



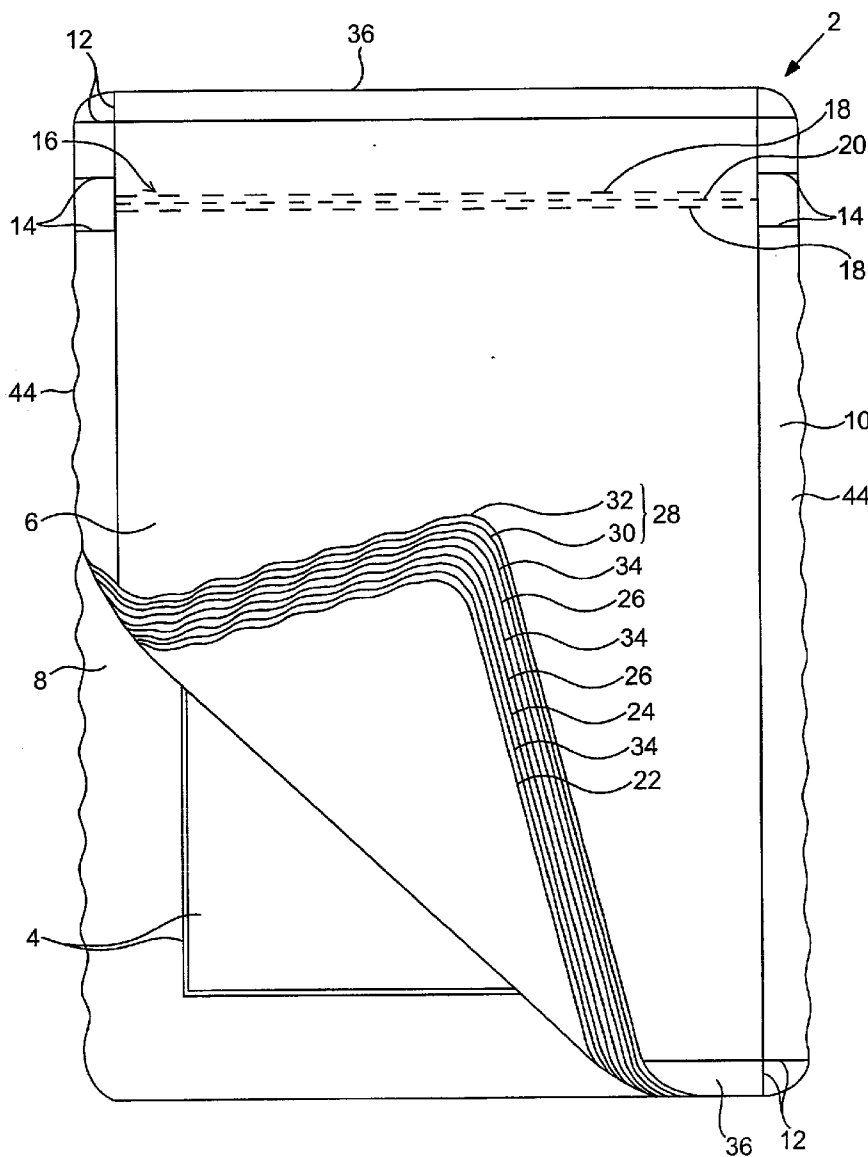
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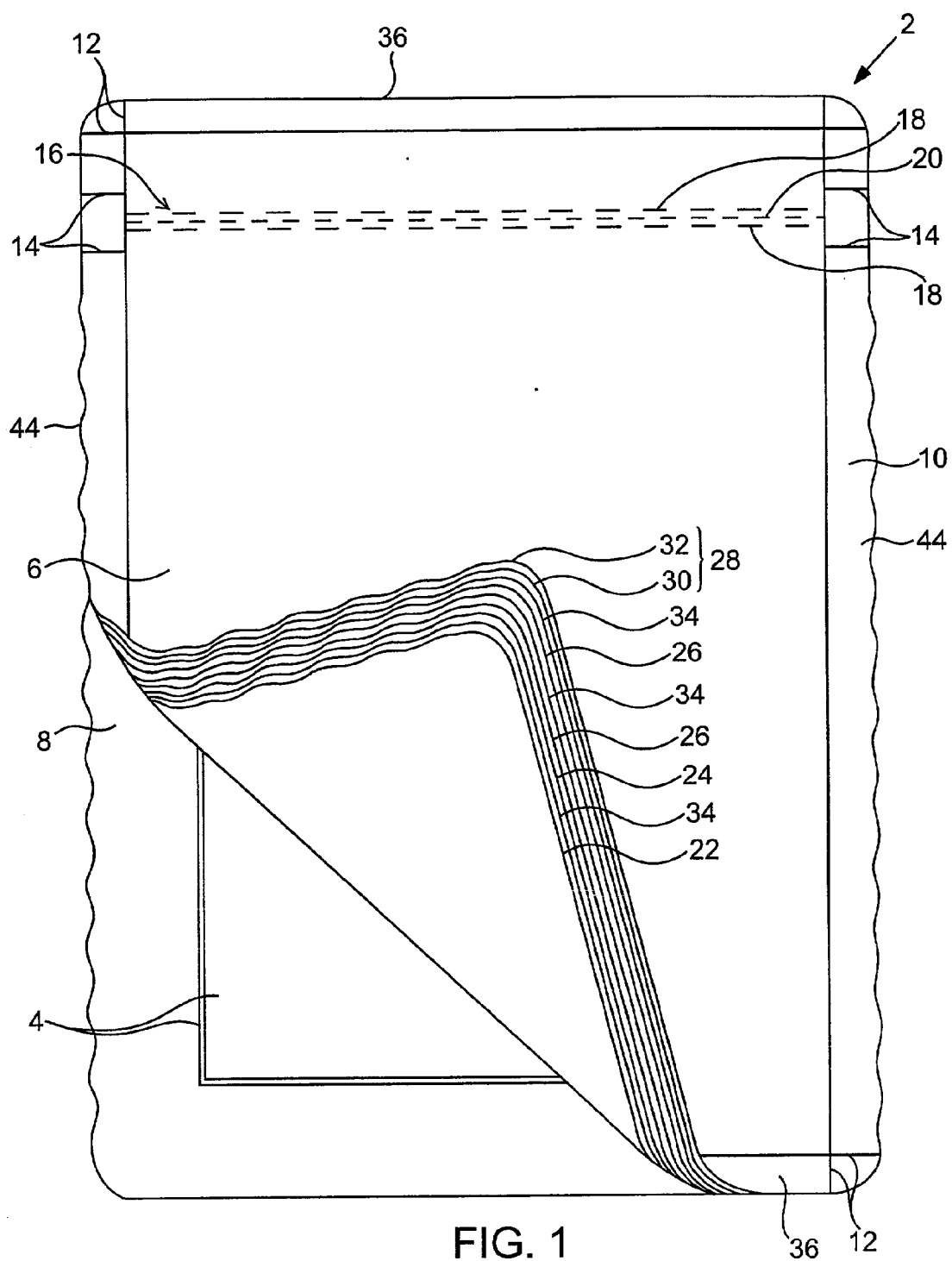
(19) **United States**(12) **Patent Application Publication****Shudo et al.**(10) **Pub. No.: US 2004/0159575 A1**(43) **Pub. Date: Aug. 19, 2004**(54) **ACCESS RESISTANT ENVELOPE**(52) **U.S. Cl. 206/532; 206/484**(76) Inventors: **Jutaro Shudo**, San Jose, CA (US);
Masanori Uematsu, Kagawa (JP)(57) **ABSTRACT**

