Trial Decision

Invalidation No. 2017-800084

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The case of the patent invalidation trial of the invention of Japanese Patent No. 5433762, entitled "SURFACE SHEET FOR WOUND DRESSING AND WOUND DRESSING", between the parties above has resulted in the following trial decision:

Conclusion

The correction of the scope of claims of Japanese Patent No. 5433762 shall be approved as the corrected scope of claims attached to the written correction request, regarding Claims [1-19] after correction.

The patents for the invention according to Claims 1-5, 8, and 14-19 of Japanese Patent No. 5433762 shall be invalidated.

The demand for trial regarding the inventions according to Claims 6, 7, and 9-13 of Japanese Patent No. 5433762 was groundless.

Seven-nineteenths of the costs in connection with the trial shall be borne by the Demandant, and 12-nineteenths by the Demandee.

Reason

No. 1 History of the procedures

The main history of the procedures of the case is shown below.

May 31, 2011 International application of the original patent (Japanese Patent Application No. 2012-518387 (Priority Claim, June 1, 2010, Japan, Priority Claim Number: Japanese Patent Application No. 2010-126338))

October 24, 2012 Patent application of the case (Japanese Patent Application No. 2012-234412)

November 8, 2013 A written opinion (Evidence A No. 10) and a written amendment

December 13, 2013 Registration of establishment (Japanese Patent No. 5433762)

June 30, 2017 Demand for trial of the case

November 6, 2017 A written reply, a request for correction

As of January 11, 2018 Notification of matters to be examined

February 1, 2018 An oral proceedings statement brief (Demandant)

February 22, 2018 An oral proceedings statement brief (Demandee)

March 22, 2018 The first oral proceeding

June 29, 2018 Advance notice of trial decision

August 3, 2018 A written statement (Demandant)

Sep. 4, 2018 A request for correction, a written statement (Demandee)

October 31, 2018 Inquiry (Demandee)

December 4, 2018 A written refutation

December 5, 2018 A written reply (Demandee)

Note that the request for correction that was made on November 6, 2017 it deemed to have been withdrawn under the provisions of Article 134-2(6) of the Patent Act.

Hereinafter, "written demand for trial" is abbreviated to "written demand", and "oral proceedings statement brief" is abbreviated to "statement brief". Also, "Evidence A No. 1", "Evidence B No. 1" and the like are abbreviated to "A-1", "B-1" and the like, respectively.

No. 2. Request for correction

1. Contents of correction

The contents of the correction according to the request for correction made on Sep. 4, 2018 (hereinafter, this is referred to as "the Correction Request", and the correction according to the Correction Request is referred to as "the Correction") are shown as follows.

(1) Correction 1

"The absorption holding layer (3) is not integrated with the liquid-permeable layer (1)" recited in Claim 1 of the scope of claims before the Correction, is corrected to "the absorption holding layer (3) is not integrated with the liquid-permeable layer (1), the through holes (13) have a depth of 100-2000 μm, and wherein the through holes (13) exist at a density of 50-400 holes/cm^2" (Claims 2-19 that refer to the recitation of Claim 1 are corrected in a similar fashion).

(2) Correction 2

"The sheet material is formed using a low-density polyethylene resin material" recited in Claim 6 of the scope of claims before the Correction, is corrected to "the sheet material is formed using a low-density polyethylene resin material, and wherein each of the through holes (13) has an opening area at the first surface (11) corresponding to a round shape of 280-1400 μm in diameter" (Claims 7-19 that refer to the recitation of Claim 6 are corrected in a similar fashion).

(3) Correction 3

"Further comprising a protective layer (4) on a surface of the absorption holding layer (3) opposite to the wound side, the protective layer (4) being made of a resin film, a woven fabric, a knitted fabric, or a nonwoven fabric" recited in Claim 9 of the scope of claims before the Correction, is corrected to "further comprising a protective layer (4) on a surface of the absorption holding layer (3) opposite to the wound side, the protective layer (4) being made of a resin film, a woven fabric, a knitted fabric, or a nonwoven fabric, wherein

the through holes have hole diameters that decrease from the first surface toward the second surface, respectively, have an opening rate of 15-60%, have a depth of 100-2000 μm, exist at a density of 50-400 holes/cm^2, have storage spaces between the wound portion and the second surface, and hold an effusion above the wound portion" (Claims 10-19 that refer to the recitation of Claim 9 are corrected in a similar fashion).

2. A group of claims

Relating to Correction 1, Claims 2-19 before the Correction cite Claim 1 directly or indirectly; relating to Correction 2, the above Claims 7-19 cite the above Claim 6 directly or indirectly; and, relating to Correction 3, the above Claims 10-19 cite Claim 9 directly or indirectly, and therefore Claim 1 before the Correction and Claims 2-19 that refer to Claim 1 directly or indirectly are a group of claims stipulated in Article 134-2(3) of the Patent Act, and the corrections according to Corrections 1-3 are ones that are requested with respect to the group of claims 1-19.

3. Suitability of the correction purpose, presence or absence of a new matter, and existence or absence of enlargement or alternation of the scope of claims

(1) Regarding Correction 1

Since the correction according to Correction 1 is one that limits, regarding "the through holes (13)" recited in Claim 1 before correction, that "the through holes (13) have a depth of 100-2000 μm, and wherein the through holes (13) exist at a density of 50-400 holes/cm^2", it is for the purpose of restriction of the scope of claims that is a matter stipulated in item (i) of the proviso to Article 134-2(1) of the Patent Act.

Then, the above-mentioned matters of "the through holes (13) have a depth of 100-2000 μm" and "the through holes (13) exist at a density of 50-400 holes/cm^2" are ones respectively based on the description of "The dimension between the first surface (11) and the second surface (12), which is also the depth of the through holes (13); i.e., the thickness of the liquid permeable layer (1), is generally preferably 100-2000 μm" of paragraph [0031] of the description attached to the application (hereinafter, referred to as "the Patent Description"), and the description of "It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2" of paragraph [0030], and, therefore, these are not ones that add a new matter, and, in addition, these are not ones that enlarge or alter the scope of claims substantially.

(2) Regarding Correction 2

Since the correction according to Correction 2 is one that limits, regarding "the through holes (13)" recited in Claim 1 that is cited by Claim 6 before correction directly or indirectly, that "each of the through holes (13) has an opening area at the first surface (11) corresponding to a round shape of 280-1400 μm in diameter", it is for the purpose of restriction of the scope of claims, which is the matter prescribed in item (i) of the proviso to Article 134-2(1) of the Patent Act.

Then, since the above-mentioned matter that "each of the through holes (13) has an opening area at the first surface (11) corresponding to a round shape of 280-1400 μm in diameter" is based on the description of paragraph [0028] of the Patent Description that "As for the diameter of the through holes (13), it is preferable that the opening area at the first surface (11) facing the wound site corresponds to a circular shape of 280-1400 μm in diameter.", it is not one that adds a new matter, and, further, it is not one that enlarge or alter the scope of claims substantially.

(3) Regarding Correction 3

The correction according to Correction 3 limits that, "through holes" recited in Claim 1, which is cited by Claim 9 before correction directly or indirectly, "have hole diameters that decrease from the first surface toward the second surface, respectively, have an opening rate of 15-60%, have a depth of 100-2000 μm, exist at a density of 50-400 holes/cm^2, have storage spaces between the wound portion and the second surface, and hold an effusion above the wound portion", and therefore it is one for the purpose of restriction of the scope of claims that is the matter prescribed in item (i) of the proviso to Article 134-2(1) of the Patent Act.

Then, the above-mentioned matters of "have hole diameters that decrease from the first surface toward the second surface, respectively", "have an opening rate of 15-60%", "have a depth of 100-2000 μm", "exist at a density of 50-400 holes/cm^2" and "have storage spaces between the wound portion and the second surface, and hold an effusion above the wound portion", are respectively based on the descriptions of paragraph [0027] of the Patent Description that "Although the through holes (13) may have any shape such as a cylindrical shape, a barrel-like shape, an hourglass shape, or the like, as shown in FIG. 1 and FIG. 2, it is preferable that each of the through holes (13) be an 'inclined hole' which gradually decreases in diameter from the side of the first surface (11) toward the second surface (12)", the description of paragraph [0030] that "Further, it is preferable that the opening rate of the through holes (13) in the first surface (11) be 15 to 60%", the description of paragraph [0031] that "The dimension between the first surface (11) and the second surface (12), which is also the depth of the through holes (13); i.e., the thickness of the liquid permeable layer (1), is generally preferably 100-2000 μm", the description of paragraph [0030] that "It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2", and the description of paragraph [0032] that "By setting the density, the opening rate, and the depth of the through holes (13) to the above preferable ranges, a proper storage space (14) can be formed between the wound site and the second surface (12), an appropriate amount of effusion can be retained on the wound

site, and the effusion can be prevented from spreading in an in-plane direction of the wound site", and therefore these are not ones that add a new matter, and, in addition, these are not ones that enlarge or alter the scope of claim substantially.

4. Closing

As described above, since the corrections according to the Correction Request are aimed at the matters prescribed in item (i) of the proviso to Article 134-2(1) of the Patent Act, and comply with the provision of Article 126(5) and (6) of the same Act as applied mutatis mutandis pursuant to the provisions of Article 134-2(3) and (9) of the same Act, the corrections shall be approved regarding Claims [1-19] after correction.

No. 3. Regarding the Invention

Since the Correction Request has been approved, the inventions according to Claims 1-19 of the Patent (hereinafter, referred to as "Inventions 1-19") are ones specified by the matters recited in Claims 1-19 of the corrected scope of claims attached to the written correction request of the case as follows.

[Claim 1]

A wound dressing comprising at least two layers of a liquid-permeable layer (1) and an absorption holding layer (3),

the wound dressing being made by directly laminating the liquid permeable layer (1) and the absorption holding layer (3) in this order from a side used to face a wound site (15),

the liquid-permeable layer (1) including a first surface (11) facing the wound site (15), a second surface (12) opposite to the first surface (11), and a plurality of through holes (13) extending through between the surfaces (11, 12) in the thickness direction,

the through holes (13) having an opening rate of 3.07% or more, and allowing liquid to pass from the first surface (11) toward the second surface (12),

the first surface (11) being made of a resin sheet material having hydrophobicity, and

the absorption holding layer (3) containing a sheet material capable of absorbing and holding water, wherein

the absorption holding layer (3) is not integrated with the liquid-permeable layer (1),

the through holes (13) have a depth of 100-2000 μm, and wherein

the through holes (13) exist at a density of 50-400 holes/cm^2.

[Claim 2]

The wound dressing according to Claim 1, wherein a contact angle with physiological saline at the first surface (11) is 85 degrees or more.

[Claim 3]

The wound dressing according to Claim 1 or Claim 2, wherein surface tension at the first surface (11) is 40 dyne/cm or less.

[Claim 4]

The wound dressing according to any one of Claims 1-3, wherein

the first surface (11) is coated with one or more water repellent substances selected from the group consisting of silicone, polyurethane, styrene-butadiene-styrene block copolymer, tetrafluoroethylene hexafluoropropylene copolymer, tetrafluoroethylene perfluoroalkylvinylether copolymer, and polytetrafluoroethylene.

[Claim 5]

The wound dressing according to any one of Claims 1 to 4, wherein

the sheet material is formed using a polyolefin resin material having a contact angle with physiological saline of 85 degrees or more.

[Claim 6]

The wound dressing according to any one of Claims 1 to 4, wherein

the sheet material is formed using a low-density polyethylene resin material, and wherein

each of the through holes (13) has an opening area at the first surface (11) corresponding to a round shape of 280-1400 μm in diameter.

[Claim 7]

A wound dressing according to any one of Claims 1 to 6, wherein

a dimension between the first surface (11) and the second surface (12) is 100-2000 μm, and wherein

each of the through holes (13) has an open area at the first surface (11) corresponding to a round shape of 280-1400 μm in diameter, has an open area at the second surface (12) smaller than the open area at the first surface (11), and the through holes (13) exist at a density of 50 to 400 holes/cm^2.

[Claim 8]

The wound dressing according to any one of Claims 1 to 7, wherein

a second liquid-permeable layer (1a) having the same configuration as the first liquid-permeable layer (1) is further laminated on a side of the absorption holding layer (3) opposite to the liquid-permeable layer (1).

[Claim 9]

The wound dressing according to any one of Claims 1 to 7, further comprising a protective layer (4) on a surface of the absorption holding layer (3) opposite to the wound side, the protective layer (4) being made of a resin film, a woven fabric, a knitted fabric, or a nonwoven fabric, wherein

the through holes have hole diameters that decrease from the first surface toward the second surface, respectively, have an opening rate of 15-60%, have a depth of 100-2000 μm, exist at a density of 50-400 holes/cm^2, have storage spaces between the wound portion and the second surface, and hold an effusion above the wound portion.

[Claim 10]

The wound dressing according to Claim 9, wherein

the protective layer (4) covers all other layers and has a larger area than that of the other layers and has an outer edge (6) protruding outside the other layers, and wherein

the outer edge (6) has an adhesive portion (7) on at least a portion of its surface in a side where the other layers are laminated.

[Claim 11]

The wound dressing according to Claim 10, wherein

the protective layer (4) comprises a non-adhesive part (8) which does not have an adhesive part (7) on the outer edge (6).

[Claim 12]

The wound dressing according to Claim 10, wherein

the protective layer (4) has a portion without the outer edge (6) outside the other layers.

[Claim 13]

The wound dressing according to Claim 10, wherein

the protective layer (4) has a slit (9) or a small hole along an outer circumference of the other layers on the outer edge (6).

[Claim 14]

The wound dressing according to any one of Claims 1 to 13, wherein

the absorption holding layer (3) is formed using an air laid nonwoven fabric.

[Claim 15]

The wound dressing according to any one of Claims 1 to 14, wherein

the absorption holding layer (3) comprises fluff pulp.

[Claim 16]

The wound dressing according to Claim 15, wherein

the absorption holding layer (3) further comprises a superabsorbent polymer, and a weight ratio of the superabsorbent polymer to the fluff pulp is 10:90 to 25:75.

