



METHOD AND APPARATUS FOR FORMING
A TRANSDERMAL DRUG DEVICE

Field of the Invention

5 The present invention relates to the field
of manufacture of medical devices for the
administration of a drug through the skin of a
patient, and more particularly relates to a method and
apparatus for the formation of such an article of
10 manufacture having a layered laminate structure
comprised of a backing layer, a drug-containing
pressure sensitive adhesive layer, and a release layer
or liner.

Background of the Invention

15 For some time now, it has been known by the
medical profession that certain drugs may be
administered to patients by being absorbed over a
period of time directly through the epidermis or skin
of the patient without using a hypodermic syringe or
20 other invasive technique. Drugs that are intended to
be administered in this manner may be compounded in a
matrix of other materials suitable for contact with
the skin of the patient. One technique for doing so
is to combine the drug to be administered
25 transdermally with a pressure sensitive adhesive which
can be firmly attached to the skin in a manner which
will assure excellent contact with the skin and allow
migration of the drug from the pressure sensitive
adhesive transdermally to the body of the patient.
30 When this technique is employed, the structure of the
article of manufacture includes a backing to protect
the pressure sensitive adhesive from contact with
other objects and to prevent loss of the drug. Also
included is a release liner which is to be removed
35 from the pressure sensitive adhesive immediately prior
to application thereof to the skin of the patient.



The structure of such transdermal drug delivery devices is shown and described in our application Serial No. 407,874, now U.S. Patent No. 5,032,207.

In order to facilitate practical and economical manufacture and use of such a transdermal device, it has been found useful to score the release liner so as to permit said liner to be easily removed from the adhesive carrying drug in one step. Our prior related applications describe various techniques and apparatus to accomplish this objective of scoring the liner to permit said liner to be easily removed from the drug-containing pressure sensitive adhesive. However, continuing development for improved manufacturing efficiency and operational considerations has resulted in improvement and variations to that described in the earlier cross-referenced applications. Accordingly, this application is directed to a reflection of those improvements.

Several apparatus and methods are believed to have been devised for intermittently or continuously scoring the release liner portion of a transdermal drug delivery device in order to permit said liner to be easily removed from the drug-containing pressure sensitive adhesive disposed between the release liner and the backing in such devices. The liner is, of course, removed from the device immediately prior to its being applied to the skin on the patient. The typical procedure for the preparation of a transdermal drug delivery device involves a plurality of steps. First, a dilution or suspension of the adhesive is compounded with an appropriate concentration of the drug and is applied to a flexible layer intended to function as a disposable release liner, frequently made of plastic. This release liner also forms, during processing, the



means to carry a pressure sensitive drug-containing adhesive through the manufacturing and cutting operation thereafter. Next, a non-releasable or primed backing material is applied over the adhesive.

5 The result is a laminate in the form of a web containing an adhesive with a backing on one side and a disposable release liner on the other side. A shaped and precisely sized device is then formed by peripheral cutting through all the layers of the
10 resulting web. The disposable release liner can then be removed and a second, scored release liner can be attached to the transdermal drug-containing adhesive.

Alternatively, the liner can be first scored and assembled with the adhesive and the backing and
15 then the laminate web cut to the desired dimensions.

The purpose of the multi-step procedure for applying the backing and the release liner to the adhesive containing the drug is to avoid problems encountered when a scored release liner is used in
20 processing. If a completely cut release liner is used prior to coating, the drug-containing adhesive can pass through the release liner at the score causing equipment problems, cracking, separation, heat damage, loss of raw materials, and possible exposure of
25 factory workers to the drug or similar environmental concerns.

Moreover, these prior art methods suffer from the disadvantage that the procedure for applying the release liner requires several steps, and thus
30 have a tendency to be more expensive in mass production than a procedure which involves fewer steps.

The present invention overcomes the difficulties and disadvantages associated with prior
35 art devices by providing a method and apparatus for simultaneously cutting an assembled transdermal drug



delivery device from a web comprising a backing layer,
a drug-containing pressure sensitive adhesive and
release liner while at the same time scoring the
release liner at a position intermediate to the
periphery of the transdermal drug delivery device.

Accomplishing the objectives of this
invention is achieved, in part, by providing cutting
edges which are simultaneously sized to cut completely
through the periphery of the laminate web to size and
form the transdermal drug delivery devices, but which
cutting edges are also sized to only cut or score the
release liner at a position intermediate to the
periphery, and which intermediate or center scoring
does not extend all the way to the adhesive nor to the
non-releasable backing. These advantages are
accomplished by the use of cutting edges having the
configuration and size of the transdermal drug
delivery device to be cut from the web which cutting
edges are sufficient in dimension to cut completely
through the web and thus through the backing,
adhesive, and release liner layers. At the same time,
the intermediate or center cutting edge is sized to
score the release liner to a point just short of the
adhesive liner or through the release layer, but not
to the adhesive.

