

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 August 2003 (07.08.2003)

PCT

(10) International Publication Number
WO 03/063829 A1

(51) International Patent Classification⁷: **A61K 9/00**,
A61F 13/20

(21) International Application Number: PCT/US03/00490

(22) International Filing Date: 7 January 2003 (07.01.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/347,719 10 January 2002 (10.01.2002) US
Not furnished 31 December 2002 (31.12.2002) US

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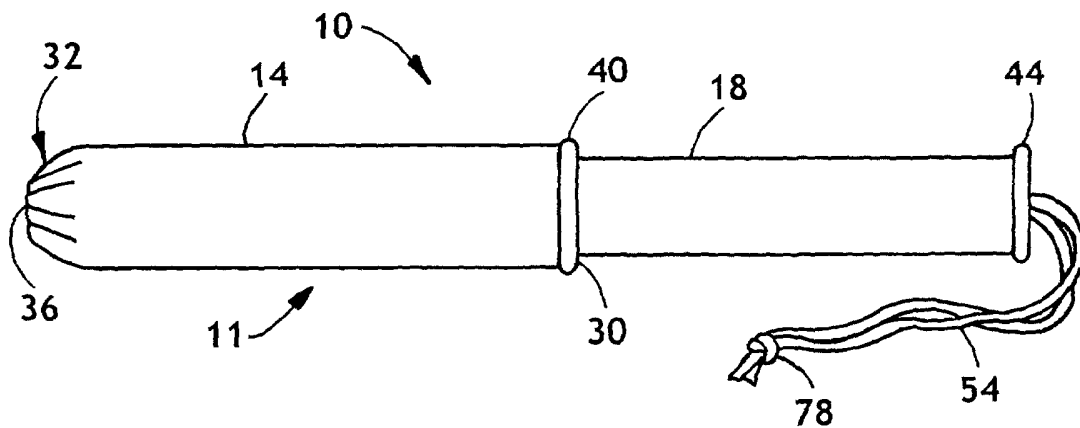
(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MEDICATED TAMPON



(57) Abstract: A tampon adapted to deliver a therapeutic agent, the tampon including a tampon body that is manufactured at a first manufacturing facility; and a dosage form coupled to the body, wherein the dosage form includes a formulation including a therapeutic agent, and wherein the dosage form is manufactured at a second manufacturing facility. Also, a method for producing a medicated tampon including manufacturing a tampon body at a first manufacturing facility; manufacturing a dosage form at a second manufacturing facility, wherein the dosage form includes a formulation including a therapeutic agent; and coupling the dosage form to the tampon body.

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MEDICATED TAMPON

CROSS-REFERENCE TO RELATED APPLICATION

5 This application claims the benefit of U.S. Provisional Application No. 60/347,719, filed January 10, 2002, herein incorporated by reference.

BACKGROUND

10 This invention pertains to a method of manufacturing delivery devices used for the application of various vaginal therapeutic treatments or other non-medicinal vaginal preparations into the vaginal cavity.

 Many disease states and physiological conditions can occur in a woman, including symptoms associated with premenstrual syndrome, menstruation, and menopause. These symptoms may include dysmenorrhea (menstrual cramping), irritability, water
15 retention, moodiness, depression, anxiety, skin changes, headaches, breast tenderness, tension, weight gain, cravings, fatigue, and hot flashes. Symptoms of conditions can include itching and other associated sensory maladies.

 Many of these symptoms are due to changes in hormonal levels throughout the menstrual cycle. Menstrual cramping is associated with increased levels of prostaglandin
20 F2 α , prostaglandin E2, and in some cases leukotrienes in the endometrium and menstrual fluid. These eicosinoids lead to restricted blood flow to the uterus and increased uterine contractions, causing pain.

 One example is dysmenorrhea, which is the occurrence of painful uterine cramps during menstruation that affects a large number of post-pubescent women. The pain of
25 dysmenorrhea originates in the uterus. Various analgesics can be effective in limiting the pain from dysmenorrhea; some have used orally-delivered analgesics, while others have searched for alternative analgesic delivery methods.

 Attempts have been made to deliver analgesics in the vicinity of the cervix and the vaginal mucosa using various vaginally-inserted devices and methods. Because many of
30 these symptoms typically occur in conjunction with menstruation, some have tried to combine an analgesic with a tampon.

 Constant mixing of the heated combination is required to produce a homogeneous compound. As the combination cools, the ingredients solidify into a solid waxy substance that is securely fastened to the tip of the tampon.

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SUMMARY OF THE INVENTION

Several problems are inherent in a process that attempts to introduce a therapeutic agent into or onto a tampon by coating, dipping, solidifying, or the like. Procedures such as these that may work in a laboratory setting may be precluded from application to an automated tampon manufacturing process. Because of stringent dosing requirements, the therapeutic agent and its carrier must be maintained in a solution that is both homogeneous and at a proper concentration and purity. These requirements are difficult to accomplish during normal operation, and are significantly more difficult to maintain when the tampon machine stops. In addition, tampons of different densities will absorb an applied liquid therapeutic agent differently, resulting in variability in agent concentrations across different tampons.

Specifically, the requirement to provide constant agitation or mixing of the ingredients to the excipient and active compounds raises concerns as to how to keep the solid active ingredient homogeneously suspended in a solution when the tampon machine stops. The use of inline mixers and recirculation of the heated liquid compound during machine stops may provide a method to keep the solution moving and mixed. However, because a machine could be stopped for several hours, the stability of some compound mixtures may be compromised by long durations at elevated temperatures, or by mechanical shear forces due to the continuous pumping of the recirculating solution.