[Claim 17]

The wound dressing according to Claim 16, wherein

the superabsorbent polymer is a sodium polyacrylate system.

[Claim 18]

The wound dressing according to any one of Claims 1 to 17, wherein

the absorption holding layer (3) has stretchability to enable deformation along at least the wound site.

[Claim 19]

The wound dressing according to any one of Claims 1 to 18, wherein

an adhesive layer (21) is included on a side opposite to the side facing the wound site (15).

No. 4 Outline of allegations of the parties and means of proof

1. Outline of the Demandant's allegation and means of proof

(1) Outline of the Demandant's allegation

The Demandant demands the trial decision that the patents concerning Claims 1-19 of Japanese Patent No. 5433762 shall be invalidated, and the costs in connection with the trial shall be borne by the Demandee.

(2) Reasons for Invalidation alleged by the Demandant

Reasons for Invalidation alleged by the Demandant are as follows.

1. Reasons for Invalidation 1 (violation of Article 29(1)(iii) and Article 29(2) of the Patent Act)

(1) Reason for Invalidation 1-1

The Invention 1 is an invention described in a publication (A-1) distributed in Japan before the patent application thereof, falls under Article 29(1)(iii) of the Patent Act, and a patent should not be granted for that, and, therefore, the patent thereof falls under Article 123(1)(ii) of the same Act and should be invalidated.

(2) Reason for Invalidation 1-2

A. Inventions 1, 4 and 7-19 are ones that could have been invented by a person skilled in the art with ease before the patent application thereof based on the inventions described in publications (A-1 to A-4, A-6, and A-7) distributed in Japan before the patent application thereof, and the Applicant should not be granted a patent for these in accordance with the provisions of Article 29(2) of the Patent Act, and, therefore the

patents thereof fall under Article 123(1)(ii) of the same Act and should be invalidated.

B. Invention 2 is one that could have been invented by a person skilled in the art with ease before the patent application thereof based on the inventions described in publications (A-1 to A-7) distributed in Japan before the patent application thereof, and the Applicant should not be granted a patent for that in accordance with the provisions of Article 29(2) of the Patent Act, and therefore the patent thereof falls under Article 123(1)(ii) of the same Act and should be invalidated.

C. Invention 3 is one that could have been invented by a person skilled in the art with ease before the patent application thereof based on the inventions described in publications (A-1 to A-4, A-6, A-7, and A-8) distributed in Japan or abroad before the patent application thereof, and the Applicant should not be granted a patent for that in accordance with the provisions of Article 29(2) of the Patent Act, and, therefore, the patent thereof falls under Article 123(1)(ii) of the same Act and should be invalidated.

D. Invention 5 is one that could have been invented by a person skilled in the art with ease before the patent application thereof based on the inventions described in publications (A-1 to A-8) distributed in Japan before the patent application thereof, and the Applicant should not be granted a patent for that in accordance with the provisions of Article 29(2) of the Patent Act, and, therefore, the patent thereof fall under Article 123(1)(ii) of the same Act and should be invalidated.

E. Invention 6 is one that could have been invented by a person skilled in the art with ease before the patent application thereof based on the inventions described in publications (A-1 to A-4, A-6, A-7, and A-9) distributed in Japan before the patent application thereof, and the Applicant should not be granted a patent for that in accordance with the provisions of Article 29(2) of the Patent Act, and therefore the patent thereof falls under Article 123(1)(ii) of the same Act and should be invalidated.

2. Reason for Invalidation 2 (violation of Article 29-2 of the Patent Act)

Inventions 1 and 3 are identical with a device described in the description, claims of utility model, or drawings attached to the application for utility model registration related to the gazette containing the utility model (A-6), and the Applicant should not be granted a patent for that in accordance with the provisions of Article 29-2 of the Patent Act, and, therefore, the patents thereof fall under Article 123(1)(ii) of the

same Act and should be invalidated.

3. Reason for Invalidation 3 (violation of Article 36(6)(i) of the Patent Act)

Since the matter of "having an opening rate of 3.07% or more" in Invention 1 is not described in the detailed description of the invention of the Patent Description, Inventions 1-19 are not ones that are described in the detailed description of the invention of the Patent Description, and the patents thereof were made with respect to a patent application that does not meet the requirement stipulated in Article 36(6)(i) of the Patent Act, and, therefore, the patents fall under Article 123(1)(iv) of the same Act and should be invalidated.

4. Reason for Invalidation 4 (violation of Article 36(6)(ii) of the Patent Act)

Regarding the matter of "having an opening rate of 3.07% or more" in Invention 1, the upper limit thereof is not prescribed, and the critical significance of "3.07%" is unclear, and thus the recitation of Claim 1 of the Patent is not clear regarding the invention for which a patent is sought, and the patent concerning Claim 1 and Claims 2-19 that cite Claim 1 have been made with respect to a patent application that does not meet the requirement stipulated in Article 36(6)(ii) of the Patent Act; therefore, the patents fall under Article 123(1)(iv) of the same Act and should be invalidated.

5. Reason for Invalidation 5 (violation of Article 17-2(3) of the Patent Act)

In Invention 1, the amendment to amend to "having an opening rate of 3.07% or more" is not one that was made within the range of the matters described in the description, the scope of claims, or the drawings originally attached to the application of the Patent, and thus the patents concerning Claim 1 and Claims 2-19 that cite Claim 1 are ones that have been made with respect to a patent application that does not meet the requirement stipulated in Article 17-2(3) of the Patent Act; therefore the patents fall under Article 123(1)(iv) of the same Act and should be invalidated.

(3) Means of proof

The Demandant has submitted A-1 to A-13 in a manner of attachment to the written demand, A-14 to A-17 in a manner of attachment to the statement brief, and A-18 to A-21 in a manner of attachment to the written refutation.

A-1: Japanese Unexamined Patent Application Publication No. 2007-130134

A-2: Microfilm of Japanese Utility Model Application No. H1-117534 (Japanese Unexamined Utility Model Application Publication No. H3-56429)

A-3: Japanese Unexamined Patent Application Publication No. 2008-113781
A-4: International Publication No. WO 2008/004380
A-5: National Publication of International Patent Application No. 2009-540988
A-6: Registered utility model No. 3159787
A-7: Japanese Unexamined Patent Application Publication No. 2010-131163
A-8: Yasuda Takeo, Test Methods and Evaluation Results of Each Dynamic Characteristic of Plastic Materials, Plastics, Japan Plastics Industry Federation, June, 2000, vol. 51, No. 6, pp. 119-127
A-9: National Publication of International Patent Application No. 2003-506151
A-10: A written opinion related to Japanese Patent Application No. 2012-234412, Zuiko Co., Ltd., as of November 8, 2013
A-11: interview record related to Japanese Patent Application No. 2012-234412, Japan Patent Office, November 6, 2013 interview
A-12: The description, the scope of claims, and the drawings originally attached to the application of Japanese Patent Application No. 2010-126338, Zuiko Co., Ltd., as of June 1, 2010
A-13: International Publication No. WO 2011/152368
A-14: National Publication of International Patent Application No. 2001-515762
A-15: Japanese Unexamined Patent Application Publication No. H7-444
A-16: National Publication of International Patent Application No. 2001-509690
A-17: McGraw-Hill Scientific and Technical Term Dictionary, version 2, Nikkan Kogyo Shimbun Co., Ltd., March 25, 1985, page 927 and page 1282
A-18: International Publication No. WO 2005/000372
A-19: National Publication of International Patent Application No. 2005-510296
A-20: Japanese Unexamined Patent Application Publication No. 2001-105504
A-21: Microfilm of Japanese Utility Model Application No. S59-165357 (Japanese Unexamined Utility Model Application Publication No. S61-80018)

2. Outline of the Demandee's allegation and means of proof
(1) Outline of the Demandee's allegation

The Demandee demands a trial decision that the demand for trial of patent invalidation of the case was groundless, and the cost in connection with the trial shall be borne by the Demandant.

(2) Means of proof

The Demandee has submitted B-1 to B-3 in a manner of attachment to the written reply.

B-1: Japanese Unexamined Patent Application Publication No. H7-80020
B-2: Japanese Unexamined Patent Application Publication No. 2008-113934
B-3: Japanese Unexamined Patent Application Publication No. 2010-57787

No. 5. Judgment on Reasons for Invalidation by the body
1. Described matters of main evidence and the like
(1) Described matters of A-1

In A-1, there are the following descriptions.

A. "[Claim 1]

A wound care product having an upper surface and a lower surface to be a wound contact surface, comprising:

an absorbent layer; and a covering layer for the absorbent layer, wherein

the covering layer in the lower surface side allows liquid to move to the absorbent layer, at least the wound contact surface of the covering layer in the lower surface side is hydrophobic, and the covering layer in the upper surface side has a pull that can be gripped.

[Claim 2]

A wound care product having an upper surface and a lower surface to be a wound contact surface, comprising:

an absorbent layer and a covering layer for the absorbent layer, wherein

the covering layer in the lower surface side has a laminated structure, at least a layer in the wound contact surface side is hydrophobic, and the covering layer in the lower surface side allows liquid to move to the absorbent layer, and the covering layer on the upper surface side has a pull that can be gripped.

...

[Claim 15]

The wound care product according to any one of Claims 1 to 14, wherein

the absorbent layer contains a substance that forms a gel when water is absorbed"

B. "[Technical Field]

[0001]

The present invention relates to a wound care product to be used for wound protection and treatment. In particular, the present invention relates to a wound care product suitable for absorbing blood, an effusion, etc. (hereinafter referred to as body fluid) from a wound.

[Background Art]

[0002]

In the treatment of burns, pressure ulcers, and other injuries, a wound care product such as multi-layered pads that include layers of gauze, absorbent cotton, absorbent fibers to protect the wound and absorb fluid from the wound is used conventionally.

However, when these wound care products absorb body fluid and the wound surface dries, the wound surface may be damaged when the wound care products are removed from the wound surface, which may be accompanied by pain or bleeding. In order to reduce such pain and bleeding at the time of peeling, various wound care products have been proposed.

...

[Problem to be solved by the invention]

[0006]

As described above, it is important for hygiene that wound care products can be not only easily removed after use so as not to cause pain or bleeding in the affected area, but also applied to the affected area in an appropriate state during use.

The present invention has been made in view of the above point, and an object of the present invention is to provide a wound care product that can be applied to an affected area easily without contaminating the wound contact surface of the wound care product at the time when applying the wound care product to the affected area."

C. "[0017]

Further, in the wound care product according to any one of Claims 1 to 14, it is preferable that the absorbent layer include a substance that forms a gel when water is absorbed (Claim 15). Thereby, a wound can be kept in a moist state and healing of a wound can be accelerated."

D. "[0021]

As shown in FIG. 1, the wound care product 10 of the present embodiment includes a sheet-like covering layer 20 located in the lower surface side of the wound care product, a sheet-like covering layer 21 located in the upper surface side of the wound care product, and an absorbent layer 40 interposed between these covering layers. The surface of the covering layer 20 in the lower surface side is provided with a hydrophobic resin layer 50 including silicone which becomes a wound contact surface, and holes 60 penetrating these layers, so that body fluid from the wound can move to the absorbent layer.

...

In the above embodiment, the description has been made about a case where the covering layer 20 in the lower surface side includes the hydrophobic resin layer 50 and has two layers of the covering layer in the lower surface side. However, in a case where the hydrophobic resin layer 50 is not provided, and a single layer of the covering layer is provided, by making at least the wound contact surface of the covering layer 20 hydrophobic, the wound care product can be easily separated from the wound when the wound care product is removed, as described above. ...

[0022]

...

As shown in FIG. 3, in the third embodiment, the covering layer 20 and the covering layer 21 are joined to each other in the upper surface side of the wound care product by the seal portion 71 outside the absorbent layer 40. ...

[0024]

FIG. 5 is a perspective view of a wound care product according to the fifth embodiment of the present invention as seen from the top surface thereof.

As shown in FIG. 5, the wound care product 10 of the fifth embodiment includes a sheet-like covering layer 23 located in the lower surface side of the wound care product, a sheet-like covering layer 24 located in the upper surface side of the wound care product, and an absorbent layer 40 interposed between these covering layers, and is configured in a roll shape as a long object continuous in one direction.

The surface of the covering layer 23 in the lower surface side is provided with a hydrophobic resin layer 50 including silicone which becomes a wound contact surface, and holes 60 penetrating these layers so that body fluid from the wound can move to the absorbent layer.

..."

E. "[0028]

Next, the covering layers 20 to 26 will be described. The covering layer only needs to be able to cover the outer shape of the absorbent layer, can be formed from one or more sheets, which can be bonded to each other at an appropriate position to cover the absorbent layer. The covering layer preferably covers the entire outer shape of the absorbent layer so that the absorbed body fluid does not leak, but there may be a portion that does not partially cover the absorbent layer.

Hereinafter, the required characteristics and functions of the covering layer will be described. First, hydrophobicity will be described. At least the wound contact surface of the covering layer in the lower surface side has hydrophobicity. In order to make it hydrophobic, the covering layer itself may be formed of a hydrophobic material,

or the covering layer is made into a laminated structure by coating a hydrophobic resin layer different from the covering layer, and so on to make the surface thereof hydrophobic. In order to easily separate the wound care product from the wound, this hydrophobic surface of the covering layer preferably has a contact angle with water of 65° or more, more preferably 90° or more. The contact angle can be measured using a contact angle meter CA-A (manufactured by Kyowa Interface Science Co., Ltd.) according to the instruction manual "Droplet method measurement operation" of the contact angle meter.
[0029]

Next, the movement of the liquid will be described. This hydrophobic surface of the covering layer is formed so that liquid such as body fluid can move to the absorbent layer. In order to make the covering layer in the lower surface side liquid-permeable, a plastic sheet such as a mesh, a perforated film or the like, or a liquid-permeable fibrous sheet such as a knitted fabric, a woven fabric, a non-woven fabric, or the like can be used. When forming a hydrophobic resin layer on the covering layer, it is only necessary to apply the hydrophobic resin layer so as not to block the holes through which liquid of the covering layer can move, or to apply the hydrophobic resin layer and then punch through the covering layer together with the hydrophobic resin layer."
F. "[0032]

Next, the material of the covering layer will be described. As the plastic sheet and the fibrous sheet for forming the covering layer, the base material thereof may be used alone, or a sheet of a laminated structure in which the same or different kinds of sheets are laminated may be used. Among these, a liquid-impermeable sheet is preferable, and by doing so, it is possible to prevent the liquid absorbed by the absorbent layer from leaking out. In addition, the covering layer is preferably formed of a stretchable sheet, which allows the skin extension to be followed well during the application of the wound care product and does not give a sense of incongruity or physical irritation during the application to the skin, and, in addition, when the pull is grasped, the lower surface of the wound care product can easily hold the horizontal plane.

