

Clarke, Modet & C^o
COLOMBIA

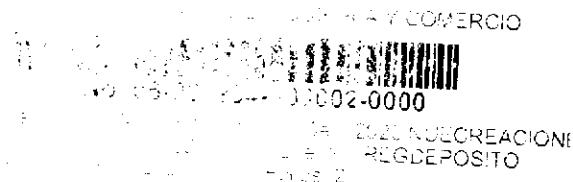
ESCOBAR - URIBE ASOCIADOS
Intellectual Property

As. 2964/P.

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES**

E. S. D.

Ref.: Expediente No. **06-031.934**
Solicitud de Patente a nombre de
McNeil-PPC, Inc.



Yo, **JIMENA ESCOBAR URIBE**, identificada como aparece al pie de mi firma, domiciliada en Bogotá, en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la sociedad **McNeil-PPC, Inc.**, con domicilio en Skillman, New Jersey, Estados Unidos de América, solicitante de la patente de la referencia, pido a usted que se proceda a examinar si la invención, cuya patente se tramita en el expediente de la referencia, es patentable.

Adjunto al presente memorial el recibo No. 07 - 87,041 de 23 de octubre de 2007, por la suma de \$404.000.00, con lo cual queda cubierta la tasa oficial correspondiente a dicho estudio.

Señor Superintendente,


JIMENA ESCOBAR URIBE
C.C.39.779.452 de Usaquén
T.P. 68.228

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 07 - 87,041
FECHA : OCTUBRE 23 DE 2007

***** CONSIGNACION *****

POSITANTE	TIPO PAGO	BANCO	CUENTA	Nº. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	71030061	23/10/2007	26,261,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	
		85 EXAMEN DE PATENTABILIDAD DE INVEN	404,000.00
		TOTAL :	\$ 404,000.00

SON: CUATROCIENTOS CUATRO MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE Nº.

2969

323

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-31934

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **577** DE

FECHA **29 DE JUNIO DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA LEY

EXPIRA EL **27 DE SEPTIEMBRE DE 2007**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



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EP 1 075 246 B1

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WO 99/056681 (11.11.1999 Gazette 1999/45)

(54) **ABSORBENT ARTICLE AND ABSORBENT INTERLABIAL DEVICE WITH SUBSTANCE
THEREON FOR MAINTAINING THE ARTICLE AND DEVICE IN POSITION**

INTERLABIALE UND MIT EINER SUBSTANZ ZUR ERHALTUNG IN POSITION BESCHICHTETE,
ABSORBIERENDE VORRICHTUNG UND ABSORBIERENDER ARTIKEL

ARTICLE ABSORBANT ET DISPOSITIF ABSORBANT INTERLABIAL DOTE D'UNE SUBSTANCE
SERVANT A SON MAINTIEN EN PLACE

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14.02.2001 Bulletin 2001/07

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(56) References cited:
EP-A- 0 597 498 WO-A-96/07379
WO-A-97/09017 WO-A-98/08475
GB-A- 1 424 619 US-A- 5 336 208
US-A- 5 609 587

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(*) European Patent Convention).

EP 1 075 246 B1

SUMMARY OF THE INVENTION

[0008] The present invention relates to absorbent devices such as sanitary napkins, pantliners, interlabial devices, and incontinence devices. In a preferred embodiment, the present invention relates to an improved absorbent device that is insertable into the interlabial space of a female wearer for catamenial purposes (including menses and mid-cycle discharges), incontinence protection (including urine), or both. The absorbent interlabial device has at least one body-contacting surface which comprises a substance that contacts the wearer's body for assisting the interlabial device in staying in place in the desired position in the interlabial space. The substance is non-adhesive, having no initial tack so that it will not stick to the wrong portions of the wearer's body when the device is placed between the labia. Non-adhesive substances include moisture-activated substances which become viscous and develop a tack when contacted by relatively small amounts of moisture.

[0009] The substance should adhere the interlabial device to the inside surfaces of the labia minora, or alternatively to the labia majora or both the labia minora and labia majora so that it remains adhered to these surfaces (on both sides of the interlabial space) when the wearer moves in a way that the labia spread (e.g., when the wearer squats). This will allow the interlabial device to remain in place during wearing conditions, and will also ensure that it is contacted by a stream of urine when the wearer urinates so that it will be removed on urination. The need for such a substance becomes more important as the loading that the interlabial device is expected to hold (that is, the weight of absorbed bodily liquids) increases. Typically, the unloaded interlabial device will weigh less than or equal to about 5 grams. As the weight of absorbed bodily liquids increases, the force of gravity on the loaded interlabial device increases. This results in the need for increased ability to hold the interlabial device in place, particularly when the exudate loading is greater than or equal to about 8 grams.

[0010] Moisture-activated substances are particularly preferred for use with the interlabial device because they can make the interlabial device easier to apply than pressure sensitive or tacky adhesive-coated devices. They are also particularly useful for sealing against this portion of the wearer's body since moisture is naturally present. Some particularly preferred moisture-activated substances are polyethylene glycols ("PEGs"), sodium carboxymethylcellulose, cellulose gums, hydroxyethyl celluloses, hydroxypropyl celluloses, hydroxypropylmethyl celluloses, functionalized guar (such as cationic guar and hydroxypropyl guar), carrageenan, glycols (dihydric alcohols) such as propylene glycols, hexylene glycols, polyols which contain three or more hydroxyl groups such as glycerin, surfactants such as polyoxyl alkylates (polyoxyethylene sterates) ethoxylated alcohols, sugar surfactants, sugars (such as glucose, fructose, and sucrose), alone or in combination with pectin, guar gum, and other gums.

[0011] Polyethylene glycols are particularly preferred for several reasons. Some of the higher molecular weight polyethylene glycols are typically solids that are capable of dissolving in water. They can be easily applied to the interlabial device. Polyethylene glycols can be applied to the body-contacting surface of the interlabial device using any conventional processing steps, which are described in greater detail below. Once applied, they will typically dry to a non-tacky solid, preferably a powder form. This is preferable since it is desirable that the substance does not form an occlusive film over the body-contacting surface of the interlabial device. Polyethylene glycols, since they are very water soluble, are also capable of losing their tendency to stick to the labia when the wearer urinates, so the interlabial device will be expelled by urination as intended. Their water solubility also ensures that they will not interfere with the ability of flushable interlabial devices to flush down a toilet, and will not float in the toilet as some other products. (The tendency for other products to float results in an extremely inconvenient situation for users who have to remove such products from the toilet bowl, and then dispose of these products.) Polyethylene glycols are also biodegradable, unlike most pressure sensitive adhesives, which are silicone-based.

[0012] These materials may also be mixed into lotion (emollient) compositions, wherein the lotion provides lubricity during the insertion process and the moisture-activated substance in the lotion will cause the composition to develop a tack when contacted by the moist labial tissues. In such a composition, the lotion or emollient can serve as a carrier for the particulate material.

[0013] The absorbent interlabial device, in one embodiment, is a small pad-like structure that comprises a liquid pervious topsheet, a liquid impervious backsheet which is joined to the topsheet, and an absorbent core positioned between the topsheet and backsheet. The device preferably comprises an axis of preferred bending, preferably located generally along the longitudinal centerline of the device. When the device is folded along this axis and inserted into the wearer's interlabial space, the topsheet maintains contact with the walls of the wearer's labia. Preferably, the liquid pervious topsheet is constructed of rayon or needle punched rayon. The absorbent core is preferably also constructed of rayon, cotton, or a blend of rayon and cotton. Preferably, the device comprises biodegradable materials. In particularly preferred embodiments, the backsheet of the absorbent interlabial device is water dispersible. A tab may be joined to the backsheet of the device to facilitate insertion and optional removal of the device with the fingers.

[0014] In alternative embodiments, the absorbent interlabial device may utilize adhesive substances. For example, in one embodiment, the absorbent interlabial device has a longitudinal centerline oriented in the same direction as a wearer's vaginal opening, a longitudinal central region along the longitudinal centerline, and a pair of longitudinal side

and the orifice of the vagina. Therefore, it will be recognized that the interlabial space as defined above may refer to the space between the inside surfaces of the labia majora, including the space between the inside surfaces of the labia minora also known as the vestibule. The interlabial space for purposes of the present description does not extend substantially beyond the orifice of the vagina into the vaginal interior.

[0019] The term "labia" as used herein refers generally to both the labia majora and labia minora. The labia terminate anteriorly and posteriorly at the anterior commissure and the posterior commissure, respectively. It will be recognized by those skilled in the art that there is a wide range of variation among women with respect to the relative size and shape of labia majora and labia minora. For purposes of the present description, however, such differences need not be specifically addressed. It will be recognized that the disposition of the absorbent interlabial device into the interlabial space of a wearer as defined above will require placement between the inside surfaces of the labia majora without regard to the precise location of the boundary between the labia majora and the labia minora for a particular wearer. For a more detailed description of this portion of the female anatomy, attention is directed to *Gray's Anatomy*, Running Press 1901 Ed. (1974), at 1025-1027.