The invention described herein resolves these problems by incorporating a dosage form onto a tampon to form a medicated tampon, whereby the dosage form would be introduced onto a tampon. In one embodiment, all or a portion the dosage form is slightly activated by an energy source, so that the carrier component will be allowed to interact with, and bond securely to, the tampon. The dosage form is sufficiently stable and may be manufactured separately in a controlled facility, whereby dose is easily controlled through controls on homogeneity, concentration, and purity.

More specifically, the invention described herein provides a tampon adapted to deliver a therapeutic agent, the tampon including a tampon body, wherein the tampon body is manufactured at a first manufacturing facility; and a dosage form adapted to be coupled to the body, wherein the dosage form includes a formulation including a therapeutic agent, and wherein the dosage form is manufactured at a second manufacturing facility.

The invention described herein further provides a method for producing a medicated tampon, the method including manufacturing a tampon body at a first manufacturing facility; manufacturing a dosage form at a second manufacturing facility,

wherein the dosage form includes a formulation including a therapeutic agent; and coupling the dosage form to the tampon body.

5 The invention described herein further provides a method for enabling a consumer to choose whether to use a medicated tampon or a non-medicated tampon, the method including providing a dosage form to the consumer, wherein the dosage form includes a formulation including a therapeutic agent, and wherein the dosage form is adapted to be used in conjunction with a tampon having a tampon body; providing a means for coupling the dosage form to the tampon body; and providing instructions concerning the use of a medicated tampon.

10 The invention described herein further provides a method for using a medicated tampon, the method including obtaining a tampon having a tampon body; obtaining a dosage form, wherein the dosage form includes a formulation including a therapeutic agent, and wherein the dosage form is adapted to be used in conjunction with the tampon; and coupling the dosage form to the tampon body.

15 The advantages of an assembly type process using a pre-manufactured dosage form over an in-line process where the medicated ingredients are applied to the tampon coincident with the tampon manufacturing process are numerous. The dosage form would be desirably produced at a qualified pharmaceutical manufacturer, which could ensure that the correct dose and purity of the active ingredient is homogeneously dispersed within the dosage form. The use of dosage forms would simplify the
20 modifications to an existing tampon manufacturing process. The use of dosage forms would allow multiple types of therapeutic agents to be applied to the tampon. The chemical and physical stabilities of the dosage form are not compromised by the assembly process onto the tampon. The process is less dependent on the physical
25 characteristics of the absorbent structure of the tampon, because only a partial phase change of the excipient ingredient(s) is required to bond with the tampon. Finally, product costs of this disclosed invention would also be advantageous because the medicated tampon is compatible with existing manufacturing processes.

30 This invention describes a therapeutic agent delivery system in cooperation with a feminine care product by providing a therapeutic agent delivery system that is integral with or associated with the feminine care product. The therapeutic agent delivery system including the therapeutic agent and carrier components can be any therapeutic agent that will be absorbed into the body through the vaginal epithelium, or deposited topically on the vaginal epithelium, for the purposes of treating a physiological disease, state, or condition.

Other objects and advantages of the present invention will become more apparent to those skilled in the art in view of the following description and the accompanying drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a two-piece tampon applicator.

Fig. 2 is a cross-sectional view of the tampon applicator shown in Fig. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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The invention as described herein will be described for exemplary purposes using a tampon as an example of a feminine care product. Also contemplated is the use of the invention described herein in conjunction with non-catamenial feminine products such as incontinence products, including female incontinence inserts.

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As used herein the term "nonwoven fabric or web" means a web having a structure of individual fibers or threads that are interlaid, but not in a regular or identifiable manner as in a knitted fabric. The term also includes individual filaments and strands, yarns or tows as well as foams and films that have been fibrillated, apertured, or otherwise treated to impart fabric-like properties. Nonwoven fabrics or webs have been formed from many processes such as for example, meltblowing processes, spunbonding processes, and

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bonded carded web processes. The basis weight of nonwoven fabrics is usually expressed in ounces of material per square yard ("osy") or grams per square meter ("gsm") and the fiber diameters useful are usually expressed in microns. Basis weights can be converted from osy to gsm simply by multiplying the value in osy by 33.91.

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As used herein the term "microfibers" means small diameter fibers having an average diameter not greater than about 75 microns, for example, having an average diameter of from about 0.5 microns to about 50 microns, or more particularly, microfibers may have an average diameter of from about 2 microns to about 40 microns. Another frequently used expression of fiber diameter is denier, which is defined as grams per 9000 meters of a fiber and may be calculated as fiber diameter in microns squared, multiplied

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by the density in grams/cc, multiplied by 0.00707. A lower denier indicates a finer fiber and a higher denier indicates a thicker or heavier fiber. For example, the diameter of a polypropylene fiber given as 15 microns may be converted to denier by squaring, multiplying the result by .89 g/cc and multiplying by .00707. Thus, a 15 micron polypropylene fiber has a denier of about 1.42 ($15^2 \times 0.89 \times .00707 = 1.415$). Outside the

United States the unit of measurement is more commonly the "tex", which is defined as the grams per kilometer of fiber. Tex may be calculated as denier/9.