Examples of the material of the covering layer include polyesters; polyolefins such as polyethylene and polypropylene; olefinic copolymers such as ethylene/vinyl acetate copolymers and ethylene/ethyl acrylate copolymers; polyamides; polyurethanes; and silicones, and these materials may be used alone or in combination of two or more.
...
[0033]

Next, the material of the hydrophobic resin layer will be described. As a material for the hydrophobic resin layer provided in the covering layer, a material having

a contact angle between the surface of the layer formed of resin and water of 65° or more may be just selected, and, for example, silicone resin, acrylic resin, methacrylic resin, polyvinyl chloride resin, polyvinylidene chloride resin, fluororesin, olefin resin, polyester resin, styrene resin, urethane resin, polyamide resin, and mixtures thereof may be cited.
...
[0034]

Next, the absorbent layer will be described. As the absorbent layer, materials having high water absorption such as cellulosic fibers, pulp, polymeric water-absorbent polymer, etc. can be used alone or in combination, and the amounts of these may be adjusted according to the required amount of absorption. In particular, it is preferable to include a substance that forms a gel upon water absorption, and, by doing so, the wound can be kept moist, and healing of the wound can be promoted. Examples of the gel-forming substance preferably include, for example, sodium carboxymethyl cellulose, a crosslinked product of sodium carboxymethyl cellulose, starch-acrylic acid (salt) graft copolymer, acrylic acid (salt) polymer, starch-acrylonitrile copolymer, polyhydric alcohol, and the like.
..."

(2) Described matters of A-6

In A-6, there are the following descriptions.

A. "[Claim 1]

A wound dressing laminated in order of a water permeable surface sheet, a water retentive sheet, a water absorbent intermediate sheet, and a water impermeable back sheet from a side in contact with a wound area, wherein the surface sheet is a perforated film having a surface wet tension defined in JIS K 6768 of 38 to 54 mN/m, a pore size of 0.1 to 3 mm, and a rate of hole area of 10 to 50%."

B. "[Technical Field]

[0001]

The present device relates to a wound dressing for use in covering and treating a wound area on a skin surface.

[Background Art]

[0002]

Conventionally, in the treatment of a wound area, it has been considered effective to just dry the wound area for the early regeneration of the skin, but in recent wound treatment, it is regarded as best to treat a wound while maintaining the wound in a moderately wet condition as the components contained in the exudate from the wound

area help to promote the healing of the wound.

[0003]

However, since the skin of the wound area is thin and easily damaged, in an excessively wet state, there is a problem that the regeneration/recovery of the skin of the wound area becomes unfavorable due to the pressure of the exudate, or the healing is rather delayed considerably as a result of damaging the wound area when the covering material is peeled off due to sticking of the covering material to the wound area.

[0004]

As a wound dressing capable of adjusting such a wet state, there have been proposed: a wound dressing for which the permeation amount of the exudate is adjusted by specifying the opening rate of the holes of the surface sheet located in the side of the wound area, or by specifying the opening rate of each of the two surface sheets (see Patent Documents 1 and 2); and a wound dressing designed to cover a wound area with a layer having a specific initial water pressure resistant function (see Patent Document 3).

[Citation List]

[Patent Literature]

[0005]

[Patent Document 1] Japanese Unexamined Patent Application Publication No. 2008-113781

[Patent Document 2] Japanese Unexamined Patent Application Publication No. 2008-113952

[Patent Document 3] International Publication No. WO 2005-000372

[0006]

However, in all the wound dressings described in Patent Documents 1 and 2, the opening rate of the surface sheet is small, so that the exudate accumulates in the wound area excessively in a case of a wound with a lot of exudates, and hence healing is rather delayed. In addition, in the wound dressing of Patent Document 3, it is essential to have high water repellency as one of the initial water pressure resistant functions, but if the water repellency is too high, the exudate is not uniformly distributed over the entire covering material covering the wound area. Then, the wet state of the wound area is not stabilized, because the exudate is scattered, thereby inevitably causing delay of the healing also in this case.

[Summary of the Device]

[Problem to be Solved by the Device]

[0007]

An object of the present device is to provide a wound dressing which is capable

of keeping the wound area constantly in a moderately wet state irrespective of the amount of the exudates, is less likely to be stuck to the wound area, and is effective for promoting healing."

C. "[0010]

In the present device, the water-permeable surface sheet coming into contact with the wound area is a perforated film having a surface wet tension as defined in JIS K 6768 (Test Method of Wet Tension for Plastic Film and Sheet) of 38 to 54 mN/m, preferably 40 to 50 mN/m, a pore diameter of 0.1 to 3 mm and a rate of hole area of 10 to 50%.

[0011]

When the surface wet tension of the perforated film is less than 38 mN/m, the water repellency is increased, the exudate is not uniformly distributed to the entire perforated film, and the exudate is partially scattered on the wound area, making early healing difficult. On the other hand, when the surface wet tension exceeds 54 mN/m, the covering material is liable to be stuck to the wound area, which causes damage to the wound area upon peeling off.

[0012]

The surface wet tension of the perforated film is also related to the pore diameter and the rate of hole area of the film, and if the pore diameter and the rate of hole area are outside the range of the present invention, even if the surface wet tension is 38 to 54 mN/m, the exudate accumulates excessively or the exudate is dried, making it difficult to maintain a uniform wet condition. As the perforated film, any film may be used as long as it is a film mainly composed of polyethylene, polypropylene, polyester, polyamide, polyurethane, etc. and having a surface wet tension with about 1 to 50 μm thickness. However, in consideration of the strength and sanitary properties and the like of the film, a polyester film having a thickness of 3 to 12 μm is preferable, and a mesh film drilled in a mortar-shaped cross-section by piercing can also be used. Here, examples of the polyester film include crystalline or amorphous polyester films such as polyethylene terephthalate, polyethylene tereisophthalate, cyclohexylene dimethyl terephthalate, and the like.

[0013]

The wound dressing of the present device is one having a water-absorptive intermediate sheet laminated on the back side of the surface sheet via a water retentive sheet. Here, the water retentive sheet exerts the function of quickly absorbing and retaining the exudate coming out through the water permeable surface sheet and making the intermediate sheet absorb the excessive exudate, so-called adjusting exudate puddles,

thereby bringing about the effect of always maintaining the wound area in a moderately wet state."

D. "[0017]

The wound dressing of the present device is made by laminating a surface sheet, a water retentive sheet, an intermediate sheet, and a back sheet from the side in contact with the wound area as described above, and the term "laminating" as referred to herein mainly indicates a state in which both sheets are merely superimposed on each other, but both of them may be partially joined by a method such as sewing, sticking, bonding, or the like. In order to prevent leaking of the exudate, it is preferred that the wound dressing of the present device is characterized in that the size of the surface sheet and the back sheet is made slightly larger than that of the water retentive sheet or the intermediate sheet and only the peripheral edge portions of both are bonded by a method such as thermal fusion bonding."

(3) Described matters of A-10

In A-10, there are the following descriptions.

"2. Explanation of amendment

By adding the matter described in the former clause of Claim 21 before amendment to Claim 1, amendment was made as 'the wound dressing being made by directly laminating the liquid permeable layer (1) and the absorption holding layer (3)', and, in addition, amendment was made as 'the through holes (13) having an opening rate of 3.07% or more'.

...

<<Grounds for amendment>>

(1) Amendment of Claim 1

The grounds for amendment of Claim 1 are Claim 21, FIG. 17, and descriptions explained below.

The ground for the numerical value of the opening rate of Claim 1 is based on 'As for the diameter of the through holes (13), it is preferable that the opening area at the first surface (11) facing the wound site corresponds to a circular shape of 280-1400 μm in diameter. ...' of paragraph [0028], and 'It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2, ...' of paragraph [0030].

Since the minimum value of the hole diameter is 280 μm, and the minimum value of the density is 50 holes/cm^2,

the opening area at the minimum hole diameter is as follows.

$50 \times \pi \times (2.8/2)2 \times 10^{-4}$ cm^2 = 3.07×10^{-2} cm^2

Therefore, the minimum value opening rate is 3.07%."

(4) Described matters of A-11

In A-11, relating to the procedure of the Patent, it is described that an interview with an examiner was performed on November 6, 2013, and the examiner "stated to the effect that a difference from each of Cited Documents can be made clear by making clear that the liquid-permeable layer and the absorption holding layer are adjacent to each other, and by adding the lower limit value of the opening rate derived from the size of the opening and the density described in the description".

(5) Described matters of A-17

In A-17, it is described that "water repellency" means "an ability to shed water, or being hydrophobic", and "hydrophobic" means "having no affinity with water, or water-repellent".

2. Description of the detailed description of the invention of the Patent Description

In the detailed description of the invention of the Patent Description, there are described the following matters.

(1) "[Technical Field]

[0001]

The present invention relates to a wound dressing suitable for the treatment of wounds such as burns, pressure ulcers, contusion, cuts, abrasions, ulcers, and the like.

[Background Art]

[0002]

In recent years, it has been found that maintaining a wound surface in a moist environment without drying the wound surface is effective for healing wounds in the treatment of wounds. In particular, since components contained in the effusion from a wound site help promote healing of wounds, it has been found that a method of treatment while keeping a moist environment due to the effusion without disinfection (hereinafter, referred to as the 'Wet Treatment Method') is effective. Thus, various wound dressings to be applied to such treatment methods have been developed.

[0003]

In order to effectively perform the Wet Treatment Method, it is essential that the effusion be adequately retained to maintain a moderate moist environment of the wound surface, and that the wound dressing should be provided with a function of allowing the effusion to be adequately retained on the wound surface rather than rapidly

sucking up the effusion. On the one hand, however, the Wet Treatment Method provides a firm fixing of the dressing to the skin so that a moist environment is maintained, and a closed region is formed on the wound surface. Therefore, when an effusion is newly exuded and stored excessively, the wound surface is compressed by the effusion, and an 'undermining phenomenon' (a phenomenon in which the skin of the wound site is wrenched by the pressure of the effusion) is caused. For this reason, it is also required that a wound dressing has a function of adequately discharging the effusion from the wound surface.

[0004]

Also, if the material in contact with the wound site has no air permeability and is strongly adhered to the wound surface, the portion that has healed or almost healed may be damaged again when the wound dressing is peeled off. Therefore, there is a need for a wound dressing which does not stick strongly to the wound surface, which is easy to peel after use, and which can be attached on a wound site so that a moist environment for treatment of the wound can be maintained in use.

...

[0008]

However, there has been desired the development of a further improved wound dressing; i.e., a wound dressing (i) which has sufficient ability to adequately retain an effusion on the wound surface without leakage of the effusion, (ii) which does not cause a wasteful spread of an effusion that causes a rash on a normal skin without wounds, (iii) which does not stick strongly to the wound surface and is easily peeled off after use, and, in addition, which when in use, can be adhered to the wound while maintaining a moist environment for the treatment of wounds, (iv) which does not produce redness or sweat-rash, (v) which does not generate off-flavors, and (vi) which is constituted of a thin and flexible material, can be fitted to a wound surface of various shapes, and does not compress the wound surface.

...

[Problem to be solved by the invention]

[0010]

It is an object of the present invention to provide a further improved wound dressing which is suitable for a method of treatment while maintaining a moist environment due to an effusion from a wound."

(2) "[0024]

(Liquid-permeable layer)

In wound healing, it is sufficient that an effusion is retained in a region near the wound site, and it is not preferable that the effusion spreads beyond the region of the wound. This is because, in a portion where the effusion spreads, a normal skin without a wound may develop a rash and the wound area may be newly expanded to delay healing.

The liquid permeable layer (1) is provided mainly for the purpose of maintaining a moist environment without rapidly sucking out the effusion at a portion where the effusion exudes from the wound, and capturing the exuded effusion so that the area of the exuded effusion does not greatly spread, thereby improving healing of the wound.

[0025]

The liquid permeable layer (1) is constituted of a surface sheet (10) made of a resin sheet material, and has a plurality of through holes (13) penetrating in the thickness direction between a first surface (11) and a second surface (12). Preferably, each of the through holes (13) is independent of each other, and, in the inside of the liquid permeable layer (1), there is no passage for passing water in an in-plane direction. Since the plurality of through holes (13) are opened at the first surface (11) of the liquid permeable layer (1), it is possible to prevent the liquid permeable layer (1) from sticking strongly to the wound site.

[0026]

As shown in FIG. 1 and FIG. 2, the sheet material constituting the liquid-permeable layer (1) is formed in an uneven shape, and the first surface (11) refers to a surface of the liquid-permeable layer (1) which is in contact with a plane in the side of the wound site, and the second surface (12) refers to a surface of the liquid-permeable layer (1) which is in contact with a plane in the opposite side of the wound site.

[0027]

Although the through holes (13) may have any shape such as a cylindrical shape, a barrel-like shape, an hourglass shape, or the like, it is preferable that, as shown in FIG. 1 and FIG. 2, each of the through holes (13) be an "inclined hole" which gradually decreases in diameter from the side of the first surface 11 toward the second surface (12).

[0028]

As for the diameter of the through holes (13), it is preferable that the opening area at the first surface (11) facing the wound site corresponds to a circular shape of 280-1400 μm in diameter. It is not preferred to have a circular shape having a diameter of less than 280 μm, because it tends to inhibit the passage of the effusion to the second surface (12). On the other hand, when it corresponds to a circle having a diameter of more than 1400 μm, it is not preferable, because other layers laminated in the side of the

second surface (12) may come into contact with the skin at the wound site via the through holes (13), so that the wound dressing (5) can be hardly peeled off from the wound site or an adequate volume of an effusion storage space cannot be secured.

