

FORM 2

THE PATENTS ACT, 1970
(39 of 1970)
AND
THE PATENTS RULES, 2003

**COMPLETE
SPECIFICATION**

(See Section 10; rule 13)

TITLE OF THE INVENTION

**“ADHESIVE PATCH ASSEMBLY WITH OVERLAY LINER AND SYSTEM AND
METHOD FOR MAKING SAME”**

APPLICANT

3M INNOVATIVE PROPERTIES COMPANY
of 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427, USA;
Nationality : USA

The following specification particularly describes
the invention and the manner in which
it is to be performed

What is claimed is:

1. An adhesive patch assembly, the assembly comprising:

a patch including

a backing having a first major surface and a second major surface opposite the first major surface, and

a skin-contact adhesive coupled to the second major surface of the backing; and

a release liner including

a first major surface and a second major surface opposite the first major surface, at least the first major surface configured to present release characteristics relative to the skin-contact adhesive of the patch,

a first portion and a second portion separated by a hinge, the first portion positioned to overlay the first major surface of the backing of the patch when the release liner is folded upon the hinge, and the second portion positioned to underlie at least one of the second major surface of the backing and the skin-contact adhesive of the patch;

wherein the first major surface of the release liner is positioned to face the patch when the patch is located between the first portion and the second portion of the release liner.

2. A method of making an adhesive patch assembly, the method comprising:

providing a patch including a backing and a skin-contact adhesive coupled to the backing;

providing a release liner having a first portion and a second portion, wherein each of the first portion and the second portion are dimensioned to accommodate the patch;

positioning the patch on the release liner, such that patch is located on the second portion of the release liner and the first portion of the release liner is free of the patch; and

folding the release liner about a hinge located between the first portion and the second portion to locate the patch between the first portion and the second portion of the release liner.

3. The assembly of claim 1 or the method of claim 2, wherein the coefficient of adhesion between the first major surface of the release liner and the first major surface of the backing of the patch is less than the coefficient of adhesion between the first major surface of the release liner and the skin-contact adhesive of the patch.

4. An adhesive patch assembly, the assembly comprising:

a patch including

a backing having a first major surface and a second major surface opposite the first major surface, and

a skin-contact adhesive coupled to the second major surface of the backing; and

a release liner including

5 a first major surface and a second major surface opposite the first major surface, at least the first major surface configured to present release characteristics relative to the skin-contact adhesive of the patch,

10 a first portion and a second portion separated by a hinge, the first portion positioned to overlay the first major surface of the backing of the patch when the release liner is folded upon the hinge, and the second portion positioned to underlie at least one of the second major surface of the backing and the skin-contact adhesive of the patch;

wherein the first major surface of the release liner is positioned to face the patch when the patch is located between the first portion and the second portion of the release liner, and

15 wherein the coefficient of adhesion between the first major surface of the release liner and the backing of the patch is less than the coefficient of adhesion between the first major surface of the release liner and the skin-contact adhesive of the patch.

20 5. The assembly of any of claims 1 and 3-4 or the method of claim 2, wherein, when the patch is located between the first portion and the second portion of the release liner, the release liner extends on all sides beyond a periphery of the patch.

25 6. The assembly of any of claims 1 and 3-5 or the method of claim 2 or 5, wherein the release liner is sized such that the first portion and the second portion extend beyond all edges of the patch when the patch is located between the first portion and the second portion of the release liner.

7. The assembly of any of claims 1 and 3-6 or the method of any of claims 2 and 5-6, wherein the first portion and the second portion of the release liner are integrally formed together.

30 8. The assembly of any of claims 1 and 3-7 or the method of any of claims 2 and 5-7, wherein the hinge includes an integral hinge.

35 9. The assembly of any of claims 1 and 3-8 or the method of any of claims 2 and 5-8, wherein the hinge is formed from at least one uncut point that connects the first portion and the second portion of the release liner.

10. The assembly of any of claims 1 and 3-9 or the method of any of claims 2 and 5-9, wherein the release liner is formed from one sheet of material.

11. The assembly of any of claims 1 and 3-10 or the method of any of claims 2 and 5-10, wherein the release liner comprises a monolithic construction.

12. The assembly of any of claims 1 and 3-11 or the method of any of claims 2 and 5-11, wherein the release liner comprises a non-laminate construction.

13. The assembly of any of claims 1 and 3-12 or the method of any of claims 2 and 5-12, wherein the release liner provides no adhesion to the backing of the patch.

14. The assembly of any of claims 1 and 3-13 or the method of any of claims 2 and 5-13, wherein the patch assembly includes no additional layers located between the first major surface of the release liner and the patch.

