UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 11,504,954 B2
APPLICATION NO. : 16/516792
DATED : November 22, 2022
INVENTOR(S) : Manuella Herb et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 10, Line 6, Claim 17, the word "polyimide" should be replaced with --polyamide--.

Column 11, Line 6, Claim 25, the word "polyimide" should be replaced with --polyamide--.

Signed and Sealed this
Twenty-eighth Day of March, 2023

Katherine Kelly Vidal

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office

PTO/SB/44 (09-07)
Approved for use through 03/31/2023. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.
(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 11,504,954

APPLICATION NO.: 16/516,792

ISSUE DATE : November 22, 2022

INVENTOR(S) : Manuella Herb et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 10, line 6, Claim 17, the word "polyimide" should be replaced with --polyamide--.

Col. 11, line 6, Claim 25, the word "polyimide" should be replaced with --polyamide--.

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):

Rankin Hill & Clark LLP
23755 Lorain Road, Suite 200
North Olmsted, Ohio 44070

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.	:	11,504,954 Confirmation No. 2546
Applicant		HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG
Issued	:	November 22, 2022
TC/A.U.	:	1612
Title	:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
Docket No.	:	TRO-45953
Customer No.	:	75626

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR PTO MISTAKE (37 C.F.R. § 1.322(a))

Commissioner for Patents
ATTN: CERTIFICATE OF CORRECTION BRANCH
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Attached is form PTO/SB/44.

The exact page and line number where the errors are shown correctly in the application file are:

Amendment E filed August 3, 2022, Claim 54, line 3, the word "polyimide" should be replaced with --polyamide--.

Amendment E filed August 3, 2022, Claim 62, line 12, the word "polyimide" should be replaced with --polyamide--.

The exact page and line (or field) in the printed patent where the errors occur are:

Col. 10, line 6, Claim 17, the word "polyimide" should be replaced with --polyamide--.

Col. 11, line 6, Claim 25, the word "polyimide" should be replaced with --polyamide--.

Because the Certificate of Correction relates to a Patent Office mistake, no fee is believe due, however if this is not the case, please charge any and all fees to Deposit Account No. 18-0160, our Order No. TRO-45953.

Please send the Certificate to:

Rankin Hill & Clark LLP
23755 Lorain Road, Suite 200
North Olmsted, Ohio 44070

Respectfully submitted,

RANKIN, HILL & CLARK LLP

By /Gregory S. Vickers/
Gregory S. Vickers, Reg. No. 45180

23755 Lorain Road, Suite 200
North Olmsted, Ohio 44070
(440) 604-0604

Electronic Acknowledgement Receipt

EFS ID:	47601730
Application Number:	16516792
International Application Number:	
Confirmation Number:	2546
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Customer Number:	75626
Filer:	Gregory Stamm Vickers/Loni Clay
Filer Authorized By:	Gregory Stamm Vickers
Attorney Docket Number:	TRO-45953
Receipt Date:	28-FEB-2023
Filing Date:	19-JUL-2019
Time Stamp:	10:45:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	TRO45953_CertificateOfCorrection.pdf	219220 9a9a8404650efd8560580203aa0da4a820fec500	no	2

Warnings:

Information:					
2	Request for Certificate of Correction	TRO45953_COCRequest.pdf	44832 fb90b4e6fc342460cde215aff8deb4128856662d	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	264052	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	11/22/2022	11504954	TRO-45953	2546

75626 7590 11/02/2022

RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 18 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Manuella Herb, Goerisried, GERMANY;
Michael Dorn, Dietmannsried, GERMANY;
Thomas Stroh, Memmingen, GERMANY;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Huhtamaki Flexible Packaging Germany GmbH & Co. KG, Ronsberg, GERMANY;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	16/516792	Confirmation No. 2546
Applicant	:	Manuella Herb et al.	
Filed	:	July 19, 2019	
TC/A.U.	:	1612	
Examiner	:	Yu, Hong	
Title	:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	
Docket No.	:	TRO-45953	
Customer No.	:	075626	

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

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

Dear Sir:

In response to the Notice of Allowance dated September 12, 2022, applicant submits the following comments set forth below.

Applicant does not agree that one or more reasons stated by the examiner for allowance of any of the claims during the prosecution of the above-identified patent application are the only reasons for allowance of such claims. Therefore, while applicant believes the claims are allowable, applicant does not acquiesce that patentability resides in only the features and/or reasons identified by the examiner.

Respectfully submitted,

RANKIN, HILL & CLARK LLP

By /Gregory S. Vickers/
Gregory S. Vickers, Reg. No. 45180

23755 Lorain Road, Suite 200
North Olmsted, Ohio 44070-2224
(440) 614-0604

Electronic Patent Application Fee Transmittal

Application Number:	16516792
Filing Date:	19-Jul-2019
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Filer:	Gregory Stamm Vickers/Loni Clay
Attorney Docket Number:	TRO-45953

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1200**

Electronic Acknowledgement Receipt

EFS ID:	46857934
Application Number:	16516792
International Application Number:	
Confirmation Number:	2546
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Customer Number:	75626
Filer:	Gregory Stamm Vickers/Loni Clay
Filer Authorized By:	Gregory Stamm Vickers
Attorney Docket Number:	TRO-45953
Receipt Date:	21-OCT-2022
Filing Date:	19-JUL-2019
Time Stamp:	12:08:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1200
RAM confirmation Number	E20220KC11203895
Deposit Account	180160
Authorized User	Loni Clay

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	TRO45953_PartB.pdf	171031 fc75fb22c50a6173516ca54f2b7433baed3cb744	no	1
Warnings:					
Information:					
2	Miscellaneous Incoming Letter	TRO45953_Reasons.pdf	69765 e2a75f80d4a370b2def0c07b4302b7a7ede4c0ce	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	38026 fe71b5921c965b58414514da9a5c2be5f24f74c6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	278822		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

75626 7590 09/12/2022
RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

TITLE OF INVENTION: FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	12/12/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
YU, HONG	1612	424-449000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 RANKIN, HILL & CLARK LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Huhtamaki Flexible Packaging Germany GmbH & Co. KG

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Ronsberg, Germany

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ☒ Corporation or other private group entity ❑ Government

4a. Fees submitted: ☒ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 18-0160

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Gregory S. Vickers/ Date October 20, 2022

Typed or printed name Gregory S. Vickers Registration No. 45180

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

75626 7590 09/12/2022

RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

EXAMINER
YU, HONG

ART UNIT	PAPER NUMBER
1612	

DATE MAILED: 09/12/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

TITLE OF INVENTION: FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	12/12/2022

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

75626 7590 09/12/2022
RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

TITLE OF INVENTION: FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	12/12/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
YU, HONG	1612	424-449000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

75626 7590 09/12/2022

RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

EXAMINER	
YU, HONG	
ART UNIT	PAPER NUMBER
1612	

DATE MAILED: 09/12/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/516,792	Applicant(s) Herb et al.	
	Examiner HONG YU	Art Unit 1612	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 08/03/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 38-66 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☑ All b) ☐ Some* c) ☐ None of the:

   1. ☑ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/HONG YU/
Primary Examiner, Art Unit 1612

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

DETAILED ACTION

Applicants' amendments and arguments are sufficient to overcome the rejections of record which are now withdrawn.

I. Action Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/03/2022 has been entered.

Receipt of the remarks and amendments filed on 08/03/2022 is acknowledged. Applicants have cancelled claims 16-37 and introduced new claims 38-66. Therefore, the elected group I and the non-elected group II as a result of restriction requirement dated 11/20/202 now encompasses claims 38-63 and claim 64-66, respectively.

Claims 38-63 are now in condition for allowance. Claim 64-66, previously withdrawn from consideration as a result of a restriction requirement, requires all the limitations of an allowable claims. Pursuant to the procedures set forth in MPEP § 821.04(a), the restriction requirement between inventions I and II, as set forth in the Office action mailed on 11/20/2020, is hereby withdrawn and claims 64-66 hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

II. Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The prior art does not teach or suggest the claimed composite. The closest prior art is Osborn et al. (US 2015/0225151 A1), Toft et al. (US 2005/0181154 A1), and Torradas et al. (US 2017/0136747 A1). Osborn et al., Toft et al., and Torradas et al. do not teach or fairly suggest the claimed composite with the same order of layers. Osborn et al., Toft et al., and Torradas et al.'s teachings, absent improper hindsight, do not direct one to obtain the composite as claimed in the instant application and described

above. For the aforementioned reasons pending claims 38-66 (now claims 1-29) are found to be allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on 9 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HONG YU/
Primary Examiner, Art Unit 1612

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	**Art Unit**
	HONG YU	1612

CPC								
Symbol							**Type**	**Version**
B32B	/	27	/	327			F	2013-01-01
A61K	/	9	/	7023			I	2013-01-01
B32B	/	27	/	325			I	2013-01-01
B32B	/	7	/	10			I	2013-01-01
B32B	/	15	/	16			I	2013-01-01
B32B	/	2250	/	04			A	2013-01-01
B32B	/	2556	/	00			A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	29	
/HONG YU/ Primary Examiner, Art Unit 1612	09 September 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

U.S. Patent and Trademark Office — Part of Paper No.: 20220908

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	**Art Unit**
	HONG YU	1612

INTERNATIONAL CLASSIFICATION				
CLAIMED				
B32B	/	27	/	32
A61K	/	9	/	70
B32B	/	15	/	16
B32B	/	7	/	10

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)		**Total Claims Allowed:** 29	
/HONG YU/ Primary Examiner, Art Unit 1612 (Primary Examiner)	09 September 2022 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 3

U.S. Patent and Trademark Office

Part of Paper No.: 20220908

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	**Art Unit**
	HONG YU	1612

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	38	10	47	19	56	28	65								
2	39	11	48	20	57	29	66								
3	40	12	49	21	58										
4	41	13	50	22	59										
5	42	14	51	23	60										
6	43	15	52	24	61										
7	44	16	53	25	62										
8	45	17	54	26	63										
9	46	18	55	27	64										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	29	
/HONG YU/ Primary Examiner, Art Unit 1612	09 September 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

CPC - Searched*		
Symbol	**Date**	**Examiner**
B32B 15/$, B32B 27/$	11/16/2020	HY
B32B 15/$, B32B 27/$	10/08/2021	HY
B32B 27/327, A61K 9/7023, B32B 27/325, B32B 7/10, B32B 15/16, B32B 2250/04, B32B 2556/00	09/09/2022	HY

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/HONG YU/ Primary Examiner, Art Unit 1612	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

Search Notes		
Search Notes	**Date**	**Examiner**
east search: inventor and assignee search and keyword search	11/16/2020 11/17/2020 11/18/2020	HY
google search	11/16/2020	HY
global dossier	11/16/2020	HY
Updated east search	05/11/2021	HY
google search	05/11/2021	HY
global dossier	05/11/2021	HY
updated east search	10/08/2021	HY
global dossier	10/08/2021	HY
google search	10/09/2021	HY
east search	04/06/2022	HY
google search	04/06/2022	HY
global dossier	04/06/2022	HY
PE2E search	09/08/2022	HY

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
B32B	27/327, 27/325, 7/10, 15/16, 2250/04, 2556/00 (USPGPUB, USPAT)	09/09/2022	HY
A61K	9/7023 (USPGPUB, USPAT)	09/09/2022	HY

/HONG YU/ Primary Examiner, Art Unit 1612	

Global Dossier

Office

US

Type

Application

16516792

0 1

US 16516792 4 Members in Patent Family (2 currently shown) ()

« ()

IP Office Type

All IP5 Offices

- EPO
- SIPO
- KIPO
- JPO
- USPTO

Non-IP5 Offices

()	Office ()	Application ()	Applicant	Title ()	App. Date ()	Priority #	Pub. # ()	Pub. Date	A
()	EP	19186607	1) Huhtamaki Flexible Packaging Germany GmbH & Co. KG,	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES AND PACKAGING FROM SUCH A FILM COMPOSITE	07/16/2019	DE 102018212303 DE 102018125195	EP 3599090 A1 () EP 3599090 B1 ()	01/29/2020 03/23/2022	

Most Recent Documents

Date	Document Description ()	Options
04/05/2022	Transmission of the certificate for a European patent pursuant to Rule 74 EPC ()	•••
02/24/2022	Decision to grant a European patent ()	•••
02/10/2022	Letter accompanying subsequently filed items ()	•••

Office Actions

Date	Document Description ()
02/24/2022	Decision to grant a European patent ()
10/27/2021	Communication about intention to grant a Eurc patent ()
12/05/2019	European search opinion ()

All Documents | Classification and Citation | View All Office Actions

()	US	16516792 View Dossier ()	1) Herb, Manuella 2) Dorn, Michael 3) Stroh, Thomas	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	07/19/2019	DE 102018212303 DE 102018125195	US 20200031107 A1 ()	01/30/2020	

USPTO BACKGROUND

FEDERAL GOVERNMENT

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1615	38036	(b32b15/$ AND b32b27/$ AND b32b7/$).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 11:59 AM
L1616	20261	L1615 AND (metal OR foil OR aluminium)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:00 PM
L1617	354	L1616 AND (Metallocene near10 polyethylene OR PE-MC OR pe-m OR m-PE OR mc-pe OR mpe)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:01 PM
L1618	123	L1617 AND (cyclo-olefin OR cycloolefin OR Cyclic near5 olefin OR coc OR Ethylene-norbornene)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:01 PM
L1619	123	L1618 AND (acrylic OR polyacrylic OR poly(acrylic acid))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:05 PM
L1620	123	L1619 AND (polyethylene OR mLLDPE OR metallocene OR mpe)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:05 PM
L1621	96	L1620 AND @ay<"2019"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:06 PM
L1622	70	L1621 NOT L1614	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:06 PM
L1623	70	L1622 AND metallocene	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:12 PM
L1624	11	L1622 AND metallocene.clm.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:14 PM
L1625	127	L1617 AND (cyclo-olefin OR cycloolefin OR Cyclic near5 olefin OR coc OR Ethylene-norbornene OR cyclic polyolefin OR cyclo$olefin OR cyclo polyolefin)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:47 PM

L1626	127	L1625 AND (acrylic OR polyacrylic OR poly(acrylic acid))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:47 PM
L1627	127	L1626 AND (polyethylene OR mLLDPE OR metallocene OR mpe)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:48 PM
L1628	99	L1627 AND @ay<"2019"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:48 PM
L1629	70	L1622 NOT L1614	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:48 PM
L1630	11	L1629 AND metallocene.clm.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:49 PM
L1631	148	L1617 AND (cyclo-olefin OR cycloolefin OR Cyclic near5 $olefin OR coc OR Ethylene-norbornene OR cyclic polyolefin OR cyclo$olefin OR cyclo polyolefin OR $norbornene)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:50 PM
L1632	127	L1626 AND (acrylic OR polyacrylic OR poly(acrylic acid))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:50 PM
L1633	127	L1632 AND (polyethylene OR mLLDPE OR metallocene OR mpe)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:51 PM
L1634	99	L1633 AND @ay<"2019"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:51 PM
L1635	70	L1629 NOT L1614	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:51 PM
L1636	16	L1626 AND (mLLDPE OR metallocene OR Metallocene near10 (polyethylene OR pe) OR PE-MC OR pe-m OR m-PE OR mc-pe OR mpe).clm.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/08 12:53 PM
L1637	4	WO "2017053221"	(US-PGPUB; USPAT; USOCR; FPRS; EPO;	ADJ	ON	ON	2022/09/09 10:55 AM

			JPO; DERWENT; IBM_TDB)				
L1638	48858	(b32b27/327 OR a61k9/7023 OR b32b27/325 OR b32b7/10 OR b32b15/16 OR b32b2250/04 OR b32b2556/00).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:28 AM
L1639	11873	L1638 AND (metal OR foil OR aluminium)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:45 AM
L1640	483	L1639 AND (mLLDPE OR metallocene OR Metallocene near10 (polyethylene OR pe) OR PE-MC OR pe-m OR m-PE OR mc-pe OR mpe).clm.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:46 AM
L1641	136	L1640 AND (cyclo-olefin OR cycloolefin OR Cyclic near5 $olefin OR coc OR Ethylene-norbornene OR cyclic polyolefin OR cyclo$olefin OR cyclo polyolefin OR $norbornene)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:46 AM
L1642	96	L1641 AND (acrylic OR polyacrylic OR poly(acrylic acid))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:46 AM
L1643	91	L1642 AND @ay<"2019"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:46 AM
L1644	76	L1643 NOT L1634	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:47 AM
L1647	76	L1644 NOT L1614	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:48 AM
L1648	14	L1647 AND (cyclo-olefin OR cycloolefin OR Cyclic near5 $olefin OR coc OR Ethylene-norbornene OR cyclic polyolefin OR cyclo$olefin OR cyclo polyolefin OR $norbornene).clm.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:50 AM

L1649	14	L1648 AND (mLLDPE OR metallocene OR Metallocene near10 (polyethylene OR pe) OR PE-MC OR pe-m OR m-PE OR mc-pe OR mpe)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	ADJ	ON	ON	2022/09/09 11:50 AM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Web Search History

date, time	web site	search string
9/9/2022 9:50:18 AM	Google	metal layer AND adhesive AND metallocene polyethylene AND cyclic olefin copolymer
9/9/2022 9:53:17 AM	Google	metal layer ANDacrylic AND metallocene polyethylene AND cyclic olefin copolymer
9/9/2022 9:53:23 AM	Google	metal layer AND acrylic AND metallocene polyethylene AND cyclic olefin copolymer
9/9/2022 10:01:02 AM	Google	aluminum layer AND acrylic AND metallocene polyethylene AND cyclic olefin copolymer

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www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 2546

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
16/516,792	07/19/2019 RULE	424	1612	TRO-45953

APPLICANTS

Huhtamaki Flexible Packaging Germany GmbH & Co. KG, Ronsberg, GERMANY;

INVENTORS

Manuella Herb, Goerisried, GERMANY;
Michael Dorn, Dietmannsried, GERMANY;
Thomas Stroh, Memmingen, GERMANY;

**** CONTINUING DATA ***************************

**** FOREIGN APPLICATIONS ***************************

GERMANY 10 2018 212 303.9 07/24/2018
GERMANY 10 2018 125 195.5 10/11/2018

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

08/01/2019

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☑ Yes ☐ No	☑ Yes ☐ No	/HONG YU/ Examiner's Signature	☐ Initials	GERMANY	3	~~22~~ 29	~~2~~ 5

ADDRESS

RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070
UNITED STATES

TITLE

FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

FILING FEE RECEIVED		
3580	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	16516792	Filing Date	2019-07-19	Docket Number (if applicable)	TRO-45953	Art Unit	1783
First Named Inventor	Manuella Herb			Examiner Name	YU, HONG		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 180160

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

X Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Signature of Registered U.S. Patent Practitioner			
Signature	/Gregory S. Vickers/	Date (YYYY-MM-DD)	2022-08-03
Name	Gregory S. Vickers	Registration Number	45180

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	16516792
Filing Date:	19-Jul-2019
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Filer:	Gregory Stamm Vickers/Loni Clay
Attorney Docket Number:	TRO-45953

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	7	100	700
INDEPENDENT CLAIMS IN EXCESS OF 3	1201	2	480	960
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	220	220
Miscellaneous:				
RCE- 2ND AND SUBSEQUENT REQUEST	1820	1	2000	2000
		Total in USD ($)		**3880**

Electronic Acknowledgement Receipt

EFS ID:	46331604
Application Number:	16516792
International Application Number:	
Confirmation Number:	2546
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Customer Number:	75626
Filer:	Gregory Stamm Vickers/Loni Clay
Filer Authorized By:	Gregory Stamm Vickers
Attorney Docket Number:	TRO-45953
Receipt Date:	03-AUG-2022
Filing Date:	19-JUL-2019
Time Stamp:	14:25:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$3880
RAM confirmation Number	E202283E26104533
Deposit Account	180160
Authorized User	Loni Clay

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		TRO45953_AmendmentE.pdf	209526 ff8747ae1c920cbcd66062c7e089322463f801ef	yes	19

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment Submitted/Entered with Filing of Continued Prosecution Application (CPA)/Request for Continued Examination(RCE)	1	1
Claims	2	8
Applicant Arguments/Remarks Made in an Amendment	9	19

Warnings:					
Information:					
2	Request for Continued Examination (RCE)	TRO45953_SecondRCE.pdf	1667127 62e1eb326207c8fcbdc51d73b5f657de3d0c12ea	no	3
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	45510 66d24e7d315d776e60f07d7a06dee9f0d038ba2c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1922163		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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 "E" and Request for Continued Examination

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

This amendment is filed in response to the Final Office action dated April 7, 2022 and serves as a second Request for Continued Examination under 37 C.F.R. 1.114. Because the three-month response period expired July 7, 2022, Applicant respectfully petitions and requests a one-month extension of time. If it is determined that an additional extension is needed, Applicant hereby petitions and requests the same. Any fees associated with the extension should be charged to our 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 **9** 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:

1-37 (canceled)

Claim 38 (new): A film composite for manufacturing a package for planar carriers of pharmaceutical active substances, comprising, in a direction from the outer side of the film composite toward its inner side:

(i) a metal layer;

(ii) an acrylic acid-containing joining layer;

(iii) a polyethylene layer; and,

(iv) 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 comprises metallocene polyethylene to tie the COC layer to the acrylic acid-containing joining layer and thereby to the metal layer to promote the delamination stability of the film composite.