[0029]

Since the through holes (13) are inclined holes, the opening area at the second surface (12) is smaller than the opening area at the first surface (11). When comparing these by a diameter of a circular shape that corresponds to an opening area (hereinafter, referred to as "opening diameter"), opening diameter at the first surface (11) is preferably 1.1 to 1.8 times, more preferably 1.2 to 1.5 times larger than opening diameter at the second surface (12).

[0030]

It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2, and more preferably at a density of 60 to 325 holes/cm^2. Further, it is preferable that the opening rate of the through holes (13) in the first surface (11) be 15 to 60%.

[0031]

The dimension between the first surface (11) and the second surface (12), which is also the depth of the through holes (13); i.e., the thickness of the liquid permeable layer (1), is preferably about 100-2000 μm, and more preferably about 250 to 500 μm."

(3) "[0032]

By setting the density, the opening rate, and the depth of the through holes (13) to the above preferable ranges, a proper storage space (14) can be formed between the wound site and the second surface (12), an appropriate amount of effusion can be retained on the wound site, and the effusion can be prevented from spreading in an in-plane direction of the wound site.

[0033]

In addition, the capacity of the storage space (14) formed in the through holes (13) is preferably 0.015-0.55 μL, more preferably 0.030-0.45 μL, particularly preferably 0.040-0.35 μL per one through hole. If the capacity of the storage space (14) is less than 0.015 μL per one through-hole, it tends to be difficult to retain the effusion on the surface of the wound site and it tends to be difficult to prevent diffusion of the effusion toward the in-plane direction of the wound site, which is not preferable. On the other hand, when the capacity of the storage space (14) exceeds 0.55 μL per one through hole, the rate of absorption of the effusion by the liquid permeation restriction layer (2) and the absorption holding layer (3) tends to be increased, and thus it becomes difficult to keep the wound site in an appropriate wet environment by the effusion, which is not preferable.

[0034]

Since at least the first surface (11) of the liquid-permeable layer (1) is hydrophobic, it is possible to prevent the liquid-permeable layer (1) from sticking excessively strongly to the wound site, and it is possible to easily detach it from the wound site after use. Further, the through holes (13) allow liquid to permeate from the first surface (11) toward the second surface (12), but, due to the hydrophobic nature of at least the first surface (11), it is possible to restrict the migration of the effusion through the through holes (13) into the absorption holding layer (3) which have water absorption (liquid absorption) and to better maintain the effusion between the liquid-permeable layer (1) and the wound site to thereby promote healing of the wound.

[0035]

The above liquid permeable layer (1) is not limited to a specific material, as long as at least the first surface (11) facing the wound site is hydrophobic.

However, in view of maintaining the effusion required for treatment between the wound site and the liquid-permeable layer (1) and easily peeling the wound dressing (5) after use, it is preferable that at least the first surface (11) have a dynamic contact angle (hereinafter also simply referred to as "contact angle") with physiological saline of 85 degrees or more, and, from the viewpoint of the wound dressing (5) being further easily peeled off after use, it is more preferable that the contact angle with physiological saline be 95 degrees or more, and particularly preferable that it be 100 degrees or more. Note that "contact angle" used in the present invention means a value measured by the θ/2 method.

[0036]

The "contact angle" is measured, for example, according to JIS K 2396. Specifically, for example, measurement is performed as follows. A sheet material of a sample is cut into 1.5 to 2 cm square and placed at a measuring site of a contact angle measuring device (Trade name: FTA-100 manufactured by First Ten Angstrom Co., Ltd.). A standard droplet reference sample of 1.5 μl is brought into contact with a sample piece from a syringe installed in the device, and each dynamic contact angle after 1, 3, 5, and 10 min is measured by a drop method (drop supply speed: 0.5 μL/sec, dropping amount: 1.5 μL) and analyzed by the above-mentioned contact angle measuring device.

[0037]

From a viewpoint that the liquid-permeable layer (1) can hold the wound dressing (5) at the wound site to such an extent that an effusion necessary for the treatment of the wound can be retained and the wound dressing (5) can be easily peeled off from the wound site after use, it is preferable that it be formed by a material having a dynamic

surface tension (hereinafter also simply referred to as "surface tension") of 40 dyne/cm or less, more preferable by a material of 35 dyne/cm or less, and more preferable by a material of 32 dyne/cm or less, because of its particularly good ease of peeling after use. When the surface tension mentioned above exceeds 40 dyne/cm, the adhesion between the liquid permeable layer (1) and the wound site is not reduced, and it is difficult to peel off the wound dressing (5) after use, so that a smooth replacement treatment cannot be performed, which is not preferable. Further, the above-mentioned surface tension may be adjusted to 40 dyne/cm or less by adding a known additive or by a corona treatment or a surface treatment such as plasma and the like.

[0038]

Specifically, the above "surface tension" is measured, for example, according to the following procedure. A sheet material of a sample is cut into 1.5 to 2 cm square and placed at a measuring site of a contact angle measuring device (Trade name: FTA-100 manufactured by First Ten Angstrom Co., Ltd.). A test mixture of 1.5 μL is extruded from a syringe installed in the device, and the surface tension is measured by a hanging drop method and analyzed by the contact angle measuring device."

(4) "[0094]

(Second Embodiment)

In the first embodiment described above, a case is described in which a liquid permeation restriction layer (2) is provided between the liquid permeable layer (1) and the absorption holding layer (3). However, in the present invention, as in the second embodiment shown in FIG. 13, for example, the liquid permeation restriction layer may be omitted.

In other words, in the second embodiment, unlike the first embodiment described above, the liquid permeation restriction layer is omitted, and the absorption holding layer (3) is directly laminated on the second surface (12) of the liquid permeation layer (1). In the second embodiment, since the liquid permeation restriction layer is omitted, it can be manufactured easily and carried out at low cost, which is preferable. In addition, in the second embodiment, although the liquid permeation restriction layer is omitted, it is possible to obtain an effect similar to that in the case where the liquid permeation restriction layer is provided, by using a material having high hydrophobicity in the liquid permeation layer (1) by preferably using a material having a contact angle with physiological saline of 85 degree or more, for example."

(5) "[0102]

(Fifth embodiment)

FIG. 17 shows the fifth embodiment of the wound dressing (5) according to the

invention.

In this fifth embodiment, unlike the first embodiment, the absorption holding layer (3) is not integrated with other layers. In other words, in the wound dressing (5) according to the fifth embodiment, the protective layer (4) is integrated with the second surface (12) of the liquid-permeable layer (1) consisting of the surface sheet (10) by welding or the like at the peripheral portion (22), and is formed into a bag shape. Then, the absorption holding layer (3) is inserted between the liquid permeable layer (1) and the protective layer (4) in a state where the absorption holding layer (3) is not fixed to the two layers (1, 4).

[0103]

In this fifth embodiment, since the absorption holding layer (3) is not fixed to the liquid permeable layer (1) or the protective layer (4) with an adhesive or the like, intense absorption by the absorption holding layer (3) is unlikely to occur, and the effusion can be prevented from moving from the liquid permeable layer (1) to the absorption holding layer (3), and thus the effusion can be favorably maintained between the wound site and the liquid permeable layer (1), which is preferable. Furthermore, since the absorption holding layer (3) is capable of moving between the liquid permeable layer (1) and the protective layer (4) along the second surface (12) of the liquid-permeable layer (1), even if a displacement stress is applied to a part of the wound dressing (5) such as the absorption holding layer (3), the displacement stress can be absorbed between the part and the wound site by the movement, and thus the stress applied to the wound site can be relieved. As a result, the liquid permeable layer (1) consisting of the surface sheet (10) hardly causes positional deviation relative to a wound site, and it is very suitable for the healing and prevention of pressure ulcers, for example. Moreover, since the absorption holding layer (3) can be moved relative to the liquid permeable layer (1) and the protective layer (4), the entire wound covering material (5) is made flexible, and thus, there is an advantage in that its texture can be improved.

[0104]

In this fifth embodiment, the absorption holding layer (3) is disposed between the liquid-permeable layer (1) and the protective layer (4). However, in the present invention, the liquid permeation restriction layer (2) may be integrally laminated on at least one of the second surface (12) of the liquid-permeable layer (1) and the surface of the absorption holding layer (3) facing thereto. In addition, in the fifth embodiment described above, the absorption holding layer (3) only has to be one that is not fixed to the liquid permeable layer (1), and it may be fixed to the protective layer (4). In this case, since the migration of an effusion from the liquid-permeable layer (1) to the

absorption holding layer (3) can be restricted and the absorption holding layer (3) can be maintained at a predetermined position with respect to the wound site, it is preferable."

3. Regarding Reason for Invalidation 1 (violation of Article 29(1)(iii) and Article 29(2) of the Patent Act)

(1) Reference date for judgment on novelty and inventive step of Inventions 1-19

Relating to Reason for Invalidation 1, the Demandant alleges to the effect that "Although the Patent has been granted regarding a patent application involving priority claim according to the provision of Article 41(1) of the Patent Act (hereinafter, referred to as 'the Priority Claim'), the point that 'the absorption holding layer (3) is not integrated with the liquid-permeable layer (1)"' which is a matter specifying the invention of Invention 1, is not described in A-12; that is, in the description, the scope of claims, or drawings originally attached to the application of the earlier application (Japanese Patent Application No. 2010-126338) (hereinafter, referred to as 'Description, etc. of Basic Application') that is deemed to be the basis of the relevant priority claim, and it is a matter added on the occasion of international application, which is the original application of the application concerning the Patent; therefore, the reference date for judgment on novelty and inventive step regarding Inventions 1-19 is not June 1, 2010, which is the priority date, but it should be May 31, 2011, which is the international application date" (the written demand, page 16, line 17 to page 20, line 4).

In contrast to this, the Demandee alleges to the effect that "Since the description of paragraph [0019] of A-12 that 'the covering material of the present invention may be also of an aspect in which it is a wound dressing composed of at least two layers, and is constituted by laminating and integrating A layer and C layer in this order from a side used so as to be in contact with a wound site.' is a description that reflects a matter that existence of an aspect in which integration is not performed is assumed, the reference date for judgment on the above-mentioned novelty and inventive step should be June 1, 2010 that is the priority date" (the written reply, page 9, line 10 to page 10, line 4).

These allegations will be discussed below.

Although the described matters of paragraph [0102]-[0104] and [FIG. 17] of the Patent Description related to the point that "the absorption holding layer (3) is not integrated with the liquid-permeable layer (1)", which is a matter specifying the invention of Invention 1, is not described in A-12, which is the Description, etc. of Basic Application, it is described in the description, the scope of claims, or drawings originally attached to the application of the international patent application, which is the original application of the application concerning the Patent (hereinafter, referred to as

"Description, etc. of Original Application") (refer to A-13), and, therefore, it can be said that Invention 1 is an invention that is not described in the Description, etc. of Basic Application, but is described in the Description, etc. of Original Application.

Therefore, since the Priority Claim does not meet the requirement of the main body of Article 41(1) of the Patent Act, and, regarding application of Article 29 of the same Act, the provision of Article 41(2) of the same Act is not applied, and, therefore, the reference date for judgment on novelty and inventive step regarding Inventions 1-19 is not June 1, 2010, which is the priority date, but is May 31, 2011, which is the international application date.

In this connection, although the Demandee alleges the above-mentioned "existence of an aspect in which integration is not performed is assumed", in A-12 (Description, etc. of Basic Application), there is no description at all relating to an aspect in which integration is not made, and thus it is natural to understand that the description of the above-mentioned paragraph [0019] is nothing but one explaining that, as an aspect in which integration is performed, it "may be also of an aspect in which it is a wound dressing composed of at least two layers, and is constituted by laminating and integrating A layer and C layer in this order from a side used so as to be in contact with a wound site."

Then, even if it is assumed that the description of paragraph [0019] is a description that reflects that existence of an aspect in which integration is not performed, the matters described in paragraph [0102]-[0104] of the Patent Description such as " ... the protective layer (4) is integrated with the second surface (12) of the liquid-permeable layer (1) consisting of the surface sheet (10) by welding or the like at the peripheral portion (22), and is formed into a bag shape. Then, the absorption holding layer (3) is inserted between the liquid permeable layer (1) and the protective layer (4) in a state where the absorption holding layer (3) is not fixed to the two layers (1, 4). ... since the absorption holding layer (3) is not fixed to the liquid permeable layer (1) or the protective layer (4) with an adhesive or the like, intense absorption by the absorption holding layer (3) is unlikely to occur, and the effusion can be prevented from moving from the liquid permeable layer (1) to the absorption holding layer (3), and thus the effusion can be favorably maintained between the wound site and the liquid permeable layer (1), which is preferable. Furthermore, since the absorption holding layer (3) is capable of moving between the liquid permeable layer (1) and the protective layer (4) along the second surface (12) of the liquid-permeable layer (1), even if a displacement stress is applied to a part of the wound dressing (5) such as the absorption holding layer (3), the displacement stress can be absorbed between the part and the wound site by the movement, and thus

the stress applied to the wound site can be relieved. As a result, the liquid permeable layer (1) consisting of the surface sheet (10) hardly causes positional deviation relative to a wound site, and it is very suitable for the healing and prevention of pressure ulcers, for example. Moreover, since the absorption holding layer (3) can be moved relative to the liquid permeable layer (1) and the protective layer (4), the entire wound covering material (5) is made flexible, and thus, there is an advantage in that its texture can be improved. ... In addition, in the fifth embodiment described above, the absorption holding layer (3) only has to be one that is not fixed to the liquid permeable layer (1), and it may be fixed to the protective layer (4). In this case, since the migration of an effusion from the liquid-permeable layer (1) to the absorption holding layer (3) can be restricted and the absorption holding layer (3) can be maintained at a predetermined position with respect to the wound site, it is preferable." and the matter described in [FIG. 17] of the Patent can never be said to be ones described in A-12 (Description, etc. of Basic Application).

Therefore, the above Demandee's allegation cannot be adopted.

