Date	August 5, 2015	Court	Intellectual Property High Court, Third Division
Case number	2014 (Gyo-Ke) 10238		
– A case in which, while the JPO examined a patent application for the invention titled "active foam" and made a decision that the description attached to the application cannot be said to have been written clearly and sufficiently so that any person ordinarily skilled in the art could work the invention, the court found that the JPO erred in making the aforementioned determination and rescinded the JPO decision.			

References: Article 36, paragraph (4), item (i) of the Patent Act

Number of related IP right, etc.: Trial against Examiner's Decision of Refusal No. 2011-20954 (trial), Patent Application No. 2006-536494 (the "Application")

Summary of the Judgment

1. This is a lawsuit filed by the plaintiffs to seek rescission of the JPO decision that dismissed the plaintiffs' request for a trial against an examiner's decision of refusal of the patent application (the "Application") for the invention titled "active foam."

The invention claimed in the Application (the "Invention") is an active foam made of natural rubber, a synthetic rubber or a synthetic resin, which has a foam sheet of a closed-cell structure and is characterized in that it is used by directly or indirectly bringing it into contact with the human body upon drug administration. In its decision, the JPO found that the description attached to the Application (the "Description") is not written in a way that any person ordinarily skilled in the art could understand and recognize the synergistic effects of the simultaneous use of a drug and the active foam of the Invention, and therefore that the Description cannot be considered to have been written clearly and sufficiently so that any person ordinarily skilled in the art could work the invention and should be considered to have failed to satisfy the requirement specified in Article 36, paragraph (4), item (i) of the Patent Act.

2. In this judgment, the court rescinded the JPO decision on the grounds that the JPO erred in making the aforementioned determination by holding as follows:

(1) The phrase "upon drug administration" included in the Description merely specifies the timing of the use of the active foam. The claims of the Invention do not specify the purpose or usage of the Invention such as increasing the effect of the drug or promoting the cure of the disease. Therefore, even if the Description fails to sufficiently disclose the synergistic effects of the simultaneous use of a drug and the active foam, if it can be said that there is any other technical significance in using the active foam "by directly or indirectly bringing it into contact with the human body," it should be construed, as far as the enablement requirement is concerned, that any person ordinarily skilled in the art "can use" the active foam of the Invention, based on the statement in the Description

and the common general technical knowledge available as of the time of the filing of the Application; and

(2) The Description explained Examination 1 by stating that the examiner measured the blood flow, body pressure, etc., of one examinee after he/she sat still on the active foam placed on a chair for thirty minutes and also carried out the same measurement after the examinee sat still directly on a chair without the active foam for thirty minutes, and made a comparison between the measurements taken in these two cases. Based on the results of the comparison, the Description concluded that it was found that "the use of the active foam would improve blood flow and decrease body pressure."

However, although this examination was conducted in such manner that the active foam was "used by directly or indirectly bringing it into contact with the human body," it is uncertain what kind of active foam was used. Moreover, in light of the common general technical knowledge available to any persons ordinarily skilled in the art as of the time of the filing of the Application, the results of the examination in which only one female examinee in her 50s was measured cannot be evaluated as objective data about human bodies in general. Furthermore, since the details of the conditions of the examination have not been sufficiently disclosed, it is difficult to immediately verify whether the effect of the active foam, i.e., "the use of the active foam would improve blood flow and decrease body pressure," which is alleged to be proven by the measurements of the blood flow and body pressure taken in this examination, is attributable to the use of the active foam or to any other factor.

Therefore, it is questionable to conclude based only on the results obtained in Examination 1 that the use of the active foam "by directly or indirectly bringing it into contact with the human body" would produce a technically meaningful effect, i.e., the promotion of blood flow in human bodies. However, there is room to say that such technically meaningful effect of the use of the active foam claimed in the Application could be considered to have been proven if the plaintiffs can give a convincing explanation about the conditions of the Examination 1 or if the results of other examinations are available and convincing.

Thus, it must be said that the JPO erred in concluding, without fully examining the aforementioned points, that the Description failed to satisfy Article 36, paragraph (4), item (i) of the Patent Act. Therefore, the JPO decision must be rescinded.

Judgment rendered on August 5, 2015
2014 (Gyo-Ke) 10238, Case of Seeking Rescission of JPO Decision
Date of conclusion of oral argument: June 24, 2015

Judgment

Plaintiff: X1
Plaintiff: X2
Defendant: Commissioner of the Japan Patent Office

Main text

1. The JPO decision made on September 22, 2014, concerning Appeal against Examiner's Decision of Refusal No. 2011-20954, shall be rescinded.
2. The defendant shall bear the court costs.