[0020] The absorbent interlabial device 20 shown in FIG. 1 has a longitudinal centerline L which runs along the "x" axis. The term "longitudinal", as used herein, refers to a line, axis or direction in the plane of the interlabial device 20 that is generally aligned with (e.g., approximately parallel to) a vertical plane which bisects a standing wearer into left and right body halves when the interlabial device 20 is worn. The terms "transverse," "lateral," or "y direction" as used herein, are interchangeable, and refer to a line, axis, or direction that is generally perpendicular to the longitudinal direction. The lateral direction is shown in FIG. 1 as the "y" direction. The absorbent interlabial device 20 shown in FIG. 1 also has a transverse centerline T. The "z" direction, shown in FIG. 2, is a direction parallel to the vertical plane described above. The term "upper" refers to an orientation in the z-direction toward the wearer's head. "Lower" or downwardly is toward the wearer's feet.

[0021] The interlabial device 20 shown in FIGS. 1-3 is in one preferred configuration. The interlabial device 20 has a body-facing (or "body-contacting" side) 20A and an opposed underside 20B. The interlabial device comprises a pad-like main body portion (or "central absorbent portion") 22 and an optional placement and removal tab 52 which is joined to the underside 20B of the main body portion 22 to provide the overall interlabial device with a "T"-shaped cross-sectional configuration. The main body portion 22 can be in any suitable configuration. Non-limiting examples of shapes for the main body portion 22 when viewed from the top as in FIG. 1 include ovoid, elliptical, trapezoidal, rectangular, triangular, diamond-shaped, or any combination of the above. As shown in FIG. 1, the preferred plan view shape for the main body portion 22 and the overall absorbent interlabial device 20 is generally ovoid or elliptical. The plan view shape of the main body portion 22 tapers from the transverse centerline T towards its front and rear ends. The main body portion 22, in this embodiment, is relatively flat in its side profile, but may taper slightly from front to rear as shown in FIG. 3.

[0022] As shown in FIGS. 1-2, the interlabial device preferably comprises a liquid pervious topsheet 42, a liquid impervious backsheet 38 joined to the topsheet 42, and an absorbent core 44 positioned between the topsheet 42 and the backsheet 38. The interlabial device 20 is preferably of a size and shape that allows at least the majority of the device 20 to fit comfortably within the wearer's interlabial space and to cover the wearer's vaginal orifice, and preferably also the wearer's urethra. The interlabial device 20 at least partially blocks, and more preferably completely blocks and intercepts the flow of menses, urine, and other bodily exudates from the wearer's vaginal orifice and urethra.

[0023] The size of the interlabial device 20 is important to its comfort and effectiveness. The length of the absorbent interlabial device 20 is measured along the longitudinal centerline L in the longitudinal direction (or "x"-direction). The absorbent interlabial device 20 preferably has a length L_1 which is greater than about 60 mm and less than about 130 mm. More preferably, the length L_1 is between about 75 mm and about 105 mm. The width of the interlabial device 20 is measured along the transverse centerline T in the transverse direction (or "y"-direction). The absorbent interlabial device 20 preferably has a width W_1 which is between about 25 mm and about 50 mm. The thickness (or caliper) is the "z"-direction dimension of the device 20. Caliper measurements given herein were measured using an AMES gauge with a 0.25 psi (1.7 kPa) (gauge) load and a 0.96 inch (2.44 cm) diameter foot. Those skilled in the art will recognize that if a 0.96 inch (2.44 cm) diameter foot is not appropriate for a particular sample size, the foot size may be varied while the load on the gauge is accordingly varied to maintain a confining pressure of 0.25 psi (1.7 kPa) (gauge). The caliper T_1 of the absorbent interlabial device 20 is preferably less than the width W_1 and the length L_1 of the device 20. Preferably, the caliper T_1 of the absorbent interlabial device 20 is less than or equal to about 8 mm, more preferably the caliper T_1 is less than or equal to about 6 mm, and even more preferably the caliper is less than or equal to about 4 mm.

[0024] Construction of the absorbent interlabial device 20 according to the particular size parameters given above results in a product with increased comfort and effectiveness compared to previous interlabial devices. For example, many women find interlabial pads which are shorter than the absorbent interlabial device 20 of the present invention to be difficult to position properly within the interlabial space. Even if such pads are positioned properly, they have an increased tendency to allow by-pass flow of body exudates around the edges of the pad. Additionally, many previous

[0032] The inner surface of topsheet 42 may be secured in contacting relation with an underlying absorbent layer. This contacting relationship results in liquid penetrating topsheet 42 faster. The topsheet 42 may be kept in a contacting relationship with an underlying layer by bonding the topsheet 42 to the underlying layer. However, it is not absolutely necessary to bond the face of the topsheet 42 to the face of the underlying layer. The topsheet 42 can be maintained in contact with an underlying absorbent component by entangling the fibers of the underlying layer with the topsheet, by fusing the topsheet 42 to an underlying absorbent layer by a plurality of discrete individual fusion bonds, or by any other means known in the art. The topsheet can also be maintained in contact with the underlying absorbent material due to the application of the pressure of the body against the body-contacting surface of the interlabial device.

[0033] It is not necessary that the topsheet 42 comprise a layer or material which is separate or distinct from the absorbent core 44. The topsheet 42 and absorbent core 44 may consist of one unitary structure in which the body-contacting surface of the absorbent core 44 will serve as the liquid pervious topsheet 42. In such an embodiment, the liquid pervious body-contacting surface may be hydrophilic or even hydrophobic so long as fluids readily penetrate through the surface and into the interior of the absorbent core 44. Additionally, such a unitary topsheet 42 and absorbent core 44 may be provided with a pore size gradient, capillary gradient, or hydrophilicity gradient, or any combination thereof, to assist in the absorption and retention of fluids in the interior of the absorbent core 44.

[0034] The absorbent core 44, which is best seen in FIG. 2, is positioned between the topsheet 42 and the backsheet 38. The absorbent core 44 provides the means for absorbing exudates such as menses and other body fluids. The absorbent core 44 preferably is generally compressible, conformable, and non-irritating to the user's skin. Preferably, the absorbent core 44 has the same general shape as the overall absorbent interlabial device 20.

[0035] The absorbent core 44 may comprise any suitable material that is capable of absorbing and/or retaining liquids (e.g. menses and/or urine). The absorbent core 44 be manufactured from a wide variety of liquid-absorbent materials commonly used in absorbent articles such as comminuted wood pulp which is generally referred to as airlaid. Examples of other suitable absorbent materials include cotton fibers or cotton linters, creped cellulose wadding; meltblown polymers including coform; chemically stiffened, modified or cross-linked cellulosic fibers; synthetic fibers such as crimped polyester fibers; peat moss; tissue including tissue wraps and tissue laminates; absorbent foams; absorbent sponges; superabsorbent polymers (in fibrous and particulate form); absorbent gelling materials; or any equivalent material or combinations of materials, or mixtures of these. Preferred absorbent materials comprise folded tissues, cotton batts, woven materials, nonwoven webs, rayon including needle punched rayon, and thin layers of foam. The absorbent core 44 may comprise a single material or a combination of materials.

[0036] A preferred material for the absorbent core 44 is batt of rayon or a rayon/cotton blend. In one particularly preferred embodiment, the absorbent core 44 is a batt which comprises a 50%/50% blend of baled bleached cotton fibers and baled rayon fibers. A tri-lobal rayon known as GALAXY rayon available from Courtaulds Fibers, Inc. of Axis, Alabama has been found to work well for the material comprising the absorbent core 44.

[0037] In other embodiments, the absorbent core 44 may consist of multiple independent layers of the same, or different materials (such as layers of absorbent materials with different absorbent properties), that are easily separable so the various layers can separate for disposal.

[0038] The backsheet 38, which is best shown in FIGS. 2 and 3, prevents the exudates absorbed and contained in the absorbent core 44 from wetting articles and/or body parts which may contact the absorbent interlabial device 20 such as pants, pajamas, undergarments, pubic hair, the wearer's thighs, etc. The backsheet 38 should be flexible and impervious to liquids (e.g., menses and/or urine). As used herein, the term "flexible" refers to materials which are compliant and will readily conform to the general shape and contours of the human body. The backsheet 38 also provides protection for the wearer's fingers as the absorbent interlabial device 20 is inserted, or as the device is optionally removed with the fingers.

[0039] The backsheet 38 may comprise a woven or nonwoven material, polymeric films such as thermoplastic films of polyethylene or polypropylene, composite materials such as a film-coated nonwoven material, or organic material such as a collagen film. Other suitable materials include biodegradable polymers that can be made into films and the like. Suitable biodegradable polymers include BIONELLE 3001 obtained from Showa High Polymer Co. of Tokyo, Japan and Matter Bi ZF03U-A obtained from Biorp Co., distributor for Novamont S.P.A. of Rome, Italy and Biopol biodegradable polymer obtained from Monsanto. In one embodiment, the backsheet may be made from a polyethylene film having a thickness of from about 0.012 mm (0.5 mil) to about 0.051 mm (2.0 mils). An exemplary polyethylene film is manufactured by Clorox Corporation of Cincinnati, Ohio, under the designation P18-0401. Preferably, however, the backsheet comprises a film having a similar thickness, only which is made of a biodegradable polymer such as the BIONELLE biodegradable polymer described above.