There are, of course, prior art devices
which relate to apparatus for scoring or cutting
material in the form of a sheet, even when the same is
formed from a laminated product. For example, Forbes,
U.S. Patent No. 3,786,732, relates to an
apparatus for scoring a sheet like material. However,
it refers to the scoring of carton blank material.
The material thereby scored, is substantially
different from a pressure sensitive adhesive
containing laminate having a degree of dimensional
instability and less resistance to cutting action. It



is recognized that the apparatus of Forbes, Jr. does not teach a formation for cutting of a drug-containing pressure sensitive adhesive sandwiched between a backing layer and a release liner.

5 Another prior art reference is Woodall, U.S. Patent No. 1,963,393, which relates to the cutting of a laminated panel, particularly for a sun visor, to protect automobile drivers. The disclosure relates a panel formed of a sheet of thermal plastic material,
10 which has a fabric on one side attached by an adhesive.

 However, both of these references constitute non-analogous prior art, because one skilled in the art attempting to construct a nearly paper-thin
15 transdermal drug delivery device, substantially in the form of a bandage, and having a dimensionally unstable cross-section, would not expect to look for guidance in the arts of cutting and scoring laminated panels or sheet materials. The laminate of the subject
20 transdermal drug delivery device includes one relatively hard surface, i.e., the release liner, a soft or flexible surface, i.e., the backing layer, and a dimensionally unstable inner layer, i.e., the drug-containing pressure sensitive adhesive.

25 Summary of the Invention

 Bearing in mind the foregoing, it is a principal object of the present invention to provide an apparatus that will, with a singular mechanical motion accomplish the purposes of moving a laminate
30 web comprising a backing layer, a drug-containing pressure sensitive adhesive layer, and a release liner through a sizing operation, while at the same time cutting a periphery of a transdermal drug delivery device to thereby size and shape said device from the
35 laminate web, while at the same time scoring the release liner of said device to a precise degree



sufficient to facilitate easy removal of that liner from the drug-containing pressure sensitive adhesive layer, while at the same time avoiding cutting the release liner to a degree which will allow adhesive or any volatile solvent contained therein to pass through the liner and thereby escape prematurely from the transdermal drug delivery device.

A further principal object of the invention is to provide a single step method which causes movement of the laminate web from which a transdermal drug delivery device is to be formed, while at the same time forming said device to a predetermined size and shape, while at the same time scoring the layer of said device used as a disposable release liner to a precise degree in a manner which will avoid premature release of the drug-containing adhesive any volatile solvent or the drug itself.

Another object of the invention is to incorporate the foregoing objectives utilizing a rotary motion capable of continuous, precisely controlled and economical motion that is appropriate for efficient mass production of transdermal drug delivery devices.

An additional object of the invention is to achieve the aforementioned cutting action along a line disposed between the rotating cylindrical members positively rotating at the same angular speed, resulting in cutting force being asserted in a substantially linear and precise manner, rather than being distributed across the entire periphery and intermediate (or center) in a less precisely controlled manner requiring greater force because all points are substantially simultaneously cut.

A related object of the invention is to achieve the foregoing objects and advantages with an apparatus and method which avoids stopping and



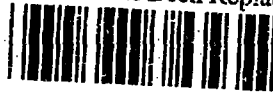
starting that is inherent in apparatus and methods which reciprocate, as is required in our prior invention disclosed in the cross-referenced related applications.

5 A collateral object of the invention is to reduce the unit manufacturing cost of transdermal drug delivery devices by utilizing rotating machinery, as opposed to reciprocating machinery, to achieve higher
10 production rates, less maintenance down time,¹ and consequent lower maintenance cost such as typically results from replacement of reciprocating machinery with rotating machinery.

 A further object of the invention is to position the cutting edges about the circumference of
15 a cylinder or roller while at the same time sizing the diameter of the cylinder such that a plurality of transdermal drug delivery devices can be cut from a moving laminate web in close packed arrangement and with a repeat length caused by prior sizing of
20 cylinder diameter to minimize waste in the web from which the transdermal drug delivery devices are cut using the inventive apparatus and method. This positioning of the cutting edges about the circumference of the cylinder is such as to close pack
25 the positioning to minimize waste of the web between the location of the transdermal drug delivery devices removed therefrom to achieve minimum waste and the greatest possible manufacturing economies.

30 Other objects and advantages will be apparent to those skilled in the art upon reference to the following descriptions and the drawings.