As used herein the term "spunbonded fibers" refers to small diameter fibers which are formed by extruding molten thermoplastic material as filaments from a plurality of fine, usually circular capillaries of a spinneret with the diameter of the extruded filaments then being rapidly reduced as, for example, described in U.S. Patent Nos. 4,340,563; 3,692,618; 3,802,817; 3,338,992; 3,341,394; 3,502,763; 3,502,538; and 3,542,615. Spunbond fibers are quenched and generally not tacky when deposited onto a collecting surface. Spunbond fibers are generally continuous and have average diameters frequently larger than 7 microns, typically between about 10 and 20 microns.

As used herein the term "meltblown fibers" means fibers formed by extruding a molten thermoplastic material through a plurality of fine, usually circular, die capillaries as molten threads or filaments into converging high velocity, usually heated, gas (e.g. air) streams which attenuate the filaments of molten thermoplastic material to reduce their diameter, which may be to microfiber diameter. Thereafter, the meltblown fibers are carried by the high velocity gas stream and are deposited on a collecting surface often while still tacky to form a web of randomly disbursed meltblown fibers. Such a process is disclosed, for example, in U.S. Patent No. 3,849,241. Meltblown fibers are microfibers that may be continuous or discontinuous and are generally smaller than 10 microns in average diameter.

As used herein "bonded carded webs" or "BCW" refers to nonwoven webs formed by carding processes as are known to those skilled in the art and further described, for example, in U.S. Patent No. 4,488,928 which is incorporated herein by reference. Briefly, carding processes involve starting with a blend of, for example, staple fibers with bonding fibers or other bonding components in a bulky ball that is combed or otherwise treated to provide a generally uniform basis weight. This web is heated or otherwise treated to activate the adhesive component resulting in an integrated, usually lofty nonwoven material.

As used herein the term "polymer" generally includes but is not limited to, homopolymers, copolymers, such as for example, block, graft, random and alternating copolymers, terpolymers, etc. and blends and modifications thereof. Furthermore, unless otherwise specifically limited, the term "polymer" shall include all possible geometrical configurations of the material. These configurations include, but are not limited to isotactic, syndiotactic, and random symmetries.

As used herein, the term "hydrophilic" means that the polymeric material has a surface free energy such that the polymeric material is wettable by an aqueous medium, i.e. a liquid medium of which water is a major component. The term "hydrophobic" includes those materials that are not hydrophilic as defined. The phrase "naturally hydrophobic" refers to those materials that are hydrophobic in their chemical composition state without additives or treatments affecting the hydrophobicity. It will be recognized that hydrophobic materials may be treated internally or externally with treatments such as surfactants and the like to render them hydrophilic.

As used herein, the term "surface" and its plural generally refer herein to the outer or the topmost boundary of an object.

As used herein, the phrase "absorbent article" refers to devices which absorb and contain body fluids, and more specifically, refers to devices which are placed against or near the skin, or against or near the vaginal vault epithelium, to absorb and contain the various fluids discharged from the body.

As used herein, the term "disposable" is used herein to describe absorbent articles that are consumable and not intended to be laundered or otherwise restored or reused as an absorbent article after a single use.

As used herein, the term "dosage form" is used herein as a generic term for a drug form including a formulation including a therapeutic agent. The drug form may be a dosage in the form of a suppository, a capsule or any other suitable form. The drug form may also be spherical, ovoid, domal, generally flat, or any other suitable shape dictated by the needs of the application of the drug form. The drug form may have convex, concave, planar, arcuate or any other suitable surfaces as dictated by the needs of the application of the drug form.

Figs. 1-2 illustrate a tampon applicator 11, including a first member 14 and a second member 18, which is designed to house a catamenial tampon 22 and provide a comfortable means of inserting the tampon 22 into a woman's vagina.

The tampon applicator 11 includes a first member 14 and a second member 18. The first member 14 can be in the form of a spirally wound, convolutedly wound or longitudinally seamed hollow tube which is formed from paper, paperboard, cardboard, or other suitable material, or a combination thereof. The first member 14 can also be in the form of a seamless plastic tube. Any plastic in the first member 14 is preferably polyethylene, but may be polypropylene or other suitable plastic. The first member 14, also commonly referred to as an outer tube, can be of any suitable dimensional

arrangement. For example, the first member 14 may be fairly rigid and have a relatively small diameter of about 10 mm to about 20 mm.

The first member 14 has a wall 24 that may have a predetermined thickness of about .2 mm to about .6 mm. When the first member 14 is spirally wound, convolutedly wound, or longitudinally wound, the wall 24 can be constructed from a single ply of material or be formed from two or more plies which are bonded together to form a laminate. The use of two or more plies or layers enables the manufacture to use certain material in the various layers that can enhance the performance of the tampon applicator 11. When two or more plies are utilized, all the plies can be spirally wound, convolutedly wound or longitudinally seamed to form an elongated cylinder. The wall 24 can be constructed using a smooth thin ply of material on the outside or exterior surface 26 which surrounds a coarser and possibly thicker ply. When the wall 24 contains at least three plies, the middle ply can be the thicker ply and the interior and exterior plies can be smooth and/or slippery to facilitate expulsion of the tampon 22 and to facilitate insertion of the first member 14 into a woman's vagina, respectively. By sandwiching a thick, coarser ply of material between two thin, smooth plies, an inexpensive first member 14 can be provided that is very functional. The wall 24 should contain one to four plies, although more plies can be utilized if desired.