Claim 39 (new): The film composite according to claim 38, wherein the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer is at least 50 wt%.

Claim 40 (new): The film composite according to claim 38, wherein the polyethylene layer comprises a metallocene linear low density polyethylene.

Claim 41 (new): The film composite according to claim 38, wherein the polyethylene layer comprises at least one of a C6 metallocene polyethylene and a C8 metallocene polyethylene.

Claim 42 (new): A film composite for manufacturing a package for planar carriers of pharmaceutical active substances, comprising, in a direction from the outer side of the film composite toward its inner side:

(i) a metal layer;

(ii) an acrylic acid-containing joining layer;

(iii) a polyethylene layer; and,

(iv) 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 comprises a C8 metallocene linear low density polyethylene and wherein

the polyethylene layer connects the COC-layer to the acrylic acid-containing joining layer and thereby to the metal layer to promote the delamination stability of the film composite.

Claim 43 (new): The film composite according to claim 42, wherein the acrylic acid-containing joining layer is an ethylene-acrylic acid (EAA) copolymer.

Claim 44 (new): The film composite according to claim 38, wherein each of the acrylic acid-containing joining layer, the polyethylene layer, and the COC layer, has a layer thickness in the range from about 7 µm to about 15 µm.

Claim 45 (new): The film composite according to Claim 44, wherein the thickness values of said layers, referred to the thinnest of said layers, differ by no more than 15%.

Claim 46 (new): The film composite according to Claim 45, wherein the thickness values of said layers, referred to the thinnest of said layers, differ by no more than 11%.

Claim 47 (new): The film composite according to Claim 44, 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.

Claim 48 (new): The film composite according to Claim 47, wherein the thickness values of said layers, referred to the thinnest of said layers, differ by no more than 15%.

Claim 49 (new): The film composite according to Claim 48, wherein the thickness values of said layers, referred to the thinnest of said layers, differ by no more than 11%.

Claim 50 (new): The film composite according to Claim 38, 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.

Claim 51 (new): The film composite according to Claim 50, wherein the at least one further layer includes a paper layer and a plastic layer.

Claim 52 (new): The film composite according to Claim 51, wherein the plastic layer is located closer to the metal layer than the paper layer.

Claim 53 (new): The film composite according to Claim 50, wherein the at least one further layer includes a plastic layer that is a biaxially oriented plastic.

Claim 54 (new): The film composite according to Claim 50, wherein the at least one further layer includes a plastic layer that is at least one of a polyethylene terephthalate and a polyamide.

Claim 55 (new): The film composite according to Claim 50, wherein the at least one further layer includes at least one of

(i) 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

(ii) 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.

Claim 56 (new): The film composite according to Claim 55, wherein the at least one further layer includes at least one of

(i) 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

(ii) a plastic layer having a thickness of 22 to 24 µm and a weight per unit area of 31 to 33 g/m^2.

Claim 57 (new): A film composite for manufacturing a package for planar carriers of pharmaceutical active substances, comprising, in a direction from the outer side of the film composite toward its inner side:

(i) a metal layer;

(ii) an acrylic acid-containing joining layer;

(iii) a polyethylene layer; and

(iv) a COC layer made of cycloolefin copolymer,

wherein the polyethylene layer comprises metallocene polyethylene to tie the COC layer to the acrylic acid-containing joining layer and thereby to the metal layer to promote the delamination stability of the film composite, and 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 about 7 µm to about 15 µm, and wherein

the thickness values of said layers, referred to the thinnest of said layers, differ by no more than 15%.

Claim 58 (new): A film composite for manufacturing a package for planar carriers of pharmaceutical active substances, comprising, in a direction from the outer side of the film composite toward its inner side:

(i) a layer made of at least one of a paper and a plastic;

(ii) a metal layer;

(iii) an acrylic acid-containing joining layer;

(iv) a polyethylene layer; and,

(v) 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 comprises metallocene polyethylene to tie the COC layer to the acrylic acid-containing joining layer and thereby to the metal layer to promote the delamination stability of the film composite, and 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 about 7 µm to about 15 µm, and wherein

the thickness values of said layers, referred to the thinnest of said layers, differ by no more than 15%.

Claim 59 (new): The film composite according to Claim 58, wherein the at least one further layer includes a paper layer and a plastic layer.

Claim 60 (new): The film composite according to Claim 59, wherein the plastic layer is located closer to the metal layer than the paper layer.

Claim 61 (new): The film composite according to Claim 60, wherein the at least one further layer includes a plastic layer that is a biaxially oriented plastic.

Claim 62 (new): The film composite according to Claim 61, wherein the at least one further layer includes a plastic layer that is at least one of a polyethylene terephthalate and a polyamide.

Claim 63 (new): The film composite according to Claim 58, wherein the at least one further layer includes at least one of

(i) a paper layer having at least one of
    a. a thickness of 35 to 45 µm and
    b. a weight per unit area of 35 to 45 g/m^2 and

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

Claim 64 (new and withdrawn from consideration): A package for a planar carrier of pharmaceutical active substances, comprising two film-composite sheets of claim 38, wherein the two film-composite sheets are arranged with mutually facing COC layers to form a carrier receiving space and wherein the two film-composite sheets are joined to one another by local sealing of regions of the COC layers.

Claim 65 (new and withdrawn from consideration): The package according to Claim 64, wherein the package is a four-side-sealed pouch having a sealed seam surrounding the carrier receiving space.

Claim 66 (new and withdrawn from consideration): The package according to Claim 65, having a planar active-substance carrier, in particular a transdermal patch, contained in the carrier receiving space, the pharmaceutical active substance containing at least one of nicotine, fentanyl and lidocaine.

REMARKS

The Final Office Action dated April 7, 2022 has been received and carefully considered. In response, Applicant respectfully submits that the prior art fails to teach the invention of this application wherein reconsideration and allowance is respectfully requested.

The currently pending claims are 38-63, which are supported by earlier claims 16-34, now cancelled. Withdrawn claims 35-37 are replaced by "new and withdrawn" claims 64-66.

In addition, Applicant requests that withdrawn claims 64-66 (earlier 35-37) be rejoined and considered upon the allowance of generic elected claim 38 (earlier 16).

Claims 16 and 18-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn et al. (US 2015/0225151 A 1) in view of Toft et al. (US 2005/0181154 A 1) and Torradas et al. (US 2017/0136747 A 1).

It is respectfully submitted that cited references do not teach the invention of this application wherein reconsideration and allowance is respectfully requested. The prior art is applied to new claims 38 and 40-63 in place of earlier claims 16 and 18-34.

The extent of Osborn's teachings is the existence of certain recited materials. The instant invention discloses and claims a specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed. The specific arrangement of layers in the specific order recited in the claims is not taught in the cited references. The Examiner has used Applicant's specification as a roadmap for the assemblage of various material layers in the order instantly claimed.

For Example, the teachings of Osborn (2 embodiments), Toft and the subject matter of Instant Claims 38, 42 and 50 are compared in Table 1:

Table 1: Comparative multilayer barriers of Osborn and the Invention

Osborn 1	Osborn 2	Toft	Invention Claim 38	Invention Claim 42	Invention Claim 50
exterior	exterior	exterior	exterior	exterior	exterior
OPET/ Paper	OPET/ Paper	PE	XXX*	XXX	XXX
PE	Primer / PE	Paper	XXX	XXX	Paper or plastic/ OPET
LDPE	LDPE	LDPE	XXX	XXX	XXX
EVA	EAA	XXX	XXX	XXX	XXX
O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)
PE or EVA	EAA	EAA	EAA/EVA	EAA/EVA	EAA/EVA
Polyolefin Bulk: PE, LLDPE, m-LLDPE	LDPE	COC + mLLDPE	PE	PE inc. C_8 m-LLDPE	PE, LLDPE, m-LLDPE
COC	COC	m-PE/ m-LLDPE	COC	COC	COC
Interior	Interior	interior	interior	Interior	interior

*XXX means this layer is not mentioned in this column.

Osborn does not disclose metallocene polyethylene in the polyethylene layer that is in between the COC layer and the acrylic acid containing joining layer as is recited in claim 38. Selecting and combining word portions and symbols together, which are found in Osborn

and/or Toft, does not teach the invention. These noted fragments from the prior art, which do not and cannot be combined as alleged, do not render obvious the claimed invention. There is no teaching or suggestion in the cited references, singly or in combination, to include metallocene polyethylene in the polyethylene layer that is in between the COC layer and the acrylic acid-containing joining layer as is recited in claim 38. Only by the improper use of hindsight reconstruction, based on the disclosure of this application, could such a leap be made.

The Examiner cites Toft and Torradas together as overcoming the shortcomings of Osborn. This combination fails. The propositions for which Toft and Torradas are cited as the alleged disclosure of Toft of a PE layer (such as m-LLDPE) next to the COC layer, and that of Torradas: LLDPE being preferred for packaging films. Toft's PE/m-LLDPE layer is interior to the COC layer. However, the combination of Osborn and Toft fail to teach or suggest the instantly claimed embodiments where the COC is the exterior layer. Osborn teaches that **only** the COC layer may be the interior layer, that is, adjacent to the product (= interior). In paragraph [0041], Osborn notes that it is *"essential that the oxygen and water barrier layer film … have an article contact layer containing ethylene norbornene copolymer which is a cyclic olefin copolymer (COC)."* Therefore the teachings of Osborn prevent the combination of any other art reference from modifying that aspect of Osborn. In that light, all other combinations of any other prior art reference, including Toft and Torradas with Osborn that purport to alter Osborn such that a COC layer is not the article contact layer (i.e., the innermost layer), are forbidden and any argumentation or rejection based thereon, is moot. For emphasis, Applicant notes that Osborn discloses not that any COC is required in the innermost layer, but that the innermost layer must be specifically ethylene norbornene copolymer.

Toft teaches that the layer including COC is adjacent to the innermost layer, (but not that the COC layer is the innermost layer) with a layer including PE (which can be m-LLDPE) as the innermost layer. There is no way to combine Toft with Osborn in this

manner as the Examiner has done. Toft teaches a paper core as an outer layer, while the outermost layer is a heat sealable PE. Neither reference, nor their combination, teaches the COC layer being the innermost or next to the innermost layer.

Torradas is cited for the propositions that (i) LLDPE is preferred as a PE layer used as a moisture barrier in a multilayer film and (ii) the exterior layer is aluminum or PE. The Examiner incorrectly interprets Torradas as further teaching that any composition layer can be in any relative location: inner, outer or a layer between the inner and outer layer. This, teaches all possible orientations and adds nothing to the conversation. There is no preferred orientation taught, meaning that the combination of Torradas with Toft and/or Osborn invited the skilled artisan to try everything, with no clear teaching that can be applied to Osborn and/or Toft. The structure layer in Osborn is the "bulk" layer which is a polyolefin such as PE or LLDPE; conversely, the structure layer in Toft is the paper layer.

Relevant to the layer thicknesses (absolute and relative) of the structure as claimed in earlier claims 22 – 27 the Examiner cites Osborn's Examples 2 and 5. Applicant notes that, although Osborn's Example 2 is a disclosure of that reference, it is a "Comparative Example" meaning it is the prior art relative to the invention of Osborn. Example 5 is the only exemplary teaching of the Osborn invention.

In the paragraph bridging pages 3-4 of the Office Action, the examiner sets forth the details of Osborn's Example 5 as an *eight-layer* film. The thicknesses of the various layers are also recited.

The Examiner concludes that:

> [A]ll layers can have the thickness of <u>less than mils</u>[1] and any increment of 0.1 or 0.01 mil there between which includes 0.4 mil (10.16 μm) (the instant claims 22 and 25) and 1.5 mil (25.4 μm) (the thickness of paper layer in the instant claims 22 and 25) (entire reference, especially abstract, figure 1, paragraph 6-12, 15, 16, 20-28, 40, 41, 46, 47, 49, 50, 51, 53, 54, 57, 68, 69, 71, 72, 78, 93, 97, and 100, and claims 1-5).
>
> Since Osborn et al. teach the adhesive, PE, and COC layers being coextruded which is the

[1] The phrase 'less than mils" is the direct quote of the Examiner and it is unknown whether the Examiner intended to include a numerical value, such as "less than 100 mils."

same as the method of producing the acrylic acid, PE, and COC layers (2nd paragraph on page 5), the thickness value (claims 23, 24, 26, and 27) of the adhesive, PE, and COC layers taught by Osborn et al. teach would be the same as those of the acrylic acid, PE, and COC layers of the claimed film.

Simply, the Examiner concludes that because a similar production procedure is used in Osborn and the claimed invention, the thickness value of any such layers would be the same as those in the claimed film. More simply, the conclusion is "because it is made in the same/similar way, the dimensions are the same." There are words to convey how improper this reasoning is to reach this conclusion: *non sequitur.*

The Examiner does not, and cannot, actually point out any clear teaching or suggestion of the claimed thickness layer ranges in the Osborn reference, or any other reference, because such teaching is not there. The use of a similar fabrication or lamination method does not axiomatically lead to the precise thicknesses as claimed in the application.

Even assuming *arguendo* that the extrapolation from Osborn leads to the same layer thicknesses as those instantly claimed, there is simply no teaching or suggestion in Osborn – or the other references – singly or in combination, that leads to the claimed relative thicknesses in present claims (58-62), former claims 22-27, 33 and 34.

The molecular structure of the m-LLDPE molecule defines its chemical and physical behavior. It has been found by the inventors of this application that C8 m-LLDPE is suitable to create a strong bond to a COC layer and to thereby prevent delamination. None of the cited prior art documents even mentions side-chain branches of m-LLDPE, and are even more silent on possible lengths of side-chain branches branching-off from the slender main PE string.

Moreover, the item 15-1 in figure 1 of Toft referenced in the Office Action on page 5, as an adhesive layer of EAA is not such a layer. Conversely, paragraph [0081] of Toft

identifies item 15-1 as an adhesive part-layer comprising an adhesive polymer, whereas this adhesive part layer according to [0083] of Toft is a maleic-anhydride graft modified LLDPE, which is not even closely resembling EAA (ethylene acrylic acid).

The Office Action explicitly refers to paragraphs [0020] and [0021] of Toft to emphasize the allegedly desirable properties of m-LLDPE, like improved tear and puncture resistance, toughness, impact strength, clarity, anti-blocking properties and heat sealing performance compared to that of ordinary LDPE [Office Action page 6]. However, this assertion ignores that the cited paragraphs of Toft conversely recommends the use of metallocene polyethylenes for the innermost layers in packaging laminates, which explains the vowed clarity, antiblocking and sealing properties which are only relevant for an exposed layer, but not for intermediate layers as is the case in the subject-matter of the recited invention.

There is no teaching in the cited references as to why a skilled practitioner in the art would use a metallocene-PE containing polyethylene layer to establish an enhanced bond between an exposed COC layer and a metal layer through an EAA layer, based on the recommendation to use metallocene polyethylenes as innermost layers. Conversely, the opposite should be true. After reading Toft, any skilled artisan would use m-PEs as exposed outer layers, but never in between other layers.

New independent claims are as follows:

Claim 42. A film composite for manufacturing a package for planar carriers of pharmaceutical active substances, comprising, in a direction from the outer side of the film composite toward its inner side:

(i) a metal layer;

(ii) an acrylic acid-containing joining layer;

(iii) a polyethylene layer; and,

(iv) 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 comprises a C8 metallocene linear low density polyethylene and

wherein the polyethylene layer connects the COC-layer to the acrylic acid-containing joining layer and thereby to the metal layer to promote the delamination stability of the film composite.

Claim 57: A film composite for manufacturing a package for planar carriers of pharmaceutical active substances, comprising, in a direction from the outer side of the film composite toward its inner side:

(i) a metal layer;

(ii) an acrylic acid-containing joining layer;

(iii) a polyethylene layer; and

(iv) a COC layer made of cycloolefin copolymer,

wherein the polyethylene layer comprises metallocene polyethylene to tie the COC layer to the acrylic acid-containing joining layer and thereby to the metal layer to promote the delamination stability of the film composite, and 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 about 7 µm to about 15 µm, and wherein

the thickness values of said layers, referred to the thinnest of said layers, differ by no more than 15%.