Facts and reasons

No. 1 Claims

Same as the main text.

No. 2 Outline of the case

1. Developments in procedures at the JPO (there are no disputes between the parties with regard to the facts accompanied by the indications of evidence.)

On May 16, 2005, the plaintiffs filed an international application for an invention titled "activated foam" (Japanese Patent Application No. 2006-536494; hereinafter referred to as the "Application"; the number of claims: 6). Since they received an examiner's decision of refusal dated June 23, 2011 (the drafting date), they filed an appeal against this decision on September 28, 2011, and submitted a written amendment on January 27, 2014 (Exhibit Ko 9; hereinafter the amendment made by this written amendment is referred to as the "Amendment").

The JPO examined this appeal as Case of Appeal against Examiner's Decision of Refusal No. 2011-20954. The JPO rendered a decision to dismiss the appeal on September 22, 2014, and served the transcript of the decision upon the plaintiffs on October 7, 2014.

On November 3, 2014, the plaintiffs filed this action to seek rescission of the JPO decision.

2. Scope of claim

Claim 1 in the Application after the Amendment is stated as follows (Exhibit Ko 9; hereinafter the invention based on this claim is referred to as the "Invention," and the description after the Amendment is referred to as the "Description").

[Claim 1]

An activated foam which is made of a natural or synthetic rubber or a synthetic resin and has a

foamed sheet of a closed-cell structure, wherein the foamed sheet contains a zirconium compound and/or a germanium compound, and which is characterized in that it is used by having it directly or indirectly contact a human body when a pharmaceutical agent is administered.

3. Reasons for the JPO decision

The reasons for the JPO decision are as described in the copy of the decision attached hereto. In summary, the JPO ruled that the statement of the Description cannot be deemed to be clear and sufficient as to enable a person ordinarily skilled in the art to work the Invention, and hence it fails to meet the requirement under Article 36, paragraph (4), item (i) of the Patent Act.

(omitted)

No. 5 Court decision

The court finds that there are errors in the JPO decision in that the JPO found the Description to fail to meet the requirement under Article 36, paragraph (4), item (i) of the Patent Act due to the lack of a statement of the effect of the combined use of the activated foam of the Invention with a drug in a manner that it enables a person ordinarily skilled in the art to understand and recognize that effect. The court determines that these errors had influence on the conclusion of the JPO decision, and therefore that the JPO decision should inevitably be rescinded.

The reasons for the court decision are as follows.

1. Statement of the Description

The plaintiffs allege that the JPO erred in finding that the statement of the Description is not clear and sufficient as to enable a person ordinarily skilled in the art to work the Invention. The Description states the Invention as follows (Exhibit Ko 1).

"Technical field

[0001]

The present invention relates to an activated foam made of natural or synthetic rubber or synthetic resin, and to an activated foam capable of facilitating blood circulation and promoting the improvement of physical condition and the cure of diseases such as cancer."

"Problems to be solved by the invention

…

[0007]

…a purpose of the present invention is to provide an activated foam having no adverse effect and capable of facilitating blood circulation and promoting the improvement of physical

condition and the cure of diseases such as cancer."

"Means to solve the problem

[0008]

As a result of earnest studies for achieving the above-described purpose, the present invention has been accomplished. Specifically, the invention relates to an activated foam made of natural or synthetic rubber or synthetic resin containing a zirconium compound and/or a germanium compound, characterized in that the foam has a closed-cell structure, and it is used by having it directly or indirectly contact a human body when a pharmaceutical agent is administered.

[0009]

The activated foam of the invention is used by the direct or indirect contact thereof with a human body, which is more effective when further producing friction between the foam and the body. The activated foam can facilitate blood circulation and promote the improvement of physical condition and the cure of diseases, but a mechanism thereof has not been elucidated.

[0010]

The zirconium compound and the germanium compound collect infrared rays, e.g. from the sun into the activated foam. Then, the infrared rays impinge on the walls of many cells inside the activated foam for repeating diffuse reflection and aggregation, and there are thereby radiated, toward the outside of the activated foam, infrared rays having wavelengths of 4 to 25 microns which exert a favorable influence on a human body. It is speculated that these infrared rays resonate with the wavelengths of a human body to activate water molecules and protein molecules in the body to enhance, through the excitometabolic effect, natural healing power originally possessed by humans. Thus, the activated foam is thought to facilitate the cure of diseases such as cancer, hypertension, diabetes, heart disease, stiffness in the shoulder, lower back pain, and allergic disease, and the improvement of physical condition, e.g. hair restoration or prevention of aging. In addition, the activated foam can be repeatedly used.