[0040] The backsheet may also permit vapors to escape from the interlabial device 20 (i.e., be breathable) while still preventing exudates from passing through the backsheet. A suitable breathable backsheet material is a laminate of an apertured film such as that described in U.S. Patent 3,929,135 issued to Thompson which is inverted so that the smaller openings of the tapered capillaries face the absorbent core 44 which is adhesively laminated to a microporous film such as that described in Exxon's U.S. Patent 4,777,073.

of a type that comprises a central absorbent portion and flexible extensions extending therefrom, the substance can be placed on the central absorbent portion, the flexible extensions, or both the central absorbent portion and the flexible extensions. The substance can, thus, be placed on a central region of the interlabial device 20, but not on the peripheral portions of the interlabial device. More preferably, however, the substance may be placed on the peripheral portions of the body-contacting surface of the interlabial device, but not in the central region. Locating the substance in the latter manner may be advantageous if it is desired to minimize any tendency for the substance to interfere with acquisition of bodily liquids into the interlabial device 20. The substance can also be used to create a seal to prevent the flow of exudates toward the ends (and/or sides) of the device. The substance can cover any of the following percentages of the surface area of the body-contacting surface of the main body portion 22, the central absorbent portion, the flexible extensions, or the entire body-contacting surface of the interlabial device (greater than or equal to about): 5%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 100%.

[0081] The substance can be applied to the interlabial device 20 in any suitable quantity. For these purposes, the quantity of the substance applied to the interlabial device 20 will be expressed in terms of the total product weight including the device and the weight of the substance. Preferably, the substance constitutes less than or equal to about 20%, more preferably less than or equal to about 10%, and most preferably less than or equal to about 5% of the total product weight, so as not to excessively contribute to the overall weight of the interlabial device. This permits more of the total product weight to be dedicated to providing absorbent capacity.

[0082] There are many possible specific embodiments of interlabial devices with various substances thereon for assisting the interlabial device in staying in place in the desired position in the interlabial space. The interlabial device can have one or more of the substances described herein applied thereto in any of the patterns of application described herein.

[0083] In other embodiments, any desirable combinations of the substances described herein, or combinations of patterns of application, or both may be used. One non-limiting example would be to apply a combination of an adhesive and a non-adhesive substance to the interlabial device. For example, in the case of an interlabial device having the configuration described in U.S. Patent 5,762,644, issued to Osborn, et al., a polyethylene glycol can be provided on the body-contacting surface of the central absorbent portion, and a pressure sensitive adhesive can be provided on the flexible extensions. Preferably, if adhesives are used, they are applied to portions of the interlabial device that do not block or retard the flow of urine from the urethra into the absorbent interlabial device 20.

[0084] In another example, the interlabial device 20 may be provided with one of the substances described herein (such as an adhesive) around the periphery of the body-contacting surface of the interlabial device to assist the device in staying in place adjacent to the wearer's labia. The substance can be applied in a continuous or an intermittent pattern, or a pattern which is partially continuous and partially intermittent. A swelling absorbent material can be placed inside the area defined by the substance. If a complete seal with the wearer's body is desired, this swelling absorbent can be used to eliminate any gaps or void spaces that may occur adjacent to the wearer's body that may occur due to misplacement of the interlabial device relative to the wearer's labia, and create a self-sealing device. Some non-limiting examples of swelling absorbent materials include, but are not limited to superabsorbent, hydrogel forming materials, absorbent foam materials, modified cross-linked cellulosic fibers, and compressed absorbent materials, such as those used in tampons.

[0085] Numerous other embodiments and properties for the substance for holding the interlabial device in place are also possible. For example, the substances described herein preferably have moisture vapor transmission rates sufficient to maintain the natural state of hydration of the labial tissue. Suitable moisture vapor transmission rates are not less than about 300 gm m/hr at a relative humidity difference of 10 to 100%. In addition, any of the substances described herein can be used in conjunction with, or be combined with emollients such as those described in U.S. Patent 5,609,587 entitled "Diaper Having a Lotioned Topsheet Comprising a Liquid Polyol Polyester Emollient and an Immobilizing Agent", issued March 11, 1997 to Roe, and U.S. Patent 5,643,588 entitled "Diaper having a Lotioned Topsheet" issued on July 1, 1997 to Roe, et al.

[0086] In addition to the various embodiments of the substances for holding the interlabial device 20 in place which are described herein, the interlabial device can be provided with other optional features. For example, it has been found that the interlabial device of the present invention provides a substantial noticeable benefit to the user in controlling odors associated with body exudates. Additional odor controlling agents may be added to seek further reductions in odors. Such odor controlling agents include, but are not limited to activated charcoals, zeolites, silica, polyacrylic acids (superabsorbents), certain quaternary compounds, triethyl citrate, cyclodextrin, or any combinations thereof. Particularly preferred cyclodextrin compounds are described in U.S. Patent 5,429,628 issued to Trihn, et al. and U.S. Patent 5,780,020 issued to Peterson, et al. In addition, deodorants can be added to further mask these odors.

[0087] Further, over-the-counter vaginal drug actives can be added for one or more of the following purposes: cleansing, providing soothing and refreshing effects, deodorizing, relieving minor irritation, reducing the number of pathogenic microorganisms, altering pH so as to encourage the growth of normal vaginal flora, producing an astringent effect, lowering surface tension, producing a mucolytic effect, or producing a proteolytic effect. Such over-the-counter vaginal

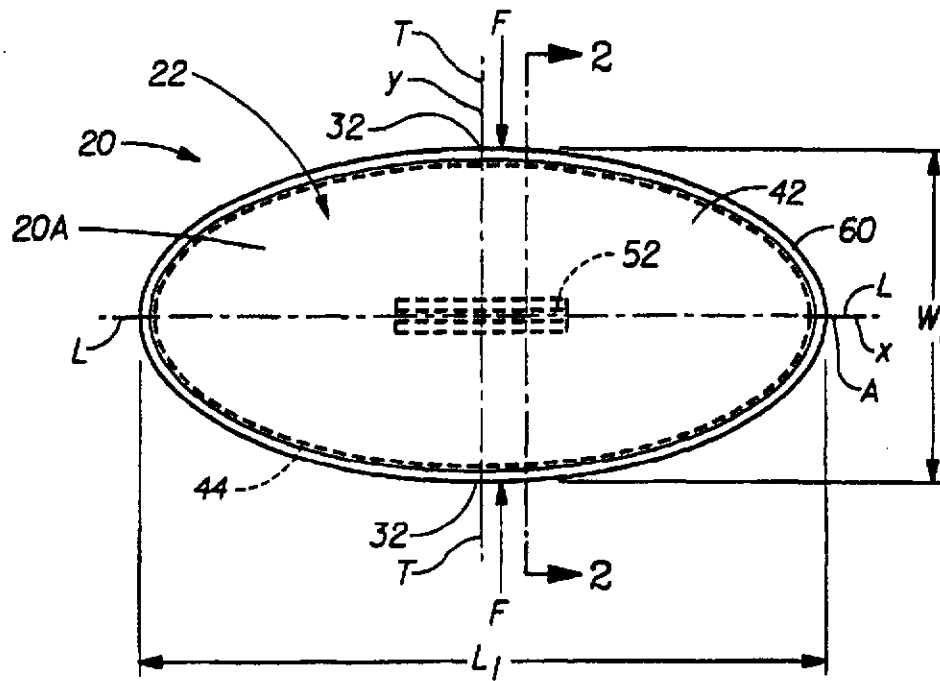


Fig. 1

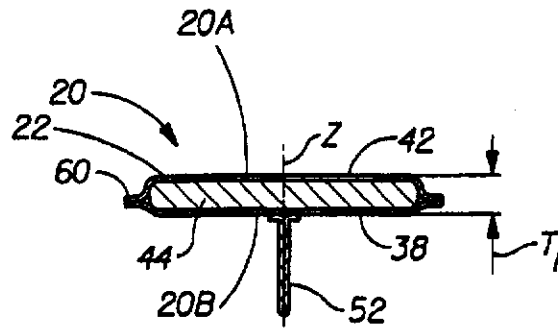


Fig. 2

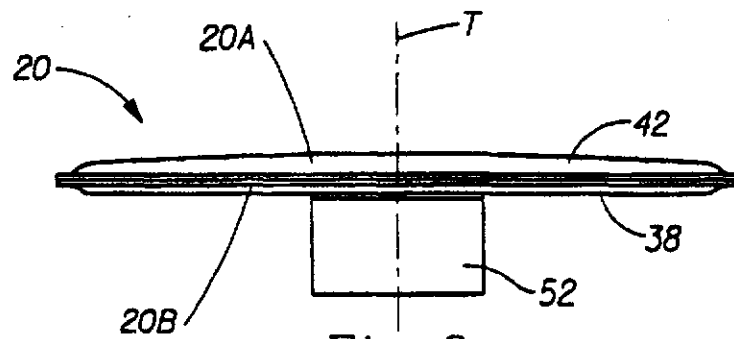


Fig. 3



US006045544A

United States Patent [19]

Hershberger et al.