New Independent claim 58 mirrors claim 57, however it requires the presence of a ~~a~~ layer made of at least one of a paper and a plastic on its outermost face.

Accordingly, it is respectfully submitted when the entire teachings of the cited references are taken into consideration, the recited invention of claims 38, 42, 57 and 58 patentably distinguish the prior art. KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007).

Moreover, it is respectfully submitted that the dependent claims 40-63 further patentably distinguish the prior art and are allowable as is outlined above.

Claims 16-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas in view of Toft.

It is respectfully submitted that new claims 38-42 (former claims 16-21) patentably distinguish Torradas and Toft.

As is discussed in greater detail above, while the cited references may disclose that certain recited materials exist, 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. The specific arrangement of layers in the specific order recited in the claims of this application is not taught in the cited references.

Torradas teaches a multilayered film. However Torradas lacks any teaching that a film utilizing metallocene polyethylene in the polyethylene layer is in between the COC layer and the acrylic acid-containing joining layer as is recited in claim 38. There is no teaching in the prior art for this combination of layers. Conversely, the cited references teach away from the combination required to obtain the multilayer barrier of claim 38 from the teachings of the prior art.

Toft fails to overcome the shortcomings in Torradas like it fails to overcome the shortcomings in Osborn. As is discussed in greater detail above, the adhesive layer of EAA is not such a layer. Conversely, paragraph [0081] of Toft identifies item 15-1 as an adhesive part-layer comprising an adhesive polymer, whereas this adhesive part-layer according to [0083] of Toft is a maleic-anhydride graft modified LLDPE, which is completely different from EAA (ethylene acrylic acid).

As discussed in greater detail above, Toft actually teaches away from the invention of this application wherein it recommends the use of metallocene polyethylenes for the use of innermost layers in packaging laminates, which explains the alleged clarity, antiblocking and sealing properties which are only relevant for an exposed layer, but not for intermediate layers as is the case in the subject-matter of the recited invention.

There is no teaching in the cited references as to why a skilled artisan would use a metallocene-PE containing polyethylene layer to establish an enhanced bond between an exposed COC layer and a metal layer through an EAA layer, based on the recommendation to use metallocene polyethylenes as innermost layers.

Accordingly, it is respectfully submitted that claim 38 patentably distinguishes the cited references and that claims 39-42 further patentably distinguish the cited references.

Claims 22-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas and Toft, as applied to claims 16-21, in view of Osborn et al. (US 2015/0225151 A1).

The subject matter of new claims 44-49, 55, 56, 58 and 63 covers the subject matter of earlier claims 22-34 and are dependent from claim 38 and patentably distinguish the cited references for at least the same reasons. As is discussed in greater detail above, Torradas, Toft and Osborn fail to disclose the specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed. Accordingly, it is respectfully submitted that claims 44-49, 55-58 and 63 are in condition for allowance wherein reconsideration and allowance is respectfully requested.

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.

The subject matter of new claims 38-63 covers the subject matter of earlier claims 16-34. As is discussed in greater detail above, Torradas, Toft and Osborn (individually or in any combination) fail to disclose the specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed. Accordingly, it is respectfully submitted that claims 38-63 (former claims 16-34) are in condition for allowance wherein reconsideration and allowance is respectfully requested.

It is respectfully submitted that the prior art fails to disclose or make obvious the recited invention of this application. 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 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 the pending claims patentably distinguish the prior art. 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 all pending claims is respectfully requested.

Examiner's Consideration of Declarations

Applicant has filed Declarations of Inventor Manuella Herb, with the responses to the first two Office Actions. In the Office Action mailed 7 April 2022, the Examiner's consideration of the second Declaration consisted of the following: "[t]he declaration ... is insufficient to overcome the rejections of pending claims... because: all argument [sic] based on the prior art with regard to m-PE vs. PE are addresses [sic] above."

While the undersigned appreciates the detailed analysis of the prior art covering some fourteen pages, the Declaration was not fully considered.

As noted in the Declaration, section 11, "metallocene C8 and LDPE, 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. 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."

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.

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,

RANKIN, HILL & CLARK LLP

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/516,792	Filing Date 07/19/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	08/03/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 29	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 5	Minus	*** 5	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/KATARA D SINGLETARY/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

75626 7590 04/07/2022

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EXAMINER	
YU, HONG	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
04/07/2022	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 16/516,792	Applicant(s) Herb et al.	
	Examiner HONG YU	Art Unit 1612	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 01/24/2022.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 16-37 is/are pending in the application.

5a) Of the above claim(s) 35-37 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 16-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

DETAILED ACTION

Status of claims

Claims 1-15 have been canceled and claims 35-37 have been withdrawn. Claims 16-34 are under examination in the instant office action.

Rejections withdrawn

Applicant's arguments and affidavit filed on 01/24/2022 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Rejections maintained

The following rejections of the claims are remained for reasons of record and the following. The text of the section of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn et al. (US 2015/0225151 A1) in view of Toft et al. (US 2005/0181154 A1) and Torradas et al. (US 2017/0136747 A1).

Osborn et al. teach a flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches comprising

an article contact layer having at least 90 wt. % of a norbornene ethylene copolymer (COC) or derivative thereof;

a polyolefin bulk layer including PE;

a first intermediate adhesive layer;

an oxygen barrier layer including aluminum foil;

a second intermediate adhesive layer; and

an exterior protective layer comprising a polymer selected from the group consisting of paper, polyamide, polyolefin, blends or derivatives thereof and

PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)

exemplified a film comprising OPET (biaxially oriented polyester terephthalate) /PE/LDPE/EVA/Al Foil base layer with three-layer coextrusion of EAA, LDPE, and an 80:20 wt % blend of LDPE:mLLDPE in example 2 and EAA, LDPE, and COC in example 5 which were extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film of

OPET/PE/ LDPE/EAA/Al foil/EAA/LDPE/LDPE:mLLDPE and a total thickness of 3.04 mils (77.2 microns) in example 2 and

0.92 mil (23.37 μm) OPET (the thickness of plastic layer in the instant claims 33 and 34)/PE/0.42 mil (10.67 μm) LDPE/0.1 mil (2.54 μm) EAA/0.35 mil (8.85 μm) All foil/0.17 mil (4.32 μm) EAA/0.65 mil (16.51 μm) LDPE/0.43 mil (10.92 μm) COC and a total thickness of 3.0 mils (76 microns) in example 5;

all layers can have the thickness of less than mils and any increment of 0.1 or 0.01 mil there between which includes 0.4 mil (10.16 μm) (the instant claims 22 and 25) and 1.5 mil (25.4 μm) (the thickness of paper layer in the instant claims 22 and 25) (entire reference, especially abstract, figure 1, paragraph 6-12, 15, 16, 20-28, 40, 41, 46, 47, 49, 50, 51, 53, 54, 57, 68, 69, 71, 72, 78, 93, 97, and 100, and claims 1-5).

Since Osborn et al. teach the adhesive, PE, and COC layers being coextruded which is the same as the method of producing the acrylic acid, PE, and COC layers (2nd paragraph on page 5), the thickness value (claims 23, 24, 26, and 27) of the adhesive, PE, and COC layers taught by Osborn et al. teach would be the same as those of the acrylic acid, PE, and COC layers of the claimed film.

Osborn et al. do not specify an embodiment with the PE layer next to COC being metallocene catalyzed (MC- or m-) LLDPE.

This deficiency is cured by Toft et al. a packaging laminate for food as illustrated in figure 1 below comprising, from exterior to food contacting interior,

item 12 being a heat sealable such as PE,

item 11 being a core of paperboard with item 14 being an intermediate layer of thermoplastic of about 23-27 g/m^2 LDPE (the claimed further layers made of plastic and/or paper in claims 28-30) bonding item 11 to

item 13 which is an aluminum foil,

item 15-1 being an adhesive layer of EAA (the instant claim 21),

item 15-2 being a barrier layer of a blend of COC and m-LLDPE, and

item 15-3 being a PE-MC layer a blend of 60-70% by weight of m-LLDPE (the instant claim 18) prepared by copolymerization of C_{4-8} α-olefins including 1-hexene (C_6) or 1-octene (C_8) (the instant claims 19 and 20) and 30-40% by weight of LDPE (the instant claim 17)

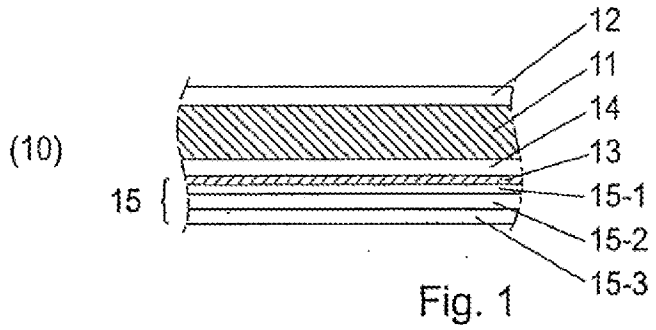


Fig. 1

and m-LLDPE having desirable properties like improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE (paragraph 20-21) (entire reference, especially abstract, figure 1, paragraph 46-53, 55, 56, 60, 79-81, and 83, and claims 1-3, 6, 7, and 9) and

Torradas et al. who teach a multilayered film, with a total thickness of < about 250 μm, for packing food, including liquid food, drug, etc., comprising

an external layer such as aluminum or PE as a good barrier to moisture permeation including MC-PE with the external layer being optionally protective coated;

one or more inner layers including barrier layers of COC;

a structure layer which can be an external layer, and/or inner layer, and barrier layer such as PE made by metallocene catalyst system for both structure and barrier functions;

one or more adhesive layers such as Elvaloy AC (the claimed ethylene acrylate copolymer in claim 21) between the outside structure layer and an inner layer with the thickness of adhesive layer being 2-10 μm, and LLDPE is preferred for packaging films (paragraph 100) (entire reference, especially abstract, paragraph 92, 93, 95, 99-101, 106, 107119, 121, 122, 126, 127, 131, 136, 137, 140, 202, 222, and 240). A structure layer which can be an external layer, and/or inner layer, and barrier layer is interpreted as a structure can be a barrier layer between external layer and inner layer.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Osborn et al., Toft et al., and Torradas et al. to replace the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. with m-LLDPE. PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8), LLDPE is preferred for packaging films, and m-LLDPE having desirable properties compared to that of ordinary LDPE were well known to a person of ordinary skill in the art at the time of the invention. The motivation for replacing the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. with m-LLDPE flows from m-LLDPE having been used in the prior art, and from m-LLDPE being recognized in the prior art as useful for the same purpose with the known advantages.

Osborn et al. do not specify the weight/unit area of paper and plastic layers (claims 33 and 34).

This deficiency is cured by the rational that it is routine optimization to determine the optimum weight/unit area for each layer.

Osborn et al. do not specifically teach weight unit of the paper layer and plastic layer (external layers) claimed by applicant. While the layer thicknesses of the paper layer and plastic layer are within those of the claimed film, the PET plastic and the paper are known packaging layer materials for achieve the same protective effect and would be reasonable to assume that they are the similar materials with the similar density and thus would result in the similar weight/unit area.

Or alternatively, weight/unit area of the paper layer and plastic layer in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize or, alternatively obvious to try to reach another workable product or process. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal weight/unit area in order to best achieve the desired results of protective effect.

Response to Applicants' arguments:

Applicants argue that Osborn et al. do not teach the claimed specific order of layers which results in the unexpected special properties, the PE layer being between COC layer and acrylic acid containing layer being metallocene (m), especially C8 m-LLDPE, which create strong bond to a COC layer for preventing delamination.

However, this argument is not deemed persuasive. First of all, C8 is not claimed in claim 16, C8 is claimed as one of the two alternative m-PEs in claim 19, and LLDPE is not claimed in claim 16, and thus the argument of Osborn et al. not teaching the claimed C8 m-LLDPE is not commensurate in scope with the scope of claim 16.

Secondly, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, as stated in the rejection above and in the previous office action, Osborn et al. teach PE layer between COC layer and adhesive layer and PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)

while Toft et al. provide the motivation to select m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8) as the PE layer based on Toft et al.'s teachings of m-LLDPE having desirable properties like improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE (paragraph 20-21) and

Torradas et al. provide the further motivation to select LLDPE based on the teachings of LLDPE being preferred for packaging films (paragraph 100).

Thus, it would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Osborn et al., Toft et al., and Torradas et al. to replace the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. with m-LLDPE. Please refer to MPEP 2145.III:

the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Lastly, with regard to the alleged the claimed specific order of layers which results in the unexpected special properties, the affidavit filed on 08/12//2021 alleged C8 m-LLDPE as a layer between COC and adhesive having delamination stability (item 10 and 11); however there is only comparison between the LDPE and m-LLDPE in the packaging film with the same layer arrangement, thus there is no evidence of the claimed specific order of layer resulting in unexpected special properties.

Osborn et al. teach PE layer between COC layer and adhesive layer and thus the is no deficiency with regard to the order of layer arrangement in Osborn et al.'s teaching while Toft et al. and Torradas et al. provides ample motivation for selecting m-LLDPE among suitable PEs (including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)) taught by Osborn et al. with expected advantages. Although Toft et al. and Torradas et al. do not teach delamination as one of the advantages of m-LLDPE over LDPE; the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant according to MPEP 2144.IV. Also, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants argue that item 15-1 in figure 1 of Toft et al. as an adhesive layer EAA is a maleic-anhydride graft modified LLDPE (paragraph 83) part-layer (paragraph 81).

However, this argument is not deemed persuasive.

First of all, Osborn et al. teach EAA layer and thus there is no deficiency in Osborn et al.'s teachings with regard to EAA layer in the instant rejection, i.e., item 15-1 in figure 1 of Toft et al. as an adhesive layer EAA is not the teaching used to cure the deficiency of Osborn et al.

Secondly, although in paragraph 81 and 83 Toft et al. adhesive layer (or part-layer) being maleic-anhydride graft modified LLDPE, Toft et al. also teach, in general, the materials for adhesive layer including maleic-anhydride graft modified LLDPE and EAA (paragraph 52) and thus maleic-anhydride graft modified LLDPE are equally suitable adhesive layer materials.

Applicants argue that the advantageous m-LLDPE taught by Toft et al. is for innermost layer.

However, this argument is not deemed persuasive. Toft et al. teach many advantages of m-LLDPE: improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE in paragraph 20-21 while Toft et al. teach the reason for m-LLDPE to be used as the innermost layer is for the improved package integrity and sealability properties in paragraph 21 and the "package integrity" is the resistance to leakage of the packaging container in paragraph 22. Toft et al. also teach m-LLDPE being used as

an intermediate layer I paragraph 56. Thus advantages of m-LLDPE other than the resistance to leakage are not limited to the innermost layer.

Respectfully, applicants' arguments are not persuasive. The predictable and expected result of the claimed composition remains predictable and expected in the absence of evidence to the contrary. Accordingly, the claims remain rejected for at least these reasons and the reasons of record.

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) in view of Toft et al. (US 2005/0181154 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify an embodiment with LLDPE being MC-LLDPE and C_8 MC-LLDPE in claims 18-20.

This deficiency is cured by Toft et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Toft et al. to specify the LLDPE in the film taught by Torradas et al. being C_8 m-LLDPE. M-LLDPE having desirable properties like improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE and m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)

were well known to a person of ordinary skill in the art at the time of the invention. The motivation for specify the LLDPE in the film taught by Torradas et al. being C_8 m-LLDPE flows from C_8 m-LLDPE having been used in the prior art, and from C_8 m-LLDPE being recognized in the prior art as useful for the same purpose with the known advantages.

Response to Applicants' arguments:

Applicants argue that Torradas et al. do not teach the claimed order of layer arrangement which results in the unexpected special properties and utilizing m-PE while Toft et al. do not cure Torradas et al.'s deficiency as discussed above.

However, this argument is not deemed persuasive. First of all, Torradas et al. teach a multilayered film comprising an external layer (such as aluminum or PE as a good barrier to moisture permeation including MC-PE with the external layer being optionally protective coated); one or more inner layers (including barrier layers of COC); a structure layer which can be an external layer, and/or inner layer, and barrier layer such as PE made by metallocene catalyst system for both structure and barrier functions; one or more adhesive layers (such as Elvaloy AC) between the outside structure layer and an inner layer. A structure layer which can be an external layer, and/or inner layer, and barrier layer is interpreted as a structure can be a barrier layer between external layer and inner layer and the one or more inner layers including PE and COC.

Secondly, Torradas et al. tech PE being suitable for both structure layer and barrier layer (paragraph 121), i.e., same PE for both structure layer and barrier layer; m-PE as one of the PEs (including LLDPE, m-PE, etc.,) having barrier property (paragraph

99-101) and thus Torradas et al. m-PE as one of the inner layers. Furthermore, as discussed above, Toft et al. provide motivation for select m-PE among the suitable PEs.

Lastly, as discussed above, there is no evidence of the claimed specific order of layer resulting in unexpected special properties in the affidavit filed on 08/12//2021.

Respectfully, applicants' arguments are not persuasive. The predictable and expected result of the claimed composition remains predictable and expected in the absence of evidence to the contrary. Accordingly, the claims remain rejected for at least these reasons and the reasons of record.

Claims 22-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) and Toft et al. (US 2005/0181154 A1), as applied to claims 16-21, in view of Osborn et al. (US 2015/0225151 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify: i) the thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers (claims 22-27); and ii) the limitations of the further layers outside the metal layer (protective layers) in claims 28-34.

These deficiency is cured by Osborn et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Osborn et al. to

specify the claimed thicknesses and the film taught by Torradas et al. having the claimed thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments:

Argument regarding the 103 rejection is basically the same as the above rejections, thus the response discussed above applies here as well and is not persuasive for reason discussed above.

Claims 16-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toft et al. (US 2005/0181154 A1) in view of Osborn et al. (US 2015/0225151 A1) and Torradas et al. (US 2017/0136747 A1).

Toft et al.'s teachings are discussed above and applied in the same manner.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **[for manufacturing a package for planar carriers of pharmaceutical active**

substances]; however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Furthermore, according to Torradas et al. a multilayered film can be used for both packing food, including liquid food, and drug.

Toft et al. do not teach the innermost layer 15-2 and 15-3 being the opposite order.