 In accordance with a major aspect of the invention, there is provided an apparatus including a plurality of cylinders in proximity to each other and
35 disposed such that the axis of each is coplanar with the axis of the other. Each such cylinder is



rotationally mounted in bearing means and supported thereby in a framework that permits the distance or pressure between the axes of the cylinders to be controlled. On at least one of these cylinders, referred to as the cutting cylinder or roller, are disposed cutting edges. These cutting edges are of two types, generally being of a type to cut and size the laminate web entirely therethrough to form the transdermal drug delivery device from the laminate web, and also of a type used to score simultaneously the release liner without affecting the drug-containing pressure sensitive adhesive adjoining the release liner, nor the backing layer adjoining the drug-containing pressure sensitive adhesive. The other cylinder is disposed and positioned in a manner proximal the cutting cylinder. The two cylinders are simultaneously driven to achieve substantially identical surface speed and in such proximity as to just permit the laminate web to pass therethrough as said cylinders rotate on their axes. Cutting action between these cylinders is achieved as said laminate web passes through the plane of the axes of both cylinders, simultaneously intersecting the peripheral cutting edges and the release liner scoring edge at the points which each of said edges are disposed on the surface of the cutting cylinder pass through the plane of the cylinder axes, thus achieving the linear cutting action above-described.

In accordance with this aspect of the invention, there is provided an apparatus comprising a rigid support means having a surface in the form of a first cylinder. This support cylinder has an axis and rotatably mounted on that axis is a shaft which, in turn, is mounted in bearing means, said bearing means being disposed within a framework. The support cylinder is later referred to as an anvil roller.

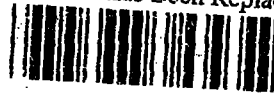


First cutting means are fixedly mounted on a second cylinder having an axis and a shaft coaxial therewith and also being rotatably mounted within bearing means. Said bearing means are disposed within a frame such that the axis of the first or support cylinder (anvil roller) and the axis of the cutting cylinder (cutting roller) are coplanar, with at least one pair of said bearing means being controllably movable with respect to a second pair of said bearing means to controllably vary the distance and/or pressure between the axes of the anvil roller and the cutting roller.

The first cutting means fixedly mounted on a surface of the cutting roller has a cutting edge extending outwardly from a surface of the cutting roller for a first predetermined distance. Said cutting edge is configured as a closed loop mounted on and projected above the surface of the cutting roller in a predetermined shape for defining a first region of the cutting roller surface.

Second cutting means are fixedly mounted on and projected above the surface of the cutting roller within said first region, said second cutting means having a cutting edge extending outwardly from the cutting roller for a second predetermined distance, said second predetermined distance being less than said first predetermined distance, said second cutting means dividing said first region of the cutting cylinder surface to form first and second sub-regions thereof.

A multilayered laminate web means includes a first layer of release liner, a second layer of a drug-containing pressure sensitive adhesive adhering to said release liner, and a third layer forming a backing adhering to the drug-containing pressure sensitive adhesive layer. Said laminate multilayered



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web is urged first layer first into communication with said first and second cutting means, said first cutting means being arranged to communicate with and penetrate through said first, second and third layers of said multilayered laminate web means, and said second cutting means being arranged to communicate with said first layer release liner only. Said urging is through the counter-rotation of the support cylinder and cutting cylinder in proximity to each other.

In accordance with another aspect of the invention there is provided a method in which a multilayered laminate web is urged between a pair of counter-rotating cylinders rotatably mounted in bearing means in proximity to each other, said multilayered laminate web being urged by said counter-rotation into a gap formed between a support cylinder and a cutting cylinder to achieve a cutting action of said multilayered laminate web along a line between the pair of cylinders and coplanar with the axis of both cylinders, with the method of cutting being established by a first cutting means fixedly mounted and projected on the surface of a cutting cylinder said first cutting means having a cutting edge extending outwardly from the cutting cylinder surface for a first predetermined distance. The cutting edge is configured as a closed loop in a predetermined shape for defining a first region projected on the cutting cylinder surface and having a second cutting edge fixedly mounted and projected on the cutting cylinder edge within said first region, said second cutting means having an edge portion extending outwardly from said cutting cylinder edge for a second predetermined distance. The second predetermined distance is less than said first predetermined distance, and said second cutting means



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divides said first region of said support cutting cylinder edge to form first and second sub-regions thereof. The laminate multilayered web means is formed of a first layer release liner, a second layer
5 formed of a drug-containing pressure sensitive adhesive adhering to said first layer, and a third layer formed of a backing adhering to said second layer. The multilayered laminate web means is urged by the counter-rotation of the cylinders in proximity
10 to each other into communication with first and second cutting means. The first cutting means is arranged to communicate with and penetrate through said first, second and third layers of said multilayered laminate web means, and said second cutting means is arranged
15 to communicate with said first layer only.

The invention will be better understood upon reference to the drawings and detailed descriptions thereof which follow, and which:

Brief Description of the Drawings

20 Figure 1 is a cross sectional view of a transdermal drug delivery device showing its multilayer laminate structure.

Figure 2 is a perspective view showing the apparatus of the invention in its simplest form, on
25 which only one cutting section is shown to form a single transdermal device.

Figure 3 is a perspective view of a cutting roller showing a close packed arrangement of cutting sections over substantially the entire surface of the
30 roller and also showing pressure journals, drive gear, and shaft ends.