15. The assembly of any of claims 1 and 3-14 or the method of any of claims 2 and 5-14, wherein the patch assembly includes no additional layers located between the first major surface of the release liner and the backing of the patch.

16. The assembly of any of claims 1 and 3-15 or the method of any of claims 2 and 5-15, wherein the patch assembly includes no additional layers located between the first major surface of the release liner and the skin-contact adhesive of the patch.

17. The assembly of any of claims 1 and 3-16 or the method of any of claims 2 and 5-16, wherein the release characteristics of the first major surface are coextensive with the first major surface

18. The assembly of any of claims 1 and 3-17 or the method of any of claims 2 and 5-17, wherein the second portion of the release liner includes at least one of a slit and a tab.

19. The assembly of any of claims 1 and 3-18 or the method of any of claims 2 and 5-18, wherein the second portion of the release liner forms a primary liner for the patch, and wherein the first portion of the release liner forms a cover liner.

20. The assembly of any of claims 1 and 3-19 or the method of any of claims 2 and 5-19, wherein the release liner includes a first dimension that is at least twice a first dimension of the patch.

21. The assembly of any of claims 1 and 3-20 or the method of any of claims 2 and 5-20, wherein the release liner includes a second dimension that is greater than a second dimension of the patch.

22. The assembly of any of claims 1 and 3-21 or the method of any of claims 2 and 5-21, wherein the coefficient of adhesion between the first major surface of the release liner and the skin-contact adhesive of the patch is less than the coefficient of adhesion between the skin-contact adhesive and skin.

23. The assembly of any of claims 1 and 3-22 or the method of any of claims 2 and 5-22, wherein the patch comprises a drug.

24. The assembly of any of claims 1 and 3-23 or the method of any of claims 2 and 5-23, wherein the patch comprises a drug reservoir layer between the backing and the skin-contact adhesive.

25. The assembly of any of claims 1 and 3-24 or the method of any of claims 2 and 5-24, wherein the patch comprises a skin penetration enhancer.

26. The assembly of any of claims 1 and 3-25 or the method of any of claims 2 and 5-25, wherein the drug is selected from the group consisting of buprenorphine, clonidine, diclofenac, estradiol, granisetron, isosorbide dinitrate, levonorgestrel, lidocaine, methylphenidate, nicotine, nitroglycerine, oxybutynin, rivastigmine, rotigotine, scopolamine, selegiline, tulobuterol, fentanyl, and combinations thereof.

27. The assembly of any of claims 1 and 3-26 or the method of any of claims 2 and 5-26, wherein the patch includes a transdermal drug delivery patch.

28. An article comprising the adhesive patch assembly of any of claims 1 and 3-27, wherein the adhesive patch assembly is packaged in a hermetically-sealed pouch.

29. The method of any of claims 2 and 5-27, wherein providing a release liner having a first portion and a second portion occurs after the patch is positioned on the release liner, such that the release liner is provided, the patch is positioned on the release liner, and the first portion and second portion of the release liner are provided such that the patch is positioned on the second portion of the release liner but not the first portion of the release liner.

30. The method of any of claims 2 and 5-29, further comprising forming at least a portion of the first portion and at least a portion the second portion in the release liner such that the first portion and the second portion of the release liner remain attached by at least one uncut point.

5 31. The method of claim 30, wherein folding the release liner includes folding the release liner along a line that includes the at least one uncut point.

10 32. The method of any of claims 2 and 5-31, wherein folding the release liner between the first portion and the second portion includes folding the first portion of the release liner over the patch and the second portion of the release liner.

15 33. The method of any of claims 2 and 5-32, wherein the release liner is provided in roll form and is fed through a series of rolls that define a machine direction, and wherein the first portion of the release liner leads in the machine direction.

34. The method of any of claims 2 and 5-33, wherein folding the release liner includes using a compressed air nozzle.

20 35. The method of any of claims 2 and 5-34, wherein folding the release liner includes using a cross-web folding rod.

25 36. The method of any of claims 2 and 5-35, wherein each of the first portion and the second portion of the release liner includes a first major surface and a second major surface opposite the first major surface, wherein the first major surface is positioned to face the patch when the patch is positioned on the release liner, and wherein at least the first major surface is configured to present release characteristics relative to the skin-contact adhesive of the patch.

30 37. The method of any of claims 2 and 5-36, wherein:
the backing of the patch includes a first major surface and a second major surface,
the skin-contact adhesive of the patch is coupled to the second major surface of the backing,
the skin-contact adhesive of the patch is adhered to the second portion of the release liner when the patch is positioned on the release liner, and
the first portion of the release liner is positioned over the first major surface of the
35 backing when the release liner is folded.