[11] Patent Number: 6,045,544
[45] Date of Patent: *Apr. 4, 2000

[54] SHAPED ABSORBENT INTERLABIAL DEVICE

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[73] Assignee: The Procter & Gamble Company,
Cincinnati, Ohio

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: 08/979,980

[22] Filed: Nov. 26, 1997

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/833,606, Jun. 26, 1997, Pat. No. 5,762,644, and a continuation-in-part of application No. 08/876,206, Jun. 16, 1997, and a continuation-in-part of application No. 08/869,897, Jun. 5, 1997, and a continuation-in-part of application No. 08/778,520, Jan. 3, 1997, and a continuation-in-part of application No. 08/778,925, Jan. 3, 1997, abandoned, and a continuation-in-part of application No. 08/778,521, Jan. 3, 1997, and a continuation-in-part of application No. 08/706,371, Aug. 28, 1996, abandoned.

[51] Int. Cl.⁷ A61F 13/15

[52] U.S. Cl. 604/385.1; 604/378; 604/330;
604/904

[58] Field of Search 604/330, 363,
604/378, 385.1, 904

Primary Examiner—John G. Weiss

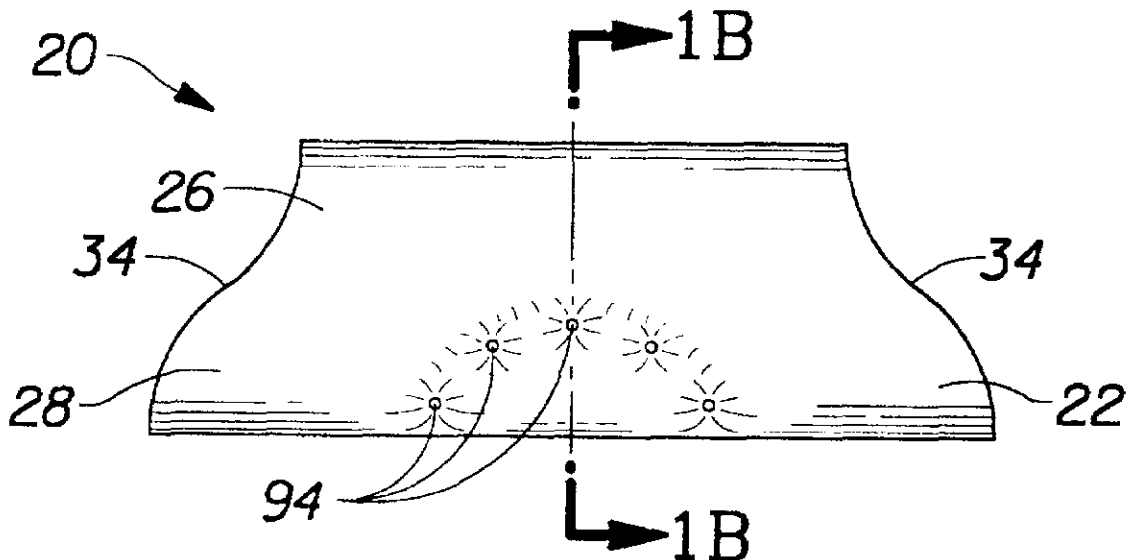
Assistant Examiner—Dennis Ruhl

Attorney, Agent, or Firm—Matthew P. Fitzpatrick; Jeffrey V. Bamber; Jacob C. Rasser

[57] ABSTRACT

Absorbent devices, and more particularly absorbent devices that are worn interlabially by female wearers for catamenial purposes, incontinence protection, or both, are disclosed. The absorbent interlabial device of the present invention comprises a main absorbent portion with an upper portion, a lower portion opposed to the upper portion, and two ends. The upper portion faces toward the vestibule of the wearer during insertion of the device into the wearer's interlabial space and during use. The ends of the absorbent device are preferably taped so that the lower portion of the interlabial device is longer than the upper portion. The ends are also provided with at least one curvilinear segment, with the ends preferably having a sinusoidal or S-shape. The absorbent interlabial device preferably also has an arcuate pattern of discrete autogenous bonds. The combination of the preferred S-shaped ends and the arcuate bonding pattern provides greater product stiffness control for simultaneous improved comfort and handling characteristics.

23 Claims, 8 Drawing Sheets



SHAPED ABSORBENT INTERLABIAL DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 08/833,606, now U.S. Pat. No. 5,762,644, filed on Jun. 26, 1997; and a continuation-in-part of application Ser. No. 08/876,206, filed on Jun. 16, 1997 pending; and a continuation-in-part of application Ser. No. 08/869,897, filed Jun. 5, 1997 pending; and a continuation-in-part of Ser. No. 08/778,520, filed on Jan. 3, 1997 pending; and a continuation-in-part of Ser. No. 08/778,925, now abandoned, filed on Jan. 3, 1997; and a continuation-in-part of Ser. No. 08/778,521, filed on Jan. 3, 1997 pending; and a continuation-in-part of Ser. No. 08/706,371, filed on Aug. 28, 1996 and now abandoned.

FIELD OF THE INVENTION

This invention relates to absorbent devices, and more particularly to a shaped absorbent device that is worn interlabially by female wearers for catamenial purposes, incontinence protection, or both.

BACKGROUND OF THE INVENTION

All manner and variety of absorbent articles configured for the absorption of body fluids such as menses, urine and feces are, of course, well known. With respect to feminine protection devices, the art has offered two basic types; sanitary napkins have been developed for external wear about the pudendal region while tampons have been developed for internal wear within the vaginal cavity for interruption of menstrual flow therefrom. Such tampon devices are disclosed in U.S. Pat. No. 4,412,833, entitled "Tampon Applicator", issued to Weigner, et al. on Nov. 1, 1983, and U.S. Pat. No. 4,413,986, entitled "Tampon Assembly With Means For Sterile Insertion", issued to Jacobs on Nov. 8, 1983.

Hybrid devices which attempt to merge the structural features of the sanitary napkins and the tampons into a single device have also been proposed. Such hybrid devices are disclosed in U.S. Pat. No. 2,092,346, entitled "Catamenial Pad", issued to Arone on Sep. 7, 1937, and U.S. Pat. No. 3,905,372, entitled "Feminine Hygiene Protective Shield", issued to Denkinger on Sep. 16, 1975. Other less intrusive hybrid devices are known as labial or interlabial sanitary napkins and are characterized by having a portion which at least partially resides within the wearer's vestibule and a portion which at least partially resides external of the wearer's vestibule. Such devices are disclosed in U.S. Pat. No. 2,662,527, entitled "Sanitary Pad", issued to Jacks on Dec. 15, 1953, and U.S. Pat. No. 4,631,062, entitled "Labial Sanitary Pad", issued to Lassen, et al. on Dec. 23, 1986.

Interlabial pads have the potential to provide even greater freedom from inconvenience because of their small size and reduced risk of leakage. Numerous attempts have been made in the past to produce an interlabial pad which would combine the best features of tampons and sanitary napkins while avoiding at least some of the disadvantages associated with each of these types of devices. Examples of such devices are described in U.S. Pat. No. 2,917,049 issued to Delaney on Dec. 15, 1959, U.S. Pat. No. 3,420,235 issued to Harmon on Jan. 7, 1969, U.S. Pat. No. 4,595,392 issued to Johnson, et al. on Jun. 17, 1986, and U.S. Pat. Nos. 5,074,855 and 5,336,208 issued to Rosenbluth, et al. on Dec. 24,

1991 and Aug. 9, 1994 respectively, and U.S. Pat. No. 5,484,429 issued to Vukos, et al. on Jan. 16, 1996. A commercially available interlabial device is the FRESH 'N FIT PADETTE® which is marketed by Athena Medical Corp. (now known as A-Fem) of Portland, Oreg. and described in U.S. Pat. Nos. 3,983,873 and 4,175,561 issued to Hirschman on Oct. 5, 1976 and Nov. 27, 1979, respectively.

Many of these devices have not met with great commercial success, however. There are drawbacks associated with all of the above products. For example, the device described in the Delaney patent does not appear to be capable of an easy and comfortable insertion, due to the possibility of the layers of absorbent material opening up during insertion. The commercially available PADETTE interlabial devices suffer from the disadvantage that the blunt edges of the device may cause wearer discomfort. Such blunt edges also increase the tendency of fluids deposited near the edges of the product to run off its edge without being absorbed into the center of the product. U.S. Pat. No. 3,983,873, issued to Hirschman, does describe an interlabial device having tapered ends, but such tapered ends are purely linear. This configuration does increase the surface area presented for absorption as compared to a non-tapered product, but the product of the present invention increases such area even beyond that achievable with the Hirschman device. Additionally, the speed at which the PADETTE interlabial device can be manufactured is limited due to its incorporation of stitching with thread. Interlabial devices without flexible extensions may not reliably cover the urethra and/or the vaginal introitus during all body movements (e.g. when the wearer is squatting). Such products may also not be reliably expelled when the wearer urinates.