[0011]

The activated foam of the invention may be used, in administering a pharmaceutical agent, by having it directly or indirectly contact a human body to increase the effect of the pharmaceutical agent. In addition, even a pharmaceutical agent which would exert an adverse effect in a large dose, if combined with the activated foam, may reduce the adverse effect because its dosage can be decreased.

[0012]

Non-limiting examples of the pharmaceutical agent include an injection agent, a skin agent for external use, a mucocutaneous agent, a nasal agent, and an oral agent. More specific examples thereof include, but are not limited to, an anti-cancer agent and an antibiotic. The

pharmaceutical agent is preferably a human-derived substance…

[0013]

Among human-derived substances, a substance having the least possible adverse effect is preferably used because it has no adverse effect when used at a normal dose. Examples thereof include sodium butyrate (hereinafter referred to as SB) and sodium butyric ester which are present in the human intestine. These substances are inhibitors of histone deacetylase (…hereinafter referred to as HDACI) that deactivates chromatin (histone deacetylase inhibitor... hereinafter referred to as HDACI), which activate chromatin to express a cancer suppressor gene, thereby arresting the cell cycle (division cycle; the life cycle of a cell from the completion of cell division to the next cell division) of a cancer cell, that is, act as anti-tumor agents…Combination of the take of any of these substances and the use of the activated foam can suppress the function of an oncogene and increase the cancer-suppressing effect thereof."

"[0016]

The form of the activated foam may be a small, portable and handy triangle patch, a bed clothing-like form such as a mat to lay on or a mat to cover, or as a portion or the whole of a garment, etc., but is not limited thereto if the form makes it possible for the foam to directly or indirectly contact a human body. If it is desired to give such effects as for curing diseases, concentrated locally on a portion of a human body, the activated foam could be formed into a sheet shape having a thickness of about 8 mm to 5 cm. When it is used as clothing material, forming the foam into a sheet shape having a thickness of about 0.3 to 5 mm facilitates the making thereof into clothing.

[0017]

The rubber component may be natural rubber or synthetic rubber. Non-limiting examples of the synthetic rubber include rubbery polymers such as chloroprene rubber (CR), styrene-butadiene rubber (SBR), acrylonitrile-butadiene rubber (NBR), acrylonitrile rubber (NRP), butadiene rubber (BR), and isoprene rubber (IR), or a mixture of plural kinds thereof.

[0018]

Non-limiting examples of the synthetic resin component include vinyl chloride resin (PVC), polypropylene (PP), and polyethylene (PE).

[0019]

A foaming agent may use a publicly-known foaming agent, but is preferably Celogen OTI (from Uniroyal, U.S.A.) or Unicell (from Dongjin, South Korea).

[0020]

The activated foam may contain both or either of the zirconium compound and the germanium compound. For cancer treatment, both of the zirconium compound and the germanium compound are preferably contained because the effect of facilitating the cure of

cancer is enhanced.

[0021]

The zirconium compound preferably uses a zirconium complex compound. Examples of the zirconium complex compound include a complex of zirconium and fluorine or the like; specific examples thereof include, but are not limited to, potassium hexafluorozirconate (K_2ZrF_6) and potassium octafluorozirconate (K_2ZrF_8). The content of the zirconium compound is preferably 10 to 80 parts by weight, based on 100 parts by weight of rubber component. A content thereof lower than the lower limit results in poor effect, and a content thereof higher than the upper limit is undesirable from the economic standpoint because no significant difference in effect is produced.

[0022]

The germanium compound preferably uses a germanium mineral or a germanium complex compound. Non-limiting examples of the germanium mineral include argyrodite (Ag_8GeS_9) and renierite ($(Cu, Zn)_{11}Fe_4(Ge, As)_2S_{16}$). Non-limiting examples of the germanium complex compound include a complex of germanium and dicarboxylic acid or amine. The content of the germanium compound is preferably 5 to 10 parts by weight, based on 100 parts by weight of rubber component. A content thereof lower than the lower limit results in poor effect, and a content thereof higher than the upper limit is undesirable from the economic standpoint because no significant difference in effect is produced."

"Effect of the invention

[0024]

According to the invention, in administering a pharmaceutical agent, the activated foam may be used by having it directly or indirectly contact a human body to increase the effect of the pharmaceutical agent. In addition, even a pharmaceutical agent which would exert an adverse effect in a large dose, if combined with the activated foam, may reduce the adverse effect because its dosage can be decreased."