The plies forming the wall 24 can be held together by an adhesive, such as glue, or by heat, pressure, ultrasonics, etc. The adhesive can be either water-soluble or water-insoluble. A water-soluble adhesive is preferred for environmental reasons in that the wall 24 will quickly break apart when it is immersed in water. Such immersion will occur should the first member 14 be disposed of by flushing it down a toilet. Exposure of the first member 14 to a municipal's waste treatment plant wherein soaking in water, interaction with chemicals, and agitation all occur will cause the wall 24 to break apart and even dissolve in a relatively short period of time.

The inside diameter of the first member 14 is usually less than about .75 inches (about 19 mm) and preferably less than about .625 inches (about 16 mm). Although the exterior diameters of tampons vary, most tampons utilized by women have an external diameter of less than about .75 inches (about 19 mm).

The first member 14 is sized and configured to house the absorbent tampon 22. As stated above, the first member 14 should have a substantially smooth exterior surface 26 which will facilitate insertion of the first member 14 into a woman's vagina. When the exterior surface 26 is smooth and/or slippery, the first member 14 will easily slide into a woman's vagina without subjecting the internal tissues of the vagina to abrasion. The first

member 14 can be coated to give it a high slip characteristic. Wax, polyethylene, a combination of wax and polyethylene, cellophane and clay are representative coatings that can be applied to the first member 14 to facilitate comfortable insertion.

5 The first member 14 can be a straight, elongated cylindrical tube formed on a central longitudinal axis X—X (see Fig. 2). It is also possible to form the first member 14 into an arcuate shape. The arcuate or curved shape can assist in providing comfort when inserting the first member 14 into a woman's vagina. With a curved tampon applicator, it is possible to employ a curved tampon which again may be more comfortable for some women to use since the shape of the tampon may better fit the curvature of a woman's
10 vagina.

Referring to Fig. 1, an insertion tip 32 is shown having a plurality of pleats or petals 36 that can radially open such that the insertion tip 32 has a diameter approximately equal to or greater than the diameter of the first member 14. The pleats 36 can be either even or odd in number and can be equally spaced apart or non-uniformly arranged.

15 Referring again to Figs. 1 and 2, the first member 14 can have a fingergrip ring 40 located approximate the second end 30. The fingergrip ring 40 can be integrally formed from the material from which the first member 14 is constructed or it can be a separate member that is secured in place by an adhesive or some other type of attachment mechanism. The fingergrip ring 40 functions to provide a means for the user to grip the
20 first member 14 and hold it between her thumb and middle finger. The user can then position her forefinger on the free end of the second member 18 and orient the first member 14 relative to her vagina while she pushes the second member 18 into the first member 14.

As stated above, the tampon applicator 11 includes a second member 18, also
25 commonly referred to as an inner tube. The second member 18, like the first member 14, can be a spirally wound, a convolutely wound or a longitudinally seamed hollow tube constructed from paper, paperboard, cardboard, or other suitable material, or a combination thereof. The second member 18 can also be in the form of a seamless plastic tube. Any plastic in the second member 18 is preferably polyethylene, but may be
30 polypropylene or other suitable plastic. The second member 18 can be constructed of the same material as the first member 14 or it can be made out of a different material. The second member 18 may also be a solid stick or use some other unique shape. It is also possible to form a fingergrip ring or flange 44 on the outer end of the second member 18 to provide an enlarged surface onto which the user's forefinger can rest. The fingergrip

ring 44 thereby functions as a seat for the forefinger and facilitates movement of the second member 18 into the first member 14.

In an alternate embodiment (not shown), the first member 14 and second member 18 of the tampon applicator 11 may be replaced by a stick applicator. The stick applicator is used to insert the tampon 22, after which the stick applicator is withdrawn.

A tampon 22 is an absorbent member primarily designed to be worn by a woman during her menstrual period to absorb menses, blood and other body fluid. The tampon 22 includes a tampon body 50 and a withdrawal string 54. The tampon body 50 is normally compressed into the form of a cylinder and can have a blunt, rounded or shaped distal or tip end 58. The tampon body 50 has a distal end 58 that is closer to the cervix when the tampon 22 is in use. The tampon body 50 also has a proximal or string end 62 that is closer to the vaginal opening when the tampon 22 is in use.

The tampon 22 commonly has a withdrawal string 54 fastened to the proximal end 62 that serves as a means for withdrawing the tampon from the woman's vagina. The withdrawal string 54 can be looped through an aperture 74 formed transversely through the tampon body 50. In addition, the withdrawal string 54 can have a knot 78 formed at the free end of the string to assure that the string 54 will not separate from the tampon body 50.

Catamenial tampons suitable for use in the present invention include an absorbent material. The absorbent material can be formed from fibers that are assembled into an absorbent sheet or ribbon. Alternatively, the absorbent material can be formed from absorbent fibers that are assembled and compressed into a generally elongated and/or cylindrical configuration. The absorbent material is desirably formed from natural cellulosic fiber, such as cotton and rayon. For example, the absorbent material can be 100% cotton, 100% rayon, a blend of cotton and rayon fibers, or other materials known to be suitable for tampons, including artificial fibers such as polyester, polypropylene, nylon or blends thereof. The absorbent material may also include degradable fibers. Other types of materials or structures may also be used, such as cellulose sponge or a sponge formed from elastomeric materials. When formed, the absorbent material typically includes interstitial space or voids between the fibers or other materials.