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A human resistance pharmaceutical package is described. A package is provided in which access to a medicated pad, such as one saturated with Lidocaine, is obstructed unless opening is attempted using a cutting tool. The package is made from two heat-sealed panels. At least one of the panels is made of multiple layers including at least an outer printable layer and a pair of oriented nylon layers. Preferably, print and a varnish coat layer is provided on the facing surfaces. Aluminum layers may provide environmental protection for package contents. Usually, panel thickness will be limited for use with standard production line machinery. Together, the composite layers are preferably not so thick as to prohibit the use of common heat sealing machinery or modified typical machinery for production.

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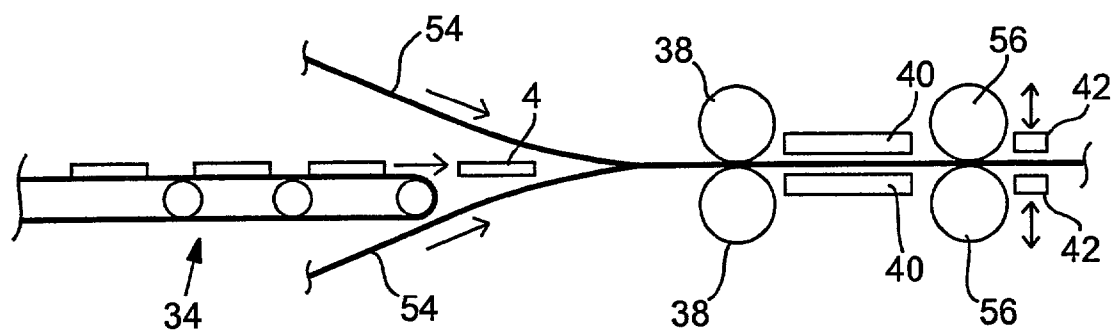


FIG. 2A

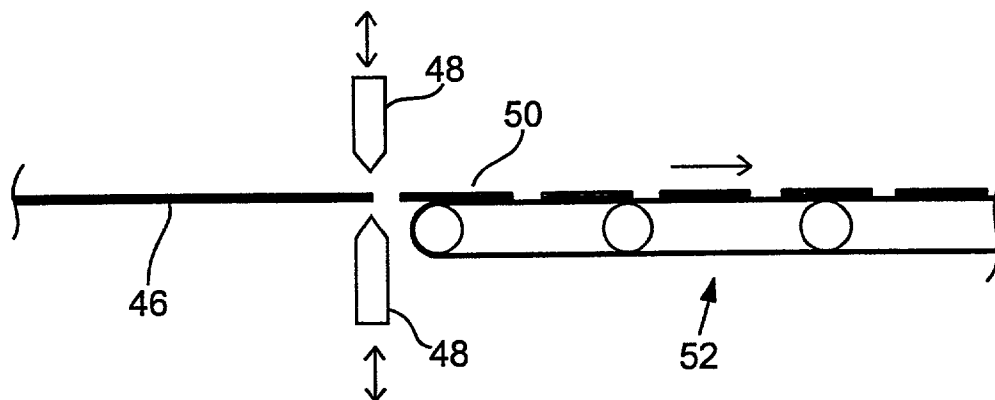


FIG. 2B

ACCESS RESISTANT ENVELOPE

FIELD OF THE INVENTION

[0001] This invention relates to packaging approaches for medical products, particularly medicated dermal pads.

BACKGROUND OF THE INVENTION

[0002] In recent years, a greater focus has been placed on safety issues associated with product packaging. Particularly with respect to drugs and foodstuffs, tamper resistant and child-resistant packaging is often either mandatory or at least practically required to sell product. For drugs, protecting against inadvertent access, however it might occur, is also important.

[0003] Access-resistant packages involving bottles and tubes containing tablets, gels, creams, ointments and the like are well known. However, for products not easily housed in such containers, few options are available. The present invention meets this need by providing an access-resistant envelop. It conveniently serves the dual purposes of basic packaging and a safety system, especially for such things as topical patch-type drug products, topical cosmetics, and medical devices.

SUMMARY OF THE INVENTION

[0004] The present invention includes tamper or access resistant envelopes or packages. It especially contemplates packaging for medicated pads constructed in such a way to avoid access by hands or teeth, particularly human hands or teeth. The inventive package is constructed so the only practicable method of opening it is with a cutter such as scissors or a knife. Accordingly, it is believed that the present invention will meet or exceed the child resistance and consumer product safety standards of the U.S. and various other countries, thereby satisfying a serious need.

[0005] The package comprises two heat-sealed panels or sides, one or both of them made of multiple layers including at least an outer printable layer and a pair of oriented nylon layers. Preferably, print and a varnish coat layer is provided on the facing surfaces and an aluminum layer, sometimes a polyacrylonitrile (PAN) layer is provided on the inside of each panel.

