

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	16/516,792	Confirmation No.	2546
Inventor(s)	:	Manuella Herb et al.		
Filed	:	July 19, 2019		
TC/A.U.	:	1612		
Examiner	:	Hong Yu		
Title	:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE		
Docket No.	:	TRO-45953		
Customer No.	:	075626		

AMENDMENT "C" SUBMITTED WITH
REQUEST FOR CONTINUED EXAMINATION
(In response to the Office Action dated May 13, 2021)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This amendment is filed in response to the Final Office action dated May 13, 2021 and with a Request for Continued Examination under 37 CFR §1.114 and the associated fee of \$1,360.00. The three-month period for responding to the Office action expires on August 13, 2021 wherein an extension of time is not needed. However, if it is determined that an extension of time is needed, hereby requests and petitions for the extension and the fees can be charged to our Deposit Account No. 18-0160, our Order No. TRO-45953. Please amend the above-identified application as follows:

- **Amendments to the Claims** are reflected in the listing of claims, which begins on page 2 of this paper.
- **Amendments to the Specification** begin on page 6 of this paper.
- **Remarks/Arguments** begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-15 (Cancelled)

16. (Previously Presented) A film composite for manufacturing a package for planar carriers of pharmaceutical active substances, encompassing, in a direction from the outer side of the film composite toward its inner side: a metal layer; an acrylic-acid-containing joining layer; a polyethylene layer; and a COC layer made of cycloolefin copolymer, a side of the COC layer which faces away from the metal layer being an exposed surface of the film composite, wherein the polyethylene layer encompasses metallocene polyethylene.
17. (Previously Presented) The film composite according to Claim 16, wherein the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer is at least 50 wt%.
18. (Previously Presented) The film composite according to Claim 16, wherein the polyethylene layer encompasses a metallocene linear low density polyethylene.
19. (Previously Presented) The film composite according to Claim 16, wherein the polyethylene layer encompasses at least one of a C6 metallocene polyethylene and a C8 metallocene polyethylene.

20. (Previously Presented) The film composite according to Claim 19, wherein the polyethylene layer encompasses only a C8 metallocene polyethylene as a metallocene polyethylene.
21. (Previously Presented) The film composite according Claim 16, wherein the acrylic-acid-containing joining layer encompasses or is made of an ethylene-acrylic acid (EAA) copolymer.
22. (Previously Presented) The film composite according to Claim 16, wherein each of the layers, from among the acrylic-acid-containing joining layer, the polyethylene layer, and the COC layer, has a layer thickness in the range from approximately 7 μm to 15 μm .
23. (Previously Presented) The film composite according to Claim 22, wherein the thickness values of said layers, referred to the thinnest of said each layers, differ by no more than 15%.
24. (Previously Presented) The film composite according to Claim 23, wherein the thickness values of said layers, referred to the thinnest of said each layers, differ by no more than 11%.
25. (Previously Presented) The film composite according to Claim 16, wherein each of the layers, from among the acrylic-acid-containing joining layer, the polyethylene layer, and the COC layer, has a layer thickness in the range from approximately 9 μm to 12 μm .

26. (Previously Presented) The film composite according to Claim 25, wherein the thickness values of said layers, referred to the thinnest of said each layers, differ by no more than 15%.
27. (Previously Presented) The film composite according to Claim 26, wherein the thickness values of said layers, referred to the thinnest of said each layers, differ by no more than 11%.
28. (Previously Presented) The film composite according to Claim 16, wherein the film composite comprises, on the side of the metal layer which faces away from the COC layer, at least one further layer made of at least one of a paper and a plastic.
29. (Previously Presented) The film composite according to Claim 28, wherein the at least one further layer includes a paper layer and a plastic layer.
30. (Previously Presented) The film composite according to Claim 29, wherein the plastic layer is located closer to the metal layer than the paper layer.
31. (Previously Presented) The film composite according to Claim 28, wherein the at least one further layer includes a plastic layer that is a biaxially oriented plastic.
32. (Previously Presented) The film composite according to Claim 28, wherein the at least one further layer includes a plastic layer that is at least one of a polyethylene terephthalate and a polyamide.
33. (Previously Presented) The film composite according to Claim 28, wherein the at least one further layer includes at least one of a paper layer having at least one of a

thickness of 35 to 45 μm and a weight per unit area of 35 to 45 g/m^2 and a plastic layer having at least one of a thickness of 19 to 27 μm and a weight per unit area of 28 to 36 g/m^2 .