"Example

…

[0031]

Foamed sheet 1 is first prepared. Rubber or synthetic resin is used as a base, and compounding is carried out according to the formulation in Table 1, followed by kneading with a roll. In this respect, the method for mixing materials is not particularly restricted, and may use a conventional mixing method as employed for a rubber or synthetic resin compound. The resultant kneaded matter is then formed into sheet form using an extruder. This sheet is vulcanized and expanded using heated air (vulcanizing process). The vulcanizing process is carried out in two stages, primary and secondary. The two-stage vulcanization leads to uniform

formation of cells throughout the foamed sheet. The above process results in the production of foamed sheet 1.

[0032]

Cover sheet 2 is then stuck on both sides of foamed sheet 1 using a rubber- or synthetic resin-based adhesive. Subsequently, a high voltage is applied to the side providing the front thereof. The voltage application is carried out under the conditions of a current of 10,000 to 800,000 amperes, a voltage of 200 to 3,300V, and a duration of 0.1 to 0.3 seconds. In this respect, a higher current is more preferable. The activated foam generates electromagnetic waves such as infrared rays. It is believed that the high-voltage is applied to one side of the activated foam to direct the electromagnetic wave so as to show directivity toward the surface side to which the voltage has been applied, although the mechanism has not been elucidated. Accordingly, the contact of the surface with a human body enables electromagnetic waves to be irradiated in a concentrated manner on the contact area, thereby enhancing the effect of curing disease or the like. The above process allows the activated foam to be completed."

"[0033] [TABLE 1]

		Example 1	Example 2	Example 3	Example 4	Example 5	Example 6
	Natural rubber	100					
	Chloroprene rubber		100			100	
	Chlorosulfonated polyethylene			100			
	PVC (vinyl chloride resin)				100		
	NRP (acrylonitrile rubber)						100
	Liquid nitril rubber						6
	Zirconium complex compound	10	20	7	80		30
	Zircon		2	20		30	
	Germanium complex compound		10	10			
	Stabilizer				3		
	Zinc oxide	5	5	5		5	5
	Magnesium oxide	3	3	3		3	

	Celogen OTI	10	10	10	10	10	
	Stearic acid						3
	DOP (plasticizer)				25		30
	Carbon black	25	20	20		20	
	Process oil	30	30	5		30	
	Sulfur	3					3
	Vulcanization accelerator DM	2					3
	Silicon oxide	12			12		20
Vulcanizing conditions	Primary	130°C × 10 min	132°C × 19 min	120°C × 8 min	160°C × 5 min	100°C × 10 min	130°C × 10 min
	Secondary	160°C × 10 min	160°C × 10 min	150°C × 8 min	100°C × 5 min	160°C × 10 min	160°C.× 10 min
	Apparent specific gravity	0.16	0.21	0.35	0.24	0.22	0.2
	Hardness	7	8	10	10	9	9

(Unit: parts by weight)

"[0035]

<Test 1>

The activated foam was then used to perform a test for determining effects thereof on body pressure and blood flow in a human. A method for measuring body pressure and blood flow will first be described.

[0036]

[Test Subject]

One female aged in her fifties was used as a subject.

[0037]

[Test Method]

The test was carried out using an instrument for measuring blood flow and body pressure (AMI3037-2, from AMI Technology). A body pressure/blood flow sensor was attached to the upper part of the thigh for measurement in the environment of a room temperature of 23°C and a humidity of 55% RH under the following two conditions. In condition 1, the activated foam was spread on a chair, on which the subject then sat in resting state for 30 minutes, followed by measuring blood flow..., blood volume…, blood velocity…, and body pressure… for 10 minutes. In condition 2, the subject sat, for control, on a chair on which the activated foam was not spread for 30 minutes, followed by measuring blood flow and the like for 10 minutes. The results are shown in Table 2... Table 2 shows the mean values of measurements of blood flow

and the like for 10 minutes... In this respect, "blood flow" refers to blood flow per 100 g of human body tissue per minute, and is determined from the amount of light reflected by red blood cells in capillary vessels. "Blood volume" refers to blood volume per cross-sectional area of 100 g of human body tissue, and the product of the blood volume and the blood velocity becomes nearly equal to the blood flow.

[0038]

[Test Results]

[0039]

[TABLE 2]

	Blood flow (ml/min. 100 g)	Blood volume	Blood velocity	Body pressure (hPa)
Condition 1	1.882	172.12	0.406	40.47
Condition 2	1.232	150.53	0.272	42.74

[0040]

As shown in Table 2… above, the use of the activated foam of the invention improves blood circulation and reduces body pressure.

[0041]

<Test 2>

[Test Subjects]

Cultures of human-derived prostate cancer cell lines (Du145, PC3, and LNCap) were used...

[0042]

[Test Method]

On culture plates 10 cm in diameter, in each of which 15 ml of medium was placed, 10^5 cells/plate each of prostate cancer cells (Du145, LNCap, and PC3) were spread and cultured for 7 to 10 days (preparatory period) under conditions of 37°C and 5% CO_2, and then the test was started...]