It has been found during development of the present invention that product comfort can be increased by providing an interlabial device with increased stiffness relative to compressive forces in the center of the product, but decreased stiffness relative to such forces near the ends of the product. The stiffer product center contributes to a greater ease of insertion and a better placement of the device within the labia as compared to prior art products. Correspondingly, the greater compressibility (or decreased stiffness) near the ends of the device contributes to greater comfort associated with wearing of the device.

Therefore, a need exists for an interlabial device with shaped edges which increase the total absorbent area of the product facing toward the floor of the vestibule. A need also exists for an interlabial device with a relatively less compressible center and relatively more compressible ends. A need also exists for an interlabial device, which can be manufactured at high speeds with a minimum of waste. A need also exists for an interlabial device that is small in size and that can be easily inserted and that provides protection against incontinence, menstrual discharges, and discharges of bodily exudates throughout a great range of wearer motions. A need also exists for an interlabial device that will reliably be expelled when the wearer urinates. A need also exists for an interlabial device which facilitates sanitary insertion and removal. That is, a need exists for a device which may be inserted into the interlabial space of a wearer while covering the fingertips, thus preventing the fingertips from touching the inside surfaces of the labia.

It is, therefore, an object of the present invention to provide an absorbent interlabial device having tapered ends with at least one curvilinear segment.

It is another object of the present invention to provide an absorbent interlabial device with a relatively less compressible center and relatively more compressible ends.

into left and right body halves when the interlabial device 20 is worn. The terms "transverse," "lateral," or "y direction" as used herein, are interchangeable, and refer to a line axis or direction that is generally perpendicular to the longitudinal direction. The lateral direction is shown in FIG. 2 as the "y" direction. The absorbent interlabial device 20 shown in FIG. 2 also has a transverse centerline T shown in FIG. 2. The "z" direction, shown in FIG. 2, is a direction parallel to the vertical plane described above. The term "upper" refers to an orientation in the z-direction toward the wearer's head. "Lower" or downwardly is toward the wearer's feet.

As shown in FIG. 1, the interlabial device 20 comprises at least a main absorbent portion 22 (or "central absorbent"). The main absorbent portion 22 includes an upper portion 26 and a lower portion 28 that is opposed to the upper portion. In use, the upper portion 26 is positioned furthest inward into the wearer's interlabial space. The main absorbent portion 22 also comprises a pair of ends 34 which are tapered (i.e. the ends are farther apart at the lower portion 28 of the device 20 than at the upper portion 26. In addition to being tapered, the ends 34 are provided with at least one curvilinear segment. The main absorbent portion 22 should be at least partially absorbent. The main absorbent portion 22 may comprise non-absorbent portions, such as a liquid impervious barrier to prevent absorbed exudates from leaking out of the main absorbent portion 22.

The interlabial device 20 should be of a suitable size and shape that allows at least a portion thereof to fit comfortably within the wearer's interlabial space and to cover the wearer's vaginal orifice, and preferably also the wearer's urethra. The interlabial device 20 at least partially blocks, and more preferably completely blocks and intercepts the flow of menses, urine, and other bodily exudates from the wearer's vaginal orifice and urethra.

The size of the interlabial device 20 is also important to the comfort associated with wearing the device. In the embodiment shown in FIG. 1, the main absorbent portion 22 of the interlabial device 20 preferably has a length as measured along the upper portion 26 of between about 15 mm and about 65 mm. The length of the main absorbent portion 22 of the interlabial device 20, measured along the lower portion 28 is preferably between about 35 mm and about 120 mm. More preferably, the length of the main absorbent portion of the interlabial device 20, measured along the upper portion 26 is about 35 mm to about 45 mm, most preferably about 38 mm, and the length measured along the lower portion 28 is about 55 mm to about 65 mm, most preferably about 62 mm. The length of interlabial device 20 can also be measured along the longitudinal centerline (at a distance halfway between the top and bottom surfaces of the device). Suitable lengths measured in this manner can include, but are not limited to lengths of 40 mm, 50 mm, and 60 mm. In addition, if desired, a user can use a system of interlabial devices of such varying lengths.

The caliper (or width) of the main absorbent portion 22 of the interlabial device as measured in the transverse direction (or "y"-direction) is preferably less than or equal to about 8 mm, more preferably the caliper is between about 3 mm and about 6 mm, most preferably, the caliper is about 4.5 mm. Caliper measurements given herein were measured using an AMES gage with a 0.25 psi (1.7 kPa) (gauge) load and a 0.96 inch (2.44 cm) diameter foot. Those skilled in the art will recognize that if a 0.96 inch (2.44 cm) diameter foot is not appropriate for a particular sample size, the foot size may be varied while the load on the gauge is accordingly varied to maintain a confining pressure of 0.25 psi (1.7 kPa) (gauge). The height (or "z"-direction dimension) of the main

absorbent portion 22 is preferably between about 8 mm and about 35 mm, and more preferably is about 20 mm.

The interlabial device 20 is preferably provided with sufficient absorbency to absorb and retain the exudates discharged from the wearer's body. The capacity of the product, however, is dependent at least partially upon the physical volume of the absorbent interlabial device 20, particularly the main absorbent portion 22 thereof. The main absorbent portion 22 preferably has a capacity of at least about 1 g of 0.9% by weight saline solution, and may have a capacity of up to about 30 g by using absorbent gels or foams that expand when wet. Capacities may typically range from about 2 to about 10 grams, for saline. Those skilled in the art will recognize that the capacity for absorption of body exudates such as menses will typically be smaller than the capacities given above for absorption of saline. A method for measuring absorbent capacity is described in the Test Methods section, below. Since the interlabial space can expand, larger volumes can be stored in the interlabial space, if the fluid is stored as a gel, which adjusts to the body pressures. Additionally, if the absorbent interlabial device 20 does not reside completely within the wearer's interlabial space, some of the absorbed exudates may be stored externally to the wearer's interlabial space.

The main absorbent portion 22 of the embodiment shown in FIGS. 1-2 may comprise any suitable type of absorbent structure that is capable of absorbing and/or retaining liquids (e.g. menses and/or urine). The main absorbent portion 22 may be manufactured in a wide variety of shapes (as viewed from the side as in FIG. 1 or as viewed from the end as in FIG. 1A). Non limiting examples of shapes for the main absorbent portion when viewed from the end as in FIG. 1A, include ovoid, trapezoidal, rectangular, triangular, cylindrical, hemispherical or any combination of the above. Viewed from the side, as in FIG. 1, the preferred shape for the main absorbent portion 22 is generally tapered with at least one curvilinear segment. In particularly preferred embodiments, the ends 34 of the device 20 have a sinusoidal or "S" shape. In the preferred embodiment shown in FIG. 1, the caliper of the lower portion 28 is smaller than the caliper of the upper portion 26. This relationship is shown more clearly in FIG. 1B, which is a cross sectional view of FIG. 1, taken along the transverse centerline T.

The main absorbent portion 22 may, likewise, be manufactured from a wide variety of liquid-absorbent materials commonly used in absorbent articles such as comminuted wood pulp which is generally referred to as airlift. Examples of other suitable absorbent materials include cotton fibers or cotton lintels, creped cellulose wadding; meltblown polymers including coform; chemically stiffened, modified or cross-linked cellulosic fibers; synthetic fibers such as crimped polyester fibers; peat moss; tissue including tissue wraps and tissue laminates; absorbent foams; absorbent sponges; superabsorbent polymers (in fibrous and particulate form); absorbent gelling materials; or any equivalent material or combinations of materials, or mixtures of these. Preferred absorbent materials comprise folded tissues, cotton batts, woven materials, nonwoven webs, needle punched rayon, and thin layers of foam. The main absorbent portion 22 may comprise a single material. Alternatively, as shown in FIG. 1A, the main absorbent portion 22 may comprise a combination of materials, such as a wrapping layer 46 surrounding a central wadding comprised of an absorbent material 44 (as shown in FIG. 2).

In the embodiment shown in FIG. 1, the main absorbent portion 22 is formed of a soft absorbent material such as rayon fibers or other suitable natural or synthetic fibers or

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15

convenient central zone for grasping the product and inserting into the labia, while the body/fingers on the inserting hand are protected from contacting the wearer's body.

As noted above for the embodiment shown in FIGS. 1-2, the flexural rigidity of the main absorbent portion 22 is also important for product comfort with the pleated structure shown in FIG. 8. An advantage of the pleated structure is that the number, thickness, and tightness of the pleats control the stiffness of the structure.