Figure 4 is a perspective view of a stack in which the pair of rollers shown in figure 2 are centrally disposed between a lower rubber covered nip
35 roller, and an upper pressure roller.



Figure 5 is a broken slightly enlarged view showing cutting sections at the top side and bottom of the cutting roller.

5 Figure 6 is an alternative embodiment of half of figure 5 which employs a field of resilient material around the cutting sections to discharge the transdermal devices and scrap from the cutting roller after the transdermal device formation has occurred.

10 Figure 7 is a greatly enlarged broken cross sectional view taken along the line 7-7 of figure 5 and showing the detail of the construction of a cutting section.

15 Figure 8 shows the flow path of a laminate web through the invention. Conventional unwinding, scrap disposal, and proprietary transdermal device pick-up and packaging equipment are shown only generally since they are not a part of the present invention.

Detailed Description of Preferred Embodiment

20 Figure 1 is a cross section view of the laminate multilayer transdermal drug delivery device 10 and also the web material from which it is formed by the present invention. The laminate web or transdermal device 10 is comprised of a release liner 25 12, a drug-containing pressure sensitive adhesive layer 14, and a backing layer 16.

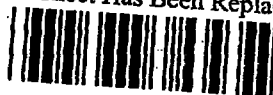
30 Figure 2 shows the essence of the invention in perspective view with a cutting roller 18 which rotates on axis 20 and an anvil roller 22 which rotates on axis 24. When viewed from left end faces 26 and 28, cutting roller 18 may, for example, rotate on axis 20 counter-clockwise and then anvil roller 22 will rotate on axis 24 clockwise. They will preferably be driven together positively so as to
35 operate with the same surface speed. Also shown in



figure 2 is a cutting section 30 having a peripheral cutting edge 32 and a center cutting edge 34.

Figure 3 illustrates a preferred embodiment of a cutting roller such as 18, except that this cutting roller 36 has the maximum number of cutting sections 30 disposed on its face in a close packed arrangement so as to minimize the losses resulting from scrap. All of the material in web 10 from which the transdermal devices are cut disposed between cutting sections 30 and 30' as shown at 38 constitutes scrap, which scrap necessarily includes not only backing material, release liner, and pressure sensitive adhesive, but also the drug for which the transdermal device formed by the present invention is to be used, which drug may be expensive. Accordingly, the preferred embodiment of the cutting roller show in figure 3 is to minimize scrap. The cutting roller of figure 3 is also shown with pressure journals 40 and 42. The purpose of these journals will be illustrated in the following figure. Also shown are shaft ends 44 which are preferably disposed within bearing blocks hereinafter illustrated for rotational support and positioning within an operating framework as hereinafter shown and described. On the drive end 46 of cutting roller 36 is also shown a driving means such as a spur gear 48 which meshes with similar driving means such as anvil roller spur gear similarly disposed for a positive drive therebetween, as illustrated in the following figure.

Figure 4 illustrates in perspective view the apparatus of the present invention through which the inventive method is practiced. Shown therein is a base 50 on which are mounted drive side frame 52 and operator side frame 54. Vertical columns 56 of drive side frame 52 and 58 of operator side frame 54 all



contain precision machined interior surfaces 60 for
slidable engagement of bearing blocks 62, 64, 66, and
68. Anvil roller bearing blocks 70 and 72 are not
slidable. Drive side frame 52 and operator side frame
5 54 both contain a top 72 centrally perforated by a
threaded hole 74 through which is disposed a threaded
pressure applicator 76 which is rotated for that
purpose using knurled knob 78. Rotationally disposed
between bearing block 68 and bearing block 62 and 68,
10 is pressure roller 80 which contains symmetrically at
both ends, a pressure journal 82 having a precision
machined circumference 84. Disposed between bearing
blocks 64 and 66 is cutting roller 86 on which can be
seen pressure journal 42 and spur gear 48. Also shown
15 are a plurality of cutting sections 30.

Before leaving the combination of the
pressure roller 80 and cutting roller 86, it is well
to examine several other features. Frame 52 retains
lips 88 which ride over the inside surfaces of
20 vertical columns 56 thereby restraining bearing blocks
within drive side frame 52 notwithstanding their
vertical movement. These lips 88 are also found in
symmetrical form on bearing blocks 62 and 64 in the
internal sides of operator's side frame 54. The
25 pattern is symmetrical with that shown for the drive
side and need not, therefore, be separately shown.
Another aspect of the relationship between pressure
roller 80 and cutting roller 86 is the existence of an
optional strain gauge 90 as shown between bearing
30 block 62 and bearing block 64 on the operator's side.
A companion strain gauge is also employed on the drive
side in symmetrical form, and strain gauges 90
cooperate with conventional electronic equipment to
permit reproducibility of the pressure applied to
35 cutting roller 86 by pressure roller 80.