[0006] The invention includes methods of producing the packaged combination of a pad and the access resistant package, the combination itself and the package itself. It further includes such variations as would be apparent to one with skill in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Each of the following figures provide examples diagrammatically illustrating aspects of the present invention.

[0008] **FIG. 1** shows an overview of the invention.

[0009] **FIG. 2A and 2B** schematically illustrate production line elements for assembling the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0010] Before the present invention is described in detail, it is to be understood that this invention is not limited to the

particular variations set forth and may, of course, vary. Various changes may be made to the invention described and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps to the objective, spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims made herein. Furthermore, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. That the upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

[0011] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, the preferred methods and materials are now described. All publications, patents and patent applications mentioned herein are incorporated herein in their entirety. The referenced items are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such material by virtue of prior invention.

[0012] It is also noted that as used herein and in the appended claims, the singular forms "a," "and," and "the" include plural referents unless the context clearly dictates otherwise. In the claims, the terms "first," "second" and so forth are to be interpreted merely as ordinal designations, they shall not be limiting in themselves. Further, the use of exclusive terminology such as "solely," "only" and the like in connection with the recitation of any claim element is contemplated. Also, it is contemplated that any element indicated to be optional herein may be specifically excluded from a given claim by way of a "negative" limitation. Finally, it is contemplated that any optional feature of the inventive variation(s) described herein may be set forth and claimed independently or in combination with any one or more of the features described herein.

[0013] Turning now to **FIG. 1**, product according to the present invention including an envelope **2** and at least one medicated pad or patch **4** is shown. The envelope comprises a first panel **6** and a second panel **8**. The first panel is shown with its constituent parts splayed apart. The second panel is preferably similarly constructed. Though two pads **4** are shown going into envelope **2**, each package typically contains anywhere from one to five pads or patches.

[0014] An exemplary pad for inclusion in the package is sold as the Endo Laboratories LIDODERM® patch available through Endo Pharmaceuticals, Inc. (Chadds Ford, Pa.:

U.S.A.) and manufactured by Teikoku Seiyaku Co. Ltd (Sanbonmatsu, Kagawa: Japan), the latter being the assignee of the present invention. It is a 5% strength patch utilizing 700 mg lidocaine in an aqueous base. Other potential active ingredient(s) other local anesthetics, e.g., Benzocaine, Dibucaine, Tetracaine; steroidal anti inflammatory drugs, e.g., Hydrocortisone, Predonisolone, Dexamethasone, Triamcinolone or Betamethasone; COX-2 specific non steroidal anti inflammatory drugs (NSAIDs), e.g., Celecoxib or Rofecoxib; other NSAIDs, e.g., Acetoaminophen, Ketoprofen, Flurbiprofen, Felbinac, Diclofenac, Indomethacin, Naproxen; antihistamines, e.g., Diphenhydramine or Tripelemamine; or other drugs such as Capsaicin, Methyl salicylate, Camphor or Phenol. Such active ingredients may be carried as in the exemplary patch, by a gel-type medium or otherwise.

[0015] The package panels are preferably joined around the periphery through heat sealing. The outer margin 10 demarcated by lines 12 are joined in a finished package 2. Line breaks 14 are indicative of a region that may initially left open or unsealed so that a sealing or resealing mechanism 16 can be inserted and then sealed in place as is preferred. The sealing mechanism is preferably a ZIPLOC® type seal with outer members 18 able to capture and release an inner member 20.

[0016] The sealing mechanism is important in situations where a volatile product, such as the referenced pad is to remain in the package after it is initially opened in the region above the seal. The sealing member allows for conveniently resealing the pouch to preserve content's efficacy (or freshness in the case of perishables stored therein). Where only one single-use pad 4 is to be included in the envelope, the sealing mechanism is preferably omitted and the envelope sealed around the entire periphery as easily accomplished by the manufacturing techniques described below.