The embodiment shown in FIG. 8 preferably has main absorbent portion 22 and flexible extension 24 dimensions similar to those described above for the embodiment shown in FIGS. 1-2. The width of the main absorbent portion 22 of the interlabial device 20 as measured in the transverse direction (y-direction) is preferably between about 2 mm and less than or equal to about 7 mm. Preferably, in a preferred embodiment, the width of the main absorbent portion of the interlabial device 20 is about 4.5 mm. As shown in FIG. 8, where the main absorbent portion 22 is of a uniform transverse dimension (i.e., there is no abrupt change in transverse dimension defining the juncture between the upper portion and lower portion) the division between the upper portion 26 and lower portion 28 is considered to be at a height equal to about one-half of the total height of the main absorbent portion 22.

The ends 34 of the main absorbent portion 22 of the device 20 shown in FIG. 8 have at least one curvilinear segment and are preferably "S"-shaped or sinusoidal as described above for the embodiment shown in FIG. 1.

The pleated design shown in FIG. 8 has the additional benefit of easily providing the flexible extensions 24. The extensions 24 can comprise the same material as the main absorbent portion 22, or they can comprise a different material. The extensions 24 are joined to the main absorbent portion 22. The extensions 24 may be integral portions of the main absorbent portion 22 (that is, the extensions 24 comprise integral extensions of the absorbent tissue material that is folded to form the main absorbent portion 22).

The main absorbent portion 22 and the flexible extensions 24 of the absorbent interlabial device 20 shown in FIG. 8 may be constructed from any of the materials and be provided with the same pattern of bonds previously discussed for the embodiments shown in FIGS. 1-2.

The embodiment shown in FIG. 8 can be provided with various optional features. For example, there may be spacers or high loft or void zones between the pleats to improve the ability of the device 20 to move exudates downward. Additionally, the pleats on the portion of the product contacting the pelvic floor do not need to be of uniform height. For example, the pleated material in the center might be higher and, therefore, easily collapsed under pressure. Such an arrangement can provide better fit and/or comfort.

In another variation of the pleated structure shown in FIG. 8, the main absorbent portion 22 may comprise a plurality of individual layers joined in a face-to-face relationship. Such a structure may have all of the same characteristics described above for the pleated structure. One benefit of the use of a plurality of individual layers is that the various layers may comprise different materials with different properties or characteristics. Each of the flexible extensions 24 may be integral with one of the individual layers or may be joined separately to the upper portion 26 of the main absorbent portion 22. Preferably, the individual layers are arranged in a side-by-side relationship so that the spaces between the layers are oriented in the z-direction.

The interlabial device 20 in any of the embodiments shown in the drawings may comprise other optional com-

16

ponents. For example, the interlabial device 20 may comprise a topsheet 42 positioned over and joined to all or a portion of its body-facing surface of the device including the flexible extensions 24, and/or a backsheet 38 positioned over and joined to all or a portion of its back surface, including the flexible extensions 24. Preferably, if a topsheet 42 and/or a backsheet 38 is used, these components are joined to at least the main absorbent portion 22. In an alternative embodiment, the main absorbent portion could be at least partially wrapped by a topsheet.

If a topsheet 42 is used, the topsheet should be compliant, soft feeling, and non-irritating to the wearer's skin. Further, the topsheet should be liquid pervious permitting liquids (e.g., menses and/or urine) to readily penetrate through its thickness. A suitable topsheet may be manufactured from a wide range of materials such as woven and nonwoven materials; polymeric materials such as apertured formed thermoplastic films, apertured plastic films, and hydroformed thermoplastic films; porous foams; reticulated foams; reticulated thermoplastic films; and thermoplastic scrims. Suitable woven and nonwoven materials can be comprised of natural fibers (e.g., wood or cotton fibers), synthetic fibers (e.g., polymeric fibers such as polyester, rayon, polypropylene, or polyethylene fibers) or from a combination of natural and synthetic fibers.

A suitable topsheet 42 for use in the present invention is formed of rayon with a basis weight of about 18 g/m² and is available from Veratec of Walpole, Mass. This material is particularly suitable for use as a topsheet 42 because it is biodegradable. This material may also be used as an outer cover 46 if an outer cover 46 is desired and a topsheet 42 is not used.

The topsheet may also comprise an apertured formed film. Apertured formed films are pervious to body exudates and, if properly apertured, have a reduced tendency to allow liquids to pass back through and rewet the wearer's skin. Thus, the surface of the formed film which is in contact with the body remains dry, thereby reducing body soiling and creating a more comfortable feel for the wearer. Suitable formed films are described in U.S. Pat. No. 3,929,135, entitled "Absorptive Structures Having Tapered Capillaries", which issued to Thompson on Dec. 30, 1975; U.S. Pat. No. 4,324,246 entitled "Disposable Absorbent Article Having A Stain Resistant Topsheet", which issued to Mullane, et al. on Apr. 13, 1982; U.S. Pat. No. 4,342,314 entitled "Resilient Plastic Web Exhibiting Fiber-Like Properties", which issued to Radcl, et al. on Aug. 3, 1982; U.S. Pat. No. 4,463,045 entitled "Macroscopically Expanded Three-Dimensional Plastic Web Exhibiting Non-Glossy Visible Surface and Cloth-Like Tactile Impression", which issued to Ahr, et al. on Jul. 31, 1984; and U.S. Pat. No. 5,006,394 "Multilayer Polymeric Film" issued to Baird on Apr. 9, 1991. The preferred topsheet for the present invention is the formed film described in one or more of the above patents and marketed on sanitary napkins by The Procter & Gamble Company of Cincinnati, Ohio as the "DRI-WEAVE" topsheet.

Another suitable topsheet 30 for the present invention is made in accordance with U.S. Pat. Nos. 4,609,518 and 4,629,643 both issued to Curro et al. on Sep. 2, 1986 and Dec. 16, 1986, respectively. Such a formed film is manufactured by Tredegar Corporation of Terre Haute, Ind.

In a preferred embodiment of the present invention, the body surface of the formed film topsheet is hydrophilic to help liquids transfer through the topsheet faster than if the body surface was not hydrophilic so as to diminish the likelihood that menstrual fluid will flow off the topsheet

rather than flowing into and being absorbed by the main absorbent portion 22. In a preferred embodiment, surfactant is incorporated into the polymeric materials of the formed film topsheet. Alternatively, the body surface of the topsheet can be made hydrophilic by treating it with a surfactant such as is described in U.S. Pat. No. 4,950,254 issued to Osborn.

If a backsheet is used, the backsheet could be impervious or semi-pervious to liquids (e.g., menses and or urine) and is preferably flexible. As used herein, the term "flexible" refers to materials which are compliant and will readily conform to the general shape and contours of the human body. The backsheet prevents the exudates absorbed and contained in the main absorbent portion 22 from wetting articles which contact the absorbent interlabial device 20 such as the wearer's undergarments. The backsheet also assists the main absorbent portion 22 in preventing the wearer's body from being soiled by exudates. Additionally, use of the backsheet may provide an improved surface for the wearer to grasp between the fingers as the absorbent interlabial device 20 is inserted, or as the device is optionally removed with the fingers.

The backsheet may comprise a woven or nonwoven material, polymeric films such as thermoplastic films of polyethylene or polypropylene, or composite materials such as a film-coated nonwoven material. Preferably, the backsheet is a polyethylene film having a thickness of from about 0.012 mm (0.5 mil) to about 0.051 mm (2.0 mils). An exemplary polyethylene film is manufactured by Clopay Corporation of Cincinnati, Ohio, under the designation P18-0401. The backsheet may permit vapors to escape from the main absorbent portion 22 (i.e., breathable) while still preventing exudates from passing through the backsheet.

If desired, the absorbent interlabial device 20 may be packaged in an individual package, such as the package 50 shown in FIGS. 15 and 16. The individual package 50 may be comprised of a number of suitable materials, including films and flushable materials. In FIGS. 15 and 16, the package 50 is made of a film which is frangibly sealed at the edges. The package 50 is provided with an opening tab 52 which can be of any suitable configuration. Suitable methods for frangibly sealing packages are described in U.S. Pat. No. 4,556,146 issued to Swanson and U.S. Pat. No. 5,462,166 issued to Minton, et al. Suitable tabs for such a package U.S. Pat. No. 5,413,568 issued to Roach, et al.

As previously discussed, the absorbent interlabial device 20 of the present invention is designed to be placed within the interlabial space of a wearer. To use the absorbent interlabial device 20 of the present invention, the wearer holds the main absorbent portion 22 between her fingers. As shown in FIG. 11, the flexible extensions 24 are spread apart so as to cover the tips of the wearer's fingers during insertion. This feature provides for a hygienic insertion of the absorbent interlabial device 20 of the present invention. The interlabial device 20 is inserted with the upper portion 26 inserted first and farthest into the interlabial space. The wearer may assume a squatting position during insertion to assist in spreading the labial surfaces. FIG. 9 shows a preferred embodiment of the absorbent interlabial device 20 of the present invention inserted into the interlabial space of a wearer W. The urogenital members shown in FIG. 9 include the bladder B, the vagina V, the urethra U, the clitoris C, the large intestine I, the anus A, the vaginal introitus VI, the hymeneal ring H, the labia minora N, and the labia majora J. FIG. 9 shows the relationship of these anatomical features of the wearer W to the absorbent interlabial device 20 when the device is properly inserted for use. Once the absorbent interlabial device 20 is inserted, the

flexible extensions 24 tend to adhere to the inside surfaces of the labia. When the wearer is standing, the labial walls close more tightly around the absorbent interlabial device 20.