Tampons 22 suitable for use in this invention are usually made of absorbent fibers, including one or both of natural and synthetic fibers, compressed into a unitary body of a size that may easily be inserted into the vaginal cavity. Fiber orientation is typically in a linearly- or radially-wound structure. Tampons 22 are normally made in an elongated cylindrical form in order that they may have a sufficiently large body of material

to provide the required absorbing capacity, but may be made in a variety of shapes. The tampon 22 is typically compressed. Compression may be achieved by predominantly longitudinally-, axially-, or radially-applied pressure, or a combination thereof. The tampon 22 may be made of various fiber blends including both absorbent and nonabsorbent fibers, which may or may not have a suitable cover or wrapper. The cover or wrapper for absorbent products, such as tampons and sanitary napkins, is often made from a sheet of nonwoven fibers, e.g., a spunbond polypropylene sheet. The tampon 22 may also include one or more of various treatments to improve the performance of the tampon 22, including reduced friction and increased absorption, delivery of the therapeutic agent, or a combination of treatments.

The fibers from which the present absorbent products are made may be produced, for example, by the meltblowing or spunbonding processes, including those producing bicomponent, biconstituent, or polymer blend fibers that are well known in the art. These processes generally use an extruder to supply melted thermoplastic polymer to a spinneret where the polymer is fiberized to yield fibers which may be staple length or longer. The fibers are then drawn, usually pneumatically, and deposited on a moving foraminous mat or belt to form the nonwoven fabric. The fibers produced in the spunbond and meltblown processes are microfibers as defined above. The manufacture of spunbond and meltblown webs is discussed generally above.

As mentioned, the nonwoven also may be a bonded carded web. Bonded carded webs are made from staple fibers, which are usually purchased in bales. The bales are placed in a picker, which separates the fibers. The fibers are sent through a combing or carding unit, which further breaks apart and aligns the staple fibers in the machine direction to form a generally machine direction-oriented fibrous nonwoven web. Once the web is formed, it then is bonded by one or more of several known bonding methods. One such bonding method is powder bonding, wherein a powdered adhesive is distributed through the web and then activated, usually by heating the web and adhesive with hot air. Another suitable bonding method is pattern bonding, wherein heated calender rolls or ultrasonic bonding equipment are used to bond the fibers together, usually in a localized bond pattern, though the web can be bonded across its entire surface if so desired. Another suitable bonding method, particularly when using bicomponent staple fibers, is through-air bonding.

An exemplary absorbent material is a nonwoven web composed of 3.0 denier polyethylene sheath/polypropylene core bicomponent staple fibers having a length of 38 millimeters. Such bicomponent fibers can be obtained from Chisso Corporation and are

typically supplied with a vendor fiber finish or other treatments. The staple fibers can be sent through an opener and uniformly mixed together before being carded into a web at a line speed of 15.24 meters per minute (50 feet per minute). Once the web is formed, it can be sent through a through-air bonder (drum type) with an air temperature of 131°C.

5 Typical dwell times within the bonder are between 3 and 4.5 seconds. The resultant web, which has a basis weight of 100 gsm and a density of 0.06 gm/cm³, can then be wound up on a roll.

A therapeutic agent delivery system 10 including a therapeutic agent can be produced integrally with the tampon 22. For the purposes of this invention, any

10 therapeutic agent that will be absorbed into a user's body through the vaginal epithelium for the purposes of treating diseases or conditions such as, for example, dysmenorrhea, can be used. Alternatively, or in addition, therapeutic and other beneficial agents such as vitamins, hormones, moisturizers, antifungal agents, antibacterial agents, pro-biotic agents that promote the growth of normal vaginal bacterial flora, and the like may be

15 similarly delivered.

Therapeutic agents for use in the invention are absorbable through the vaginal epithelium and travel to the uterus by a unique portal of veins and arteries which are known to exist between the vagina, the cervix and the uterus. This anastomosis eliminates so called first pass metabolism by the liver, effectively delivering higher

20 concentrations of therapeutic agent to the uterus than would otherwise be available via oral dosing. One skilled in the art knows the efficacy of therapeutic agents in such an application when introduced at a particular anatomical location. For example, when the therapeutic agent is selected to treat dysmenorrhea, it preferably is selected from the group consisting of nonsteroidal anti-inflammatory drugs (NSAIDs), prostaglandin

25 inhibitors, COX-2 inhibitors, local anesthetics, calcium channel blockers, potassium channel blockers, β-adrenergic agonists, leukotriene blocking agents, smooth muscle inhibitors, and drugs capable of inhibiting dyskinetic muscle contraction.

The dosage form 64 can be any drug, excipient, formulation, compound, or combination thereof that is desirable to introduce into the vaginal cavity. The dosage form

30 64 can be combined with any absorbent tampon design. The dosage form 64 is preferably positioned at the distal end 58 of the tampon 22. The dosage form 64 can be designed to partially cover the absorbent structure on the tip of the tampon 22 or fully cover the tampon tip. The medicated tampons can be formed into specific shapes such as various cup shapes to enhance the drug contact area with the cervix, posterior fornix,

vaginal epithelium areas, or conformance to other anatomical areas within the vaginal cavity.