[0043]

After starting the test, the culture was managed, in the experimental group, by vertically placing each culture plate in between the activated foams. In the control group, the culture was performed in a state free of the activated foam...

[0044]

The day immediately before the start of the test was set to day 0, and cells were collected at the 1st, 2nd, and 3rd week thereafter. Cells at the 3rd week of culture were fixed and then electron-microscopically observed (a).

[0045]

In addition, mRNA… was extracted from the cells at the 3rd week of culture. The extracted mRNA was hybridized…, followed by analyzing the results…(b).

[0046]

[Test Results]

It was noted in the experimental group that the proliferation of each kind of prostate cancer cells had the following characteristics.

[0047]

(a) A morphological difference was observed between electron-microscopic appearances in cells at the 3rd week in the experimental and control groups. Specifically, each cancer cell having contacted the activated foam for 3 weeks had more cytoplasmic vacuoles, less visible internal structures of mitochondria, and a less clear nuclear membrane… relative to that of the control group... Thus, it is shown that apoptosis occurs in the cells in which the activated foam has been used.

[0048]

The term "apoptosis" refers to genetically programmed cell death, i.e., the suicide of a cell. A cancer cell means a cell which continues proliferation due to disorders in the apoptosis system.

[0049]

(b) The results…of cDNA microarray at the 3rd week...

[0050]

For Du145, the experimental group showed up-regulation in FasL (2.3 fold), Fas (1.4 fold), TRADD (1.4 fold), CASP1, 4, and 10 (1.7, 1.2, and 1.7 fold), and DFF40 (1.7 fold) compared to the control group. For PC3, the experimental group showed up-regulation in CD40 (1.4 fold) and TNF (1.4 fold) compared to the control group. For LNCap, the experimental group showed up-regulation in Fas (1.6 fold), CASP8 (1.6 fold), and CASP3 (1.3 fold) compared to the control group. In this respect, FasL, Fas, TRADD, CASP1, 4, and 10, DFF40, CD40, and TNF form a gene group which starts up the apoptosis circuit. These results show that apoptosis is facilitated in the experimental group using the activated foam compared to the control group.

[0051]

[Discussion]

The following can be said from the above-described test results. The activated foam starts up the apoptosis circuit and facilitates the effect of weakening the function of cancer cells.

[0052]

<Test 3>

The activated foam and SB as HDACI were used against human prostate cancer cells to

carry out a cancer cell proliferation suppressing test. This test can be used to specifically reveal a revolutionary method for treating or preventing prostate cancer and to suggest that it may be, in principle, effective against any cancer...

[0053]

HDACI typified by SB prevents the deacetylation by HDAC to eliminate the inactivation of the chromatin. Thus, HDACI activates a cancer suppressor gene and the like whose functions are weakened to act so as to suppress the proliferation of cancer cells.

[0054]

[Test Subjects]

Cultures of human-derived prostate cancer cell lines (Du145, PC3, and LNCap) were used...

[0055]

[Test Method]

Each kind of prostate cancer cells (Du145, LNCap, or PC3) was cultured at a concentration of 10^3 cells/100 μl in a 96-well microplate. In the experimental group, 6 μl of 0, 1, 2, or 3 mM SB was added to the plate, and the plate was vertically placed in between the activated foams. The SB-containing culture medium was exchanged every two days. In the control group, the culture was carried out without using the activated foam while 6 μl of 0, 1, 2, or 3 mM SB was added...

"[0058]

[Test Results]

The activated foam significantly suppressed the proliferation of each kind of human prostate cancer cells irrespective of the presence of the hormone dependency thereof in the presence of even a low concentration (1 mM) of SB compared to that in the presence of a high concentration (3 mM) of SB without the activated foam… That is, the activated foam acted in association with SB to distinctly suppress the proliferation of human prostate cancer cells.

[0059]

[Discussion]

The following can be said from the above-described test results... the activated foam can be used simultaneously with HDACI to facilitate the suppressive effect of HDACI against proliferation of human prostate cancer cells. In principle, this method is thought to be an effective therapy against any cancer. In addition, SB is a substance which is present in the intestine in a human body and induces no allergic reaction. Thus, the 1 mM concentration thereof demonstrated to be effective in the present test has extremely low toxicity against a living body and is free of adverse effects such as allergy."

"Industrial applicability

[0061]

The activated foam of the invention may be used, in administering a pharmaceutical agent by having it directly or indirectly contact a human body to increase the effect of the pharmaceutical agent. In addition, even a pharmaceutical agent which would exert an adverse effect in a large dose, if combined with the activated foam, may reduce the adverse effect because its dosage can be decreased."