The interlabial device 20 is preferably at least partially retained in place by exerting a slight laterally outwardly-oriented pressure on the inner surfaces of the wearer's labia minora, labia majora, or both. Additionally, the product may also be held by attraction of naturally moist labial surfaces to the tissue comprising the flexible extensions 24. Optionally, the flexible extensions 24 or other portions of the device 20 may be provided with a bio-compatible adhesive to assist the adhesion of the device 20 to the inside surfaces of the wearer's labia. The strength of such an adhesive should be selected to assist the absorbent interlabial device 20 in staying in place, while still allowing for reliable, and comfortable removal of the device from the wearer's interlabial space.

The absorbent interlabial device 20 can be worn as a "stand alone" product. Alternatively, it can be worn as a back up to a tampon, or in combination with a sanitary napkin, pantliner, or incontinence pad for menstrual or incontinence use. If the absorbent interlabial device 20 is used with a sanitary napkin, the sanitary napkin can be of any thickness. Use with a sanitary napkin may be preferred at night to reduce rear soiling. The interlabial device 20 can be worn in conventional panties, or it can be used with menstrual shorts.

Numerous alternative embodiments of the absorbent interlabial device of the present invention are possible. For example, these products are designed to be removed by urination, although an alternative extraction string or loop may be used. These products may also be used with emollients and/or medicinal treatments. For example, a suitable emollient for use on the absorbent interlabial device 20 of the present invention is comprised of about 50% petrolatum, about 39% Cetearyl Alcohol, and about 15% Cetareth-10. These interlabial products may be constructed of materials which are biodegradable and/or which will fragment in water with agitation (as in a toilet).

Preferably, the absorbent interlabial device 20 of the present invention is toilet disposable. The term "toilet-disposable" as used herein includes the following characteristics of an absorbent interlabial device: flushability, dispersibility, settleability, and biodegradability. As used herein, the terms "flushable" and "flushability" refer to a product's ability to pass through typically commercially available household toilets and plumbing systems without causing clogging or similar problems that can be directly associated with the physical structure of the product. It is recognized, however, that there can be many differences between the various types of toilets available. Therefore, for the purposes of the appended claims, a test to determine the flushability a catamenial product, such as an absorbent interlabial device, is set out in the TEST METHODS section of this specification.

In these or other embodiments, the absorbent interlabial device 20 may be provided with channels or areas of increased absorbent material 44 density. Such regions of increased density may be arranged so as to help direct the flow of bodily fluids toward the center of the device 20 due to the wicking action provided by these density gradients.

The absorbent interlabial device 20 may also be constructed with a plurality of slits in the main absorbent portion 22 so as to permit bending of the product in multiple independent directions. Such a structure allows the product to more easily respond to the stresses associated with body movements.

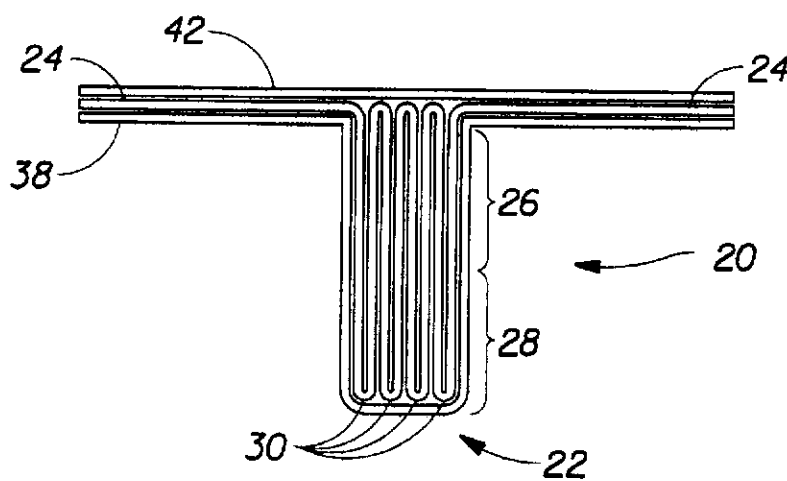


Fig. 8

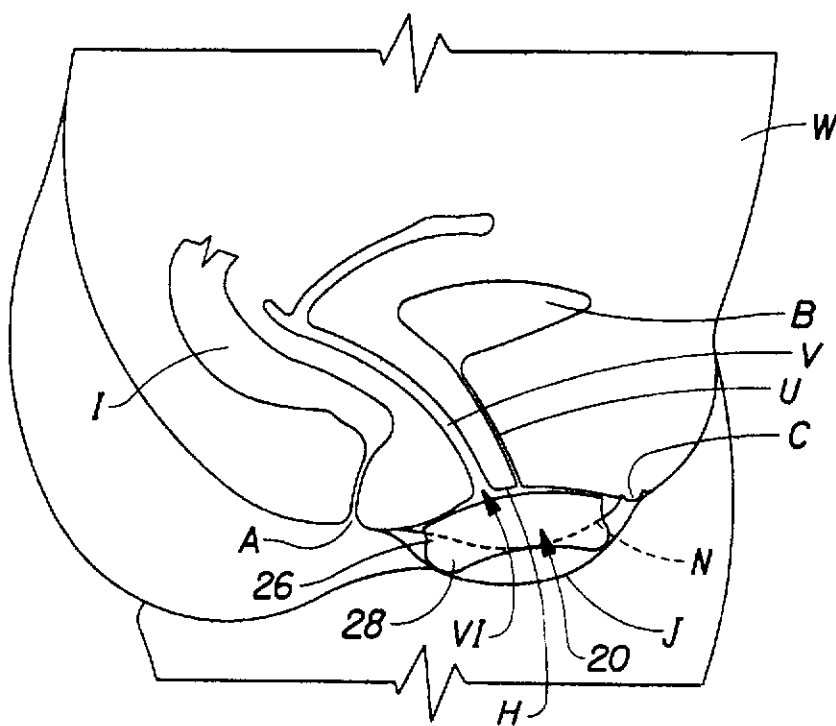


Fig. 9

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Doctora
JIMENA ESCOBAR URIBE
Abogada

ASUNTO	Radicación	06-31934
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	0518
	Folios	05

Patente de Invención



Patente de Modelo de Utilidad

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

Descripción:	Folios: 7 a 35	como se radicó inicialmente
Reivindicaciones:	Folios: 36 a 42	como se radicó inicialmente
Dibujos:	Folios: 43 a 46	como se radicó inicialmente
Prioridad:	País: estados Unidos	
	Número: 11/096,086	
	Fecha: 31 de marzo de 2005	

2. Objeto de la invención

La presente patente de invención consiste en:

Artículo absorbente que se puede unir al cuerpo que comprende: una superficie de cara la cuerpo; una superficie de de cara a la prenda de vestir; un adhesivo dispuesto sobre dicha superficie de cara al cuerpo; para asegurar dicho artículo al cuerpo, y una ayuda de colocación táctil que es perceptible táctilmente para la usuaria desde dicha superficie de cara a la prenda de vestir de dicho artículo.

El problema planteado en esta solicitud es la dificultad de la usuaria al ubicar el artículo de higiene femenina en el sitio apropiado contra el cuerpo, reduciendo la eficiencia total y causando fallas del producto.

Para solucionar este problema técnico se desarrolla un artículo sanitario

3. De la solicitud de Patente (según el caso)

Descripción (artículo 28 D. 486)

- Se debe corregir el siguiente error de mecanografía, folio 18 línea 19 "600%" y "polímetro" folio 32 línea 8.

Reivindicaciones (artículo 30 D 486)

- Se debe corregir el siguiente error de mecanografía, reivindicación 4 "circula".
- Las reivindicaciones 1, 20 y 22 no son concisas, ya cada una presenta el mismo alcance de las características técnicas para el artículo absorbente.
- La reivindicación 22, no tiene sustento en la descripción, cuando caracteriza la capa de barrera con una estructura y una disposición tal que una porción de ella se extiende mas allá de un borde terminal de dicha capa de cubierta, ya que en la descripción se habla claramente que "la capa cubierta 42 y la capa de barrera 50 se unen a lo largo de sus porciones marginales de tal manera que forman un cercado o sello de reborde que mantiene a la capa absorbente 44 atrapada".

Por lo anterior, el capítulo reivindicatorio no cumple con el requisito de claridad, y sustento en la descripción de acuerdo al art. 30 de la Decisión 486.