The content and structure of the dosage form 64, including possible therapeutic agents, beneficial agents, excipients, and the like, are further described in co-pending
5 patent application _____, incorporated herein by reference.

In one embodiment, the formulation including a therapeutic agent is produced in tablet, capsule, or suppository form. In alternate embodiments, the tablet, suppository, or capsule may be designed to melt at approximately body temperature, or to dissolve or otherwise disperse in the presence of sufficient humidity or appropriate chemistry, such as
10 a suitable pH. The physical form of the formulation including a therapeutic agent is referred to herein as a dosage form 64, although the dosage form 64 may be in any suitable form including, but not limited to, tablets, capsules, suppositories, disks, lozenges, coatings, and the like.

The dosage form 64 may be produced by the same manufacturer as the
15 manufacturer of the tampon 22. The dosage form 64 may also be produced by a separate manufacturer and provided to the tampon manufacturer in any suitable manner. As an example, a dosage form manufacturer with a facility specifically designed for pharmaceutical manufacturing can produce the dosage form 64 under conditions such that homogeneity, concentration, and purity of the dosage form 64 are closely controlled,
20 and such that production is in accordance with applicable regulations. The dosage form 64 can then be sealed and shipped to the tampon manufacturer. The tampon manufacturer can then apply the dosage form 64 to a tampon 22 under appropriately-controlled conditions. In this manner, the dosage form 64 is produced by a manufacturer with appropriate experience, and the tampon manufacturer is relieved of establishing a
25 pharmaceutical-production facility.

The dosage form 64 after being shipped from the dosage form manufacturer to the tampon manufacturer can be fed into a machine process where it may be combined with a tampon 22. In one method of assembling the therapeutic tampon system 10, a portion of the dosage form 64 is heated to partially melt the excipient in that portion. In alternate
30 embodiments, all or a portion of the dosage form 64 may be partially or fully melted. The dosage form 64 is then abutted with the tampon body 50 such that the partially-melted portion is applied with appropriate pressure to engage the tampon body 50. The partially-melted portion then re-solidifies, becoming attached to the tampon body 50. In one embodiment, the dosage form 64 is thereby mechanically engaged with the fibers of the

tampon body 50. In another embodiment, the dosage form 64 is thereby chemically engaged with the tampon body 50.

In one embodiment described herein, a pre-made dosage form 64 is attached to the tampon body 50 using pressure, a heat source, or a combination of pressure and heat, to partially or fully melt a portion of the dosage form 64 itself. In an alternate embodiment, this attachment could be accomplished in a manufacturing environment by introducing a small amount of heated, melted SUPPOCIRE-brand suppository base onto the distal end 58 of the tampon body 50 just prior to introducing the dosage form 64 onto the distal end 58. The heat contained in the melted SUPPOCIRE-brand suppository base partially melts the dosage form 64 and creates a secure bond when both liquids cool and solidify. Solidification may be assisted by cooling the tampon body 50.

In an alternate method of assembly, the dosage form 64 is at least partially coated with a suitable biologically-compatible adhesive as is known in the art and then abutted with the tampon body 50 such that the dosage form 64 is affixed to the tampon body 50.

In an alternate embodiment, the tampon 22 and the dosage form 64 are provided to a consumer, either in the same or separate packaging. The packaging of the dosage form 64, the tampon 22, or both may include instructions concerning use of a medicated tampon including when a medicated tampon should be used, how it should be used, and how the dosage form 64 and the tampon body 50 may be coupled. The tampon 22 and the dosage form 64 may be provided by the same vendor, or acquired by the consumer from different vendors. For this embodiment, the dosage form 64 may be designed to be compatible with only one type or brand of tampon 22, or with more than one type or brand of tampon 22. The consumer can then apply the dosage form 64 to the tampon 22 as needed, or use the tampon 22 without a dosage form 64.

In one embodiment, the tampon 22 provided has a recess 66 at the distal end 58, at the proximal end 62, or at any point between the distal and proximal ends 58, 62, where the recess is designed to accommodate the dosage form 64. Other embodiments of dosage form 64 and tampon 22 structure and arrangement are as described above.

In alternate embodiments, the tampon 22 and/or the dosage form 64 are provided with a biologically-compatible adhesive or other suitable means to facilitate attachment of the dosage form 64 to the tampon 22. The biologically-compatible adhesive may be covered by a removable protective strip or covering. The tampon 22 may include a recess 66 adapted to capture the dosage form 64 by physical pressure alone, such as a slot in the distal end 58 of the tampon 22 into which the dosage form 64 may be inserted, and in which the tampon 22 encloses at least a portion of the dosage form 64. The dosage form

64 may include a portion that is self-heating upon exposure to air or humidity once the dosage form packaging is opened. The dosage form 64 may also include a portion that is heated by the dosage form packaging. The tampon body 50 may include a portion that is self-heating upon exposure to air or humidity once the tampon body packaging is opened.

5 The tampon body 50 may also include a portion that is heated by the tampon body packaging. In any of these cases, the heated portion of the dosage form 64 or the tampon body 50 is then abutted to the other of the tampon body 50 and the dosage form 64 by the consumer such that the dosage form 64 bonds with the tampon body 50 as the portion of the dosage form 64 cools or otherwise sets.

10 In another alternate embodiment, the tampon 22 provided to the consumer includes a gap between the distal end 58 of the tampon 22 and the petals 36. The consumer can then combine the dosage form 64 with the tampon 22 simply by inserting the dosage form 64 into the gap. The dosage form 64 is thereby held in place between the tampon body 50 and the petals 36, and is inserted with the insertion of the tampon
15 body 50.