2. Whether the Description meets the enablement requirement

(1) Substance of the enablement requirement

Article 36, paragraph (4), item (i) of the Patent Act provides that the statement of the detailed explanation of the invention in a description must be "clear and sufficient as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention."

The patent system grants an inventor an exclusive right to work his/her invention for a predetermined period of time, in compensation for his/her disclosing the invention to the public. For this purpose, the description attached to a patent application must contain a statement by which the technical matters of the invention are disclosed to the public. Article 36, paragraph (4), item (i) of the Patent Act provides as above probably because, if the detailed explanation of the invention contained in the description fails to state the invention clearly and sufficiently to such extent that it enables a person ordinarily skilled in the art to work the invention, this is, after all, equal to the invention not being disclosed to the public, in which case there will be no basis for granting an inventor an exclusive right prescribed in the Patent Act.

In the case of an invention of a product, the working of the invention means producing, using, etc. the product (Article 2, paragraph (3), item (i) of the Patent Act), and accordingly, the phrase "enable any person ordinarily skilled in the art…to work the invention" referred to in Article 36, paragraph (4), item (i) of the Act means to enable such person to produce and use the product. When an invention of a product is claimed in an application, the process of producing the product and the process of using the product need to be specifically stated. However, even without such statement, if a person ordinarily skilled in the art would have been able to produce and use the product based on the statement of the description and drawings as well as the common general technical knowledge available at the time of the filing of the application, the claimed invention is deemed to meet the enablement requirement.

In order to find that a person ordinarily skilled in the art would have been "able to use" the product, it should be deemed to be necessary that such person would have been able to use the product of the patented invention in a manner that the use has at least some technical meaning, such as in a manner that the function and effect intended by the invention can be achieved.

This reasoning can be applied to the Invention as follows. The Invention, which relates to an activated foam as described in No. 2-2 above, is an invention of a product. In order for the Invention to meet the enablement requirement, it is necessary and sufficient that a person

ordinarily skilled in the art would have been able to produce the activated foam of the Invention and use that activated foam, based on the statement of the Description and the drawings as well as the common general technical knowledge available at the time of the filing of the Application.

(2) Whether a person ordinarily skilled in the art would have been able to produce the activated foam

The court first examines whether a person ordinarily skilled in the art would have been able to produce the activated foam of the Invention based on the statement of the Description.

According to 1. above, the Description states six types of activated foam as Examples 1 to 6, which were produced by mixing components such as rubber (natural rubber, chloroprene rubber, and acrylonitrile rubber), synthetic resin (chlorosulfonated polyethylene and vinyl chloride resin), zirconium compound (zirconium complex compound and zircon), and germanium compound (germanium complex compound), and the processes of producing them ([0031] to [0033]). The Description specifically states seven types of rubber components and three types of synthetic resin to be used for the production of the activated foam ([0017] and [0018]), and also states two types of zirconium compound and two types of germanium compound to be contained in the activated foam, together with their content in relation to rubber component ([0021] and [0022]). The Description further provides examples of the form of the activated foam, including a small, portable and handy triangle patch, a bed clothing-like form such as a mat to lay on or a mat to cover, or as a portion or the whole of a garment, etc. ([0016]).

It should be said that a person ordinarily skilled in the art who has accessed the statement of these matters would have been able to combine one of the various types of rubber or synthetic resin with one of the various types of zirconium compound and/or germanium compound stated in the Description, and produce the activated foam of the Invention, that is, "an activated foam which is made of a natural or synthetic rubber or a synthetic resin and has a foamed sheet of a closed-cell structure, wherein the foamed sheet contains a zirconium compound and/or a germanium compound," in line with the production process described in the examples. It should also be said that such a person would have been able to form that activated foam into a shape so as to have it "directly or indirectly contact a human body when a pharmaceutical agent is administered," such as a mat to lay on.

(3) Whether a person ordinarily skilled in the art would have been able to use the activated foam

The next question is whether a person ordinarily skilled in the art would have been able to use the activated foam of the Invention based on the statement of the Description and the common general technical knowledge available at the time of the filing of the Application. Since a person ordinarily skilled in the art would have been able to produce the activated foam in the form as described in (2) above, it may naturally be possible for such person to use the

activated foam by having it "directly or indirectly contact a human body when a pharmaceutical agent is administered." In this connection, the court examines what technical meaning lies in such a manner of using the activated foam.