34. (Previously Presented) The film composite according to Claim 28, wherein the at least one further layer includes at least one of a paper layer having at least one of a thickness of 39 to 41 μm and a weight per unit area of 39 to 41 g/m^2 and a plastic layer having a thickness of 22 to 24 μm and a weight per unit area of 31 to 33 g/m^2 .
35. (Withdrawn from Consideration) A package for a planar carrier of pharmaceutical active substances, for example a transdermal patch, encompassing two film-composite sheets, each of the film-composite sheets being in accordance with Claim 16 and the two film-composite sheets being arranged with mutually facing COC layers to form a carrier receiving space and the two film-composite sheets being joined to one another by local sealing of regions of the COC layers.
36. (Withdrawn from Consideration) The package according to Claim 35, wherein the package is a four-side-sealed pouch having a sealed seam surrounding the carrier receiving space.
37. (Withdrawn from Consideration) The package according to Claim 35, having a planar active-substance carrier, in particular a transdermal patch, received in the carrier receiving space, the pharmaceutical active substance containing at least one of nicotine, fentanyl and lidocaine.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification in accordance with the attached Substitute Specification:

Attached hereto are:

A Marked Substitute Specification

A Clean version of the Substitute Specification

The amendments in the Specification do not include new matter.

REMARKS

The Final Office Action dated May 13, 2021 has been received and carefully considered. In response, Applicant appreciates the time spent by the Patent Examiner wherein this Amendment includes the discussed Declarations. Accordingly, reconsideration and allowance is respectfully requested.

Again, Applicant appreciates the time spent by the Patent Examiner on June 18, 2021 to discuss this rejection and the specific arrangement of layers wherein the order of these layers have been found to produce a superior result. Attached to this Amendment is a declaration of Manuella Herb who is the Senior Manager Product Development for the Applicant.

In addition, upon further review of this application, Applicant has discovered a few typographical errors in the translation of this application that are addressed by the attached amended specification. Consideration of these amendments is respectfully requested. It is respectfully submitted that these amendments do not include new matter.

The currently pending claims are 16-34. Claims 35-37 have been withdrawn from consideration in view of the restriction.

The Office Action confirms that the claim objections of claims 18 & 21 have been withdrawn. However, the Office Action maintained the rejections in view of the prior art.

Claims 16 and 18-34 were rejected as being unpatentable over Osborn et al. (US 2015/0225151 A1) in view of Torradas et al. (US 2017/0136747 A1).

Attached hereto is a Declaration of Manuella Herb who is the Senior Manager Product Development for the Applicant and she has worked in the packaging industry for over 22 years and she has significant experience in packaging and material designs for packaging.

While Osborn may disclose that m-LLDPE exists, that is the extent of the teaching. The invention of this application relates to a specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed.

As far as the disclosure in paragraphs [0076] and [0078] of Osborn, disclosed is mLLDPE used in the examples, this can only refer directly to comparative example 2 presented in paragraph [0097] of Osborn, where the disclosed mLLDPE has no relation or interaction to any COC-layer. As far as example 5, primarily referenced in the Office Action, this example refers to the identity of the base films of examples 5 and 2, this can only refer to the structure OPET/primer/LDPE/EAA/Al-foil which forms the base film of example 2 (which in turn corresponds to the base film of example 1, but without having been corona treated). Contrary to example 2, the layer structure on the inner, product-contacting side of the aluminum foil is EAA/LDPE/COC. Consequently, in example 5 the sealant layer mLLDPE of example 2 is replaced by a layer of COC.

The invention claimed in this application is directed to a specific arrangement of layers and the order of these layers that have been found to produce a superior result. It is respectfully submitted that maintaining a rejection of the claims improperly ignores the arrangement of different layers made up of different chemical materials. Moreover, it disregards the order of appearance of the layers within the multilayer structure.

It has been found that the recited invention has unexpected effects in using certain metallocene polyethylene to tie the COC-layer to the EAA-layer and thereby to the aluminum foil.

It has been found and proven by laboratory testing that using metallocene C8 LLDPE as a layer connecting the COC-layer to the adhesive (EAA) layer surprisingly and tremendously promotes the delamination stability of the multilayer structure. Using regular LDPE allows to create a multilayer structure, but the COC-layer more or less easily delaminates or can be peeled off of the neighboring regular LDPE-layer. According to the results of laboratory tests conducted in March 2020, the bond between a regular LDPE layer and a COC layer connected to the regular LDPE layer within a laminate structure of paper/-adhesive/polyethylene terephthalate/adhesive/aluminum/ethylene acrylic acid copolymer/-LDPE/COC has a strength per length of 0.5 N per 15 mm. The tests were executed according to industry standard DIN 55543-5.