This deficiency is cured by Osborn et al. and Torradas et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al., Osborn et al., and Torradas et al. to exchange the COC layer and MC-PE layer in the film taught by Toft et al. with the innermost layer being COC and MC-PE being the layer before it. OCO as the innermost layer and PE next to it according to Osborn et al. and MC-PE being one of the PE before the innermost layer according to Torradas et al. was well known to a person of ordinary skill in the art at the time of the invention. The motivation for exchanging the COC layer and MC-PE layer in the film taught by Toft et al. flows from COC being the innermost layer and MC-PE being the layer next to it having been used in the prior art, and from COC being the innermost layer and MC-PE being the layer next to it being recognized in the prior art as useful for the same purpose of packaging film.

Toft et al. do not teach the thicknesses and thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers (claims 22-27) and the further layers outside the metal layer (protective layers) in claims 31-34.

This deficiency is cured by Osborn et al. whose teachings are discussed above.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al. and Osborn et al. to specify the claimed thicknesses and the film taught by Toft et al. having the claimed thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments:

Argument regarding the 103 rejection is basically the same as the above rejections, thus the response discussed above applies here as well and is not persuasive for reason discussed above.

Response to applicants' 37 CFR 1.132 declaration:

The declaration under 37 CFR 1.132 filed 01/24/2022 is insufficient to overcome the rejections of pending claims as set forth in the last Office action because: all argument based on the prior art with regard to m-PE vs PE are addresses above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on 9 am - 5:30 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, Applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HONG YU/
Primary Examiner, Art Unit 1612

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

CPC - Searched*		
Symbol	**Date**	**Examiner**
B32B 15/$, B32B 27/$	11/16/2020	HY
B32B 15/$, B32B 27/$	10/08/2021	HY

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/HONG YU/ Primary Examiner, Art Unit 1612	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

Search Notes		
Search Notes	**Date**	**Examiner**
east search: inventor and assignee search and keyword search	11/16/2020 11/17/2020 11/18/2020	HY
google search	11/16/2020	HY
global dossier	11/16/2020	HY
Updated east search	05/11/2021	HY
google search	05/11/2021	HY
global dossier	05/11/2021	HY
updated east search	10/08/2021	HY
global dossier	10/08/2021	HY
google search	10/09/2021	HY
east search	04/06/2022	HY
google search	04/06/2022	HY
global dossier	04/06/2022	HY

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

/HONG YU/
Primary Examiner, Art Unit 1612

Web Search History

date, time	web site	search string
4/6/2022 1:32:59 PM	Google	packaging film AND aluminum AND acrylic acid adhesive AND metallocene polyethylene AND cycloolefin
4/6/2022 1:38:43 PM	Google	packaging film AND aluminum AND adhesive AND metallocene polyethylene AND cycloolefin

Global Dossier

Office

US

Type

Application

16516792

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US 16516792 4 Members in Patent Family (2 currently shown) ()

« ()

IP Office Type

All IP5 Offices

- EPO
- SIPO
- KIPO
- JPO
- USPTO

Non-IP5 Offices

()	Office ()	Application ()	Applicant	Title ()	App. Date ()	Priority #	Pub. # ()	Pub. Date	A
()	EP	19186607	1) Huhtamaki Flexible Packaging Germany GmbH & Co. KG,	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES AND PACKAGING FROM SUCH A FILM COMPOSITE	07/16/2019	DE 102018212303 DE 102018125195	EP 3599090 A1 () EP 3599090 B1 ()	01/29/2020 03/23/2022	

Most Recent Documents

Date	Document Description ()	Options
04/05/2022	Transmission of the certificate for a European patent pursuant to Rule 74 EPC ()	•••
02/24/2022	Decision to grant a European patent ()	•••
02/10/2022	Letter accompanying subsequently filed items ()	•••

Office Actions

Date	Document Description ()
02/24/2022	Decision to grant a European patent ()
10/27/2021	Communication about intention to grant a Eurc patent ()
12/05/2019	European search opinion ()

All Documents | Classification and Citation | View All Office Actions

()	US	16516792 View Dossier ()	1) Herb, Manuella 2) Dorn, Michael 3) Stroh, Thomas	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	07/19/2019	DE 102018212303 DE 102018125195	US 20200031107 A1 ()	01/30/2020

(http://www.uspto.gov/)

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USPTO BACKGROUND

USPTO BACKGROUND

FEDERAL GOVERNMENT

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L9	64,742	(b32b15/$ and b32b27/$).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30
L10	36,126	L9 and (metal or foil or aluminium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30
L11	466	L10 and (Metallocene near10 polyethylene or PE-MC or pe-m or m-PE or mc-pe or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30
L12	147	L11 and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30
L13	147	L12 and polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30
L14	127	L13 and ((laminate or laminating or layer or coat or coating or film or package or packaging).ti. or (laminate or laminating or layer or coat or coating or film or package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30
L15	35	L14 and (acrylic or polyacrylic or poly(acrylic acid)) with (adhesive or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30
L16	35	L15 and (polyethylene or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/04/06 13:30

EAST Search History (Interference)

<This search history is empty>

4/6/2022 1:31:27 PM
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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/516,792	Filing Date 07/19/2019	☑ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/24/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ANGELA D JOHNSON/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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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 "D"

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

This amendment is filed in response to the Non-Final Office action dated October 27, 2021 wherein the three-month period for responding to the Office action expires on January 27, 2022 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.
- **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. (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.

REMARKS

The Non-Final Office Action dated October 27, 2021 has been received and carefully considered. In response, Applicant respectfully submits that the prior art fails to teach the invention of this application 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. The previous grounds for rejection were withdrawn and new grounds for rejection have been asserted.

Claims 16 and 18-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn et al. (US 2015/0225151 A 1) in view of Toft et al. (US 2005/0181154 A 1) and Torradas et al. (US 2017/0136747 A 1).

Attached hereto is a Second 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.

It is respectfully submitted that cited references do not teach the invention of this application wherein reconsideration and allowance is respectfully requested.

While Osborn may disclose that certain recited materials exist, 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. The specific arrangement of layers in the specific order recited in the claims is not taught in the cited references.

Osborn does not disclose metallocene polyethylene in the polyethylene layer that is in between the COC layer and the acrylic-acid containing joining layer as is recited in claim 16. Selecting and combing word portions and symbols together, which are found in Osborn, does not teach the invention. These noted fragments from the prior art, which do not and cannot exist as alleged, do not make the recited invention obvious. There is no teaching in the cited references to utilizing metallocene polyethylene in the polyethylene layer that is in between the COC layer and the acrylic-acid containing joining layer as is recited in claim 16 even though these materials exist individually. Only by the improper use of hindsight reconstruction, based on the disclosure of this application, could such a leap in technology be made. Toft and Torradas fail to overcome the shortcomings in Osborn.

In greater detail, it is respectfully submitted that Osborn does not teach a multilayer packaging film suitable for packaging transdermal drug delivery patches comprising i.e. "PE including LDPE, m-LLDPE being catalyzed by hexene (C6) or 1-octene (C8)" [see OA: middle of page 4]. Conversely, this purported teaching is impossible. In this respect, m-LLDPE is not catalyzed by hexene or octene, but by a metallocene, hence the name m-LLDPE or metallocene LLDPE. Metallocenes are very effective metal catalysts. They consist of minute particles of positively charged metal ions sandwiched between two cyclopentadienyl anions, which have five atoms per ring. They are also known as single-site catalysts because they have only one active site per catalyst particle, which are all identical. See http://polymerdatabase.com/polymer%20chemistry/Metallocene.html (copy attached to the Second Declaration of Manuella Herb)

In addition, the additional label "C8" designates the length of the side-chain branchings of the respective metalloscene-catalyzed polymers. This is standard language and clear to the person of ordinary skills in the art. "LLDPE" means linear low density

polyethylene. The term "linear" means that, in contrast to regular HDPE, LLDPE has a rather straight polymer chain with almost no or only short molecular branches branching-off from the main ethylene polymer string. C8 m-LLDPE has longer branches, namely of eight carbon atoms, branching-off as side-chain branches than m-LLDPE that is labeled with "C" and lower digit.

The molecular structure of the m-LLDPE molecule defines its chemical and physical behavior. It has been found by the inventors of this application that C8 m-LLDPE is suitable to create a strong bond to a COC layer and to thereby prevent delamination. None of the cited prior art documents even mentions side-chain branches of m-LLDPE, and are even more silent on possible lengths of side-chain branches branching-off from the slender main PE string.

Moreover, the item 15-1 in figure 1 of Toft referenced in the Office Action on page 5. as an adhesive layer of EAA is not such a layer. Conversely, paragraph [0081] of Toft identifies item 15-1 as an adhesive part-layer comprising an adhesive polymer, whereas this adhesive partlayer according to [0083] of Toft is a maleic-anhydride graft modified LLDPE, which is not even closely resembling EAA (ethylene acrylic acid).

The Office Action explicitly refers to paragraphs [0020] and [0021] of Toft to emphasize the allegedly desirable properties of m-LLDPE, like improved tear and puncture resistance, toughness, impact strength, clarity, anti-blocking properties and heat sealing performance compared to that of ordinary LDPE [Office Action page 6]. However, this assertion ignores that the cited paragraphs of Toft conversely recommends the use of metallocene polyethylenes for the innermost layers in packaging laminates, which explains the vowed clarity, antiblocking and sealing properties which are only relevant for an exposed layer, but not for intermediate layers as is the case in the subject-matter of the recited

invention.

There is no teaching in the cited references as to why a skilled practitioner in the art would use a metallocene-PE containing polyethylene layer to establish an enhanced bond between an exposed COC layer and a metal layer through an EAA layer, based on the recommendation to use metallocene polyethylenes as innermost layers. Conversely, the opposite should be true. After reading Toft, any skilled artisan would use m-PEs as exposed outer layers, but never in between other layers.

Accordingly, it is respectfully submitted when the entire teachings of the cited references are taken into consideration, the recited invention of 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).

Moreover, it is respectfully submitted that the dependent claims 18-34 further patentably distinguish the prior art and are allowable as is outlined above.

Claims 16-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas in view of Toft.

It is respectfully submitted that claims 16-21 patentably distinguish Torradas and Toft.

As is discussed in greater detail above, while the cited references may disclose that certain recited materials exist, 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. The specific arrangement of layers in the specific order recited in the claims of this application is not

taught in the cited references.

As is referenced in the Office Action, Torradas teaches a multilayered film. But, the Office Action does not point to anywhere in Torradas wherein it teaches a film utilizing metallocene polyethylene in the polyethylene layer that is in between the COC layer and the acrylic-acid containing joining layer as is recited in claim 16. There is no teaching in the prior art for this combination of layers. In fact, the cited references go in a different direction in their choice and arrangement of layers wherein they teach away from the recited invention. KSR.

Toft fails to overcome the shortcomings in Torradas like it fails to overcome the shortcomings in Osborn. As is discussed in greater detail above, the adhesive layer of EAA is not such a layer. Conversely, paragraph [0081] of Toft identifies item 15-1 as an adhesive part-layer comprising an adhesive polymer, whereas this adhesive partlayer according to [0083] of Toft is a maleic-anhydride graft modified LLDPE, which is not even closely resembling EAA (ethylene acrylic acid).

As discussed in greater detail above, Toft actually teaches away wherein it recommends the use of metallocene polyethylenes for the use of innermost layers in packaging laminates, which explains the vowed clarity, antiblocking and sealing properties which are only relevant for an exposed layer, but not for intermediate layers as is the case in the subject-matter of the recited invention.

There is no teaching in the cited references as to why a skilled practitioner in the art would use a metallocene-PE containing polyethylene layer to establish an enhanced bond between an exposed COC layer and a metal layer through an EAA layer, based on the recommendation to use metallocene polyethylenes as innermost layers.

Accordingly, it is respectfully submitted that claim 16 patentably distinguishes the cited references and that claims 17-21 further patentably distinguish the cited references.

Claims 22-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas and Toft, as applied to claims 16-21, in view of Osborn et al. (US 2015/0225151 A 1).

Claims 22-34 are dependent from claim 16 and patentably distinguish the cited references for at least the same reasons. As is discussed in greater detail above, Torradas, Toft and Osborn fail to disclose the specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed. Accordingly, it is respectfully submitted that claims 22-34 are in condition for allowance wherein reconsideration and allowance is respectfully requested.

Claims 16-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Toft et al. (US 2005/0181154 A 1) in view of Osborn and Torradas.

As is discussed in greater detail above, Torradas, Toft and Osborn fail to disclose the specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed. Accordingly, it is respectfully submitted that claims 16-34 are in condition for allowance wherein reconsideration and allowance is respectfully requested.

It is respectfully submitted that the prior art fails to disclose or make obvious the recited invention of this application. 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 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. 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.

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,

RANKIN, HILL & CLARK LLP

By /Gregory S. Vickers/
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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	

SECOND DECLARATION UNDER 37 CFR 1.132

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

I, Manuella Herb hereby declare and state:

1. I am the Senior Manager Product Development for the Applicant of this application, namely, Huhtamaki Flexible Packaging Germany GmbH & Co. KG.

2. I have worked in the packaging industry for over 22 years and have significant experience in packaging and material designs for packaging.

3. I am one of the inventors of the film composite for packaging transdermal patches and package made of such a film of the above-identified patent application.

4. 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.

5. It has been found that the recited invention has unexpected effects in using a metallocene polyethylene to tie the COC-layer to the acrylic-acid-containing joining layer and thereby to the aluminum foil.

10. It has been 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.

11. In addition, metallocene C8 and LDPE, 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. 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.

12. While Osborn comprehensively lists the many different kinds of polyethylene that there are available for forming layers, Osborn, Torradas and Toft are silent with regard to using a metallocene polyethylene to tie the COC-layer to the acrylic-acid-containing joining layer and thereby to the aluminum foil.

13. Osborn does not teach a multilayer packaging film suitable for packaging transdermal drug delivery patches comprising i. a. "PE including LDPE, m-LLDPE being catalyzed by hexene (C6) or 1-octene (C8)" [see OA: middle of page 4]. Conversely, this purported teaching is impossible. In this respect, m-LLDPE is not catalyzed by hexene or octene, but by a metallocene, hence the name m-LLDPE or metallocene LLDPE. Metallocenes are very effective metal catalyst. They consist of minute particles of positively charged metal ions sandwiched between two cyclopentadienyl anions, which have five atoms per ring. They are also known as single-site catalysts because they have only one active site per catalyst particle, which are all identical.

See: http://polymerdatabase.com/polymer%20chemistry/Metallocene.html (copy attached).

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.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements and the like may jeopardize the validity of this document, declares that s/he is properly authorized to execute this document on behalf of the applicant; and all statements made of his/her own knowledge are true and all statements made on information and belief are believed to be true.

Name: Manuella Herb

Title Senior Manager Product Development
Huhtamaki Flexible Packaging Germany GmbH & Co. KG.

Date: 11.01.2022

Huhtamaki Flexible Packaging
Germany GmbH & Co. KG
97671 Ronsberg

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BACK TO INDEX

COMMERCIAL METALLOCENE CATALYSTS

Akzo-Nobel

Albemarle

Honeywell

METALLOCENE COORDINATION CATALYST

Metallocenes are very effective metal catalyst. They consist of minute particles of positively charged metal ions sandwiched between two cyclopentadienyl anions, which have five atoms per ring. They are also known as single-site catalysts because they have only one active site per catalyst particle, which are all identical.

Metallocene catalysts were discovered in the 1950s.[1] Despite the early discovery, it took more than 20 years before technology was developed that allowed the economical large scale production of metallocene polyolefins. A significant breakthrough was achieved in the late 1970s when Sinn and Kaminsky combined metallocene catalysts with methylalumoxane [$(MeAlO)_n$] (MAO) which enhances the activity by a factor of 10 000.[2-4]

The metallocene catalyzed polymerization has many advantages over traditional polymerization techniques; it results in very pure, and consistent resins with well defined properties. For example, a wide variety of metallocene polyethylenes can be produced with very different properties ranging from very soft with low melting point to high melting point with good heat resistance. Many derivatives of early metallocenes are active catalysts for olefin polymerization. Unlike traditional and still widely used heterogeneous Ziegler-Natta catalysts, metallocenes are homogeneous. The polymerization with metallocenes and other coordination catalyst involves coordination of the monomer to the transition metal site before insertion at one end of the polymer chain. The coordination step is responsible for the versatility of these catalysts; since the arriving monomer needs to coordinate to the active site before propagation can occur, the electronic and steric environment around it will control the polymerization and, thus, the polymer microstructure, the propagation and chain transfer rates, the co-monomer reactivity ratios, and the stereo- and regio-selectivity.

Only a few metallocene anions are known. The most famous example is ferrocenium, $[Fe(C_5H_5)_2]^+$, which is the blue iron-III-complex derived from oxidation of orange iron-II-ferrocene. Other important five member rings are idenyl and fluorenyl

SUMMARY

METALLOCENE CATALYSTS

are single-site catalysts, consisting of minute particles of positively charged metal ions sandwiched between two (substituted) cyclopentadienyl anions.

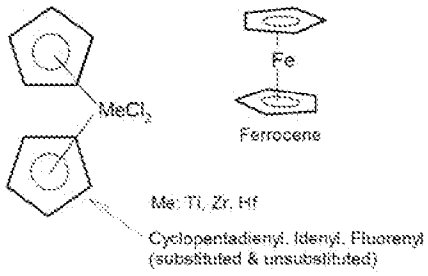
They are also known as single-site catalysts because they have only one active site per catalyst particle.

Metallocene catalysts enable the resin manufacturers to tailor polyolefins with specific properties to meet precise performance requirements.

COORDINATION POLYMERIZATION

is an addition polymerization in which successive monomers are added to the organometallic active center. The method permits the synthesis of unbranched, stereospecific high molecular weight polyolefins such as stereoregular polyethylene (PE).

Coordination catalysts are extensively used to polymerize (high performance) polyolefins but are rarely used in the polymerization of polar monomers.



References & Notes

1. D.S. Breslow and N. Newburg, *J. Am. Chem. Soc.*, 79, 5072 (1957)
2. W. Kaminsky, *J. Chem. Soc., Dalton Trans.*, pp. 1413-1418 (1998)
3. H. Sinn, W. Kaminsky, H. J. Vollmer and R. Woldt, *Angew. Chem.*, 92, 396 (1980)
4. W. Kaminsky, Macromol. *Chem. Phys.*, 197, 3907 (1996)

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Properties of commercial commodity and engineering polymers.