A. In relation to the problem to be solved by the Invention, the Description states that the purpose of the Invention is to "provide an activated foam…capable of facilitating blood circulation and promoting the improvement of physical condition and the cure of diseases such as cancer" ([0007]). However, the Description also states that a mechanism of such effect "has not been elucidated" ([0009]). With regard to the mechanism of action, although the Description states that the infrared rays with specific wavelengths radiated toward the outside of the activated foam by a zirconium compound and germanium compound resonate with the wavelengths of a human body to enhance the natural healing power possessed by humans ([0010]), this is nothing more than a speculation, as the Description itself admits.

B. The Description provides the results of <Test 1>, in which the blood flow, blood volume, blood velocity, and body pressure were measured with regard to one subject after sitting on a chair covered with the activated foam in resting state for 30 minutes, and these measurements were compared with the measurements taken with regard to the subject after sitting on a chair without the activated foam in resting state for 30 minutes. Based on these test results, it concludes that "the use of the activated foam improves blood circulation and reduces body pressure" ([0035] to [0040]).

However, although this test was conducted in a manner that the activated foam is used by "having it directly or indirectly contact a human body," the details of the activated foam used in this test (in particular, whether it contains either or both of zirconium compound and germanium compound, and the content thereof) are unclear from the Description, which does not state such details. Furthermore, even in light of the common general technical knowledge shared among persons ordinarily skilled in the art at the time of the filing of the Application, the test results can hardly be assessed as being objective and applicable to human bodies in general, because the test was conducted with regard to only one subject who was a woman in her fifties. The details of the test conditions are also unclear. Therefore, it is impossible to immediately verify whether the effect that is said to be inferred from the blood volume and body pressure measured in this test, that is, "the use of the activated foam improves blood circulation and reduces body pressure," is attributed to the use of the activated foam or any other causes.

Then, it is questionable to conclude based only on the results of <Test 1> that the use of the activated foam by "having it directly or indirectly contact a human body" has a technical meaning in that it can facilitate blood circulation. Nonetheless, there may be room to find that the technical meaning in the use of the activated foam of the Invention has been proved if a convincing explanation of the conditions of <Test 1> is provided or if other test results are

available and convincing.

C. Based on the results of <Test 2>, the Description states that "The activated foam starts up the apoptosis circuit and facilitates the effect of weakening the function of cancer cells" ([0051]).

However, <Test 2> was conducted in a manner that prostate cancer cells were cultivated by vertically placing each culture plate in between the activated foams and comparing the cells thus cultured with the cells cultured without using activated foams. In this test, the activated foam was used in a manner that is completely different from the manner in which the activated foam is assumed to be used by "having it directly or indirectly contact a human body." Therefore, even in light of the common general technical knowledge shared among persons ordinarily skilled in the art at the time of the filing of the Application, it cannot be concluded based on these test results that the use of the activated foam by "having it directly or indirectly contact a human body" has any technical meaning in that it can weaken the function of cancer cells.

D. With regard to the effect of the Invention and its industrial applicability, the Description further states that: "The activated foam of the invention may be used, in administering a pharmaceutical agent by having it directly or indirectly contact a human body to increase the effect of the pharmaceutical agent. In addition, even a pharmaceutical agent which would exert an adverse effect in a large dose, if combined with the activated foam, may reduce the adverse effect because its dosage can be decreased" ([0024] and [0061]). In connection with these effects, the Description states that, based on the results of <Test 3>, "the activated foam can be used simultaneously with HDACI to facilitate the suppressive effect of HDACI against proliferation of human prostate cancer cells. In principle, this method is thought to be an effective therapy against any cancer" ([0059]).

However, <Test 3> was also conducted in a manner that prostate cancer cells were cultured by adding SB to each microplate and vertically placing the microplate in between the activated foams, and comparing the cells thus cultured with the cells cultured by adding SB but not using the activated foams. In this test, the activated foam was used in a manner that is completely different from the manner in which the activated foam is assumed to be used by "having it directly or indirectly contact a human body." Therefore, even in light of the common general technical knowledge shared among persons ordinarily skilled in the art at the time of the filing of the Application, it cannot be concluded based on these test results that the use of the activated foam by "having it directly or indirectly contact a human body" has any technical meaning in that it can increase the effect of the pharmaceutical agent.

(4) JPO's decision

Based on the discussion above, the court examines whether the JPO made an appropriate decision.

The JPO concluded that the Description fails to meet the requirement prescribed in Article

36, paragraph (4), item (i) of the Patent Act on the grounds that it fails to state the effect of the combined use of the activated foam with a pharmaceutical agent in a manner that a person ordinarily skilled in the art could understand and recognize it.

