and further applying coating, it is found difficult to separate the particles of isoleucine and leucine as those having the particle diameter before the kneading. Accordingly, it is extremely difficult for a person ordinarily skilled in the art to analyze, from the Defendant's Preparation sold in the market, the particle size of the branched-chain amino acids contained therein and to know that the Defendant's Preparation comprises the structure stated in Claim 3 of the First Patented Invention and has been manufactured by the method stated in Claim 1 of the First Patented Invention by using normally available analysis technology (evidence sufficient enough to reverse the abovementioned findings has not been submitted by the plaintiff).

As such, the sale of the Defendant's Preparation in the market is insufficient to serve as grounds to find that Claims 1 and 3 of the First Patented Invention were publicly worked as prescribed in Article 29, paragraph (1), item (ii) of the Patent Act.

(4) According to the abovementioned findings, Claims 1 and 3 of the First Patented Invention cannot be found to have grounds for invalidation for being patented in violation of Article 29, paragraph (1), item (ii) of the Patent Act.

(omitted)

6. According to the abovementioned findings, the Plaintiff's Preparation and the manufacturing process thereof fall within the technical scope of Claims 1 and 3 of the First Patented Invention. Moreover, the plaintiff cannot be found to hold a non-exclusive license based on prior use with respect to Claims 1 and 3 of the First Patented Invention. Furthermore, it cannot be said that the defendant's act of exercising his/her right based on the First Patent Right is an abuse of right due to reasons such that the First Patented Invention obviously has grounds for invalidation. Accordingly, the defendant holds the right to seek an injunction based on the First Patent Right against the plaintiff's act of manufacturing and selling the Plaintiff's Preparation, and thus the plaintiff's claims for a declaratory judgment to find that the defendant does not have the right to seek an injunction is groundless.

On the other hand, the Plaintiff's Manufacturing Process does not fall within the technical scope of Claims 1 and 2 of the Second Patented Invention, and thus, the defendant does not have the right to seek an injunction based on the Second Patent Right against the plaintiff's acts of manufacturing the Plaintiff's Preparation by the Plaintiff's Manufacturing Process and selling the Plaintiff's Preparation manufactured by the Plaintiff's Manufacturing Process. Therefore, the plaintiff's claim for a declaratory judgment to find that the defendant does not have the right to seek an injunction is well-grounded.

Thus the judgment shall be rendered in the form of the main text.

Tokyo District Court, 46th Civil Division

Presiding judge: MIMURA Ryoichi

Judge: FURUKAWA Kenichi

Judge: YOSHIKAWA Izumi

Attachment

List of the Plaintiff's Preparation

Product name/trade name "BRANUTE GRANULES"

a. A granular drug preparation with good content uniformity that only contains the following amount of active ingredients in one unit (4.73g):

L-isoleucine: 952mg

L-leucine: 1904mg

L-valine: 1144mg

b. Isoleucine powder and leucine powder, for which the results of the particle diameter distribution measurement conducted by a "Laser-diffraction-scattering particle-size-measuring

device (HORIBA LA-920)" manufactured by HORIBA, ltd. are as stated in the following pages, will be used as raw materials. According to the measurement results, the particle diameter distribution, content rate of particles with a particle size of smaller than 20μm, and the volumetric basis median diameter of each raw material are as follows.

(A) Raw material isoleucine powder

Particle diameter distribution: approximately 6 to 450μm

Particles with a particle size of smaller than 20μm: approximately 20% on the volumetric basis

Volumetric basis median diameter: 57.7μm

(B) Raw material leucine powder

Particle diameter distribution: approximately 4.5 to 520μm

Particles with a particle size of smaller than 20μm: approximately 30% on the volumetric basis

Volumetric basis median diameter: 38.7μm

The results of the particle diameter distribution measurement are omitted.

Attachment

List of the Plaintiff's Manufacturing Process

a. A particle mixture containing HPC-L and three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine;

b. Kneading the particle mixture mentioned in A. above by adding a kneading liquid, which is prepared by having uncontrolled room temperature distilled water contain Macrogol 6000 under an environment of room temperature of 16 to 26°C;

c. Leaving the temperature of the kneaded material to be supplied to the extrusion granulator to room temperature without making any control at the time of conducing extrusion granulation by the extrusion granulator ("Twin Dome Granulator TDG-110" manufactured by Fuji Paudal co., ltd. and sold by Dalton Co., Ltd.) under the environment of the abovementioned room temperature;

d. As a result of not controlling the temperature of the kneaded material inside the abovementioned granulator, the temperature of the kneaded material exceeds 30°C;

e. A manufacturing process of a granular drug that contains as active ingredients only three kinds of branched-chain amino acids consisting of isoleucine, leucine, and valine under the conditions mentioned in d. above.