In various embodiments, the tampon 22 may include a recess, a dimple, a depression, a concavity, or a reservoir (generically a recess) 66 at the distal end 58 (see Fig. 2), at the proximal end 62, or at any location between the distal and proximal ends 58, 62. The recess 66 is designed to accommodate the dosage form 64, which can be
20 applied to the recess by any method described herein or by any other suitable method.

In use, and referring to Fig. 2, the applicator 11 functions because the second member 18 is telescopically movable relative to the first member 14. As the second member 18 is pushed into the first member 14, the tampon 22 is forced forward against the pleats or petals 36. The contact by the tampon 22 causes the pleats 36 to radially
25 open to a diameter that is sufficient to allow the tampon 22 to be expelled from the first member 14. With the tampon 22 properly positioned in the woman's vaginal cavity, the tampon applicator 11 is withdrawn and properly discarded.

Once the tampon 22 is properly positioned in the woman's vaginal cavity, the tampon body 50 may absorb menses and other bodily fluids, and the dosage form 64 may
30 also deliver the therapeutic agent to the vaginal epithelium. From there, the therapeutic agent is transferred to the uterus by normal bodily functions to relieve the condition to be treated.

The invention has been described with reference to various specific and illustrative embodiments and techniques. However, it should be understood that many variations

and modifications may be made while remaining within the spirit and scope of the invention.

Accordingly, this invention is intended to embrace all such alternatives, modifications and variations that fall within the spirit and scope of the appended claims.

5

We claim:

- 5 1. A tampon adapted to deliver a therapeutic agent, the tampon comprising:
a tampon body, wherein the tampon body is manufactured at a first manufacturing
facility; and
a dosage form adapted to be coupled to the body, wherein the dosage form
includes a formulation including a therapeutic agent, and wherein the dosage form is
manufactured at a second manufacturing facility.
- 10 2. The tampon of claim 1, wherein the first manufacturing facility is that of a
pharmaceutical manufacturer.
3. The tampon of claim 1, wherein the second manufacturing facility is that of
15 a tampon manufacturer.
4. The tampon of claim 1, wherein the tampon body and the dosage form are
adapted to be coupled by a manufacturer.
- 20 5. The tampon of claim 1, wherein the dosage form is shipped to the first
manufacturing facility, and wherein the dosage form is coupled to the tampon body in the
first manufacturing facility.
6. The tampon of claim 1, wherein the tampon body is shipped to the second
25 manufacturing facility, and wherein the dosage form is coupled to the tampon body in the
second manufacturing facility.
7. The tampon of claim 1, wherein the dosage form is coupled to the tampon
body by partially melting the dosage form.
- 30 8. The tampon of claim 7, wherein partially melted dosage form partially
absorbs into the tampon body.
9. The tampon of claim 7, wherein the dosage form is partially melted by
35 heating the tampon body, and contacting the dosage form with the body.

10. The tampon of claim 1, wherein the dosage form is coupled to the tampon body using a biologically-compatible adhesive.

11. The tampon of claim 1, wherein the dosage form and the tampon body are adapted to be sold separately to a consumer.

12. The tampon of claim 1, wherein the tampon body and the dosage form are adapted to be coupled by a consumer.

13. The tampon of claim 12, wherein the dosage form is coupled to the tampon body by the consumer by partially melting the dosage form.

14. The tampon of claim 13, wherein partially melted dosage form partially absorbs into the tampon body.

15. The tampon of claim 12, wherein the dosage form is partially melted by heating the tampon body, and wherein the dosage form is coupled to the tampon body by the consumer contacting the dosage form with the tampon body.

16. The tampon of claim 12, wherein the dosage form is coupled to the tampon body by the consumer using a biologically-compatible adhesive.

17. The tampon of claim 16, wherein the dosage form includes the biologically-compatible adhesive, and wherein the biologically-compatible adhesive is protected by a covering.

18. The tampon of claim 1, wherein the first and second manufacturing facilities are the same manufacturing facility.

30

19. A method for producing a medicated tampon, the method comprising:
manufacturing a tampon body at a first manufacturing facility;
manufacturing a dosage form at a second manufacturing facility, wherein the
dosage form includes a formulation including a therapeutic agent; and
5 coupling the dosage form to the tampon body.

20. The method of claim 19, further comprising shipping one or both of the
tampon body and dosage form such that the tampon body and the dosage form reside in
the same manufacturing facility.

10

21. The method of claim 19, wherein the coupling act is performed in a
manufacturing facility.

22. The method of claim 19, further comprising melting at least a portion of the
15 dosage form.

23. The method of claim 22, wherein the melting act includes heating the
tampon body, and contacting the dosage form with the body.

20 24. The method of claim 22, wherein the melting act includes heating the
dosage form, and contacting the dosage form with the body.

25. The method of claim 22, wherein the melting act includes heating the
dosage form, and contacting the dosage form with body, wherein the body has been
25 cooled.

26. The method of claim 19, further comprising applying a biologically-
compatible adhesive to one of the tampon body and the dosage form.

30 27. The method of claim 19, further comprising providing the tampon body to a
consumer.