[0017] Either one or both of the panels comprise a number of material layers. Most preferably, the following layers are contemplated. Broadly speaking, such a package usually employs an inside layer 22, an aluminum layer 24, at least two oriented nylon layers 26, and cosmetic external layers 28, preferably comprising a layer 30 upon which print is applied and a print-protective layer 32. Between adjacent primary layers, adhesive layers 34 are employed. The adhesives used may be of any sort normally used to adhere packaging materials. It may, however, be desired to use a layer of polyethylene (PE) to seal adjoining layers upon the application of heat as further described below.

[0018] Typically, inside layer 22 comes into direct contact with the packaged product. During manufacture, it is preferably melted and adhered to an opposing panel layer by heat sealing in the packaging process. In such instances, layer 22 may comprise PE, ethylene methacrylic acid copolymer (EMAA), or ethylene acrylic acid copolymer (EAA). In cases where the packaged products include a volatile substance such as a volatile oil, PAN can be used on or as the inside layer to moderate adsorption of the volatile substance.

[0019] The next major layer 24 is an optional aluminum layer. Such a layer contributes to the stability of the packaged contents. It is substantially gas and light impermeable

so as to shield package contents 4 from the external environment and associated degradation (e.g., oxidization, other reaction or chemical breakdown).

[0020] Further, one or more resistance medium layers 26 are provided. Most preferably, at least two medium layers comprising oriented nylon are provided. This material is both flexible and tough and (especially when taken together) is extremely resistant to opening by human hands or teeth.

[0021] As stated above, external layers 28 may comprise a printed layer 30 and a protective layer 32. Layer 30 may comprise paper, a polyester film, or another material, especially one with is easily printed upon. Any number of approaches may be taken toward printing as would be apparent to those with skill in the art. If applied, especially to protect the print, layer 30 may comprise varnish as is commonly used for such applications.

[0022] Usually, overall panel thickness is limited to facilitate processing with standard production line machinery. Together, the total thickness of the layers on each side of package 2 are less than about 200 μm thick since greater thickness may prohibit manufacture using modified common heat sealing machinery. Where a total of 4 oriented nylon plies of material are employed in the package, they are preferably each between about 20 and 45 μm thick to facilitate manufacturing, while still exhibiting sufficient strength.

[0023] Where only one pair of oriented nylon layers is used (on either side or one on each), the material may be twice as thick without causing manufacturing difficulties. It is most preferred, however, that the package is constructed with at least two oriented nylon plies on each side of the package. Regardless, FIGS. 2A and 2B show portions of a manufacturing line adapted to produce the inventive package.

[0024] As shown in FIG. 2A, a packaged combination of pad(s) and the envelope or bag is prepared by supplying pads 4 by a conveyer 34 and material for panels 6 and 8 in a continuous web, e.g., in sheets or as unrolled from a spool. These webbing pieces 54 may be layed-up in advance and fed from a single feed roll as shown or each panel layer may be provided by separate feed rollers or as otherwise convenient. The layers of panel material may ultimately be fully laminated together or laminated around a periphery. In either case, they may be referred to as a "laminated."

[0025] The panel material and pad(s) are brought into proximity of one another before the panel material is cut along the horizontal sides 36 by heat-cutter type rollers 38. Following this, horizontal heat sealers 40 in close proximity to the webbing pieces heat the material. Then, rollers 56 compress the material together to securely bond them. Next, vertical heat sealers 42 are actuated to seal the vertical sides 44 of the envelope as now-joined material continues through the production line.

[0026] As shown in FIG. 2B, the joined web 46 of partially trimmed material progresses until it encounters vertical heat cutters 48. From this point, finished product 50 is transported to bulk packaging by a second conveyer 52.

EXAMPLE

[0027] For ease of manufacturing and material handling, the oriented nylon plies of a given side of the package

preferably have a grain or orientation aligned (i.e., placed substantially parallel) with one another. When the layers of material are oriented thus, rip or slip properties normally associated with oriented nylon packages are, surprisingly, not observed. Oriented nylon is actually often chosen for packaging material since packages using one layer of material on each side that is joined around the package periphery is easy torn open once a small rip is started. In the four-ply oriented nylon pouches according to the present invention, where the material grain of the sheets of oriented nylon are aligned with one another, it might be thought that similar tear propagation might occur.