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PHYSICS OF POLYMERS

Physical and mechanical properties of polymers

PHYS. CONTENTS

CHEMISTRY OF POLYMERS

Chemical properties and synthesis of organic polymers

CHEM. CONTENTS

Electronic Acknowledgement Receipt

EFS ID:	44788834
Application Number:	16516792
International Application Number:	
Confirmation Number:	2546
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Customer Number:	75626
Filer:	Gregory Stamm Vickers/Loni Clay
Filer Authorized By:	Gregory Stamm Vickers
Attorney Docket Number:	TRO-45953
Receipt Date:	24-JAN-2022
Filing Date:	19-JUL-2019
Time Stamp:	12:32:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		TRO45953_AmendmentD.pdf	134194 1b543ad07165052039dcb734c448ab4489d61a81	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	13

Warnings:					
Information:					
2	Affidavit-traversing rejectns or objectns rule 132	TRO45953_HerbDeclaration.pdf	347749 861b1bbe4eaa44563a44f0d08df6fac94dc44eb5	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	481943		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

75626 7590 10/27/2021

RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

EXAMINER
YU, HONG

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
10/27/2021	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 16/516,792	Applicant(s) Herb et al.	
	Examiner HONG YU	Art Unit 1612	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 08/12/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 16-37 is/are pending in the application.

5a) Of the above claim(s) 35-37 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 16-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

DETAILED ACTION

The final rejection dated 10/13/2021 is vacated and replaced with the instant non-final rejection.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/12/2021 has been entered.

Status of claims

Claims 1-15 have previously been canceled and claims 35-37 have been withdrawn. Claims 16-34 are under examination in the instant office action.

Rejections withdrawn

Applicant's arguments and affidavit filed on 08/12/2021 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant's affidavit has overcome the35 U.S.C. 103(a) rejections of claims 16 and 18-34 over Osborn et al. (US 2015/0225151 A1) and Torradas et al. (US 2017/0136747 A1), of claims 16, 17, and 21 over Torradas et al. (US 2017/0136747 A1) and Osborn et al. (US 2015/0225151 A1) (Osborn et al. (US 2015/0225151 A1) in this rejection was inadvertently included in the heading of this rejection), of claims 18-20 and 22-34 over Torradas et al. (US 2017/0136747 A1) and Osborn et al. (US 2015/0225151 A1), and of claims 16-34 over Toft et al. (US 2005/0181154 A1), Osborn et al. (US 2015/0225151 A1), and Torradas et al. (US 2017/0136747 A1) from the previous Office Action. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

New Ground of Rejections

Upon reconsideration the examiner is applying the following new ground of rejections. The text of the section of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn et al. (US 2015/0225151 A1) in view of Toft et al. (US 2005/0181154 A1) and Torradas et al. (US 2017/0136747 A1).

Osborn et al. teach a flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches comprising

an article contact layer having at least 90 wt. % of a norbornene ethylene copolymer (COC) or derivative thereof;

a polyolefin bulk layer including PE;

a first intermediate adhesive layer;

an oxygen barrier layer including aluminum foil;

a second intermediate adhesive layer; and

an exterior protective layer comprising a polymer selected from the group consisting of paper, polyamide, polyolefin, blends or derivatives thereof and

PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)

exemplified a film comprising OPET (biaxially oriented polyester terephthalate) /PE/LDPE/EVA/Al Foil base layer with three-layer coextrusion of EAA, LDPE, and an 80:20 wt % blend of LDPE:mLLDPE in example 2 and EAA, LDPE, and COC in example 5 which were extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film of

OPET/PE/ LDPE/EAA/Al foil/EAA/LDPE/LDPE:mLLDPE and a total thickness of 3.04 mils (77.2 microns) in example 2 and

0.92 mil (23.37 μm) OPET (the thickness of plastic layer in the instant claims 33 and 34)/PE/0.42 mil (10.67 μm) LDPE/0.1 mil (2.54 μm) EAA/0.35 mil (8.85 μm) All foil/0.17 mil (4.32 μm) EAA/0.65 mil (16.51 μm) LDPE/0.43 mil (10.92 μm) COC and a total thickness of 3.0 mils (76 microns) in example 5;

all layers can have the thickness of less than mils and any increment of 0.1 or 0.01 mil there between which includes 0.4 mil (10.16 μm) (the instant claims 22 and 25) and 1.5 mil (25.4 μm) (the thickness of paper layer in the instant claims 22 and 25) (entire reference, especially abstract, figure 1, paragraph 6-12, 15, 16, 20-28, 40, 41, 46, 47, 49, 50, 51, 53, 54, 57, 68, 69, 71, 72, 78, 93, 97, and 100, and claims 1-5).

Since Osborn et al. teach the adhesive, PE, and COC layers being coextruded which is the same as the method of producing the acrylic acid, PE, and COC layers (2nd paragraph on page 5), the thickness value (claims 23, 24, 26, and 27) of the adhesive, PE, and COC layers taught by Osborn et al. teach would be the same as those of the acrylic acid, PE, and COC layers of the claimed film.

Osborn et al. do not specify an embodiment with the PE layer next to COC being metallocene catalyzed (MC- or m-) LLDPE.

This deficiency is cured by Toft et al. a packaging laminate for food as illustrated in figure 1 below comprising, from exterior to food contacting interior,

item 12 being a heat sealable such as PE,

item 11 being a core of paperboard with item 14 being an intermediate layer of thermoplastic of about 23-27 g/m^2 LDPE (the claimed further layers made of plastic and/or paper in claims 28-30) bonding item 11 to

item 13 which is an aluminum foil,

item 15-1 being an adhesive layer of EAA (the instant claim 21),

item 15-2 being a barrier layer of a blend of COC and m-LLDPE, and

item 15-3 being a PE-MC layer a blend of 60-70% by weight of m-LLDPE (the instant claim 18) prepared by copolymerization of C_{4-8} α-olefins including 1-hexene (C_6) or 1-octene (C_8) (the instant claims 19 and 20) and 30-40% by weight of LDPE (the instant claim 17)

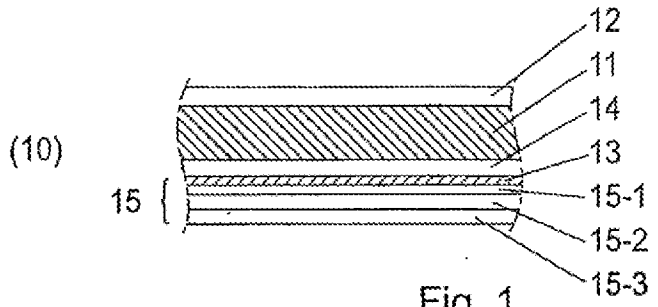


Fig. 1

and m-LLDPE having desirable properties like improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE (paragraph 20-21) (entire reference, especially abstract, figure 1, paragraph 46-53, 55, 56, 60, 79-81, and 83, and claims 1-3, 6, 7, and 9) and

Torradas et al. who teach a multilayered film, with a total thickness of < about 250 μm, for packing food, including liquid food, drug, etc., comprising

an external layer such as aluminum or PE as a good barrier to moisture permeation including MC-PE with the external layer being optionally protective coated;

one or more inner layers including barrier layers of COC;

a structure layer which can be an external layer, and/or inner layer, and barrier layer such as PE made by metallocene catalyst system for both structure and barrier functions;

one or more adhesive layers such as Elvaloy AC (the claimed ethylene acrylate copolymer in claim 21) between the outside structure layer to an inner layer with the thickness of adhesive layer being 2-10 μm, and LLDPE is preferred for packaging films

(paragraph 100) (entire reference, especially abstract, paragraph 92, 93, 95, 99-101, 106, 107119, 121, 122, 126, 127, 131, 136, 137, 140, 202, 222, and 240). A structure layer which can be an external layer, and/or inner layer, and barrier layer is interpreted as a structure can be a barrier layer between external layer and inner layer.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Osborn et al., Toft et al., and Torradas et al. to replace the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. with m-LLDPE. PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8), LLDPE is preferred for packaging films, and m-LLDPE having desirable properties compared to that of ordinary LDPE were well known to a person of ordinary skill in the art at the time of the invention. The motivation for replacing the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. with m-LLDPE flows from m-LLDPE having been used in the prior art, and from m-LLDPE being recognized in the prior art as useful for the same purpose with the known advantages.

Osborn et al. do not specify the weight/unit area of paper and plastic layers (claims 33 and 34).

This deficiency is cured by the rational that it is routine optimization to determine the optimum weight/unit area for each layer.

Osborn et al. do not specifically teach weight unit of the paper layer and plastic layer (external layers) claimed by applicant. While the layer thicknesses of the paper layer and plastic layer are within those of the claimed film, the PET plastic and the

paper are known packaging layer materials for achieve the same protective effect and would be reasonable to assume that they are the similar materials with the similar density and thus would result in the similar weight/unit area.

Or alternatively, weight/unit area of the paper layer and plastic layer in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize or, alternatively obvious to try to reach another workable product or process. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal weight/unit area in order to best achieve the desired results of protective effect.

Response to Applicants' arguments and applicants' 37 CFR 1.132 declaration:

Applicant's arguments and declaration under 37 CFR 1.132, filed on 08/12/2021, have been fully considered but they are moot in view of new ground of rejections.

Nevertheless the examiner would like to point out that m-LLDPE is not claimed in claim 16, i.e., not commensurate in scope with the m-LLDPE in the experiment in the declaration and the better stability resulted from using m-LLDPE over LDPE is expected based on the teachings of Toft et al., and Torradas et al.

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) in view of Toft et al. (US 2005/0181154 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify an embodiment with LLDPE being MC-LLDPE and C_8 MC-LLDPE in claims 18-20.

This deficiency is cured by Toft et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Toft et al. to specify the LLDPE in the film taught by Torradas et al. being C_8 m-LLDPE. M-LLDPE having desirable properties like improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE and m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8) were well known to a person of ordinary skill in the art at the time of the invention. The motivation for specify the LLDPE in the film taught by Torradas et al. being C_8 m-LLDPE flows from C_8 m-LLDPE having been used in the prior art, and from C_8 m-LLDPE being recognized in the prior art as useful for the same purpose with the known advantages.

Claims 22-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) and Toft et al. (US 2005/0181154 A1), as applied to claims 16-21, in view of Osborn et al. (US 2015/0225151 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify: i) the thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers (claims 22-27); and ii) the limitations of the further layers outside the metal layer (protective layers) in claims 28-34.

These deficiency is cured by Osborn et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Osborn et al. to specify the claimed thicknesses and the film taught by Torradas et al. having the claimed thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments and applicants' 37 CFR 1.132 declaration:

Applicant's arguments and declaration under 37 CFR 1.132, filed on 08/12/2021, have been fully considered but they are moot in view of new ground of rejections.

Nevertheless the examiner would like to point out that m-LLDPE is not claimed in claim 16, i.e., not commensurate in scope with the m-LLDPE in the experiment in the declaration and the better stability resulted from using m-LLDPE over LDPE is expected based on the teachings of Toft et al., and Torradas et al. and Torradas et al. specify LLDPE being preferred, not LDPE in the comparison.

Claims 16-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toft et al. (US 2005/0181154 A1) in view of Osborn et al. (US 2015/0225151 A1) and Torradas et al. (US 2017/0136747 A1).

Toft et al.'s teachings are discussed above and applied in the same manner.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **[for manufacturing a package for planar carriers of pharmaceutical active substances]**; however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Furthermore, according to Torradas et al. a multilayered film can be used for both packing food, including liquid food, and drug.

Toft et al. do not teach the innermost layer 15-2 and 15-3 being the opposite order.

This deficiency is cured by Osborn et al. and Torradas et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al., Osborn et al., and Torradas et al. to exchange the COC layer and MC-PE layer in the film taught by Toft et al. with the innermost layer being COC and MC-PE being the layer before it. OCO as the innermost layer and PE next to it according to Osborn et al. and MC-PE being one of the PE before the innermost layer according to Torradas et al. was well known to a person of ordinary skill in the art at the time of the invention. The motivation for exchanging the COC layer and MC-PE layer in the film taught by Toft et al. flows from COC being the innermost layer and MC-PE being the layer next to it having been used in the prior art, and from COC being the innermost layer and MC-PE being the layer next to it being recognized in the prior art as useful for the same purpose of packaging film.

Toft et al. do not teach the thicknesses and thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers (claims 22-27) and the further layers outside the metal layer (protective layers) in claims 31-34.

This deficiency is cured by Osborn et al. whose teachings are discussed above.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al. and Osborn et al. to specify the claimed thicknesses and the film taught by Toft et al. having the claimed thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A

flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments and applicants' 37 CFR 1.132 declaration:

Applicant's arguments and declaration under 37 CFR 1.132, filed on 08/12/2021, have been fully considered but they are moot in view of new ground of rejections.

Nevertheless the examiner would like to point out that m-LLDPE is not claimed in claim 16, i.e., not commensurate in scope with the m-LLDPE in the experiment in the declaration and the better stability resulted from using m-LLDPE over LDPE is expected based on the teachings of Toft et al., and Torradas et al. and Toft et al. specify m-LLDPE being preferred, not the use of LDPE in the comparison.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on 9 am - 5:30 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, Applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HONG YU/
Primary Examiner, Art Unit 1612

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

CPC - Searched*		
Symbol	**Date**	**Examiner**
B32B 15/$, B32B 27/$	11/16/2020	HY
B32B 15/$, B32B 27/$	10/08/2021	HY

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
east search: inventor and assignee search and keyword search	11/16/2020 11/17/2020 11/18/2020	HY
google search	11/16/2020	HY
global dossier	11/16/2020	HY
Updated east search	05/11/2021	HY
google search	05/11/2021	HY
global dossier	05/11/2021	HY
updated east search	10/08/2021	HY
global dossier	10/08/2021	HY
google search	10/09/2021	HY

/HONG YU/ Primary Examiner, Art Unit 1612	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/HONG YU/ Primary Examiner, Art Unit 1612	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1594	61,608	(b32b15/$ and b32b27/$).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1595	34,702	S1594 and (metal or foil or aluminium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1596	444	S1595 and (Metallocene near10 polyethylene or PE-MC or pe-m or m-PE or mc-pe or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1597	140	S1596 and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1598	140	S1597 and polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1599	121	S1598 and ((laminate or laminating or layer or coat or coating or film or package or packaging).ti. or (laminate or laminating or layer or coat or coating or film or package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1600	33	S1599 and (acrylic or polyacrylic or poly(acrylic acid)) with (adhesive or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1601	33	S1600 and (polyethylene or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25

S1602	33	S1601	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25

EAST Search History (Interference)

<This search history is empty>

10/26/2021 9:05:30 AM
C:\Users\hyu1\Documents\EAST\Workspaces\16516792.wsp

Global Dossier

Office

US

Type

Application

16516792

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US 16516792 4 Members in Patent Family (2 currently shown) ()

« ()

IP Office Type

All IP5 Offices

- EPO
- SIPO
- KIPO
- JPO
- USPTO

Non-IP5 Offices

()	Office	Application	Applicant	Title	App. Date	Priority #	Pub. # ()	Pub. Date
()	EP	19186607	1) Huhtamaki Flexible Packaging Germany GmbH & Co. KG,	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES AND PACKAGING FROM SUCH A FILM COMPOSITE	07/16/2019	DE 102018212303 DE 102018125195	EP 3599090 A1 ()	01/29/2020

Most Recent Documents

Date	Document Description ()	Options
07/21/2020	Letter accompanying subsequently filed items ()	•••
07/21/2020	Reply to invitation to file a copy of priority search results ()	•••
07/21/2020	Priority search results ()	•••

Office Actions

Date	Document Description ()
12/05/2019	European search opinion ()

All Documents | Classification and Citation | View All Office Actions

()	Office	Application	Applicant	Title	App. Date	Priority #	Pub. # ()	Pub. Date
()	US	16516792	1) Herb, Manuella 2) Dorn, Michael 3) Stroh, Thomas	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	07/19/2019	DE 102018212303 DE 102018125195	US 20200031107 A1 ()	01/30/2020

Most Recent Documents

Date	Document Description ()	Options
08/12/2021	Applicant Arguments/Remarks Made in an Amendment ()	•••
08/12/2021	Fee Worksheet (SB06) ()	•••
08/12/2021	Request for Continued Examination (RCE) ()	•••

Office Actions

Date	Document Description ()
05/13/2021	Final Rejection ()
11/20/2020	Non-Final Rejection ()

All Documents | Classification and Citation | View All Office Actions

(http://www.uspto.gov/)

BROWSE BY TOPIC

ABOUT THIS SITE

USPTO BACKGROUND

FEDERAL GOVERNMENT

Web Search History

date, time	web site	search string
10/9/2021 11:01:02 AM	Google	package film AND aluminum AND acrylic AND m-lldpe
10/9/2021 11:03:50 AM	Google	package film AND aluminum AND acrylic AND cyclo olefin copolymer AND m-lldpe
10/9/2021 11:03:53 AM	Google	package film AND aluminum AND acrylic AND cyclic olefin copolymer AND m-lldpe
10/9/2021 11:04:14 AM	Google	package film AND aluminum AND acrylic AND cocAND m-lldpe
10/9/2021 11:06:57 AM	Google	package film AND aluminum AND acrylic AND co AND m-lldpe

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

75626 7590 10/13/2021

RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

EXAMINER
YU, HONG

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
10/13/2021	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 16/516,792	Applicant(s) Herb et al.	
	Examiner HONG YU	Art Unit 1612	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 08/12/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 16-37 is/are pending in the application.

5a) Of the above claim(s) 35-37 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 16-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/12/2021 has been entered.

Status of claims

Claims 1-15 have previously been canceled and claims 35-37 have been withdrawn. Claims 16-34 are under examination in the instant office action.

Rejections withdrawn

Applicant's arguments and affidavit filed on 08/12/2021 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant's affidavit has overcome the35 U.S.C. 103(a) rejections of claims 16 and 18-34 over Osborn et al. (US 2015/0225151 A1) and Torradas et al. (US 2017/0136747 A1), of claims 16, 17, and 21 over Torradas et al. (US 2017/0136747 A1) and Osborn et al. (US 2015/0225151 A1) (Osborn et al. (US 2015/0225151 A1) in this rejection was inadvertently included in the heading of this rejection), of claims 18-20 and 22-34 over Torradas et al. (US 2017/0136747 A1) and Osborn et al. (US 2015/0225151 A1), and of claims 16-34 over Toft et al. (US 2005/0181154 A1), Osborn et al. (US 2015/0225151 A1), and Torradas et al. (US 2017/0136747 A1) from the previous Office Action. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

New Ground of Rejections

Upon reconsideration the examiner is applying the following new ground of rejections. The text of the section of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn et al. (US 2015/0225151 A1) in view of Toft et al. (US 2005/0181154 A1) and Torradas et al. (US 2017/0136747 A1).