28. The method of claim 19, further comprising providing the dosage form to a
consumer.

35

29. The method of claim 19, wherein the coupling act is performed by a consumer.

5 30. The method of claim 29, wherein the coupling act includes partially melting the dosage form.

10 31. The method of claim 30, wherein the coupling act includes heating the tampon body, and contacting the dosage form with the tampon body to partially melt the dosage form.

32. The method of claim 29, wherein the coupling act includes affixing the dosage form to the tampon body using a biologically-compatible adhesive.

15 33. The method of claim 32, wherein the coupling act includes removing a protective covering from the biologically-compatible adhesive.

34. A method for enabling a consumer to choose whether to use a medicated tampon or a non-medicated tampon, the method comprising:
20 providing a dosage form to the consumer, wherein the dosage form includes a formulation including a therapeutic agent, and wherein the dosage form is adapted to be used in conjunction with a tampon having a tampon body;
providing a means for coupling the dosage form to the tampon body; and
providing instructions concerning the use of a medicated tampon.
25

35. A method for using a medicated tampon, the method comprising:
obtaining a tampon having a tampon body;
obtaining a dosage form, wherein the dosage form includes a formulation including
30 a therapeutic agent, and wherein the dosage form is adapted to be used in conjunction with the tampon; and
coupling the dosage form to the tampon body.

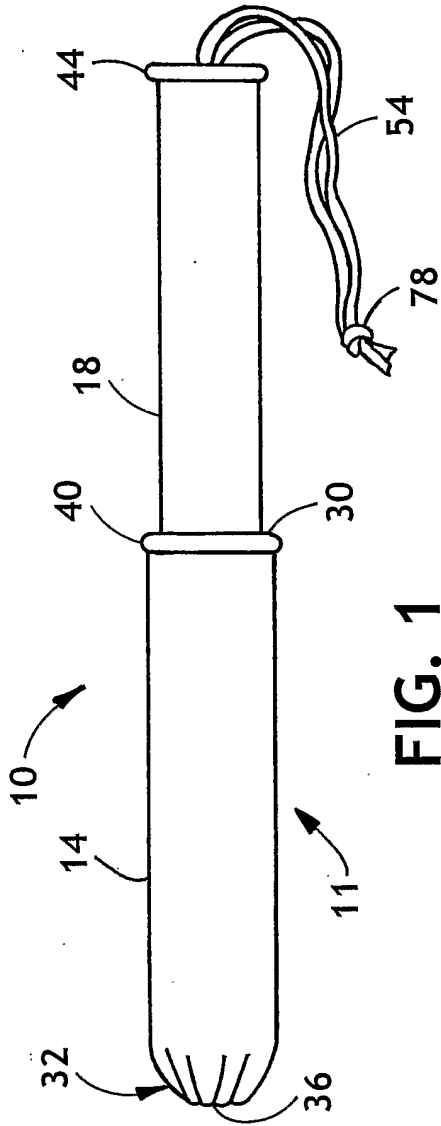


FIG. 1

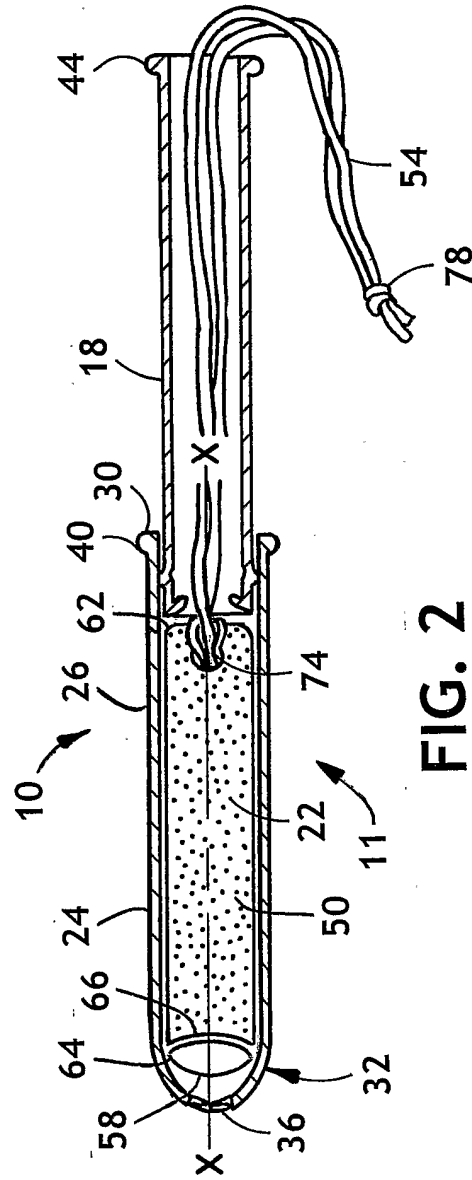


FIG. 2

INTERNATIONAL SEARCH REPORT

 International Application No
 PCT/US 03/00490

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K9/00 A61F13/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
 Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 A61K A61F A61M A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 110 793 A (PASQUINI MICHEL) 13 June 1984 (1984-06-13) page 1, line 22 - line 28 page 2, line 22 -page 4, line 8 figures claims --- -/--	1-6, 10-12, 16-21, 26-29, 32, 34, 35



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *P* document published prior to the international filing date but later than the priority date claimed

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- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

4 July 2003

Date of mailing of the international search report

14/07/2003

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INTERNATIONAL SEARCH REPORT

 Int il Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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