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Rotationally supported between bearing blocks 70 and 72 is anvil roller 92 which cooperates with the cutting edges of cutting sections 30 to size and form the transdermal drug delivery devices. Anvil roller 92 includes, on the drive end, spur gear 94 which interconnects with cutting roller spur gear 48 to achieve a positive drive between anvil roller 92 and cutting roller 86. It is anvil roller 92 which is preferably driven by mechanical means connected to its drive shaft that penetrates bearing block 72, but the drive means is conventional and not shown. The entire circumference of anvil roller 92 is preferably precision machined, but this is particularly important at the ends because of contact with pressure journal 42 on the drive side and a symmetrical pressure journal 40 not visible in figure 4, but readily seen in figure 3. Pressure journals 42 and 40 establish a precise minimum spacing between anvil roller 92 and the cutting edges of cutting sections 30 on the surface of cutting roller 86.

The bottom roller in this stack is a rubber covered nip roller 96 which is not driven, except by contact with or pressure communicated from anvil roller 92. It is brought into contact by an adjusting mechanism which may optionally be eccentric 96, which is symmetrically provided at both the operator's side frame 54 as illustrated in figure 4, and also at drive side frame 52. The combination of anvil roller 92 and rubber nip roller 96 feed the laminate layered web of figure 1 into the previously described combination to achieve the inventive method using the inventive apparatus.

Turning now to figure 5, a broken front elevation view of cutting roller 86 is shown in a slightly enlarged view with cutting sections 30 at the top and bottom of the roller and also on the side

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facing the viewer. As briefly described in regard to figure 2, cutting sections 30 are comprised of a peripheral cutting edge 32 and an intermediate or center cutting edge 34. Peripheral cutting edge 32 is shown to wrap around the circumference of the roller in this figure. Although the dimensions are more fully described hereinafter, and cannot be readily seen with the degree of enlargement shown in figure 5, it should be understood that peripheral cutting edge 32 is intended to cut entirely through release layer 12, drug-containing pressure sensitive layer 14, and backing layer 16 as illustrated in figure 1, while center cutting edge 34 is intended to score release liner 12 without entering drug-containing pressure sensitive adhesive layer 14 or backing layer 16. The technology for doing so in a planar format is described in our parent application, Serial No. 407,874, now U.S. Patent No. 5,032,207, which is incorporated herein by reference.

Although the method and apparatus of this invention can be used with release liners that are less flexible, more flexible, or equally flexible as the combination of the backing and drug-containing pressure sensitive adhesive layers, it is desirable to use a backing having the same order of frangibility as the release liner, so that the force needed to cut the entire device, and at the same time score only the release liner, is about the same.

It is important to understand that the present invention represents several improvements over similar technology that is the subject of our prior application Serial No. 407,874, now U. S. Patent No. 5,032,207, which employed similar dimensional technology in a planar, reciprocating, total cut at one time, separately fed technique. As an improvement thereon, the present inventive method and apparatus



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achieved cutting essentially along a line representing the closest point between the cutting edges of cutting sections 30 of cutting roller 86 as seen in figure 4 and the surface of anvil roller 92. Thus as a given cutting section 30 translates by rotation of cutting roller 86 past the aforescribed line, cutting takes place progressively around the circumference of a given transdermal drug delivery device as the same translates through the closest proximity between the anvil roller and the cutting roller. Moreover, this motion also feeds the web at precisely the right speed to achieve a quality cut with maximum efficiency. The same also results in a continuous rotary motion thereby eliminating reciprocating motion which is inefficient, maintenance prone, slow, and less subject to uniformity.

Figure 6 shows an alternative embodiment to that shown in the previous figures in which the cutting sections 30 are surrounded by a layer of highly resilient material, such as a foam rubber 98. Foam rubber 98 will be seen not only to surround the peripheral cutting edge 32, but is disposed on either side of center cutting edge 34 as shown at 100. The resilient material 98 and 100 is intended to achieve rapid discharge of the cut transdermal devices from cutting roller 86 as well as the scrap left after cutting as shown at 38 in this figure, and in figure 2.

Figure 7 is a greatly enlarged cross sectional view of cutting section 30 taken along the line 7-7 of figure 5. It shows that, contrary to the disclosure of our parent application Serial No. 407,874, now U.S. Patent No. 5,032,207 the peripheral cutting edge 32 is in the form of an inverted V. That is also the configuration of center cutting edge 34 as illustrated in figures 5 and 6. The difference in

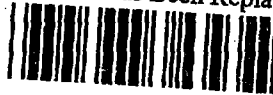


height between peripheral cutting edge 34 and center cutting edge 32, which has a shorter dimension is clearly shown by the great enlargement of figure 7. Specifically, the peripheral cutting edge 32 generally has a circumference of from 3 to 40 mm and preferably from 7.9 to 17.7 mm depending on the surface areas appropriate for delivery of the drug. It has a radius of 0.48 to 6.4 mm, and preferably 1.3 to 2.8 mm, again depending on the appropriate radius for the drug to be delivered, as is known to those skilled in the art.