Osborn et al. teach a flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches comprising

an article contact layer having at least 90 wt. % of a norbornene ethylene copolymer (COC) or derivative thereof;

a polyolefin bulk layer including PE;

a first intermediate adhesive layer;

an oxygen barrier layer including aluminum foil;

a second intermediate adhesive layer; and

an exterior protective layer comprising a polymer selected from the group consisting of paper, polyamide, polyolefin, blends or derivatives thereof and

PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)

exemplified a film comprising OPET (biaxially oriented polyester terephthalate) /PE/LDPE/EVA/Al Foil base layer with three-layer coextrusion of EAA, LDPE, and an 80:20 wt % blend of LDPE:mLLDPE in example 2 and EAA, LDPE, and COC in example 5 which were extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film of

OPET/PE/ LDPE/EAA/Al foil/EAA/LDPE/LDPE:mLLDPE and a total thickness of 3.04 mils (77.2 microns) in example 2 and

0.92 mil (23.37 μm) OPET (the thickness of plastic layer in the instant claims 33 and 34)/PE/0.42 mil (10.67 μm) LDPE/0.1 mil (2.54 μm) EAA/0.35 mil (8.85 μm) All foil/0.17 mil (4.32 μm) EAA/0.65 mil (16.51 μm) LDPE/0.43 mil (10.92 μm) COC and a total thickness of 3.0 mils (76 microns) in example 5;

all layers can have the thickness of less than mils and any increment of 0.1 or 0.01 mil there between which includes 0.4 mil (10.16 μm) (the instant claims 22 and 25) and 1.5 mil (25.4 μm) (the thickness of paper layer in the instant claims 22 and 25)

(entire reference, especially abstract, figure 1, paragraph 6-12, 15, 16, 20-28, 40, 41, 46, 47, 49, 50, 51, 53, 54, 57, 68, 69, 71, 72, 78, 93, 97, and 100, and claims 1-5).

Since Osborn et al. teach the adhesive, PE, and COC layers being coextruded which is the same as the method of producing the acrylic acid, PE, and COC layers (2nd paragraph on page 5), the thickness value (claims 23, 24, 26, and 27) of the adhesive, PE, and COC layers taught by Osborn et al. teach would be the same as those of the acrylic acid, PE, and COC layers of the claimed film.

Osborn et al. do not specify an embodiment with the PE layer next to COC being metallocene catalyzed (MC- or m-) LLDPE.

This deficiency is cured by Toft et al. a packaging laminate for food as illustrated in figure 1 below comprising, from exterior to food contacting interior,

item 12 being a heat sealable such as PE,

item 11 being a core of paperboard with item 14 being an intermediate layer of thermoplastic of about 23-27 g/m^2 LDPE (the claimed further layers made of plastic and/or paper in claims 28-30) bonding item 11 to

item 13 which is an aluminum foil,

item 15-1 being an adhesive layer of EAA (the instant claim 21),

item 15-2 being a barrier layer of a blend of COC and m-LLDPE, and

item 15-3 being a PE-MC layer a blend of 60-70% by weight of m-LLDPE (the instant claim 18) prepared by copolymerization of C_{4-8} α-olefins including 1-hexene (C_6) or 1-octene (C_8) (the instant claims 19 and 20) and 30-40% by weight of LDPE (the

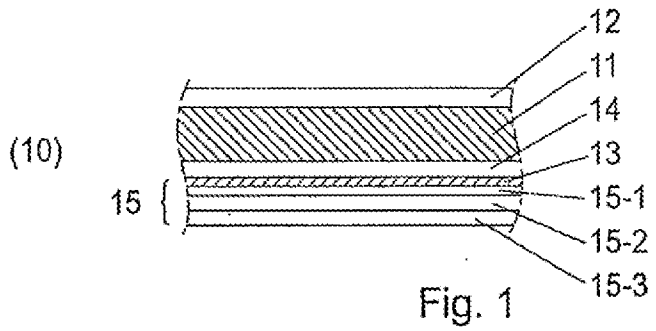


Fig. 1

instant claim 17) and m-LLDPE having desirable properties like improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE (paragraph 20-21) (entire reference, especially abstract, figure 1, paragraph 46-53, 55, 56, 60, 79-81, and 83, and claims 1-3, 6, 7, and 9) and

Torradas et al. who teach a multilayered film, with a total thickness of < about 250 μm, for packing food, including liquid food, drug, etc., comprising

an external layer such as aluminum or PE as a good barrier to moisture permeation including MC-PE with the external layer being optionally protective coated;

one or more inner layers including barrier layers of COC;

a structure layer which can be an external layer, and/or inner layer, and barrier layer such as PE made by metallocene catalyst system for both structure and barrier functions;

one or more adhesive layers such as Elvaloy AC (the claimed ethylene acrylate copolymer in claim 21) between the outside structure layer to an inner layer with the thickness of adhesive layer being 2-10 μm, and LLDPE is preferred for packaging films (paragraph 100) (entire reference, especially abstract, paragraph 92, 93, 95, 99-101, 106, 107119, 121, 122, 126, 127, 131, 136, 137, 140, 202, 222, and 240). A structure

layer which can be an external layer, and/or inner layer, and barrier layer is interpreted as a structure can be a barrier layer between external layer and inner layer.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Osborn et al., Toft et al., and Torradas et al. to replace the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. with m-LLDPE. PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8), LLDPE is preferred for packaging films, and m-LLDPE having desirable properties compared to that of ordinary LDPE were well known to a person of ordinary skill in the art at the time of the invention. The motivation for replacing the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. with m-LLDPE flows from m-LLDPE having been used in the prior art, and from m-LLDPE being recognized in the prior art as useful for the same purpose with the known advantages.

Osborn et al. do not specify the weight/unit area of paper and plastic layers (claims 33 and 34).

This deficiency is cured by the rational that it is routine optimization to determine the optimum weight/unit area for each layer.

Osborn et al. do not specifically teach weight unit of the paper layer and plastic layer (external layers) claimed by applicant. While the layer thicknesses of the paper layer and plastic layer are within those of the claimed film, the PET plastic and the paper are known packaging layer materials for achieve the same protective effect and

would be reasonable to assume that they are the similar materials with the similar density and thus would result in the similar weight/unit area.

Or alternatively, weight/unit area of the paper layer and plastic layer in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize or, alternatively obvious to try to reach another workable product or process. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal weight/unit area in order to best achieve the desired results of protective effect.

Response to Applicants' arguments and applicants' 37 CFR 1.132 declaration:

Applicant's arguments and declaration under 37 CFR 1.132, filed on 08/12/2021, have been fully considered but they are moot in view of new ground of rejections.

Nevertheless the examiner would like to point out that m-LLDPE is not claimed in claim 16, i.e., not commensurate in scope with the m-LLDPE in the experiment in the declaration and the better stability resulted from using m-LLDPE over LDPE is expected based on the teachings of Toft et al., and Torradas et al.

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) in view of Toft et al. (US 2005/0181154 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify an embodiment with LLDPE being MC-LLDPE and C_8 MC-LLDPE in claims 18-20.

This deficiency is cured by Toft et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Toft et al. to specify the LLDPE in the film taught by Torradas et al. being C_8 m-LLDPE. M-LLDPE having desirable properties like improved tear and puncture resistance, toughness, impact strength, clarity, antiblocking properties and heat sealing performance compared to that of ordinary LDPE and m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8) were well known to a person of ordinary skill in the art at the time of the invention. The motivation for specify the LLDPE in the film taught by Torradas et al. being C_8 m-LLDPE flows from C_8 m-LLDPE having been used in the prior art, and from C_8 m-LLDPE being recognized in the prior art as useful for the same purpose with the known advantages.

Claims 22-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) and Toft et al. (US 2005/0181154 A1), as applied to claims 16-21, in view of Osborn et al. (US 2015/0225151 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify: i) the thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers (claims

22-27); and ii) the limitations of the further layers outside the metal layer (protective layers) in claims 28-34.

These deficiency is cured by Osborn et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Osborn et al. to specify the claimed thicknesses and the film taught by Torradas et al. having the claimed thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments and applicants' 37 CFR 1.132 declaration:

Applicant's arguments and declaration under 37 CFR 1.132, filed on 08/12/2021, have been fully considered but they are moot in view of new ground of rejections.

Nevertheless the examiner would like to point out that m-LLDPE is not claimed in claim 16, i.e., not commensurate in scope with the m-LLDPE in the experiment in the declaration and the better stability resulted from using m-LLDPE over LDPE is expected

based on the teachings of Toft et al., and Torradas et al. and Torradas et al. specify LLDPE being preferred, not LDPE in the comparison.

Claims 16-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toft et al. (US 2005/0181154 A1) in view of Osborn et al. (US 2015/0225151 A1) and Torradas et al. (US 2017/0136747 A1).

Toft et al.'s teachings are discussed above and applied in the same manner.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **[for manufacturing a package for planar carriers of pharmaceutical active substances]**; however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Furthermore, according to Torradas et al. a multilayered film can be used for both packing food, including liquid food, and drug.

Toft et al. do not teach the innermost layer 15-2 and 15-3 being the opposite order.

This deficiency is cured by Osborn et al. and Torradas et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al., Osborn et al., and

Torradas et al. to exchange the COC layer and MC-PE layer in the film taught by Toft et al. with the innermost layer being COC and MC-PE being the layer before it. OCO as the innermost layer and PE next to it according to Osborn et al. and MC-PE being one of the PE before the innermost layer according to Torradas et al. was well known to a person of ordinary skill in the art at the time of the invention. The motivation for exchanging the COC layer and MC-PE layer in the film taught by Toft et al. flows from COC being the innermost layer and MC-PE being the layer next to it having been used in the prior art, and from COC being the innermost layer and MC-PE being the layer next to it being recognized in the prior art as useful for the same purpose of packaging film.

Toft et al. do not teach the thicknesses and thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers (claims 22-27) and the further layers outside the metal layer (protective layers) in claims 31-34.

This deficiency is cured by Osborn et al. whose teachings are discussed above.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al. and Osborn et al. to specify the claimed thicknesses and the film taught by Toft et al. having the claimed thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, MC-PE structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well

known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments and applicants' 37 CFR 1.132 declaration:

Applicant's arguments and declaration under 37 CFR 1.132, filed on 08/12/2021, have been fully considered but they are moot in view of new ground of rejections.

Nevertheless the examiner would like to point out that m-LLDPE is not claimed in claim 16, i.e., not commensurate in scope with the m-LLDPE in the experiment in the declaration and the better stability resulted from using m-LLDPE over LDPE is expected based on the teachings of Toft et al., and Torradas et al. and Toft et al. specify m-LLDPE being preferred, not the use of LDPE in the comparison.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on 9 am - 5:30 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, Applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HONG YU/
Primary Examiner, Art Unit 1612

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

CPC - Searched*		
Symbol	**Date**	**Examiner**
B32B 15/$, B32B 27/$	11/16/2020	HY
B32B 15/$, B32B 27/$	10/08/2021	HY

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
east search: inventor and assignee search and keyword search	11/16/2020 11/17/2020 11/18/2020	HY
google search	11/16/2020	HY
global dossier	11/16/2020	HY
Updated east search	05/11/2021	HY
google search	05/11/2021	HY
global dossier	05/11/2021	HY
updated east search	10/08/2021	HY
global dossier	10/08/2021	HY
google search	10/09/2021	HY

/HONG YU/ Primary Examiner, Art Unit 1612	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/HONG YU/ Primary Examiner, Art Unit 1612	

Web Search History

date, time	web site	search string
10/9/2021 11:01:02 AM	Google	package film AND aluminum AND acrylic AND m-lldpe
10/9/2021 11:03:50 AM	Google	package film AND aluminum AND acrylic AND cyclo olefin copolymer AND m-lldpe
10/9/2021 11:03:53 AM	Google	package film AND aluminum AND acrylic AND cyclic olefin copolymer AND m-lldpe
10/9/2021 11:04:14 AM	Google	package film AND aluminum AND acrylic AND cocAND m-lldpe
10/9/2021 11:06:57 AM	Google	package film AND aluminum AND acrylic AND co AND m-lldpe

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1594	61,608	(b32b15/$ and b32b27/$).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1595	34,702	S1594 and (metal or foil or aluminium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1596	444	S1595 and (Metallocene near10 polyethylene or PE-MC or pe-m or m-PE or mc-pe or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1597	140	S1596 and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1598	140	S1597 and polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1599	121	S1598 and ((laminate or laminating or layer or coat or coating or film or package or packaging).ti. or (laminate or laminating or layer or coat or coating or film or package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1600	33	S1599 and (acrylic or polyacrylic or poly(acrylic acid)) with (adhesive or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25
S1601	33	S1600 and (polyethylene or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25

S1602	33	S1601	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/10/08 10:25

EAST Search History (Interference)

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Global Dossier

Office

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Application

16516792

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US 16516792 4 Members in Patent Family (2 currently shown) ()

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IP Office Type

All IP5 Offices

- EPO
- SIPO
- KIPO
- JPO
- USPTO

Non-IP5 Offices

()	Office	Application	Applicant	Title	App. Date	Priority #	Pub. # ()	Pub. Date
()	EP	19186607	1) Huhtamaki Flexible Packaging Germany GmbH & Co. KG,	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES AND PACKAGING FROM SUCH A FILM COMPOSITE	07/16/2019	DE 102018212303 DE 102018125195	EP 3599090 A1 ()	01/29/2020

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Date	Document Description ()	Options
07/21/2020	Letter accompanying subsequently filed items ()	•••
07/21/2020	Reply to invitation to file a copy of priority search results ()	•••
07/21/2020	Priority search results ()	•••

Office Actions

Date	Document Description ()
12/05/2019	European search opinion ()

All Documents | Classification and Citation | View All Office Actions

()	Office	Application	Applicant	Title	App. Date	Priority #	Pub. # ()	Pub. Date
()	US	16516792	1) Herb, Manuella 2) Dorn, Michael 3) Stroh, Thomas	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	07/19/2019	DE 102018212303 DE 102018125195	US 20200031107 A1 ()	01/30/2020

Most Recent Documents

Date	Document Description ()	Options
08/12/2021	Applicant Arguments/Remarks Made in an Amendment ()	•••
08/12/2021	Fee Worksheet (SB06) ()	•••
08/12/2021	Request for Continued Examination (RCE) ()	•••

Office Actions

Date	Document Description ()
05/13/2021	Final Rejection ()
11/20/2020	Non-Final Rejection ()

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USPTO BACKGROUND

FEDERAL GOVERNMENT

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	16516792	Filing Date	2019-07-19	Docket Number (if applicable)	TRO-45953	Art Unit	1783
First Named Inventor	Manuella Herb			Examiner Name	YU, HONG		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 180160

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

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Applicant Signature

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Signature of Registered U.S. Patent Practitioner			
Signature	/Gregory S. Vickers/	Date (YYYY-MM-DD)	2021-08-12
Name	Gregory S. Vickers	Registration Number	45180

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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SUBSTITUTE SPECIFICATION - CLEAN

FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

The present invention relates to a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, encompassing, in a direction from the designated outer side of the film composite toward its designated 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.

BACKGROUND OF THE INVENTION

A film composite of this kind, for the aforesaid purpose of manufacturing a package for pharmaceutical active-substance carriers, is known from WO 2015/123211 A1. The film composite of the species comes into direct contact with the planar carrier of a pharmaceutical active substance, and thus with the pharmaceutical active substance itself. The relevant pharmaceutical active substances are active substances such as nicotine, fentanyl, or lidocaine. The stress on the film composite produced by these pharmaceutical active substances is considerable. It is necessary to ensure in this context on the one hand that the film composite survives as such over the long term in order to prevent undesired release of the pharmaceutical active substance of the active-substance carrier. Even if the film composite survives, i.e., does not at least locally delaminate, for example, under the influence of the pharmaceutical active substance diffusing into composite layers, it is necessary on the other hand to ensure that the pharmaceutical active substance cannot diffuse or migrate through the film composite.

In order to increase the diffusion barrier effect of the film composite with respect to the pharmaceutical active substances packaged by it, it is known to select the proportion of cycloolefin copolymer (COC) in the COC layer that is innermost in the subsequent

package to be as high as possible. As the COC concentration in the COC layer rises, however, it becomes increasingly difficult to maintain the stability of the film composite, for example to prevent delamination or similar disintegration phenomena.

WO 2017/114922 A1 also discloses film composites for creating packages for planar pharmaceutical active substance carriers.

SUMMARY OF THE INVENTION

An object of the present invention is therefore to embody the film composite recited initially with the greatest possible chemical and mechanical stability with regard to the pharmaceutical active substances that are to be packaged, in light of its purpose of constituting a safe, including childproof, package for planar pharmaceutical active-substance carriers.

This object is achieved according to the present invention by a film composite of the kind recited initially in which the polyethylene layer encompasses metallocene polyethylene. The reason is that experiments have shown that given otherwise identical dimensions for the film composite, adhesion of the COC layer to the polyethylene layer is considerably better when the polyethylene layer encompasses metallocene polyethylene. "Metallocene polyethylene" in this context is polyethylene that has been manufactured in known fashion using metallocene catalysts.

The higher the COC concentration in the COC layer, the greater the gain in adhesion, in terms of the adhesive effect between the COC layer and the polyethylene layer, which is achievable by the use of metallocene polyethylene as compared with conventional polyethylene. Because the COC layer comprises a COC proportion that is as high as possible (at least 95 wt%, preferably at least 99.8 wt%, of the mass of the COC as a whole) in order to achieve a maximum barrier effect with respect to pharmaceutical active substances that are stored in the planar active-substance carrier, a particularly significant adhesion advantage can be achieved with the utilization, as presented here, of

metallocene polyethylene in the polyethylene layer arranged between the acrylic-acid-containing joining layer and the COC layer.

In doubtful cases, for example if more than one polymer layer of the film composite contains COC, a COC layer is to be considered a "COC layer" for purposes of the present Application only if it contains at least 50 wt% COC in terms of its layer mass. The aforesaid polyethylene layer that contains metallocene polyethylene is preferably devoid of COC.

In principle, an improvement in the adhesion of the COC layer to the polyethylene layer can already be achieved with comparatively small quantities of metallocene polyethylene. In a context of comparative samples of different film-composite sheets that are otherwise dimensionally identical, the improvement in the adhesive effect is particularly large if the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer is at least 50 wt%. It is therefore also possible in principle to use so-called polyethylene blends, in which metallocene polyethylene is blended with non-metallocene polyethylene, to constitute the polyethylene layer.

Because of the advantageous adhesion-enhancing effect of metallocene polyethylene, the proportion thereof (always in percent by weight) in terms of the total polyethylene contained in the polyethylene layer is preferably as high as possible, preferably higher than 90 wt%, particularly preferably higher than 96 wt%.

It has proven to be advantageous, in order to enhance the adhesion effect and also the processability of the film composite on corresponding processing machines to produce packages constituted therefrom, if the polyethylene layer encompasses a metallocene LLDPE. The polyethylene layer preferably encompasses only metallocene LLDPE as the metallocene polyethylene.