[0028] However, comparative results shown otherwise. A pouch like that described above using two 25 μm oriented nylon layers (oriented in the same direction) for each side was compared to a pouch using only one 50 μm layer on each side. The overall construction of the pouches compared were as follows:

Front Side Laminate	Back Side Laminate
<u>Inventive Package Example:</u>	
(Outside)	(Inside)
Varnish Coating layer	EMAA layer (18 μm)
Printed Paper layer	Aluminum layer (7 μm)
Adhesive layer	Adhesive layer
Oriented Nylon layer (25 μm)	Oriented Nylon layer (25 μm)
Adhesive layer	Adhesive layer
Oriented Nylon layer (25 μm)	Oriented Nylon layer (25 μm)
Adhesive layer	Adhesive layer
Aluminum layer (7 μm)	Printed Paper layer
EMAA layer (18 μm)	Varnish Coating layer
(Inside)	(Outside)
<u>Comparative Package Example:</u>	
(Outside)	(Inside)
Varnish Coating layer	EMAA layer (18 μm)
Printed Paper layer	Aluminum layer (7 μm)
Adhesive layer	Adhesive layer
Oriented Nylon layer (50 μm)	Oriented Nylon layer (50 μm)
Adhesive layer	Adhesive layer
Aluminum layer (7 μm)	Printed Paper layer
EMAA layer (18 μm)	Varnish Coating layer
(Inside)	(Outside)

[0029] With these pouches, the task set for the test was to open a pouch given 5 minutes without any tools. Using only their hands and teeth, 2 out of 20 grown men were able to open the second pouch. However, none were able to open the first pouch using multiple plies of oriented nylon material on each side. Both are easily opened with scissors or another cutting implement.

Claims

[0030] Though the invention has been described in reference to a single example, optionally incorporating various features, the invention is not to be limited to the set-up described. It is to be understood that the breadth of the present invention is to be limited only by the literal or equitable scope of the claims.

That said, we claim:

1. An access resistant envelope comprising:
 - a first panel and a second panel, at least one of said panels in the form of a laminate comprising a plurality of oriented nylon layers.
2. The envelope of claim 1, wherein said plurality of oriented nylon layers is a pair of oriented nylon layers.
3. The envelope of claim 1, wherein both of said panels are in the form of a laminate comprising a plurality of oriented nylon layers.
4. The envelope of claim 3, wherein each plurality of oriented nylon layers is a pair of oriented nylon layers, thereby providing 4 oriented nylon layers.
5. The envelope of claim 4, wherein each oriented nylon layers is between about 20 to 45 μm thick.
6. The envelope of claim 1, wherein said at least one panel in the form of a laminate further comprises an external printable layer and an internal aluminum layer.
7. The envelope of claim 1, wherein both of said panels are in the form of a laminate further comprises an external printable layer and an internal aluminum layer.
8. An access resistant medical product envelope comprising an access resistant envelope as described in claim 1 containing at least one medicated pad.
9. The medical product envelope of claim 8, wherein said at least one medicated pad includes an active ingredient selected from a group of drugs consisting of local anesthetic drugs, steroidal anti inflammatory drugs, non steroidal anti inflammatory drugs, COX-2 specific non steroidal anti inflammatory drugs, Capsaicin, Methyl salicylate, Camphor and Phenol.
10. An access resistant medical product envelope made by a method comprising:
 - providing a medicated pad having first and second sides, and webbing pieces on each of said pad sides, wherein at least one of said webbing pieces comprises a plurality of oriented nylon layers;
 - sealing said webbing pieces together to form a periphery around said pad; and
 - cutting said envelope from said webbing pieces sealed together.
11. The method of claim 10, wherein two oriented nylon layers are provided.
12. The method of claim 11, wherein said two oriented nylon layers are aligned in orientation.
13. The method of claim 10, wherein four oriented nylon layers are provided.
14. The method of claim 11, wherein said four oriented nylon layers are aligned in orientation.
15. The method of claim 10, wherein adjacent oriented nylon layer are thermally bonded together using a polyethylene layer.
16. The method of claim 10, wherein said webbing pieces are thermally bonded using at least one layer of material selected from a group of plastics consisting of polyethylene, ethylene methacrylic acid copolymer, ethylene acrylic acid copolymer and polyacrylonitrile.

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