(2) Regarding Reason for Invalidation 1-1

A. Invention A-1

As viewed from the matters summed up in the above-mentioned 1.(1), there is described the following A-1 invention in A-1.

<<Invention A-1>>

A wound care product having an upper surface and a lower surface to be a wound contact surface, comprising:

a lower surface side covering layer located in the lower surface side; an upper surface side covering layer located in the upper surface side; and an absorbent layer interposed between the covering layers, wherein

the lower surface side covering layer has a laminated structure, at least a layer in the side of the wound contact surface is a hydrophobic resin layer, a lot of holes penetrating these layers are provided, and body fluid from the wound is allowed to move to the absorbent layer, wherein

the absorbent layer is a layer comprising a material having high water absorption, wherein

the lower surface side covering layer and the upper surface side covering layer are joined to each other by a seal portion outside the absorbent layer, and covers the absorbent layer.

B. Comparison

"Lower surface side covering layer", "absorbent layer", "wound contact surface", "hole", and "wound care product" of Invention A-1 respectively correspond to "liquid-permeable layer", "absorption holding layer", "first surface", "through hole", and "wound dressing" of Invention 1.

Therefore, the corresponding feature and the different features between Invention 1 and Invention A-1 are as follows.

<<Corresponding Feature>>

A wound dressing comprising at least two layers of a liquid-permeable layer and an absorption holding layer,

the wound dressing being made by laminating the liquid permeable layer and the absorption holding layer in this order from a side used to face a wound site, wherein

the liquid-permeable layer includes a first surface facing the wound site, a second surface opposite to the first surface, and a plurality of through holes extending through between the surfaces in the thickness direction,

the through holes allow liquid to pass from the first surface toward the second surface,

the first surface is made of a resin sheet material having hydrophobicity, and wherein

the absorption holding layer contains a sheet material capable of absorbing and holding water.

<<Different Feature 1A>>

Regarding "through holes", in Invention 1, the holes "have an opening rate of 3.07% or more", "have a depth of 100-2000 μm", and "exist at a density of 50-400 holes/cm^2", whereas, in Invention A-1, an opening rate, a depth, and an existence density are unclear.

<<Different Feature 1B>>

Regarding "absorption holding layer", in Invention 1, it is "directly laminated" with "liquid-permeable layer", and "is not integrated with the liquid-permeable layer", whereas, in Invention A-1, it is unclear whether it is "directly laminated" with "the liquid-permeable layer" and "is not integrated with the liquid-permeable layer".

C. Judgment on Different Features

Since <<Different Feature 1A>> is one related to whether or not there is a prescription of an opening rate, a depth, and an existence density of "through holes", and

<<Different Feature 1B>> is related to whether or not there is a prescription of the relation between "absorption holding layer" and "liquid-permeable layer", these different features are not prima facie different features in which only expression is different, but are substantive different features.

Therefore, it cannot be said that Invention 1 is Invention A-1.

D. Summary

As above, it cannot be said that Invention 1 is Invention A-1, and it does not fall under Article 29(1)(iii) of the Patent Act, and therefore it cannot be decided that the patent thereof should be invalidated on the ground that it falls under Article 123(1)(ii) of the same Act.

(3) Regarding Reason for Invalidation 1-2

A. Regarding Invention 1

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

The comparison, the corresponding feature, and the different features between Invention 1 and Invention A-1 are as indicated in the above-mentioned 3.(2)B.

(C) Judgment on the Different Features

Regarding <<Different Feature 1A>>

The matter of "have an opening rate of 3.07% or more" of Invention 1 is based on the value of the opening area at the minimum hole diameter, $50 \times \pi \times (2.8/2)2 \times 10^{-4}$ $cm^2 = 3.07 \times 10^{-2}$ cm^2, calculated from the minimum value of the hole diameter of 280 μm and the minimum value of the density of 50 holes/cm^2 in the description of paragraph [0028] of the Patent Description that "As for the diameter of the through holes (13), it is preferable that the opening area at the first surface (11) facing the wound site corresponds to a circular shape of 280-1400 μm in diameter. ...", and the description of paragraph [0030] that "It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2, ..." (refer to the above-mentioned 2.(2)), and this is obvious also from the described matters of A-10 and 11 (refer to the above-mentioned 1.(3) and (4)).

Then, in light of, in addition to the description of "It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2, ..." mentioned above, there being described in paragraph [0030] of the Patent Description that "it is preferable

that the opening rate of the through holes (13) in the first surface (11) be 15 to 60%.", there being described in paragraph [0031] that "The dimension between the first surface (11) and the second surface (12), which is also the depth of the through holes (13); i.e., the thickness of the liquid permeable layer (1), is preferably about 100-2000 μm, and more preferably about 250 to 500 μm.", and, there being described in paragraph [0032] that "By setting the density, the opening rate, and the depth of the through holes (13) to the above preferable ranges, a proper storage space (14) can be formed between the wound site and the second surface (12), an appropriate amount of effusion can be retained on the wound site, and the effusion can be prevented from spreading in an in-plane direction of the wound site." (the underlines were given by the body), "an opening rate of 3.07% or more" of Invention 1 is not one prescribing the above-mentioned "preferable" opening rate, but it is nothing but one that just indicates a degree of openings according to "through holes", and thus it is reasonable to understand that there is no special technical significance in the numerical value "3.07%".

Here, although the above-mentioned "storage space" is stipulated by "opening area" and "depth" of "through holes", in order to form "through holes" as "a proper storage space" for "an appropriate amount of effusion to be retained on the wound site" mentioned above, it can be said that stipulation of a suitable "opening area" and a "depth" becomes the requirement thereof.

However, since the matter as the above-mentioned "have an opening rate of 3.07% or more" is one that stipulates only the lower limit value of "opening rate", even if "opening area" of "through holes" are calculated from "opening rate" and "existence density", it becomes one that may include "through holes" of too small an opening area by which a storage space capable of holding an effusion is not formed or ones of too large an opening area, it can never be said that this matter is one that stipulates a suitable "opening area".

Therefore, a matter of a degree that "through holes" just "have an opening rate of 3.07% or more", "have a depth of 100-2000 μm", and "exist at a density of 50-400 holes/cm^2" cannot be said that it specifies that "a proper storage space" for "an appropriate amount of effusion to be retained on the wound site" is formed, and thus it is reasonable to understand that there is no special technical significance.

On the other hand, since "hole" in Invention A-1 is, as viewed from each description of A-1 (the above-mentioned 1.(1)A. (refer to [Claim 1] and [Claim 2]); D. (refer to paragraph [0021] and [0024]); and E. (refer to [0029])), one that is provided so as to be able to move body fluid from a wound to the absorbent layer, even if there is no mention about matters such as an opening rate, a depth, and an existence density of "hole"

in A-1, it is a design matter that can be adopted accordingly on the occasion of reification of Invention A-1 for a person skilled in the art to be able to just set these matters within a numerical value range of Invention 1 concerning the above-mentioned <<Different Feature 1A>>, which may include a hole to move body fluid from a wound to the absorbent layer in order "to be able to move body fluid from a wound to the absorbent layer" mentioned above.

Therefore, it can be concluded that, in Invention A-1, it is a matter that could have been achieved accordingly by a person skilled in the art to make an opening rate, a depth, and an existence density of "holes" be of a degree of the constitution of the Invention 1 concerning <<Different Feature 1A>>.

Regarding <<Different Feature 1B>>

Regarding the matter that "absorption holding layer" in Invention 1 is "directly laminated" with "the liquid-permeable layer", it is described in paragraph [0094] of the Patent Description that "in the second embodiment, unlike the first embodiment described above, the liquid permeation restriction layer is omitted, and the absorption holding layer (3) is directly laminated on the second surface (12) of the liquid permeation layer (1). In the second embodiment, since the liquid permeation restriction layer is omitted, it can be manufactured easily and carried out at low cost, which is preferable." (refer to the above-mentioned 2.(4)).

In addition, regarding the matter that "absorption holding layer" in Invention 1 "is not integrated with the liquid-permeable layer", it is described in paragraph [0102] of the Patent Description that "In this fifth embodiment, unlike the first embodiment, the absorption holding layer (3) is not integrated with other layers. In other words, in the wound dressing (5) according to the fifth embodiment, the protective layer (4) is integrated with the second surface (12) of the liquid-permeable layer (1) consisting of the surface sheet (10) by welding or the like at the peripheral portion (22), and is formed into a bag shape. Then, the absorption holding layer (3) is inserted between the liquid permeable layer (1) and the protective layer (4) in a state where the absorption holding layer (3) is not fixed to the two layers (1, 4)." (refer to the above-mentioned 2.(5)).

On the other hand, in A-1, regarding "a covering layer located in the lower surface side; a covering layer located in the upper surface side; and an absorbent layer interposed between the covering layers" in Invention A-1, it is not described that some sort of layer should intervene between "a covering layer located in the lower surface side" and "an absorbent layer", or that "a covering layer located in the lower surface side" and "an absorbent layer" should be fixed.

However, as viewed from, for example, the description of paragraph [0034] of A-3 that "Since the surface sheet 2 and the absorbable sheet 5 are disposed in contact with each other without being bonded, the movable range of the surface sheet 2 can be made wider toward the plane direction. For this reason, even if the therapy pad 1 shifts toward the plane direction, the surface sheet 2 of this therapy pad 1 in contact with the wound site comes not to shift over this wound part easily. Therefore, rubbing between the surface sheet 2 and the wound site due to shifting of this therapy pad 1 can be prevented from occurring, and a burden on this wound site can be reduced.", the description of paragraph [0017] of A-6 that "The wound dressing of the present device is made by laminating a surface sheet, a water retentive sheet, an intermediate sheet, and a back sheet from the side in contact with the wound area as described above, and the term 'laminating' as referred to herein mainly indicates a state both sheets are merely superimposed on each other ... In order to prevent leaking of the exudate, it is preferred that the wound dressing of the present device is characterized in that the size of the surface sheet and the back sheet is made slightly larger than that of the water retentive sheet or the intermediate sheet and only the peripheral edge portions of the two are bonded by a method such as thermal fusion bonding.", and the descriptions of paragraphs [0060]-[0062] of A-7 that "Although the wound dressing of the present invention has the first layer (1) and the second layer (2) as requisite constituent components, and does not have a sheet material that limits passage of an effusion to the second layer (2) (permeable sheet material) between the first layer (1) and the second layer (2), a permeable sheet material may be provided between the first layer (1) and the second layer (2) as desired. ... The wound dressing in FIG. 3 is one in which the second sheet material and the liquid-permeable sheet (8) are sandwiched by the first sheet material and the third sheet material that are wider than the former sheets, and the peripheries of the first sheet material and the third sheet material protruding outside are joined by the heat seal (9). Note that, between the respective sheets, an adhesive agent and the like does not interpose in particular. ... In a wound dressing of the present invention, it is not necessary that the respective layers are integrated by an adhesive agent, and, when the third layer (3) is included, the peripheries of the first layer (1) and the third layer (3) should be simply joined by a seal and the like, as shown in FIG. 3.", it can be said that it was a well-known technology before the application of the Patent to make, in a wound care product composed of a layer having a liquid permeation function located in the wound contact surface side, a layer located in the upper surface side, and a layer having a function of liquid absorption interposed between these layers, "the layer having a function of liquid absorption" be directly laminated with "a layer having a liquid permeation function located in the wound contact surface side" and make it not be

integrated with "the layer having a liquid permeation function located in the wound contact surface side" in question, and adoption or rejection thereof could have been determined accordingly by a person skilled in the art in consideration of manufacturing cost and the like.

Therefore, it can be concluded that it could have been done by a person skilled in the art accordingly to "directly laminate" an "absorbent layer" in Invention A-1 with a "covering layer located in the lower surface side", and make it be "not integrated with" the relevant covering layer located in the lower surface side.

(D) Summary

As above, Invention 1 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art illustrated in A-3, A-6, and A-7.

B. Regarding Invention 2

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 2 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 2>>

In Invention 2, "a contact angle with physiological saline at the first surface is 85 degrees or more", whereas, in Invention A-1, a contact angle with physiological saline at the "wound contact surface" of "the lower surface side covering layer" is unclear.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 2>> will be discussed below.

Regarding "the lower surface side covering layer" of Invention A-1, it is described in paragraph [0028] of A-1 that "the required characteristics and functions of the covering layer will be described. First, hydrophobicity will be described. At least

the wound contact surface of the covering layer in the lower surface side has hydrophobicity. In order to make it hydrophobic, the covering layer itself may be formed of a hydrophobic material, or the covering layer is made into a laminated structure by coating a hydrophobic resin layer different from the covering layer, and so on to make the surface thereof hydrophobic. In order to easily separate the wound care product from the wound, this hydrophobic surface of the covering layer preferably has a contact angle with water of 65° or more, more preferably 90° or more. The contact angle can be measured using a contact angle meter CA-A (manufactured by Kyowa Interface Science Co., Ltd.) according to the instruction manual "Droplet method measurement operation" of the contact angle meter". (refer to the above-mentioned 1.(1)E.).

In addition, it is common general technical knowledge that physiological saline has an osmotic pressure close to that of body fluid than that of water.

In view of the above, it is reasonable to understand that, regarding "hydrophobicity" which should be provided in a "wound contact surface" of "the lower surface side covering layer" of Invention A-1, by which "body fluid from the wound is allowed to move to the absorbent layer", instead of stipulating by a water contact angle, stipulating it by a contact angle with physiological saline, which is more close to body fluid, is a design related matter that could have been achieved by a person skilled in the art accordingly.

Therefore, it can be concluded that it would have been achieved by a person skilled in the art with ease to stipulate "hydrophobicity" that should be provided in the "wound contact surface" of "the lower surface side covering layer" of Invention A-1 by a contact angle with physiological saline of 85 degrees or more.

(D) Summary

As above, Invention 2 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art and the common general technical knowledge illustrated in A-3, A-6, and A-7.

C. Regarding Invention 3

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 3 and Invention A-1 are as indicated in the above-mentioned 3.(3)B., and the two inventions are different

in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 3>>

In Invention 3, "surface tension at the first surface is 40 dyne/cm or less", whereas, in Invention A-1, surface tension at "wound contact surface" of "the lower surface side covering layer" is unclear.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 3>> will now be discussed below.