As stated above, peripheral cutting edge 32 is sized, in cooperation with the thickness of the web shown in figure 1 to pass completely through the web, thus cutting through the release liner 12, drug-containing pressure sensitive adhesive layer 14, and backing material 16. Contrariwise, center cutting edge 34 scores the release liner 12 and does not penetrate drug-containing pressure sensitive adhesive layer 14 or backing liner 16. By way of illustration and in general, and without limitation, cutting edge 32 is preferably from 100 to 1,500 microns in height from the base surface of cutting roller 86, and more preferably 900 to 1,000 microns, and even more preferably 930 to 950 microns, although obviously the height of the cutting edge is dependent on the thickness of the web.

Similarly, center cutting edge 34 is preferably 100 to 1,500 microns, and more preferably 850 to 950 microns, and even more preferably 925 to 945 microns, although again the height is totally dependent on the thickness of the release liner. For example, with a web of 10 microns in thickness where the release liner is 6 microns in thickness, cutting edge 32 would be 937 microns in height, which center cutting edge 34 would be 935 microns in height. That is, center cutting edge 34 has to extend sufficiently

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into the release liner to cause a score, but not sufficiently to cut the drug-containing pressure sensitive adhesive layer.

Turning finally to figure 8, a schematic is shown of the web path by which the inventive method and apparatus operates. A quantity or stock of a laminate multilayer web as shown in figure 1, preferably in rolled form, is provided to the inventive apparatus and method and unwound using conventional technology as shown at 102. The web 10 enters the stack of rollers beneath a lower rubber cover nip roller 96 whose speed is derived by contact with or pressure transmitted from anvil roller 92. The rotational speed and diameter of rubber covered roller 96 sets the web 10 speed into exact conformity with a continuous rotary motion cutting that occurs thereafter. That is, the speed of web 10 is achieved by contact with rubber covered nip roller 96, in contact and combination with the speed of anvil roller 92. Web 10 then travels from between the nip formed by rubber covered nip roller 96 and anvil roller 92 around to the top of anvil roller 92 to enter into the cutting method and apparatus as occurs between cutting roller 86 and anvil roller 92 as hereinabove described. After cutting takes place, the web 10 is now comprised of scrap material surrounding each of the cutting sections 30 and the transdermal devices which maintain momentarily their position within web 10. Web 10 then travels across a transfer plate 104, which is perforated to prevent the buildup of adhesion or static electricity. The transdermal drug delivery devices are then removed from the web and packaged for storage, shipment, sale, and use, using equipment generally described for that purpose at 106. The same is not shown, described, or claimed in the present application as not constituting part of the present

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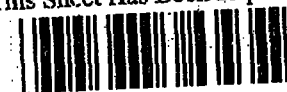
invention although it is proprietary. The remainder of web 10 constituting scrap is then continuously fed to waste disposal 108, of conventional means.

5 While the invention has been described in connection with a preferred embodiment, it will be understood that there is no intention to thereby limit the invention. On the contrary, there is intended to be covered all alternatives, modifications and
10 equivalents as may be included within the spirit and scope of the invention as defined by the appended claims, which are the sole definition of the invention.



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CLAIMS

1. An apparatus for forming a transdermal drug delivery device from a multilayer web having layers of a backing material, a drug-containing pressure sensitive adhesive, and a release liner comprising:

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a frame;

an anvil roller mounted in the frame to rotate about its axis;

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a cutting roller having a cylindrical surface mounted in the frame to rotate about its axis, which axis is coplanar with the axis of the anvil roller;

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at least one cutting section fixedly mounted on and projecting above said surface having a first cutting edge extending outwardly a first predetermined distance from the surface and configured as a closed loop for defining a region on said surface, and a second cutting edge extending outwardly from said surface a second predetermined distance, said second predetermined distance being less than said first predetermined distance, said second cutting edge dividing said region to form two sub-regions thereof;

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means to position the cutting roller in proximity to the anvil roller; and

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a drive means to counter-rotate the anvil roller and the cutting roller to urge the multilayer web between these rollers such that, progressively along a line coplanar with the axes of these rollers, the first cutting edge communicates with and cuts through the multilayer web while the second cutting edge communicates with and scores only the release liner.

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2. The apparatus of claim 1 which further comprise bearing means to support a shaft concentric with the axis of the anvil roller.

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3. The apparatus of claim 1 which further comprises bearing means to support a shaft concentric with the axis of the cutting roller.

5 4. The apparatus of claim 1 which further comprises:

a pressure roller rotatably mounted in the frame and having pressure roller journals at either end;

10 a means to exert force against the pressure roller; and

complimentary pressure journals on the cutting roller to rotationally communicate with the pressure roller journals.

15 5. The apparatus of claim 4 which further comprises bearing means to support a shaft concentric with the pressure roller journals.

6. The apparatus of claim 5 in which the bearing means is slidable with respect to the frame.

20 7. The apparatus of claim 6 in which the means to exert force on the pressure roller is a threaded pressure applicator, which threaded pressure applicator cooperates with a threaded hole in the frame.