In order to achieve good running properties for a film-composite web in the aforementioned processing machines, the density of the metallocene polyethylene is advantageously in a range between 0.917 and 0.921 g/m^2. In order to achieve permanent

sealed seams with high strength and high density, the metallocene polyethylene additionally or alternatively has a melt flow index (melt flow rate, MFR) of between 6 and 10 g/10 min., measured per ISO 1133 at a test temperature of 190°C and using a test element having a weight of 2.16 kg. This is because in addition to the COC, constituting the external barrier layer and sealing layer, the polyethylene layer can contribute to sealed join of the film composite.

Any type of metallocene polyethylene in the polyethylene layer provides a desired enhancement of the adhesion effect of the COC layer on the polyethylene layer, compared with a polyethylene layer of the same dimensions and/or the same weight per unit area in the film composite. In addition, however, the rigidity of the polyethylene layer, and thus of the film composite as a whole, can be influenced by using different types of metallocene polyethylene. Advantageous rigidity of the polyethylene layer, in a context of predefined dimensions thereof, can be obtained by the fact that the polyethylene layer encompasses a C6 metallocene polyethylene and/or a C8 metallocene polyethylene, or is made of the aforesaid types of metallocene polyethylene. According to previous experiments, for a predefined film composite and in particular for a predefined dimension and/or weight per unit area of the polyethylene layer, C8 metallocene polyethylene offers the best results in terms of achieving on the one hand layer rigidity of the polyethylene layer and on the other hand composite rigidity of the film composite.

It is understandably advantageous for that reason if the polyethylene layer encompasses only a C8 metallocene polyethylene as a metallocene polyethylene. Based on what is stated above, it is particularly preferably a C8 metallocene LLDPE.

The polyethylene layer is preferably applied using the extrusion method, particularly preferably coextruded with the COC layer.

A commercially available metallocene polyethylene that is outstandingly applicable as a polyethylene layer in the aforesaid film composite is the polyethylene obtainable from the Dow Chemical Company under the trade name "Elite™ 5811."

In order to achieve the greatest possible adhesion effect for the partial composite, made up of a polyethylene layer and COC layer, on the metal layer, the acrylic-acid-containing joining layer preferably encompasses or is made of an ethylene-acrylic acid (EAA) copolymer.

The acrylic-acid-containing joining layer is preferably also applied onto the metal layer by extrusion. Particularly preferably, a partial composite made up of an acrylic-acid-containing joining layer, in particular an EAA layer; a polyethylene layer; and a COC layer is applied onto the metal layer by coextrusion in one collective extrusion step.

The metal layer serves as an oxygen barrier and gas barrier to protect package contents from external influences, and furthermore as a barrier for pharmaceutical active substances and constituents thereof which reach the metal layer as a result of diffusion through the COC layer, the polyethylene layer, and the acrylic-acid-containing joining layer. Preferably the metal layer is an aluminum layer.

Preferably each of the layers, from among the acrylic-acid-containing joining layer, polyethylene layer, and COC layer, has a layer thickness in the range from approximately 7 µm to 15 µm. On the one hand this ensures outstanding attachment to the metal layer; on the other hand, in this thickness range not only the COC layer but also the polyethylene layer can serve to produce a sealed join to the COC layer of a film composite of similar construction. Because, in the instance recited, the polyethylene layer located below the COC layer can also contribute in particularly effective and reliable fashion to production of a sealing join, the values indicated above for the melt flow index (MFR) are highly advantageous in terms of achieving outstanding sealing properties for the film composite having the exposed COC layer. The thickness values of the three, preferably coextruded layers (acrylic-acid-containing joining layer, polyethylene layer, and COC layer) are preferably each in the range from 9 µm to 12 µm. In order to achieve outstanding sealing properties with the involvement not only of the COC layer as an external sealing layer but also the polyethylene layer located therebelow, there is preferably little difference between the layer thicknesses of the polyethylene layer and of the COC layer. In order to

achieve optimum attachment of the COC layer and the polyethylene layer to the metal layer without thereby making the film composite undesirably thick, the thickness of the acrylic-acid-containing joining layer also preferably differs little from the thickness of the two layers recited above (polyethylene layer and COC layer). The thickness values of the aforesaid layers, referred to the thinnest of the aforesaid layers, preferably differ by no more than 15%, preferably by no more than 11%. A triple composite made up of an acrylic-acid-containing joining layer, a polyethylene layer, and a COC layer can then easily be coextruded, the resulting film composite then exhibiting very good running properties on processing machines for processing the film composite to yield a package, and furthermore exhibiting very good sealing properties.

In principle, the film composite can be used as it is described above. For further protection of the film composite it can have, on that side of the metal layer which faces away from the COC layer, at least one further layer made of paper and/or plastic. As a result, the metal layer is a completely internal layer of the film composite, and as such is better protected from external influences. Because the COC layer as a rule is an entirely internally located layer of a package constituted from the film composite, provision of the at least one further layer simplifies the application of product information onto the outer side of the film composite which faces toward the consumer, which information would otherwise need to be applied, with greater complexity, onto the metal layer.

The at least one further layer is preferably laminated onto the metal layer or onto a further layer already present thereon. A solvent-containing laminating adhesive having a coating weight per unit area of 2 to 4 g/m^2, preferably having a coating weight per unit area of 3 g/m^2, is preferably used for this.

For easy imprinting and for child safety of a package constituted from the film composite, in order to prevent undesired opening and exposure of the pharmaceutical active substances packaged therein, the film composite preferably comprises, on that side of the metal layer which faces away from the COC layer, both a further layer made of paper and a further layer made of plastic. Because of the particular easy imprintability of the

paper layer and thus a particularly simple and inexpensive capability for equipping the film composite, and/or a package constituted therewith, with consumer information, the plastic layer is preferably located closer to the metal layer than is the paper layer. The paper layer is preferably an external layer of the film composite. A imprint printed onto the paper layer can be at least partly, or preferably completely, covered by a protective layer, for example a clear lacquer.

To protect against undesired tearing by children, the further layer made of plastic is preferably a biaxially oriented plastic.

In experiments, polyethylene terephthalate and/or polyamide have proven successful as a plastic for the at least one further plastic layer. Plastic layers made of the aforesaid plastics have sufficient mechanical and thermal stability and, especially in oriented form, provide a further barrier effect against diffusion of gases and vapors. The further plastic layer can thus, in one direction, protect the metal layer from chemical attack from outside, and in the opposite direction can additionally retain the pharmaceutical active substance, or constituents thereof, if they happen to pass through the metal layer.

When the film composite has a further layer made of paper on that side of the metal layer which faces away from the COC layer, that paper layer preferably has a thickness of 35 to 45 µm, particularly preferably 39 to 41 µm. Additionally or alternatively, the further layer made of paper can have a weight per unit area of 35 to 45 g/m^2, in particular 39 to 41 g/m^2.

When the film composite has, on that side of the metal layer which faces away from the COC layer, a further layer made of plastic, the latter layer preferably has a thickness of 19 to 27 µm, in particular 22 to 24 µm. Additionally or alternatively, the additional layer made of plastic has a weight per unit area of 28 to 36 g/m^2, in particular 31 to 33 g/m^2. These values for thickness and weight per unit area offer a very good compromise among sufficient mechanical strength, thermal stability, and low overall thickness for the film composite.

Because the above-described film composite is particularly suitable for manufacturing a package for a planar carrier of pharmaceutical active substances, for example a transdermal patch, the present invention also relates to such a package encompassing two film-composite sheets each made of a film composite as described and refined above. The film-composite sheets are arranged with mutually facing COC layers to form a carrier receiving space, and are joined to one another by local sealing of COC layer regions. Portions of the mutually facing COC layer regions are sealed to one another, preferably with participation of the polyethylene layer that has metallocene polyethylene and is located below the COC layers. The sealed seam then preferably encompasses a mixture of COC and metallocene polyethylene. The sealed seam then extends, in a thickness direction, into the polyethylene layer. Other portions of the mutually facing COC layer regions of the two film-composite sheets are located unjoinedly opposite one another. When a planar carrier of pharmaceutical active substances is received in the package, said carrier is located between respective oppositely located portions, unjoined to one another, of a COC layer of a film-composite sheet involved in the constitution of the package.

A "planar carrier of pharmaceutical active substances" is understood to be a substrate that respectively has, in its two principal directions of extent that are orthogonal to one another and to the substrate thickness direction, dimensions that are at least 10 times, preferably at least 30 times, greater than the dimension of the substrate in a thickness direction, and that is embodied to release a pharmaceutical active substance stored in the substrate.

To save space while providing durably effective shielding of the pharmaceutical active substance packaged therein, the package can be a four-side-sealed pouch having a sealed seam surrounding the carrier receiving space.

A planar active-substance carrier received in the carrier receiving space of the package as described above is preferably a transdermal patch. The pharmaceutical active

substance in the active-substance carrier preferably encompasses nicotine and/or fentanyl and/or lidocaine and/or another known active substance for administration by means of a transdermal patch.

The "designated" internal or external side of the film composite refers respectively to that side of the film composite which respective constitutes, on a package subsequently constituted from the film composite, a portion of the inner side or the outer side of the package.

The film composite preferably comprises only the layers recited in the present Application.

These and other objects, aspects, features and advantages of the invention will become apparent to those skilled in the art upon a reading of the Detailed Description of the invention set forth below taken together with the drawings which will be described in the next section.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take physical form in certain parts and arrangement of parts, a preferred embodiment of which will be described in detail and illustrated in the accompanying drawings which form a part hereof and wherein:

FIG. 1 is a cross-sectional view through an embodiment according to the present invention of a film composite of the present Application;

FIG. 2 is a plan view of a package, constituted with participation of the film composite of FIG. 1, of a transdermal patch; and

FIG. 3 is a cross-sectional view of the package of FIG. 2 along section plane III-III of FIG. 2.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawings wherein the showings are for the purpose of illustrating preferred and alternative embodiments of the invention only and not for the purpose of limiting the same, in FIG. 1, an embodiment according to the present invention of a film composite of the present Application is labeled in general with the number 10. The depiction in FIG. 1 is merely schematic. In particular, the thicknesses of the individual layers of film composite 10 are not illustrated accurately to scale. Film composite 10 has on its designated inner side a COC layer 12 that has a COC content of approximately 99.8 wt%. The proportion of COC in COC layer 12 is selected to be as high as possible in order to provide, with COC layer 12, an optimum barrier layer against migration and diffusion of pharmaceutical active substances such as nicotine and/or fentanyl and/or lidocaine. A surface 12a of COC layer 12 constitutes an exposed outer surface of film composite 10. COC layer 12 preferably has a thickness of 9.8 to 10.0 µm.

A polyethylene layer 14 is joined to COC layer 12 by coextrusion. Polyethylene layer 14 is preferably devoid of COC, and encompasses at least 50 wt% metallocene polyethylene, preferably C8 metallocene LLDPE. In the example depicted, the proportion of C8 metallocene LLDPE in terms of the total polyethylene mass of polyethylene layer 14 is more than 95 wt%. Extremely good adhesion of COC layer 12 to polyethylene layer 14, and thus good protection from delamination, are thereby achieved. The use of C8 metallocene LLDPE, as opposed to the C4 or C6 types that are also possible, results not only in good adhesion of COC layer 12 to a polyethylene layer 14 but also in a polyethylene layer 14 having advantageous rigidity properties. The melt flow index (MFR) of polyethylene layer 14 is approximately 8 g/10 min., measured per ISO 1133 at a test temperature of 190°C using a test weight of 2.16 kg. The density of polyethylene layer 14 is preferably 0.919 g/m^2.

Thanks to the value selected for the melt flow index, although polyethylene layer 14 is not an external layer of film composite 10 it can participate in a sealed join of film composite 10 on COC layer 12 side. High sealing strength values, and a very high-quality sealed

seam, are thereby achieved. COC layer 12 is not only a barrier layer of film composite, but also its sealable layer.

In the example depicted, the thickness of polyethylene layer 14 is between 10.8 and 11.0 µm. Polyethylene layer 14 and COC layer 12 are thus of approximately equal thickness; COC layer 12 can be slightly thinner. This balanced thickness relationship between polyethylene layer 14 and COC layer 12 also contributes to the attainment of permanently strong and diffusion-proof sealed joins.

On the side facing away from COC layer 12, polyethylene layer 14 is joined to a joining layer 16 made of an ethylene-acrylic acid (EAA) copolymer, in order to join COC layer 12 and polyethylene layer 14, by means of joining layer 16, to an aluminum layer 18.

Joining layer 16, which is between 10.6 and 10.8 µm thick in the example depicted, has been coextruded together with polyethylene layer 14 and COC layer 12, and applied onto aluminum layer 18 in the course of coextrusion.

Aluminum layer 18, which serves as a further barrier layer, is 8 to 10 µm thick, preferably 9 µm thick, in the example depicted.

A film composite made up of layers 12, 14, 16, and 18 is already a stable composite that is outstandingly suitable for manufacturing a package for products that contain pharmaceutical active substances such as nicotine, fentanyl, or lidocaine.

In order to protect the aforesaid composite, made up of layers 12, 14, 16, and 18, from being undesirably opened or torn by curious children, who might thereby gain access to a packaged pharmaceutical active substance that is entirely unsuitable for children, a layer 22 made of biaxially oriented plastic, preferably of polyethylene terephthalate or polyamide, is laminated, by means of a layer 20 made of solvent-containing laminating adhesive at an application weight of 3 g/m^2, onto that side of aluminum layer 18 which faces away from COC layer 12.

Layer 22 can be imprinted on its side facing away from aluminum layer 18 product so that information regarding a product that is packaged using film composite 10 can be conveyed to a consumer. Layer 22 can then be an externally located layer, opposite from COC layer 12, of film composite 10.

Layer 22 can also be a paper layer rather than a plastic layer 22.

In the example depicted in FIG. 1 film composite 10 comprises, in addition to plastic layer 22, an externally located paper layer 26 joined by means of a further laminating-adhesive layer 24 made of solvent-containing laminating adhesive.

Paper layer 26 can be imprinted on its outward-facing exposed surface 26a. The imprint can be covered by a protective layer, for example clear lacquer.

In the example depicted, plastic layer 22 has a thickness of approximately 22.7 to 23.3 µm. Paper layer 26, on the other hand, has a thickness of approximately 39.5 to 40.5 µm at a weight per unit area of approximately 40 g/m^2.

The total thickness of film composite 10 is thus between 108.4 µm and 110.6 µm.

Film composite 10 not only has outstanding barrier properties with respect to migration and diffusion of pharmaceutical active substances or constituents thereof from outer surface 12a of COC layer 12 to outer surface 26a of paper layer 26. The rigidity of film composite 10 is furthermore very suitable for constitution of a package, and it has outstanding running properties on processing machines for processing film composite 10.

FIG. 2 is a plan view of a package 30 constituted from two film-composite sheets of film composite 10 of FIG. 1, for packaging planar carriers of pharmaceutical active substances. Because of the plan view, only one film-composite sheet 32 is visible. A further film-composite sheet 33 is located behind film-composite sheet 32 depicted in FIG.

2 and is concealed by it (see FIG. 3). The viewer of FIG. 2 is looking onto outer side 26a of paper layer 26 of film-composite sheet 32. A "film-composite sheet" is understood for purposes of the present Application to mean any predetermined piece cut out of a film composite, regardless of the manner of cutting. The cut-out piece can therefore also be stamped or the like.

Package 30 is configured in the form of a four-side-sealed pouch having a surrounding sealed seam 34. Located radially inside sealed seam 34 is a carrier receiving space 36 in which a planar carrier 38 of a pharmaceutical active substance (see FIG. 3) is received.

Package 30 can comprise a notch 40 at at least one point, for example in an edge region, for easier opening.

FIG. 3 is a longitudinal section through package 30 of FIG. 2 along section plane III-III of FIG. 2. Section plane III-III is oriented orthogonally to the drawing plane of FIG. 2.

The distribution of layers within film-composite sheets 32 and 33 is no longer depicted separately in FIG. 3 in the longitudinal section through sheets 32 and 33. That distribution corresponds to the layer distribution of film composite 10 as depicted in FIG. 1. The two COC layers 12 of the respective film-composite sheets 32 and 33 are arranged facing toward one another and are fused to one another along sealed seam 34. A transdermal patch 39, constituting a planar carrier 38 of a pharmaceutical active substance, is received in carrier receiving space 36 that is constituted radially inside sealed seam 34. Carrier receiving space 36 is thus radially externally delimited by sealed seam 34 and orthogonally thereto by the two film-composite sheets 32 and 33.

Sealed seam 34 extends, in a thickness direction of the respective film-composite sheets 32 and 33, not only through the respective COC layers 12 that also serve as sealing layers but also, beyond those COC layers 12, into polyethylene layers 14. Sealed seam 34 is thus constituted by COC layers 12 (which are in contact with one another before sealing) of the two film-composite sheets 32 and 33 and by material of polyethylene layers 14

which are located, from the viewpoint of the contact point of the two COC layers 12 before sealed seam 34 is produced, behind the respective COC layers 12. Because the material of COC layers 12, like the material of polyethylene layers 14, is an olefin, the materials of the two layers 12 and 14 are mutually compatible and can blend with one another in sealed seam 34.

While considerable emphasis has been placed on the preferred embodiments of the invention illustrated and described herein, it will be appreciated that other embodiments, and equivalences thereof, can be made and that many changes can be made in the preferred embodiments without departing from the principles of the invention. Furthermore, the embodiments described above can be combined to form yet other embodiments of the invention of this application. Accordingly, it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation.

ABSTRACT OF THE DISCLOSURE

a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, 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 provision is made that the polyethylene layer encompasses metallocene polyethylene.

SUBSTITUTE SPECIFICATION - MARKED

FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

The present invention relates to a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, encompassing, in a direction from the designated outer side of the film composite toward its designated 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.

BACKGROUND OF THE INVENTION

A film composite of this kind, for the aforesaid purpose of manufacturing a package for pharmaceutical active-substance carriers, is known from WO 2015/123211 A1. The film composite of the species comes into direct contact with the planar carrier of a pharmaceutical active substance, and thus with the pharmaceutical active substance itself. The relevant pharmaceutical active substances are active substances such as nicotine, fentanyl, or lidocaine. The stress on the film composite produced by these pharmaceutical active substances is considerable. It is necessary to ensure in this context on the one hand that the film composite survives as such over the long term in order to prevent undesired release of the pharmaceutical active substance of the active-substance carrier. Even if the film composite survives, i.e., does not at least locally delaminate, for example, under the influence of the pharmaceutical active substance diffusing into composite layers, it is necessary on the other hand to ensure that the pharmaceutical active substance cannot diffuse or migrate through the film composite.