"Wound contact surface" of "the lower surface side covering layer" of Invention A-1 is, as described in the above-mentioned 5.(3)B.(C), one having "hydrophobicity", and, in A-1, in addition to the description that "In order to make it hydrophobic, the covering layer itself may be formed of a hydrophobic material, or the covering layer is made into a laminated structure by coating a hydrophobic resin layer different from the covering layer, and so on to make the surface thereof hydrophobic." (paragraph [0028]), it is described that "Examples of the material of the covering layer include polyesters; polyolefins such as polyethylene and polypropylene; olefinic copolymers such as ethylene/vinyl acetate copolymers and ethylene/ethyl acrylate copolymers; polyamides; polyurethanes; and silicones, and these materials may be used alone or in combination of two or more." (paragraph [0032]).

Further, in A-1, relating to "hydrophobicity" that should be provided in the "wound contact surface" of "the lower surface side covering layer" mentioned above, it is described that "As a material for the hydrophobic resin layer provided in the covering layer, a material having a contact angle between the surface of the layer formed of resin and water of 65° or more may be just selected, and, for example, silicone resin, acrylic resin, methacrylic resin, polyvinyl chloride resin, polyvinylidene chloride resin, fluororesin, olefin resin, polyester resin, styrene resin, urethane resin, polyamide resin, and mixtures thereof may be cited." (paragraph [0033]), and, from this description, it is perceived that "hydrophobicity" that should be provided in the "wound contact surface" of "the lower surface side covering layer" of Invention A-1 mentioned above is "a contact angle with water of 65° or more".

Here, when looking at Table 5 and Table 6 of A-8 describing a contact angle and surface tension of various kinds of plastic, it is perceived that, among resins illustrated in paragraphs [0032] and [0033] of A-1, "polypropylene" whose contact angle is 91° has

surface tension of 31 dyne/cm, "polyethylene (density 0.92)" whose contact angle is 81° has surface tension of 32 dyne/cm, "polyethylene (density 0.955)" whose contact angle is 73° has surface tension of 31 dyne/cm, and "polyvinylchloride" whose contact angle is 68° has surface tension of 39 dyne/cm.

Then, according to A-17 (refer to the above-mentioned 1.(5)), "hydrophobicity" and "water-repellency" are synonymous, and, as it is illustrated, regarding "polytetrafluoroethylene", in Table 5 of A-8 that its contact angle is larger than the contact angles of the other polymers, and in Table 6 of A-8 that its surface tension is smaller than the surface tension of the other polymers, it is a matter of common general technical knowledge that the larger the contact angle, the higher the water repellency; that is, hydrophobicity, and the smaller the surface tension, the higher the water repellency; that is, hydrophobicity.

In view of the above, it can be concluded that it would have been achieved by a person skilled in the art with ease to stipulate "hydrophobicity" that should be provided in the "wound contact surface" of "the lower surface side covering layer" of Invention A-1 by surface tension and make that value be 40 dyne/cm or less.

(D) Summary

As above, Invention 3 is one that could have been invented by a person skilled in the art with ease based on Invention A-1, the above-mentioned well-known art illustrated in A-3, A-6, and A-7, and the common general technical knowledge illustrated in A-8.

D. Regarding Invention 4

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Relating to comparison and the corresponding feature between Invention 4 and Invention A-1, in light of there being the description regarding "wound contact surface" of "the lower surface side covering layer" of Invention A-1 in A-1 that "As a material for the hydrophobic resin layer provided in the covering layer ..., for example, silicone resin, acrylic resin, methacrylic resin, polyvinyl chloride resin, polyvinylidene chloride resin, fluororesin, olefin resin, polyester resin, styrene resin, urethane resin, polyamide resin, and mixtures thereof may be cited." (paragraph [0033]), the "wound contact surface" of "the lower surface side covering layer" of Invention A-1 corresponds to "the first surface"

that "is coated with one or more water repellent substances selected from the group consisting of silicone, polyurethane, styrene-butadiene-styrene block copolymer, tetrafluoroethylene hexafluoropropylene copolymer, tetrafluoroethylene perfluoroalkylvinylether copolymer, and polytetrafluoroethylene" of Invention 4, and therefore the two inventions are different only in <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

(C) Judgment on Different Features

The judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

(D) Summary

Therefore, Invention 4 is one that could have been invented by a person skilled in the art with ease based on, as with the Invention 1, Invention A-1 and the above-mentioned well-known art illustrated in A-3, A-6, and A-7.

E. Regarding Invention 5

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 5 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 5>>

In Invention 5, regarding "the first surface is a resin sheet material having hydrophobicity" of Invention 1, "the sheet material is formed using a polyolefin resin material having a contact angle with physiological saline of 85 degrees or more", whereas, in Invention A-1, it is unclear whether "the lower surface side covering layer" is formed using such a material or not.

(C) Judgment on Different Features

The judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 5>> will now be discussed below.

As described in the above-mentioned 3.(3)B.(C), it can be concluded that it would have been achieved by a person skilled in the art with ease to stipulate "hydrophobicity" that should be provided in "the lower surface side covering layer" of Invention A-1 as a contact angle with physiological saline of 85 degrees or more.

Then, as a material of "the lower surface side covering layer" of Invention A-1, in A-1, there is a description that "Examples of the material of the covering layer include polyesters; polyolefins such as polyethylene and polypropylene; olefinic copolymers such as ethylene/vinyl acetate copolymers and ethylene/ethyl acrylate copolymers; polyamides; polyurethanes; and silicones, and these materials may be used alone or in combination of two or more." (paragraph [0032]), and, in light of there being also illustrated polyolefin resin materials such as polyethylene and polypropylene, it is easy for a person skilled in the art to make "the lower surface side covering layer" of Invention A-1 be a sheet material formed using a polyolefin resin material having a contact angle with physiological saline of 85 degrees or more.

(D) Summary

As above, Invention 5 is one that could have been invented by a person skilled in the art with ease based on Invention A-1, the above-mentioned well-known art, and the common general technical knowledge illustrated in A-3, A-6, and A-7.

F. Regarding Invention 6

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 6 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 6A>>

In Invention 6, regarding "the first surface is a resin sheet material having hydrophobicity" of Invention 1, "the sheet material is formed using a low-density polyethylene resin material", whereas, in Invention A-1, it is unclear whether "the lower surface side covering layer" is formed using such a material.

<<Different Feature 6B>>

Regarding "through holes", in Invention 6, the holes have "an opening rate of

3.07% or more", "have a depth of 100-2000 μm", "exist at a density of 50-400 holes/cm^2", and "have an opening area at the first surface (11) corresponding to a round shape of 280-1400 μm in diameter", whereas, in Invention A-1, all of an opening rate, a depth, an existence density, and an opening area at the lower surface to be the wound contact surface are unclear.

(C) Judgment on Different Features

Judgment on <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

Regarding <<Different Feature 6A>>

As the material of "the lower surface side covering layer" of Invention A-1, polyethylene is illustrated in A-1 (refer to the above-mentioned 1.(1)F), and it is a matter of common general technical knowledge that, in polyethylene, there are high-density polyethylene that is relatively hard, and low-density polyethylene that is relatively soft, and the low-density polyethylene is used as a material of ones for which flexibility is required such as a sheet and a film, without having to await illustration.

Further, it was a well-known technology before the application of the Patent to use low-density polyethylene as a material of a sheet constituting "a layer having a liquid permeation function located in the wound contact surface side" of a wound care product, as described, for example, in paragraph [0016] of A-9 that "The perforated film 38 can be fabricated using some suitable materials. Polymers suitable for forming the perforated film 38 include ... any material capable of being formed into a film ... low-density polyethylene (LDPE), linear low-density polyethylene (LLDPE) ... are included, but the invention is not limited to these.", and adoption or rejection thereof is a matter of a degree that could have been determined by a person skilled in the art in light of functions or manufacturing cost and the like required for the sheet.

Therefore, it would have been achieved by a person skilled in the art with ease to make "the lower surface side covering layer" of Invention A-1 be a sheet material formed using a low-density polyethylene resin material.

Regarding <<Different Feature 6B>>

As indicated in the above-mentioned No. 5.3.(3)A.(C), it can be said that, in order to form "through holes" as "a proper storage space" for "an appropriate amount of effusion to be retained on the wound site", it is required to stipulate a suitable "opening area" and a "depth", and Invention 6 has the matters indicated in the above-mentioned <<Different Feature 6B>> of "an opening rate of 3.07% or more", "have a depth of 100-

2000 μm", "exist at a density of 50-400 holes/cm^2", and "has an opening area at the first surface (11) corresponding to a round shape of 280-1400 μm in diameter" as matters specifying the invention.

On the other hand, Invention A-1 is, as is also obvious from the fact that it is described in paragraph [0034] of A-1 that " ... As the absorbent layer, materials having high water absorption such as cellulosic fibers, pulp, polymeric water-absorbent polymer, etc. can be used alone or in combination, and the amounts of these may be adjusted according to the required amount of absorption. In particular, it is preferable to include a substance that forms a gel upon water absorption, and, by doing so, the wound can be kept moist and healing of the wound can be promoted. ..." (refer to the above-mentioned 1.(1)F), an invention in which, while making the "absorbent layer" be equipped with a function that "the wound can be kept moist and healing of the wound can be promoted", "hole" is simply made to be one by which "body fluid from the wound is allowed to move to the absorbent layer", and there is no description that becomes motivation to make "hole" have the above-mentioned function instead of or in addition to "absorbent layer", and there is no description suggesting this, either.

Therefore, regarding the matter specifying the invention of Invention 6 indicated in the above-mentioned <<Different Feature 6B>>, even if it is described in the scope of claims of A-4 that "A wound dressing ... [4] the thickness of the sheet material of the first layer is 100-2000 μm; the small holes respectively have an opening diameter at the surface in the side used so as to be in contact with a wound site of 280-1400 μm in corresponding diameter, have an opening diameter at the other surface that is smaller than the opening diameter at the surface in the side used so as to be in contact with the wound site, and exist at a density of 50-400 holes/cm^2 ....", there is described a technical matter in paragraph [0024]-[0029] that "As a hole diameter of the through holes, it is preferred that, in the first sheet material, an opening diameter at the surface in the side used so as to be in contact with the wound site (hereinafter, referred to as "wound-side surface") be 280-1400 μm in corresponding diameter. ... In addition, it is preferred that the through holes exist at a density of 50-400 holes/cm^2, and it is more preferred that the through holes exist at a density of 60-325 holes/cm^2. Further, as an opening rate of the through holes at wound-side surface, it is preferred that it be 15-60% relative to the entire first sheet material. ... It is advantageous to make density, an opening rate, and a depth of through holes be within the above-mentioned desirable ranges, in a point of forming a proper storage space between the wound surface and the second layer to hold an appropriate effusion on the wound surface, and, in conjunction with this, preventing spread of effusion in the in-plane direction.", and, further, there is described in [Claim 4] and paragraphs

[0021]-[0024] of A-7 a similar technical matter, this matter does not become motivation to make, in Invention A-1 in which there is no specification about an opening rate, a depth, an existence density, and an opening area of "hole", that is, there is no prescription at all regarding "hole", the function as "the wound can be kept moist and healing of the wound can be promoted" that is provided in "absorbent layer" be equipped further in "hole"; therefore, it cannot be said that it would have been achieved by a person skilled in the art with ease to adopt the technical matters described in A-4 and A-7 to Invention A-1.

In this connection, the Demandant alleges, in page 3, line 15 to page 8, line 12 of the written statement (Demandant), and page 13, line 13 to page 17, line 23 of the written refutation, to the effect that there is motivation to apply the technical matter described in A-4 to Invention A-1.

This allegation is one that says that, in light of the common general technical knowledge (that Wet Treatment Method is effective and that it is effective to use a sheet having high initial water pressure resistance in the side of the wound site) that is perceived from described matters of A-18 (Well-known Example 1 in the written statement (Demandant)) and A-19 (Well-known Example 2 in the written statement (Demandant)) on the premise that Invention A-1 has a constitution that the "absorbent layer" that is "a layer comprising a material having high water absorption" of Invention A-1 "includes a substance that forms a gel upon water absorption", there is the above-mentioned motivation.

However, even if Invention A-1 has the constitution that the "absorbent layer" thereof "includes a substance that forms a gel upon water absorption", and, in addition, even if the above-mentioned common general technical knowledge is perceived from A-18 and A-19, in A-1, there is no description leading to, in light of the above-mentioned common general technical knowledge, realization thereof; that is, in A-1, there is no description at all leading to an idea that the function of "the wound can be kept moist and healing of the wound can be promoted" which is provided in the "absorbent layer" is made to be further provided in the "hole".

Therefore, the above-mentioned Demandant's allegation has a leap in logic, and thus cannot be adopted.

(D) Summary

Therefore, it cannot be said that Invention 6 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the matters described in A-2 to A-4, A-6, A-7, and A-9.

G. Regarding Invention 7

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 7 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 7>>

In Invention 7, "a dimension between the first surface and the second surface is 100-2000 μm, and wherein each of the through holes has an open area at the first surface corresponding to a round shape of 280-1400 μm in diameter, has an open area at the second surface smaller than the open area at the first surface, and the through holes exist at a density of 50 to 400 holes/cm^2", whereas, in Invention A-1, the dimension between the "wound contact surface" of "lower side covering layer" and the surface in the opposite side, and the size, the shape, and the existence density of the "holes" are unclear.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 7>> will now be discussed below.

As also indicated in the above-mentioned 3.(3)F.(C), although Invention 7 is one in which, regarding the through holes, suitable "opening area" and "depth" are specified, and "a proper storage space" for "an appropriate amount of effusion to be retained on the wound site" is formed, in contrast to this, Invention A-1 is an invention in which, while making "absorbent layer" be equipped with a function that "the wound can be kept moist and healing of the wound can be promoted", "hole" is simply made to be one by which "body fluid from the wound is allowed to move to the absorbent layer", and there is no description that becomes motivation to make "hole" have the above-mentioned function instead of or in addition to "absorbent layer", and there is no description suggesting this, either; therefore, it cannot be said that it would have been achieved by a person skilled in the art with ease to adopt the technical matters described in A-4 and A-7 in order to make "hole" have the function of "the wound can be kept moist and healing of the wound can be promoted" provided in "absorbent layer" of Invention A-1.

