

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 "B"

Commissioner for Patents
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This amendment is filed in response to the Non-Final Office Action dated November 20, 2020. The three-month period for responding to the Office action expired on February 20, 2021. Accordingly, Applicant respectfully submits that a one month extension of time is needed. However, if it is determined that an additional extension is needed, it is hereby requested and any fees should be charged to the deposit account noted below and in this application. 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.
- **Remarks/Arguments** begin on page 6 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. (Currently Amended) The film composite according to Claim 16, wherein the polyethylene layer encompasses a metallocene linear low density polyethyleneLLDPE.
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. (Currently Amended) The film composite according Claim 16, wherein the acrylic-acid-containing joining layer encompasses or is made of an ethylene-acrylic acid ~~EAA~~ (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.

REMARKS

The Office Action dated November 20, 2020 has been received and carefully considered. In response, Applicant has amended the claims to address the objections of the claims. It is respectfully submitted that the prior art does not teach the invention wherein reconsideration and allowance is respectfully requested.

The currently pending claims are 16-34. Claims 35-37 have been withdrawn from consideration in view of the restriction wherein an Election was made by phone on July 15, 2020. Applicant hereby confirms the Election.

Claim 18 was objected to for its recitation of the acronym "LLDPE" and Claim 21 was objected to because there is no space between "[ethylene-acrylic acid]" and "[EAA]" and since EAA is the acronym of ethylene-acrylic acid, "[EAA]" should be in parentheses. Applicant appreciates the thorough review of the claims and has made the needed changes. Reconsideration of these objections is therefore respectfully requested.

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).

As the Examiner knows, the determination regarding whether an invention as claimed is obvious in view of the prior art must be made in accordance with the standards set forth in the Supreme Court's opinion in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007). In the KSR case, the Court made it clear that in order to reject a claim under 35 U.S.C. §103, there must be an explicit analysis explaining the apparent reason why a person of ordinary skill in the art would combine known elements described in the prior art in the way claimed. The person of ordinary skill in the art would have to see the

benefit of making the combination. The person of ordinary skill in the art would have to recognize that it would improve similar devices or methods in the same way. The critical inquiry is whether the claimed improvement is more than the predictable use of prior-art elements according to their established functions. If it is, then the improvement is not obvious under 35 U.S.C. §103(a). Further, to establish a prima facie case of obviousness, the references cited by the Office must disclose all claim limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As will be discussed more below, even if each limitation may be found in the prior art a claim is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). Rather, the Office must identify an apparent reason to combine the known elements in the fashion claimed. *Id.* "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*, citing *In re Kahn*, 441 F.3d 977,988 (Fed. Cir. 2006). This reason must be free of the distortion caused by hindsight bias and may not rely on ex post reasoning. *KSR*, 127 S.Ct. at 1742. The test for obviousness requires that all teachings in the prior art must be considered, including those that teach against a proposed combination or modification of the prior art. MPEP §2143.01 ("Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another.") citing *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). While Osborn may disclose that m-LLDPE exists, that is the extent of the teaching. In addition, the remaining prior art, such as *Torradas*, does not overcome this shortcomings.

In greater detail, claim 16 recites 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. Claim 16 recites a specific arrangement of layers in a specific order that is not taught by the prior art.

Upon review of Osborn, which is the priority document to the WO-publication already cited in the introductory portion of the present application, while Osborn mentions that metallocene LLDPE (linear low density polyethylene) does exist, that is the extent of its teaching. (see [0015], [0027] of Osborn).

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.

Further, 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.

In the remaining cited prior art in the Office Action, the COC is part of a multilayer

structure, but is not used as a product-contacting exposed layer.

The recited invention of claim 16 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 claim 16 improperly ignores the arrangement of different layers made up of different chemical materials, and can be only based on focusing merely on the presence of materials and improper hindsight reconstruction based on the disclosure of this application. Moreover, it disregards the order of appearance of the layers within the multilayer structure.

In addition, it has been found that the recited invention does have unexpected effects in using certain metallocene polyethylene to tie the COC-layer to the EAA-layer and thereby to the aluminum foil.

In this respect, Applicant has found (and has proof by laboratory reports) 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. In addition, metallocene C8 and LDPE, as is recited in claim 19, 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. In other words, the adhesion between metallocene C8 LDPE-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 there are available for forming layers, Osborn and likewise 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.

Given the many different kinds of polyethylene disclosed by Osborne alone, and further taking into account the different kinds of possible metallocene-catalyzation of polyethylene, it is respectfully submitted that the person skilled in the art would not have discovered the invention of this application without the use of improper hindsight reconstruction based on the disclosure of this application. There is no suggestion or explanation as to why or how the person skilled in the art would have tested out these many kinds of available polyethylene kinds for the LDPE disclosed by Osborne and found the significant benefit of C8 mLLDPE being used as the neighboring partner for COC-layer. It is respectfully submitted that there is a particular effect involved in using C8 mLLDPE.

Accordingly, it is respectfully submitted that the prior art does not make obvious the layer structure of the claims under KSR.

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

As is noted above, 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.

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 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.

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.

Further, Applicant petitions for a one-month extension of time to submit this response.

Accordingly, reconsideration and allowance is respectfully requested. However, if an additional 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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