25 8. The apparatus of claim 7 in which the threaded pressure applicator causes movement of the pressure roller by sliding its bearings with respect to the frame, thereby applying pressure through the pressure roller journals and complimentary pressure journals to the cutting roller.

30 9. The apparatus of claim 8 in which the bearing means of the cutting roller is slidable with respect to the frame and pressure applied to the cutting roller from its pressure journals in part positions the cutting roller in proximity to the anvil roller.
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10. The apparatus of claim 9 which further comprises pressure measuring devices attached to the frame to permit reproducibility of the positioning and pressure of the cutting roller in proximity to the anvil roller.

11. The apparatus of claim 1 which further comprises a positive drive connection between the cutting roller and the anvil roller to achieve substantially identical surface speeds.

12. The apparatus of claim 11 in which the positive drive connection is meshing spur gears on the anvil roller and cutting roller.

13. The apparatus of claim 1 which further comprises a resiliently covered nip roller rotatably mounted in the frame in proximity to the anvil roller, which nip roller rotation is caused by at least one of contact with and pressure communicated from the anvil roller, which nip roller in cooperation with the anvil roller urges the multilayer web toward the cutting roller at substantially a same linear speed as a surface speed of the cutting roller and anvil roller.

14. The apparatus of claim 1 which further comprises a transfer plate disposed in close proximity to the anvil roller and cutting roller to receive the transdermal drug delivery devices and scrap remains of the web from which the said devices were cut and scored.

15. The apparatus of claim 1 in which the cutting roller is sized with a diameter to achieve a repeat length when rotating that minimizes scrap losses from the web.

16. The apparatus of claim 15 in which cutting sections are positioned on the cutting roller in a close packed pattern to minimize scrap losses from the web.



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17. The apparatus of claim 1 which further comprises a field of resilient material attached to the cutting roller in proximity to but not touching the first and second cutting edges.

5 18. An apparatus for forming a transdermal drug delivery device from a multilayer web having layers of a backing material, a drug-containing pressure sensitive adhesive, and a release liner comprising:

a frame;

10 a pressure roller rotatably mounted in the frame and having pressure roller journals at either end;

a means to exert force against the pressure roller;

15 an anvil roller mounted in the frame to rotate about its axis;

20 a cutting roller having a cylindrical surface mounted in the frame to rotate about its axis, which axis is coplanar with the axis of the anvil roller, said cutting roller having complimentary pressure journals on either end to rotationally communicate with the pressure roller journals;

25 at least one cutting section fixedly mounted on and projecting above said surface having a first cutting edge extending outwardly a first predetermined distance from the surface and configured as a closed loop for defining a region on said surface, and a second cutting edge extending outwardly from said surface a second predetermined distance, said second predetermined distance being less than said first predetermined distance, said second cutting edge dividing said region to form two sub-regions thereof;

30 means to position the cutting roller in proximity to the anvil roller;

35 a resiliently covered nip roller rotatably mounted in the frame in proximity to the anvil roller,



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which nip roller rotation is caused by at least one of contact width and pressure communicated from the anvil roller, which nip roller in cooperation with the anvil roller urges the multilayer web toward the cutting roller at substantially a same linear speed as a surface speed of the cutting roller and anvil roller; and

a drive means to counter-rotate the anvil roller and the cutting roller to urge the multilayer web between these rollers such that, progressively along a line coplanar with the axes of these rollers, the first cutting edge communicates with and cuts through the multilayer web while the second cutting edge communicates with and scores only the release liner.

19. The apparatus of claim 18 which further comprises bearing means to support a shaft concentric with the axis of the anvil roller.

20. The apparatus of claim 18 which further comprises bearing means to support a shaft concentric with the axis of the cutting roller.

21. The apparatus of claim 18 which further comprises bearing means to support a shaft concentric with the pressure roller journals.

22. The apparatus of claim 21 in which the bearing means is slidable with respect to the frame.

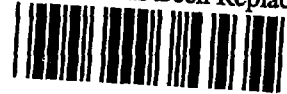
23. The apparatus of claim 22 in which the means to exert force on the pressure roller is a threaded pressure applicator, which threaded pressure applicator cooperates with a threaded hole in the frame.

24. The apparatus of claim 23 in which the threaded pressure applicator causes movement of the pressure roller by sliding its bearings with respect to the frame, thereby applying pressure through the



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pressure roller journals and complimentary pressure journals to the cutting roller.

25. The apparatus of claim 24 in which the bearing means of the cutting roller is slidable with respect to the frame and pressure applied to the cutting roller from its pressure journals in part positions the cutting roller in proximity to the anvil roller.

26. The apparatus of claim 25 which further comprises pressure measuring devices attached to the frame to permit reproducibility of the positioning and pressure of the cutting roller in proximity to the anvil roller.