(D) Summary

As above, it cannot be said that Invention 7 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the matters described in A-2 to A-4, A-6, and A-7.

H. Regarding Invention 8

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 8 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 8>>

In Invention 8, "a second liquid-permeable layer having the same configuration as the first liquid-permeable layer is further laminated on a side of the absorption holding layer opposite to the liquid-permeable layer", whereas, in Invention A-1, a layer having the same configuration with "the lower surface side covering layer" is not laminated on the surface of "absorbent layer" opposite to "the lower surface side covering layer".

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 8>> will now be discussed below.

In A-2, there are described matters that "It is necessary that also the surface material 4 has air permeability, and it is formed of a similar member with the wound surface covering material 3 mentioned above." (the description, page 5, line 19 to page 6, line 1), and "To the surface material 4, water repellent treatment may be applied by a water repellent agent such as silicon or fluorine." (the description, page 6, lines 14-16), and, from FIG. 1 thereof, it is perceived that, on the surface of the absorption material 2 in the opposite side of the wound surface covering material 3, the surface material 4 having the same configuration with the wound surface covering material 3 is further laminated.

Then, in A-1, although there is no description that the "wound care product" of

Invention A-1 is one for treatment of an anaerobic wound in particular, it can be concluded that it is a matter of a degree that could have been determined appropriately by a person skilled in the art whether or not to, in Invention A-1, in light of the described matters of A-2, laminate a layer having the same configuration with "the lower surface side covering layer" on the surface of the "absorbent layer" in the side opposite to "the lower surface side covering layer".

(D) Summary

As above, Invention 8 is one that could have been invented by a person skilled in the art with ease based on Invention A-1, the described matter of A-2, and the above-mentioned well-known art illustrated in A-3, A-6, and A-7.

I. Regarding Invention 9

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 9 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 9>>

In Invention 9, it is described as "further comprising a protective layer on a surface of the absorption holding layer opposite to the wound side, the protective layer being made of a resin film, a woven fabric, a knitted fabric, or a nonwoven fabric", and "through holes" "have hole diameters that decrease from the first surface toward the second surface, respectively, have an opening rate of 15-60%, have a depth of 100-2000 μm, exist at a density of 50-400 holes/cm^2, have storage spaces between the wound portion and the second surface, and hold an effusion above the wound portion", whereas, in Invention A-1, an opening rate, a depth, and an existence density are unclear, and it is not specified whether the effusion can be held, either.

(C) Judgment on Different Features

Judgment on <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 9>> will now be discussed below.

Invention 9 is provided with the constitution of, regarding "through holes", "have storage spaces between the wound portion and the second surface, and hold an effusion above the wound portion", whereas, Invention A-1 is an invention in which, while making the "absorbent layer" be equipped with a function that "the wound can be kept moist and healing of the wound can be promoted", the "hole" is simply made to be one by which "body fluid from the wound is allowed to move to the absorbent layer", and there is no description that becomes motivation to make the "hole" have the above-mentioned function instead of or in addition to "absorbent layer", and there is no description suggesting this, either; therefore, it cannot be said that it would have been achieved by a person skilled in the art with ease to adopt the technical matters described in A-4 and A-7 in order to make the "hole" have the function of "the wound can be kept moist and healing of the wound can be promoted" provided in the "absorbent layer" of Invention A-1.

(D) Summary

As above, it cannot be said that Invention 9 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the matters described in A-2 to A-4, A-6, and A-7.

J. Regarding Inventions 10-13

In light of the judgments indicated in the above-mentioned 3.(2)I.(C), it cannot be said that Inventions 10-13 that include all the matters specifying the invention of Invention 9, and, further, take technical matters as matters specifying the invention are ones that could have been invented by a person skilled in the art with ease based on Invention A-1, and the matters described in A-2 to A-4, A-6, and A-7.

K. Regarding Invention 14

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 14 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 14>>

In Invention 14, "the absorption holding layer is formed using an air laid nonwoven fabric", whereas, in Invention A-1, it is not specified that "absorbent layer" is formed using an air laid nonwoven fabric.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 14>> will now be discussed below.

To form the absorbent layer of a wound care product using an air laid nonwoven fabric was, as illustrated in the descriptions of A-4 that "As the third sheet material, an air laid nonwoven fabric is particularly preferable." (refer to paragraph [0065]), and of A-7 that "As the second sheet material, an air laid nonwoven fabric is particularly preferable." (refer to paragraph [0038]), a well-known technology in advance of the application of the Patent, and adoption or rejection thereof is a matter of a degree that could have been determined by a person skilled in the art appropriately.

Then, in A-1, it is described that "As the absorbent layer, materials having high water absorption such as cellulosic fibers, pulp, polymeric water-absorbent polymer, etc. can be used alone or in combination", and thus it should be concluded that it is a matter of a degree that could have been achieved by a person skilled in the art coming into contact with the above-mentioned well-known art illustrated in A-4 and A-7 accordingly to form "absorbent layer" of Invention A-1 using an air laid nonwoven fabric that can be said to be a type of a fiber product.

(D) Summary

As above, Invention 14 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art illustrated in A-3, A-4, and A-7.

L. Regarding Invention 15

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 15 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature

1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 15>>

In Invention 15, "the absorption holding layer comprises fluff pulp", whereas, in Invention A-1, the "absorbent layer" does not have fluff pulp.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 15>> will now be discussed below.

To make the absorbent layer of a wound care product have fluff pulp was, as it is described in A-4 that "Since, in an air laid nonwoven fabric, elements such as fibers constituting a nonwoven fabric are adhered by an adhesive agent in a pressurizing state, resin powder, fluff pulp, or the like having high water absorbent property does not easily drop out when the wound dressing is used by cutting it, and so on." (refer to paragraph [0068]), and there is a similar description in paragraph [0041] of A-7, a well-known technology in advance of the application of the Patent, and adoption or rejection thereof is a matter of a degree that could have been determined by a person skilled in the art appropriately.

Then, in A-1, it is described that "As the absorbent layer, materials having high water absorption such as cellulosic fibers, pulp, polymeric water-absorbent polymer, etc. can be used alone or in combination", and thus it should be concluded that it is a matter of a degree that could have been achieved by a person skilled in the art coming into contact with the above-mentioned well-known art illustrated in A-4 and A-7 accordingly to make "absorbent layer" of Invention A-1 have fluff pulp.

(D) Summary

As above, Invention 15 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art illustrated in A-3, A-4, and A-7.

M. Regarding Invention 16

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 16 and Invention

A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B., and <<Different Feature 15>> indicated in the above-mentioned 3.(2)L.(B).

<<Different Feature 16>>

In Invention 16, "the absorption holding layer further comprises a superabsorbent polymer, and a weight ratio of the superabsorbent polymer to the fluff pulp is 10:90 to 25:75", whereas, in Invention A-1, the "absorbent layer" does not have fluff pulp and, further, does not have a high absorption polymer.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C), and judgment on <<Different Feature 15>> is as indicated in the above-mentioned 3.(3)L.(C).

<<Different Feature 16>> will now be discussed below.

In paragraph [0034] of A-1, it is described that "As the absorbent layer, materials having high water absorption such as cellulosic fibers, pulp, polymeric water-absorbent polymer, etc. can be used alone or in combination, and the amounts of these may be adjusted according to the required amount of absorption." (refer to the above-mentioned 1.(1)E.).

In addition, it was a well-known technology before the application of the Patent to make the absorbent layer of a wound care product have fluff pulp as well as a high absorbable polymer, as described in A-4 that "Since, in an air laid nonwoven fabric, elements such as fibers constituting a nonwoven fabric are adhered by an adhesive agent in a pressurizing state, resin powder, fluff pulp, or the like having high water absorbent property does not easily drop out when the wound dressing is used by cutting it, and so on." (refer to paragraph [0068]), and as described in paragraph [0041] of A-7 similarly, and adoption or rejection thereof and a blending ratio to other materials on the occasion of adoption are matters of a degree that could have been determined by a person skilled in the art appropriately.

In view of the above, it should be concluded that it is a matter of a degree that could have been achieved by a person skilled in the art coming into contact with the above-mentioned well-known art illustrated in A-4 and A-7 accordingly to make the "absorbent layer" of Invention A-1 have, in addition to fluff pulp, a high absorbable polymer, and a weight ratio to fluff pulp be about 10:90-25:75.

(D) Summary

As above, Invention 16 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art illustrated in A-3, A-4, and A-7.

N. Regarding Invention 17

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 17 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B., <<Different Feature 15>> indicated in the above-mentioned 3.(2)L.(B), and <<Different Feature 16>> indicated in the above-mentioned 3.(2)M.(B).

<<Different Feature 17>>

In Invention 17, "the superabsorbent polymer is a sodium polyacrylate system", whereas, in Invention A-1, the "absorbent layer" does not have fluff pulp and further does not have a high absorption polymer of a sodium polyacrylate system.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C), judgment on <<Different Feature 15>> is as indicated in the above-mentioned 3.(3)L.(C), and judgment on <<Different Feature 16>> is as indicated in the above-mentioned 3.(3)M.(C).

<<Different Feature 17>> will now be discussed below.

In paragraph [0034] of A-1, it is further described that "In particular, it is preferable to include a substance that forms a gel upon water absorption, and, by doing so, the wound can be kept moist and healing of the wound can be promoted. Examples of the gel-forming substance preferably include, for example, sodium carboxymethyl cellulose, a crosslinked product of sodium carboxymethyl cellulose, starch-acrylic acid (salt) graft copolymer, acrylic acid (salt) polymer, starch-acrylonitrile copolymer, polyhydric alcohol, and the like." (refer to the above-mentioned 1.(1)E.).

Further, to make the absorbent layer of a wound care product have a high absorbable polymer of a sodium polyacrylate system as well as fluff pulp was, as further

described in paragraph [0068] of A-4 that "The absorption material is a material that causes absorption, swelling, and gelling in a short time when coming into contact with liquid. As such absorption material, it is preferred to use a polyacrylic acid system ..., so-called high water absorbent resin (SAP), or natural polysaccharide having high water absorption performance such as alginic acid and dextran." (refer to paragraph [0068]), and as described also in paragraph [0041] of A-7 similarly, a well-known technology before the application of the Patent, and adoption or rejection thereof and a blending ratio to other materials on the occasion of adoption is a matter of a degree that could have been determined by a person skilled in the art appropriately.

In view of the above, it should be concluded that it is a matter of a degree that could have been achieved by a person skilled in the art coming into contact with the above-mentioned well-known art illustrated in A-4 and A-7 accordingly to make "absorbent layer" of Invention A-1 have, in addition to fluff pulp, a high absorbable polymer of a sodium polyacrylate system further, and make a weight ratio to fluff pulp be about 10:90-25:75.

(D) Summary

As above, Invention 17 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art illustrated in A-3, A-4, and A-7.

O. Regarding Invention 18

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 18 and Invention A-1 is as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 18>>

In Invention 18, "the absorption holding layer has stretchability to enable deformation along at least the wound site", whereas, in Invention A-1, it is unclear whether "absorbent layer" is provided with stretchability capable of deforming along at least the wound site.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 18>> will now be discussed below.

To make the absorbent layer of a wound care product have stretchability capable of deformation along the wound site was, as described in A-4 that "In addition, stretchability may be given to the third sheet material by making a cut in the third sheet material (Note by the trial decision: this corresponds to "absorbent layer" of Invention A-1) intermittently by, for example, forming holes by perforation and the like." (refer to paragraph [0074]), and as there being a similar description in paragraph [0043] of A-7, a well-known technology before the application of the Patent, and adoption or rejection thereof is a matter of a degree that could have been determined by a person skilled in the art appropriately.

In view of the above, it should be concluded that it is a matter of a degree that could have been achieved by a person skilled in the art coming into contact with the above-mentioned well-known art illustrated in A-4 and A-7 accordingly to make the "absorbent layer" of Invention A-1 have stretchability capable of deformation along the wound site.

(D) Summary

As above, Invention 18 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art illustrated in A-3, A-4, and A-7.

P. Regarding Invention 19

(A) Invention A-1

Invention A-1 is as indicated in the above-mentioned 3.(2)A.

(B) Comparison

Comparison and the corresponding feature between Invention 19 and Invention A-1 are as indicated in the above-mentioned 3.(2)B., and the two inventions are different in the following point, in addition to <<Different Feature 1A>> and <<Different Feature 1B>> indicated in the above-mentioned 3.(2)B.

<<Different Feature 19>>

In Invention 19, "an adhesive layer is included on a side opposite to the side facing the wound site", whereas Invention A-1 does not have an adhesive layer on a

surface of "the lower surface side covering layer" opposite to the side facing the wound site.

(C) Judgment on Different Features

Judgment on <<Different Feature 1A>> and <<Different Feature 1B>> is as indicated in the above-mentioned 3.(3)A.(C).

<<Different Feature 19>> will now be discussed below.

In a wound care product, to make a surface of a side opposite to the side of a layer facing a wound site be brought into close contact with another member was, as described, for example, in A-4 that "It is preferred that the first layer (Note by the trial decision: this corresponds to "the lower surface side covering layer" of Invention A-1) and the following second layer be appressed to each other as far as possible, and, specifically, at the interface surface between the first layer and the second layer, the layers be appressed to each other to the extent that, as shown in FIG. 3, an effusion does not spread in an in-plane direction even if the above storage space is filled with the effusion." (refer to paragraph [0040]), a well-known technology before the application of the Patent, and adoption or rejection thereof is a matter of a degree that could have been determined by a person skilled in the art appropriately.

Furthermore, it was a commonly used art before the application of the Patent to provide, in order to make members be brought into close contact with each other, an "adhesive layer" on a surface of one of the members.

In view of the above, it should be concluded that, in Invention A-1, to have an adhesive layer on the surface of "the lower surface side covering layer" in a side opposite to the side facing the wound site is a matter of a degree that could have been achieved by a person skilled in the art coming into contact with the above-mentioned well-known art illustrated in A-4 accordingly.