In addition, metallocene C8 LLDPE, as is recited in the claims, increases the ties (lamination forces) between the polyethylene layer and the COC-layer to such an extent that, with the same laboratory equipment that allows for a rather easy delamination of the COC-layer from the neighboring regular LDPE-layer, the COC-layer cannot be delaminated from the metallocene C8 LLDPE layer without destroying the multilayer structure as such. This was shown by a comparative delamination test conducted by the same laboratory with the same equipment on a modified laminate. The modified laminate was the same as the laminate described above, with the only exception that the layer of regular LDPE was replaced by a C8 metallocene LLDPE layer of the same weight per unit area as that of the regular LDPE layer. The bond strength per length between the C8 metallocene LLDPE layer and the COC layer was so large that any attempt to delaminate the C8 metallocene

LLDPE layer and the COC layer resulted in a destruction of the laminate by tearing without achieving a delamination of the C8 metallocene LLDPE layer and the COC layer. The equipment used in the tests detected delamination forces per length between other layers of the laminate of up to 3.3 N per 15 mm. In other words, the adhesion between metallocene C8 LLDPE-layer and a COC-layer is significantly greater than the cohesion of the respective material within each layer. This effect was neither known, nor could it be expected.

While Osborn comprehensively lists the many different kinds of polyethylene that are available for forming layers, Osborn and the remaining cited documents, are silent with regard to the type of metallocene-catalyzed LLDPE. C8 is one of the possibilities to metallocene-catalyze LLDPE, but not the only one. As far as Osborn discloses terms C2 to C10 in [0015], this disclosure relates to monomers, but not to locations for the metallocene-catalyzation to be effective within the carbon-molecule-string of a polyethylene polymer.

It is respectfully submitted that the prior art fails to disclose or make obvious the recited invention of this application. Again, the invention of this application relates to a specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed. While the prior art discloses a many different types of materials, the prior art fails to disclose or make obvious the recited arrangement of layers. Moreover, the prior art fails to teach the significance or the understanding associated with the specific arrangement of layers wherein claim 16 patentably distinguishes the prior art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007). Further, the cited references fail to disclose all claim limitations wherein the claim is not obvious. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Accordingly, reconsideration and allowance of claim 16 is respectfully requested.

Claims 18-34 are dependent from claim 16 and patentably distinguish the prior art for at least the same reasons.

Claim 19 further patentably distinguishes the prior art by reciting the polyethylene layer encompasses at least one of a C6 metallocene polyethylene and a C8 metallocene polyethylene. The prior art fails to disclose or make obvious such as polyethylene layer.

Claims 16, 17, and 21 were rejected as being unpatentable over Torradas in view of Osborn. It is respectfully submitted that Torradas in view of Osborn does not disclose or make obvious the recited invention of claim 16 for at least the reasons outlined above. The prior art as a whole fail to disclose or even recognize the significant properties associated with the specific arrangement of layers in a specific order that creates these properties.

Claims 17 and 21 are dependent from claim 16 and patentably distinguish the prior art for at least the same reasons.

Claims 18-20 and 22-34 were rejected as being unpatentable over Torradas, as applied to claims 16, 17, and 21, in view of Osborn. It is respectfully submitted that Torradas in view of Osborn does not disclose or make obvious the recited invention of claim 16 for at least the reasons outlined above. Claims 18-20 and 22-34 are dependent from claim 16 and patentably distinguish the prior art for at least the same reasons.

Claims 16-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Toft et al. (US 2005/0181154 A1) in view of Osborn and Torradas. It is respectfully submitted that Toft fails to overcome the shortcomings of Torradas and Osborn wherein claims 16-34 patentably distinguish the prior art.

It is respectfully submitted that each issue raised in the above-identified Office Action has been addressed by this amendment wherein reconsideration and allowance is respectfully requested. However, it is noted that the arguments raised in this response address certain patentably distinct features of the invention of this application, but these are not to be construed as the only patentably distinct features. Moreover, while Applicant has focused on only certain patentably distinguishing features of the independent and dependent claims in the interest of brevity, this is not to be construed as limiting the patentably distinguishing features or to give any features more weight over other features. Accordingly, reconsideration and allowance is respectfully requested in view of this amendment.

In addition, Applicant requests that withdrawn claims 35-37 be rejoined and considered upon the allowance of generic elected claim 16.

Further, Applicant respectfully submits that an extension of time is not needed to submit this response. However, if an extension is deemed to be needed, Applicant hereby petitions for any needed extension of time to submit this response. The fees associated with any needed extension can be charged to our Deposit Account No. 18-0160, our Order No. TRO-45953.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. TRO-45953.

Respectfully submitted,

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