27. The apparatus of claim 18 which further comprises a positive drive connection between the cutting roller and the anvil roller to achieve substantially identical surface speeds.

28. The apparatus of claim 27 in which the positive drive connection is meshing spur gears on the anvil roller and cutting roller.

29. The apparatus of claim 18 which further comprises a transfer plate disposed in close proximity to the anvil roller and cutting roller to receive the transdermal drug delivery devices and scrap remains of the web from which the said devices were cut and scored.

30. The apparatus of claim 18 in which the cutting roller is sized with a diameter to achieve a repeat length when rotating that minimizes scrap losses from the web.

31. The apparatus of claim 30 in which cutting sections are positioned on the cutting roller in a close packed pattern to minimize scrap losses from the web.

32. The apparatus of claim 18 which further comprises a field of resilient material attached to



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the cutting roller in proximity to but not touching the first and second cutting edges.

33. A method for forming transdermal drug delivery devices from a multilayer web having layers of a backing material, a drug-containing pressure sensitive adhesive and a release liner comprising:

feeding the multilayer web toward a cutting roller in proximity to an anvil roller, both rollers being mounted in a frame for rotation about their axes which are coplanar;

counter-rotating the cutting roller and anvil roller;

progressively along a line coplanar with the axes of both rollers cutting a region completely through the multilayer web using a first cutting edge configured as a closed loop and extending outwardly sufficiently from a surface of the cutting roller to penetrate all layers of the web; and

simultaneously along said line scoring only the release liner using a second cutting edge configured to divide the region into two sub-regions and extending outwardly from the surface of the cutting roller not sufficiently to penetrate the adhesive layer.

34. The method of claim 33 which further comprises substantially synchronizing a linear speed of the multilayer web with surface speeds of both rollers.

35. The method of claim 34 in which substantially synchronizing linear speed of the multilayer web with surface speeds of both rollers is achieved by passing the web between a resiliently covered nip roller rotatably mounted in proximity to the anvil roller, which nip roller rotates by at least one of contact with and pressure communicated from the anvil roller.



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36. The method of claim 33 which further comprises applying pressure to the cutting roller using a pressure roller rotatably mounted in the frame in proximity to the cutting roller, said pressure
5 resulting from rotational communication between pressure roller journals and complimentary pressure journals on the cutting roller.

37. The method of claim 36 which further comprises monitoring the pressure applied to the
10 cutting roller using a pressure measuring device attached to the frame to permit reproducibility of said pressure.

38. The method of claim 33 which further comprises cutting regions in the multilayer web and
15 scoring the release liner in each such region in a close packed arrangement to minimize scrap losses from the web.

39. The method of claim 33 which further comprises cutting regions in the multilayer web and
20 scoring the release liner in each such region with a cutting roller repeat length to minimize scrap losses from the web.

40. An apparatus for forming a transdermal drug delivery device from a multilayer web having layers of
25 a backing material, a drug-containing pressure sensitive adhesive, and a release liner, comprising:

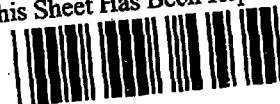
an anvil roller supported in a manner for rotating about its axis;

30 a cutting roller having a cylindrical surface and supported for rotating about its axis, which axis is coplanar with the axis of the anvil roller, and said cutting roller being positionable in proximity to said anvil roller;

35 at least one cutting section fixedly mounted on and projecting above said surface, and having a first cutting edge extending outwardly a first



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predetermined distance from said surface and
 configured as a predetermined shape for defining a
 region on said surface, and a second cutting edge
 extending outwardly from said surface a second
 5 predetermined distance, said second predetermined
 distance being less than said first predetermined
 distance, said second cutting edge dividing said
 region to form two sub-regions thereof; and

said anvil roller and cutting roller being
 10 counter rotatable in relation to each other, whereby
 counter rotation of said anvil roller and cutting
 rollers functions to urge the multilayer web between
 said cutting roller and anvil roller such that,
 15 progressively along a line coplanar with the axes of
 the rollers, the first cutting edge communicates with
 and cuts through the multilayer web while the second
 cutting edge communicates with and scores only the
 release liner.

41. A method for forming transdermal drug
 20 delivery devices from a multilayer web having layers
 of a backing material, a drug-containing pressure
 sensitive adhesive and a release liner, comprising the
 steps of:

feeding the multilayer web toward a cutting
 25 roller which is in proximity to an anvil roller, both
 rollers supported in a manner for rotation about their
 axes which are coplanar;

progressively along a line coplanar with the
 axes of both rollers, cutting a region completely
 30 through the multilayer web using a first cutting edge
 configured as a predetermined shape, and extending
 outwardly sufficiently from a surface of the cutting
 roller to penetrate all layers of the web; and

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- 5 simultaneously along said line, scoring only the release liner using a second cutting edge configured to divide the predetermined shape region into two sub-regions, with said second cutting edge extending outwardly from the surface of the cutting roller a distance insufficient to penetrate the adhesive layer.



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