4. Reivindicaciones relativas a un uso o a un segundo uso (*artículos 14 y 21 D 486*)

La reivindicación independiente 23 se refiere al uso del artículo absorbente que se puede adherir al cuerpo, por medio de unos pasos que muestran como se emplean o se hacen funcionar partes del artículo, como son la ayuda de colocación táctil y el adhesivo, para un fin determinado.

5. Determinación del Estado de la Técnica

- La fecha para determinar el estado de la técnica es el 31 de marzo de 2005, de acuerdo al la fecha de prioridad invocada.
Tendiendo en cuenta la anterior fecha indicada, se realiza la búsqueda de las anterioridades de la presente solicitud, encontrándose los siguientes documentos relevantes:

Nº	Documento	Título	Fecha de publicación
D1	EP1075246	ABSORBENT INTERLABIAL DEVICE WITH SUBSTANCE THEREON FOR MAINTAINING THE DEVICE IN POSITION	2001-02-14
D2	US6045544	SHAPED ABSORBENT INTERLABIAL DEVICE	2000-04-04

6. Análisis de patentabilidad (según requisito) (artículo 14 D486)

Novedad (*artículo 16 D486*)

sobre dicha superficie de cara al cuerpo para asegurar dicho artículo al cuerpo, una ayuda de colocación táctil que es perceptible táctilmente para la usuaria desde dicha superficie de cara a la prenda de vestir de dicho artículo”.

La reivindicación 20 dice: “Un artículo absorbente que se puede unir al cuerpo que comprende: una capa cubierta; una capa barrera; un adhesivo aplicado a un lado de la cara al cuerpo de dicha capa cubierta para asegurar dicho artículo a cuerpo; una ayuda de colocación táctil que es perceptible táctilmente para la usuaria a partir de dicha superficie de cara a la prenda de vestir de dicho artículo, dicha ayuda de colocación táctil esta dispuesta en un sitio adaptado para ser alineado con la abertura vaginal de la usuaria”.

La reivindicación 22 dice: “Un artículo absorbente que comprende: una capa cubierta, una capa barrera, en donde dicha barrera se estructura y se dispone tal que una porción de ella se extiende mas allá de un borde terminal de dicha capa de cubierta, un adhesivo para asegurar dicho artículo al cuerpo, dicha porción de dicha barrera que se extiende mas allá de dicho borde terminal de dicha cubierta, una ayuda de colocación táctil que es perceptible táctilmente por la usuaria a partir de dicha superficie e cara a la prenda de vestir de dicho artículo, dicha ayuda de colocación táctil que esta dispuesta en un sitio adaptado para ser alineado con la abertura vaginal de la usuaria”.

D1 relata dispositivos absorbentes como toallas sanitarias, pantaletas, dispositivos interlabiales y dispositivos de incontinencia. El dispositivo interlabial tiene al menos un superficie que contacta el cuerpo de la usuaria (Pág. 3 párrafo 008). El dispositivo interlabial absorbente lo componen una hoja superior permeable a los líquidos, una hoja posterior impermeable a los líquidos la cual esta unida a la hoja superior. Una marca unida a la hoja inferior puede facilitar la inserción y opcionalmente la remoción del dispositivo interlabial (Pág. 3 párrafo 0013). Otra alternativa de la invención es que el dispositivo interlabial puede utilizar sustancias adhesivas (Pág. 3 párrafo 0014). El dispositivo interlabial muestra una superficie que enfrenta el cuerpo (20A) y al lado opuesto (20B) y una marca opcionalmente removible para la colocación (52) la cual es unida en el lado inferior 20B de la porción del cuerpo principal (22) para proveer un dispositivo interlabial con forma de “T” como configuración seccional transversal. La porción del cuerpo principal 22 puede tener cualquier configuración disponible (Pág. 5 párrafo 0021). La hoja posterior (38) según figura 2 y 3, provee que los exudados absorbidos y contenidos en el recubrimiento absorbente (44) no hagan contacto con las prendas de vestir de la usuario (Pág. 7 párrafo 0038). Otro ejemplo del dispositivo interlabial puede contener algunas sustancias adhesivas descritas aquí como adhesivos alrededor de la periferia de la superficie de contacto con el cuerpo (Pág. 13 párrafo 0084).

D2 describe un dispositivo absorbente y particularmente una forma de dispositivo absorbente que puede ser usado interlabialmente por usuarias femeninas para propósitos catameniales o protección contra la incontinencia o ambos (Col. 1 líneas 21-24). Un objeto de esta invención es proveer un dispositivo de absorción interlabial que puede ser insertado interlabialmente sin que las manos de la usuaria toquen la superficie interna de los labios (Col. 1 líneas 21-24). Otro objeto de la invención es proveer un dispositivo interlabial que de indicios para ayudar a la usuaria ha colocar adecuadamente el dispositivo (Col. 1 líneas 24-25). La

líneas 1-15). La superficie al cuerpo es un alamina de una hoja superior hidrofílica (Col. 16 líneas 63-67). Si se usa una hoja posterior esta puede ser impermeable o semi-impermeable a los líquidos y preferiblemente flexible (Col. 17 líneas 7-9). Opcionalmente la extensión flexible (24) o otra porción del dispositivo (20) puede tener un adhesivo bio-compatible para ayudar en la adhesión del dispositivo en la superficie interior de los labios de la usuaria (Col. 18 líneas 11-14). La estructura mostrada en la figura 8, también provee una zona central conveniente para agarrar el producto e insertarlo en los labios mientras que los dedos de la mano de la usuaria que inserta el dispositivo se protegen de entrar en contacto con su cuerpo (Col. 15 líneas 1-3).

Análisis de las diferencias con respecto al estado de la técnica:

*Reiv.	Características Esenciales	D1 EP1075246	D2 US6045544
1	Un artículo absorbente que se puede unir al cuerpo que comprende:	SI (Pág. 3 párrafo 008)	SI (Col. 1 líneas 21-24)
	superficie de cara al cuerpo	SI (Pág. 5 párrafo 0021)	SI (Col. 16 líneas 1-15)
	una superficie de cara a la prenda de vestir	SI (Pág. 5 párrafo 0021)	SI (Col. 17 líneas 7-9)
	un adhesivo dispuesto sobre dicha superficie de cara al cuerpo para asegurar dicho artículo al cuerpo	SI (Pág. 13 párrafo 0084)	SI (Col. 18 líneas 11-14)
	una ayuda de colocación táctil que es perceptible táctilmente para la usuaria desde dicha superficie de cara a la prenda de vestir de dicho artículo	SI (Pág. 5 párrafo 0021)	SI (Col. 15 líneas 1-3)
20	Un artículo absorbente que se puede unir al cuerpo que comprende:	SI (Pág. 3 párrafo 008)	SI (Col. 1 líneas 21-24)
	una capa cubierta	SI (Pág. 5 párrafo 0021)	SI (Col. 16 líneas 1-15)
	una capa barrera	SI (Pág. 5 párrafo 0021)	SI (Col. 17 líneas 7-9)
	un adhesivo aplicado a un lado de la cara al cuerpo de dicha capa cubierta para asegurar dicho artículo a cuerpo	SI (Pág. 13 párrafo 0084)	SI (Col. 18 líneas 11-14)
	una ayuda de colocación táctil que es perceptible táctilmente para la usuaria a partir de dicha superficie de cara a la prenda de vestir de dicho artículo, dicha ayuda de colocación táctil esta dispuesta en un sitio adaptado para ser alineado con la abertura vaginal de la usuaria	SI (Pág. 5 párrafo 0021)	SI (Col. 15 líneas 1-3)
22	un artículo absorbente que se puede unir al cuerpo que comprende:	SI (Pág. 3 párrafo 008)	SI (Col. 1 líneas 21-24)
	una capa cubierta	SI (Pág. 5 párrafo 0021)	SI (Col. 16 líneas 1-15)
	una capa barrera, se estructura y se dispone tal que una porción de ella se extiende mas allá de un borde terminal de dicha capa de cubierta	SI (Pág. 5 párrafo 0021)	SI (Col. 17 líneas 7-9)
	un adhesivo para asegurar dicho artículo al cuerpo, dicha porción de dicha barrera que	SI (Pág. 13	SI (Col. 18

	prenda de vestir de dicho artículo dicha ayuda de colocación táctil que esta dispuesta en un sitio adaptado para ser alineado con la abertura vaginal de la usuaria".		
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*Reiv. = Reivindicación

De acuerdo con el cuadro anterior donde se comparan las características técnicas de las reivindicaciones 1, 20 y 22 con los documentos D1 y D2, se concluye que el artículo absorbente descrito en estas reivindicaciones, ya era conocido en el estado de la técnica. Por lo tanto la reivindicación 1, 20 y 22 con sus dependientes no pueden considerarse nuevas.

7. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

Documento N°	Reivindicaciones afectadas	Requisito que afecta
EP1075246	1-22	Novedad
US6045544	1-22	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de 60 días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha
22 ENE. 2009

CONCEPTO TÉCNICO N° 0030	EXAMINADOR TÉCNICO Código N° 202090
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