However, the phrase "when a pharmaceutical agent is administered" referred to in the claim of the Invention, in literal terms, merely specifies the timing of the use of the activated foam, and the claim of the Invention does not specify the purpose or usage of the Invention such as increasing the effect of the pharmaceutical agent or promoting the cure of the disease. Therefore, even if the Description fails to sufficiently disclose the effect of the combined use of the activated foam with a pharmaceutical agent, if it can be said that the use of the activated foam by "having it directly or indirectly contact a human body when a pharmaceutical agent is administered" has any other technical meaning, it should be considered, as far as the enablement requirement is concerned, that any person ordinarily skilled in the art would have been "able to use" the activated foam of the Invention, based on the statement in the Description and the common general technical knowledge available at the time of the filing of the Application. As explained in (3)B above, there may be room to find that a person ordinarily skilled in the art would have been "able to use" the activated foam of the Invention in a manner that it can exert the effect of facilitating blood circulation, if the necessary points are examined.

Hence, it must be said that there are errors in the JPO decision in that the JPO, without fully examining these points, concluded that the Description fails to meet the requirement prescribed in Article 36, paragraph (4), item (i) of the Patent Act on the grounds mentioned above, and therefore the JPO decision should inevitably be rescinded.

3. Defendant's allegations

(1) The defendant alleges that in order to find that the Description states the activated foam of the Invention in a manner that a person ordinarily skilled in the art would have been "able to use" the activated foam, it is necessary for the Description to state the effect of the combined use of the activated foam with a pharmaceutical agent in a manner that a person ordinarily skilled in the art could understand and recognize it, or in other words, to prove the pharmacological action regarding the effect of such combined use, as in the case of an invention of medicinal use (No. 4-1 above).

However, as explained in 2(4) above, the phrase "when a pharmaceutical agent is administered" referred to in the claim of the Invention, in literal terms, merely specifies the timing of the use of the activated foam, and the claim of the Invention does not specify the purpose or usage of the Invention such as increasing the effect of the pharmaceutical agent or promoting the cure of the disease. Consequently, it cannot be said that in the process of determining whether the Description meets the enablement requirement, it is necessary to prove the pharmacological action regarding the effect of the combined use of the activated foam with

a pharmaceutical agent, as in the case of an invention of medicinal use.

(2) The defendant alleges that there is no error in the JPO decision ruling that the Description cannot be deemed to clearly state what kind of effect and function the activated foam of the Invention would have for increasing the effect of SB in suppressing the proliferation of prostate cancer cells in vivo (No. 4-2 above). The defendant also alleges that since there are various kinds of pharmaceutical agents, even if the Description states the effects of the activated foam in facilitating blood circulation, enhancing metabolism and weakening the function of cancer cells, it cannot be said that the activated foam is capable of increasing the effect of any kind of pharmaceutical agents (No. 4-4 above).

However, as mentioned above, the claim of the Invention does not specify the purpose or usage of the Invention such as increasing the effect of the pharmaceutical agent or promoting the cure of the disease. What is more, the function and effect aimed at by the Invention are not limited to increasing the effect of a pharmaceutical agent but include facilitating blood circulation and improving the physical condition. Consequently, even if the Description does not clearly state how the effect of a pharmaceutical agent can be increased by using the activated foam when administering the pharmaceutical agent, or whether the activated foam has the effect of increasing the effect of any kind of pharmaceutical agents, it cannot be concluded immediately that the statement of the Description fails to meet the enablement requirement.

(3) The defendant alleges that even taking into account the results of <Test 1> to <Test 3> provided in the Description, it cannot be said that the Description states the mode of applying the activated foam in a manner that a person ordinarily skilled in the art could understand and recognize it (No. 4-3 above).

However, the Description discloses the mode of applying the activated foam itself by providing examples of the use as a bed clothing-like form or a portion or the whole of a garment, and also discloses the mode of using the activated foam at least in <Test 1>, setting aside <Test 2> and <Test 3>, by explaining that the test subject sat on a chair covered with the activated foam. Accordingly, one would naturally assume that the mode of using the activated foam, that is, the use of the activated foam by "having it directly or indirectly contact with a human body," refers to the mode of use disclosed in the Description or any other mode of use similar thereto. Consequently, it cannot be said that the Description fails to state the mode of applying the activated foam to the extent that a person ordinarily skilled in the art could understand and recognize it.

(4) Therefore, the defendant's allegations mentioned above cannot be accepted.

4. Conclusion

For the reasons stated above, the plaintiffs' claim is well-grounded, and therefore the court shall uphold their claim and render a judgment in the form of the main text.

Intellectual Property High Court, Third Division

Judge: TANAKA Masaya

Judge: KAMIYA Koki

Presiding Judge TSURUOKA Toshihiko was unable to sign and seal due to a transfer of position.

Judge: TANAKA Masaya