(D) Summary

As above, Invention 19 is one that could have been invented by a person skilled in the art with ease based on Invention A-1 and the above-mentioned well-known art illustrated in A-3 and A-4.

Q. Summary

As above, since the patents concerning Inventions 1-5, 8 and 14-19 are ones that were made in violation of the provisions of Article 29(2) of the Patent Act, those patents fall under Article 123(1)(ii) of the same Act, and should be invalidated.

On the other hand, the patents concerning the Inventions 6, 7, and 9-13 are not ones that violate the prescriptions of Article 29(2) of the Patent Act, and thus it cannot be decided that those patents should be invalidated on the ground that those fall under Article 123(1)(ii) of the same Act.

4. Regarding Reason for Invalidation 2 (violation of Article 29-2 of the Patent Act)

(1) Regarding Invention 1

A. A-6 device

As viewed from the matters summed up in the above-mentioned 1.(2), in A-6, the following A-6 device is described.

<<A-6 device>>

A wound dressing laminated in order of a water permeable surface sheet, and a water retentive sheet from a side in contact with a wound site, wherein

the water permeable surface sheet coming into contact with the wound site is a perforated film of an opening rate of 10-50%,

the perforated film is a film mainly composed of polyethylene, polypropylene, polyester, polyamide, polyurethane, or the like having a surface wet tension of 38-54 mN/m,

the water retentive sheet absorbs and holds the effusion coming out through the water permeable surface sheet promptly, and wherein

a thickness of the perforated film is about 10-50 μm.

B. Comparison

"Surface sheet", "water retentive sheet", and "wound dressing" of the A-6 device correspond to "liquid-permeable layer", "absorption holding layer", and "wound dressing" of Invention 1, respectively.

Therefore, the corresponding features and the different features between Invention 1 and A-6 device are as follows.

<<Corresponding Feature>>

A wound dressing comprising at least two layers of a liquid-permeable layer and an absorption holding layer,

the wound dressing being made by laminating the liquid permeable layer and the absorption holding layer in this order from a side used to face a wound site, wherein

the liquid-permeable layer includes a first surface facing the wound site, a second surface opposite to the first surface, and a plurality of through holes extending through between the surfaces in the thickness direction,

the through holes have an opening rate of 3.07% or more, and allow liquid to pass from the first surface toward the second surface,

the first surface is made of a resin sheet material, and wherein

the absorption holding layer contains a sheet material capable of absorbing and holding water.

<<Different Feature 1C>>

Regarding "absorption holding layer", in Invention 1, the "absorption holding layer" is "directly laminated" with "the liquid-permeable layer", and the "absorption holding layer" "is not integrated with the liquid-permeable layer", whereas, in the A-6 device, the "water retentive sheet" is "directly laminated" with the "surface sheet", and it is unclear whether it "is not integrated with the surface sheet".

<<Different Feature 1D>>

Regarding the "resin sheet material", in Invention 1, it is one "having hydrophobicity", whereas, in the A-6 device, it is one "having a surface wet tension of 38-54 mN/m".

<<Different Feature 1E>>

Regarding "through holes", "through holes" of Invention 1 are ones that "have a depth of 100-2000 μm" and "exist at a density of 50-400 holes/cm^2", whereas, in the A-6 device, "a thickness of the perforated film is about 10-50 μm"; that is, the depth of the holes of "perforated film", is "about 10-50 μm".

C. Judgment on Different Features

Regarding <<Different Feature 1C>>

Regarding the matter that the "absorption holding layer" in Invention 1 is "directly laminated" with "the liquid-permeable layer", in paragraph [0094] of the Patent Description, it is described that "in the second embodiment, unlike the first embodiment described above, the liquid permeation restriction layer is omitted, and the absorption holding layer (3) is directly laminated on the second surface (12) of the liquid permeation layer (1). In the second embodiment, since the liquid permeation restriction layer is omitted, it can be manufactured easily and carried out at low cost, which is preferable." (refer to the above-mentioned 2.(4)).

In addition, regarding the matter that "absorption holding layer" in Invention 1 "is not integrated with the liquid-permeable layer", in paragraph [0102] of the Patent Description, it is described that "In this fifth embodiment, unlike the first embodiment, the absorption holding layer (3) is not integrated with other layers. In other words, in

the wound dressing (5) according to the fifth embodiment, the protective layer (4) is integrated with the second surface (12) of the liquid-permeable layer (1) consisting of the surface sheet (10) by welding or the like at the peripheral portion (22), and is formed into a bag shape. Then, the absorption holding layer (3) is inserted between the liquid permeable layer (1) and the protective layer (4) in a state where the absorption holding layer (3) is not fixed to the two layers (1, 4)." (refer to the above-mentioned 2.(5)).

On the other hand, regarding the "surface sheet" and "water retentive sheet" of A-6 device, as viewed from the description of paragraph [0017] of A-6 that "The wound dressing of the present device is made by laminating a surface sheet, a water retentive sheet, an intermediate sheet, and a back sheet from the side in contact with the wound as described above ..." (refer to the above-mentioned 1.(2)D.), it is understood as a state in which some sort of another layer is not interposed therebetween; that is, the layers are laminated directly.

In addition, as viewed from the description of the same paragraph [0017] that "the term 'laminating' as referred to herein mainly indicates a state in which both sheets are merely superimposed on each other, but both of them may be partially joined by a method such as sewing, sticking, bonding, or the like. In order to prevent leaking of the exudate, it is preferred that the wound dressing of the present device is characterized in that the size of the surface sheet and the back sheet is made slightly larger than that of the water retentive sheet or the intermediate sheet and only the peripheral edge portions of both are bonded by a method such as thermal fusion bonding.", it can be said that there is described that A-6 also includes an aspect in which the "water retentive sheet" in A-6 device is not integrated with the "surface sheet".

Therefore, <<Different Feature 1 C>> is a difference merely in expression, and it is not a substantive different feature.

Regarding <<Different Feature 1D>>

Relating to the matter of the "surface sheet" of the A-6 device "having a surface wet tension of 38-54 mN/m", it is described in paragraph [0010] and [0011] of A-6 that "In the present device, the water-permeable surface sheet coming into contact with the wound area is a perforated film having a surface wet tension as defined in JIS K 6768 (Test Method of Wet Tension for Plastic Film and Sheet) of 38 to 54 mN/m, preferably 40 to 50 mN/m ... When the surface wet tension of the perforated film is less than 38 mN/m, the water repellency is increased, the exudate is not uniformly distributed to the entire perforated film, and the exudate is partially scattered on the wound area, making early healing difficult. On the other hand, when the surface wet tension exceeds 54

mN/m, the covering material is liable to be stuck to the wound area, which causes damage to the wound area upon peeling off." (refer to the above-mentioned 1.(2)C.).

Here, considering that "hydrophobicity" and "water-repellent" are understood to be synonymous according to A-17 (refer to the above-mentioned 1.(5)), it can be said that the above-mentioned description of A-6 that the "surface sheet" of the A-6 device "has a surface wet tension of 38-54 mN/m" is synonymous with a matter that, in the A-6 device, the "surface sheet" "has hydrophobicity".

Therefore, <<Different Feature 1D>> is a difference merely in expression, and is not a substantive different feature.

Regarding <<Different Feature 1E>>

The depth of "through holes" of Invention 1; that is, the thickness of "liquid-permeable layer" through which the above-mentioned "through holes" extend, is "100-2000 μm".

On the other hand, regarding the thickness of "perforated film" of the A-6 device, it is only described in paragraph [0012] of A-6 that " ... As the perforated film, any film may be used as long as it is a film mainly composed of polyethylene, polypropylene, polyester, polyamide, polyurethane, etc. and having a surface wet tension of about 1 to 50 μm thickness. However, in consideration of the strength and sanitary properties and the like of the film, a polyester film having a thickness of 3 to 12 μm is preferable ...", and, in A-6, it is not described that the thickness thereof is made to be a thickness largely exceeding 50 μm, and there is no description suggesting this, either.

In addition, regarding the thickness of the above-mentioned "perforated film", there is no evidence suggesting that to make the thickness largely exceed 50 μm is nothing but, for example, a very minor design difference on the occasion of reification of A-6 device.

Therefore, <<Different Feature 1E>> is a substantive different feature.

D. Summary

In light of the above, it cannot be said that Invention 1 is identical with the A-6 device.

(2) Regarding Invention 3

In light of the judgment indicated in the above-mentioned 4.(1)C., it cannot be said that Invention 3 that includes all the matters specifying the invention of Invention 1 and, further makes a technical matter be a matter specifying the invention is identical with

the A-6 device.

(3) Summary

As above, since the patents concerning Inventions 1 and 3 are not ones that have been made in violation of the provisions of Article 29-2 of the Patent Act, the patents thereof do not fall under Article 123(1)(ii), and the patent concerning Inventions 1 and 3 cannot be invalidated by Reason for Invalidation 2.

5. Regarding Reason for Invalidation 3 (violation of Article 36(6)(i) of the Patent Act)

The phrase "an opening rate of 3.07% or more" is not described in the detailed description of the invention of the Patent Description.

However, as indicated in the above-mentioned 3.(3)A.(C), "have an opening rate of 3.07% or more" of Invention 1 is based on the value of an opening area at the minimum hole diameter, $50 \times \pi \times (2.8/2)2 \times 10^{-4}$ $cm^2 = 3.07 \times 10^{-2}$ cm^2, calculated from the minimum value of the hole diameter 280 μm, and the minimum value of the density 50 holes/cm^2 in the description of paragraph [0028] of the Patent Description that "As for the diameter of the through holes (13), it is preferable that the opening area at the first surface (11) facing the wound site corresponds to a circular shape of 280-1400 μm in diameter. ...", and the description of paragraph [0030] that "It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2, ..." (refer to the above-mentioned 2.(2)), and, therefore, it is a matter that is equivalent to a matter described in the detailed description of the invention of the Patent Description.

Therefore, it cannot be said that Inventions 1-19 are inventions that are not described in the detailed description of the invention of the Patent Description only on the ground that the above-mentioned phrase of "an opening rate of 3.07% or more" is not described in the detailed description of the invention of the Patent Description.

As above, regarding the point whether or not "an opening rate of 3.07% or more" of Invention 1 is described in the detailed description of the invention of the Patent Description, since the recitation of the scope of claims of the Patent meets the requirement stipulated in Article 36(6)(i) of the Patent Act, the patent thereof does not fall under Article 123(1)(iv) of the same Act, and the patent concerning the Inventions 1-19 cannot be invalidated by Reason for Invalidation 3.

6. Regarding Reason for Invalidation 4 (violation of Article 36(6)(ii) of the Patent Act)

In Invention 1, the description of "have an opening rate of 3.07% or more" itself is clear.

In addition, in Invention 1, as long as "through holes" that are deemed to "have an opening rate of 3.07% or more" as mentioned above are prescribed as "a lot of" holes provided in "liquid-permeable layer", it is obvious for a person skilled in the art that Invention 1 is not one that also includes ones having an opening rate, for example, near 100%, at which holes cannot exist substantially.

Furthermore, as indicated in the above-mentioned 3.(3)A.(C), it is obvious that "an opening rate of 3.07% or more" of Invention 1 is not one that prescribes the "preferable" opening rate described in paragraph [0032] of the Patent Description, but it is nothing but one just indicating a degree of openings due to "through holes", and thus, in the numerical value "3.07%" itself, there is no special technical significance such as critical significance.

Therefore, regarding "have an opening rate of 3.07% or more" of Invention 1, it cannot be said that Inventions 1-19 are not clear only on the ground that there is no specification about the upper limit of the opening rate.

As above, since the recitation of the scope of claims of the Patent meets the requirement stipulated in Article 36(6)(ii) of the Patent Act, and the patents thereof do not fall under Article 123(1)(iv) of the same Act, the patents according to the Inventions 1-19 cannot be invalidated by Reason for Invalidation 4.

7. Regarding Reason for Invalidation 5 (violation of Article 17-2(3) of the Patent Act)

The matter of "have an opening rate of 3.07% or more" of Invention 1 is a matter added to Claim 1 of the scope of claims by the amendment made on November 8, 2013.

Relating to the above-mentioned matter, in the description originally attached to the application of the Patent, it is described in paragraph [0028] that "As for the diameter of the through holes (13), it is preferable that the opening area at the first surface (11) facing the wound site corresponds to a circular shape of 280-1400 μm in diameter. ...", and it is described in paragraph [0030] that "It is preferable that the through holes (13) be present at a density of 50 to 400 holes/cm^2, ...", and the above-mentioned matter is based on the value of an opening area at the minimum hole diameter, $50 \times \pi \times (2.8/2)2 \times 10^{-4}$ $cm^2 = 3.07 \times 10^{-2}$ cm^2, calculated from the minimum value of the hole diameter 280 μm, and the minimum value of the density 50 holes/cm^2 in the description of paragraph [0028] and [0030], and, therefore, it is a matter that is equivalent to a matter described in the detailed description of the invention of the Patent Description.

Therefore, the amendment to add the above-mentioned matter is one that was made within the matters described in the description, the scope of claims, or the drawings

originally attached to the application, meets the requirement stipulated in Article 17-2(3) of the Patent Act, the patents thereof do not fall under Article 123(1)(i) of the same Act, and, therefore, the patents concerning the Inventions 1-19 cannot be invalidated by Reason for Invalidation 5.

No. 6. Closing

As above, the patents concerning Inventions 1-5, 8 and 14-19 should be invalidated due to Reason for Invalidation 1-2 alleged by the Demandant.

On the other hand, the patents concerning Inventions 6, 7 and 9-13 cannot be invalidated due to Reason for Invalidation 1-1 to Reason for Invalidation 5 alleged by the Demandant.

Seven-nineteenths of the costs in connection with the trial shall be borne by the Demandant, and 12-nineteenths by the Demandee under the provisions of Article 64 of Code of Civil Procedure which is applied mutatis mutandis pursuant to Article 169(2) of the Patent Act.

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

February 18, 2019

Chief administrative judge: INOUE, Shigeo
Administrative judge: WATANABE, Toyohide
Administrative judge: SENJU, Akio