In order to increase the diffusion barrier effect of the film composite with respect to the pharmaceutical active substances packaged by it, it is known to select the proportion of cycloolefin copolymer (COC) in the COC layer that is innermost in the subsequent

package to be as high as possible. As the COC concentration in the COC layer rises, however, it becomes increasingly difficult to maintain the stability of the film composite, for example to prevent delamination or similar disintegration phenomena.

WO 2017/114922 A1 also discloses film composites for creating packages for planar pharmaceutical active substance carriers.

SUMMARY OF THE INVENTION

An object of the present invention is therefore to embody the film composite recited initially with the greatest possible chemical and mechanical stability with regard to the pharmaceutical active substances that are to be packaged, in light of its purpose of constituting a safe, including childproof, package for planar pharmaceutical active-substance carriers.

This object is achieved according to the present invention by a film composite of the kind recited initially in which the polyethylene layer encompasses metallocene polyethylene. The reason is that experiments have shown that given otherwise identical dimensions for the film composite, adhesion of the COC layer to the polyethylene layer is considerably better when the polyethylene layer encompasses metallocene polyethylene. "Metallocene polyethylene" in this context is polyethylene that has been manufactured in known fashion using metallocene catalysts.

The higher the COC concentration in the COC layer, the greater the gain in adhesion, in terms of the adhesive effect between the COC layer and the polyethylene layer, which is achievable by the use of metallocene polyethylene as compared with conventional polyethylene. Because the COC layer comprises a COC proportion that is as high as possible (at least 95 wt%, preferably at least 99.8 wt%, of the mass of the COC as a whole) in order to achieve a maximum barrier effect with respect to pharmaceutical active substances that are stored in the planar active-substance carrier, a particularly significant adhesion advantage can be achieved with the utilization, as presented here, of

metallocene polyethylene in the polyethylene layer arranged between the acrylic-acid-containing joining layer and the COC layer.

In doubtful cases, for example if more than one polymer layer of the film composite contains COC, a COC layer is to be considered a "COC layer" for purposes of the present Application only if it contains at least 50 wt% COC in terms of its layer mass. The aforesaid polyethylene layer that contains metallocene polyethylene is preferably devoid of COC.

In principle, an improvement in the adhesion of the COC layer to the polyethylene layer can already be achieved with comparatively small quantities of metallocene polyethylene. In a context of comparative samples of different film-composite sheets that are otherwise dimensionally identical, the improvement in the adhesive effect is particularly large if the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer is at least 50 wt%. It is therefore also possible in principle to use so-called polyethylene blends, in which metallocene polyethylene is blended with non-metallocene polyethylene, to constitute the polyethylene layer.

Because of the advantageous adhesion-enhancing effect of metallocene polyethylene, the proportion thereof (always in percent by weight) in terms of the total polyethylene contained in the polyethylene layer is preferably as high as possible, preferably higher than 90 wt%, particularly preferably higher than 96 wt%.

It has proven to be advantageous, in order to enhance the adhesion effect and also the processability of the film composite on corresponding processing machines to produce packages constituted therefrom, if the polyethylene layer encompasses a metallocene LLDPE. The polyethylene layer preferably encompasses only metallocene LLDPE as the metallocene polyethylene.

In order to achieve good running properties for a film-composite web in the aforementioned processing machines, the density of the metallocene polyethylene is advantageously in a range between 0.917 and 0.921 g/m^2. In order to achieve permanent

sealed seams with high strength and high density, the metallocene polyethylene additionally or alternatively has a melt flow index (melt flow rate, MFR) of between 6 and 10 g/10 min., measured per ISO 1133 at a test temperature of 190°C and using a test element having a weight of 2.16 kg. This is because in addition to the COC, constituting the external barrier layer and sealing layer, the polyethylene layer, ~~constituting the external barrier layer and sealing layer,~~ can contribute to sealed join of the film composite.

Any type of metallocene polyethylene in the polyethylene layer provides a desired enhancement of the adhesion effect of the COC layer on the polyethylene layer, compared with a polyethylene layer of the same dimensions and/or the same weight per unit area in the film composite. In addition, however, the rigidity of the polyethylene layer, and thus of the film composite as a whole, can be influenced by using different types of metallocene polyethylene. Advantageous rigidity of the polyethylene layer, in a context of predefined dimensions thereof, can be obtained by the fact that the polyethylene layer encompasses a C6 metallocene polyethylene and/or a C8 metallocene polyethylene, or is made of the aforesaid types of metallocene polyethylene. According to previous experiments, for a predefined film composite and in particular for a predefined dimension and/or weight per unit area of the polyethylene layer, C8 metallocene polyethylene offers the best results in terms of achieving on the one hand layer rigidity of the polyethylene layer and on the other hand composite rigidity of the film composite.

It is understandably advantageous for that reason if the polyethylene layer encompasses only a C8 metallocene polyethylene as a metallocene polyethylene. Based on what is stated above, it is particularly preferably a C8 metallocene LLDPE.

The polyethylene layer is preferably applied using the extrusion method, particularly preferably coextruded with the COC layer.

A commercially available metallocene polyethylene that is outstandingly applicable as a polyethylene layer in the aforesaid film composite is the polyethylene obtainable from the Dow Chemical Company under the trade name "Elite™ 5811."

In order to achieve the greatest possible adhesion effect for the partial composite, made up of a polyethylene layer and COC layer, on the metal layer, the acrylic-acid-containing joining layer preferably encompasses or is made of an ethylene-acrylic acid (EAA) copolymer.

The acrylic-acid-containing joining layer is preferably also applied onto the metal layer by extrusion. Particularly preferably, a partial composite made up of an acrylic-acid-containing joining layer, in particular an EAA layer; a polyethylene layer; and a COC layer is applied onto the metal layer by coextrusion in one collective extrusion step.

The metal layer serves as an oxygen barrier and gas barrier to protect package contents from external influences, and furthermore as a barrier for pharmaceutical active substances and constituents thereof which reach the metal layer as a result of diffusion through the COC layer, the polyethylene layer, and the acrylic-acid-containing joining layer. Preferably the metal layer is an aluminum layer.

Preferably each of the layers, from among the acrylic-acid-containing joining layer, polyethylene layer, and COC layer, has a layer thickness in the range from approximately 7 µm to 15 µm. On the one hand this ensures outstanding attachment to the metal layer; on the other hand, in this thickness range not only the COC layer but also the polyethylene layer can serve to produce a sealed join to the COC layer of a film composite of similar construction. Because, in the instance recited, the polyethylene layer located below the COC layer can also contribute in particularly effective and reliable fashion to production of a sealing join, the values indicated above for the melt flow index (MFR) are highly advantageous in terms of achieving outstanding sealing properties for the film composite having the exposed COC layer. The thickness values of the three, preferably coextruded layers (acrylic-acid-containing joining layer, polyethylene layer, and COC layer) are

preferably each in the range from 9 µm to 12 µm. In order to achieve outstanding sealing properties with the involvement not only of the COC layer as an external sealing layer but also the polyethylene layer located therebelow, there is preferably little difference between the layer thicknesses of the polyethylene layer and of the COC layer. In order to achieve optimum attachment of the COC layer and the polyethylene layer to the metal layer without thereby making the film composite undesirably thick, the thickness of the acrylic-acid-containing joining layer also preferably differs little from the thickness of the two layers recited above (polyethylene layer and COC layer). The thickness values of the aforesaid layers, referred to the thinnest of the aforesaid layers, preferably differ by no more than 15%, preferably by no more than 11%. A triple composite made up of an acrylic-acid-containing joining layer, a polyethylene layer, and a COC layer can then easily be coextruded, the resulting film composite then exhibiting very good running properties on processing machines for processing the film composite to yield a package, and furthermore exhibiting very good sealing properties.

In principle, the film composite can be used as it is described above. For further protection of the film composite it can have, on that side of the metal layer which faces away from the COC layer, at least one further layer made of paper and/or plastic. As a result, the metal layer is a completely internal layer of the film composite, and as such is better protected from external influences. Because the COC layer as a rule is an entirely internally located layer of a package constituted from the film composite, provision of the at least one further layer simplifies the application of product information onto the outer side of the film composite which faces toward the consumer, which information would otherwise need to be applied, with greater complexity, onto the metal layer.

The at least one further layer is preferably laminated onto the metal layer or onto a further layer already present thereon. A solvent-containing laminating adhesive having a coating weight per unit area of 2 to 4 g/m^2, preferably having a coating weight per unit area of 3 g/m^2, is preferably used for this.

For easy imprinting and for child safety of a package constituted from the film composite, in order to prevent undesired opening and exposure of the pharmaceutical active substances packaged therein, the film composite preferably comprises, on that side of the metal layer which faces away from the COC layer, both a further layer made of paper and a further layer made of plastic. Because of the particular easy imprintability of the paper layer and thus a particularly simple and inexpensive capability for equipping the film composite, and/or a package constituted therewith, with consumer information, the plastic layer is preferably located closer to the metal layer than is the paper layer. The paper layer is preferably an external layer of the film composite. A imprint printed onto the paper layer can be at least partly, or preferably completely, covered by a protective layer, for example a clear lacquer.

To protect against undesired tearing by children, the further layer made of plastic is preferably a biaxially oriented plastic.

In experiments, polyethylene terephthalate and/or polyamide have proven successful as a plastic for the at least one further plastic layer. Plastic layers made of the aforesaid plastics have sufficient mechanical and thermal stability and, especially in oriented form, provide a further barrier effect against diffusion of gases and vapors. The further plastic layer can thus, in one direction, protect the metal layer from chemical attack from outside, and in the opposite direction can additionally retain the pharmaceutical active substance, or constituents thereof, if they happen to pass through the metal layer.

When the film composite has a further layer made of paper on that side of the metal layer which faces away from the COC layer, that paper layer preferably has a thickness of 35 to 45 µm, particularly preferably 39 to 41 µm. Additionally or alternatively, the further layer made of paper can have a weight per unit area of 35 to 45 g/m^2, in particular 39 to 41 g/m^2.

When the film composite has, on that side of the metal layer which faces away from the COC layer, a further layer made of plastic, the latter layer preferably has a thickness of

19 to 27 µm, in particular 22 to 24 µm. Additionally or alternatively, the additional layer made of plastic has a weight per unit area of 28 to 36 g/m^2, in particular 31 to 33 g/m^2. These values for thickness and weight per unit area offer a very good compromise among sufficient mechanical strength, thermal stability, and low overall thickness for the film composite.

Because the above-described film composite is particularly suitable for manufacturing a package for a planar carrier of pharmaceutical active substances, for example a transdermal patch, the present invention also relates to such a package encompassing two film-composite sheets each made of a film composite as described and refined above. The film-composite sheets are arranged with mutually facing COC layers to form a carrier receiving space, and are joined to one another by local sealing of COC layer regions. Portions of the mutually facing COC layer regions are sealed to one another, preferably with participation of the polyethylene layer that has metallocene polyethylene and is located below the COC layers. The sealed seam then preferably encompasses a mixture of COC and metallocene polyethylene. The sealed seam then extends, in a thickness direction, into the polyethylene layer. Other portions of the mutually facing COC layer regions of the two film-composite sheets are located unjoinedly opposite one another. When a planar carrier of pharmaceutical active substances is received in the package, said carrier is located between respective oppositely located portions, unjoined to one another, of a COC layer of a film-composite sheet involved in the constitution of the package.

A "planar carrier of pharmaceutical active substances" is understood to be a substrate that respectively has, in its two principal directions of extent that are orthogonal to one another and to the substrate thickness direction, dimensions that are at least 10 times, preferably at least 30 times, greater than the dimension of the substrate in a thickness direction, and that is embodied to release a pharmaceutical active substance stored in the substrate.

To save space while providing durably effective shielding of the pharmaceutical active substance packaged therein, the package can be a four-side-sealed pouch having a sealed seam surrounding the carrier receiving space.

A planar active-substance carrier received in the carrier receiving space of the package as described above is preferably a transdermal patch. The pharmaceutical active substance in the active-substance carrier preferably encompasses nicotine and/or fentanyl and/or lidocaine and/or another known active substance for administration by means of a transdermal patch.

The "designated" internal or external side of the film composite refers respectively to that side of the film composite which respective constitutes, on a package subsequently constituted from the film composite, a portion of the inner side or the outer side of the package.

The film composite preferably comprises only the layers recited in the present Application.

These and other objects, aspects, features and advantages of the invention will become apparent to those skilled in the art upon a reading of the Detailed Description of the invention set forth below taken together with the drawings which will be described in the next section.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take physical form in certain parts and arrangement of parts, a preferred embodiment of which will be described in detail and illustrated in the accompanying drawings which form a part hereof and wherein:

FIG. 1 is a cross-sectional view through an embodiment according to the present invention of a film composite of the present Application;

FIG. 2 is a plan view of a package, constituted with participation of the film composite of FIG. 1, of a transdermal patch; and

FIG. 3 is a cross-sectional view of the package of FIG. 2 along section plane III-III of FIG. 2.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawings wherein the showings are for the purpose of illustrating preferred and alternative embodiments of the invention only and not for the purpose of limiting the same, in FIG. 1, an embodiment according to the present invention of a film composite of the present Application is labeled in general with the number 10. The depiction in FIG. 1 is merely schematic. In particular, the thicknesses of the individual layers of film composite 10 are not illustrated accurately to scale. Film composite 10 has on its designated inner side a COC layer 12 that has a COC content of approximately 99.8 wt%. The proportion of COC in COC layer 12 is selected to be as high as possible in order to provide, with COC layer 12, an optimum barrier layer against migration and diffusion of pharmaceutical active substances such as nicotine and/or fentanyl and/or lidocaine. A surface 12a of COC layer 12 constitutes an exposed outer surface of film composite 10. COC layer 12 preferably has a thickness of 9.8 to 10.0 µm.

A polyethylene layer 14 is joined to COC layer 12 by coextrusion. Polyethylene layer 14 is preferably devoid of COC, and encompasses at least 50 wt% metallocene polyethylene, preferably C8 metallocene LLDPE. In the example depicted, the proportion of C8 metallocene LLDPE in terms of the total polyethylene mass of polyethylene layer 14 is more than 95 wt%. Extremely good adhesion of COC layer 12 to polyethylene layer 14, and thus good protection from delamination, are thereby achieved. The use of C8 metallocene LLDPE, as opposed to the C4 or C6 types that are also possible, results not only in good adhesion of COC layer 12 to a polyethylene layer 14 but also in a polyethylene layer 14 having advantageous rigidity properties. The melt flow index (MFR) of polyethylene layer 14 is approximately 8 g/10 min., measured per ISO 1133 at a test

temperature of 190°C using a test weight of 2.16 kg. The density of polyethylene layer 14 is preferably 0.919 g/m^2.

Thanks to the value selected for the melt flow index, although polyethylene layer 14 is not an external layer of film composite 10 it can participate in a sealed join of film composite 10 on COC layer 12 side. High sealing strength values, and a very high-quality sealed seam, are thereby achieved. COC layer 12 is not only a barrier layer of film composite, but also its sealable layer.

In the example depicted, the thickness of polyethylene layer 14 is between 10.8 and 11.0 µm. Polyethylene layer 14 and COC layer 12 are thus of approximately equal thickness; COC layer 12 can be slightly thinner. This balanced thickness relationship between polyethylene layer 14 and COC layer 12 also contributes to the attainment of permanently strong and diffusion-proof sealed joins.

On the side facing away from COC layer 12, polyethylene layer 14 is joined to a joining layer 16 made of an ethylene-acrylic acid (EAA) copolymer, in order to join COC layer 12 and polyethylene layer 14, by means of joining layer 16, to an aluminum layer 18.

Joining layer 16, which is between 10.6 and 10.8 µm thick in the example depicted, has been coextruded together with polyethylene layer 14 and COC layer 12, and applied onto aluminum layer 18 in the course of coextrusion.

Aluminum layer 18, which serves as a further barrier layer, is 8 to 10 µm thick, preferably 9 µm thick, in the example depicted.

A film composite made up of layers 12, 14, 16, and 18 is already a stable composite that is outstandingly suitable for manufacturing a package for products that contain pharmaceutical active substances such as nicotine, fentanyl, or lidocaine.

In order to protect the aforesaid composite, made up of layers 12, 14, 16, and 18, from being undesirably opened or torn by curious children, who might thereby gain access to a packaged pharmaceutical active substance that is entirely unsuitable for children, a layer 22 made of biaxially oriented plastic, preferably of polyethylene terephthalate or polyamide, is laminated, by means of a layer 20 made of solvent-containing laminating adhesive at an application weight of 3 g/m^2, onto that side of aluminum layer 18 which faces away from COC layer 12.

Layer 22 can be imprinted on its side facing away from aluminum layer 18 product so that information regarding a product that is packaged using film composite 10 can be conveyed to a consumer. Layer 22 can then be an externally located layer, opposite from COC layer 12, of film composite 10.

Layer 22 can also be a paper layer rather than a plastic layer 22.

In the example depicted in FIG. 1 film composite 10 comprises, in addition to plastic layer 22, an externally located paper layer 26 joined by means of a further laminating-adhesive layer 24 made of solvent-containing laminating adhesive.

Paper layer 26 can be imprinted on its outward-facing exposed surface 26a. The imprint can be covered by a protective layer, for example clear lacquer.

In the example depicted, plastic layer 22 has a thickness of approximately 22.7 to 23.3 µm. Paper layer 26, on the other hand, has a thickness of approximately 39.5 to 40.5 µm at a weight per unit area of approximately 40 g/m^2.

The total thickness of film composite 10 is thus between 108.4 µm and 110.6 µm.

Film composite 10 not only has outstanding barrier properties with respect to migration and diffusion of pharmaceutical active substances or constituents thereof from outer surface 12a of COC layer 12 to outer surface 26a of paper layer 26. The rigidity of film

composite 10 is furthermore very suitable for constitution of a package, and it has outstanding running properties on processing machines for processing film composite 10.

FIG. 2 is a plan view of a package 30 constituted from two film-composite sheets of film composite 10 of FIG. 1, for packaging planar carriers of pharmaceutical active substances. Because of the plan view, only one film-composite sheet 32 is visible. A further film-composite sheet 33 is located behind film-composite sheet 32 depicted in FIG. 2 and is concealed by it (see FIG. 3). The viewer of FIG. 2 is looking onto outer side 26a of paper layer 26 of film-composite sheet 32. A "film-composite sheet" is understood for purposes of the present Application to mean any predetermined piece cut out of a film composite, regardless of the manner of cutting. The cut-out piece can therefore also be stamped or the like.

Package 30 is configured in the form of a four-side-sealed pouch having a surrounding sealed seam 34. Located radially inside sealed seam 34 is a carrier receiving space 36 in which a planar carrier 38 of a pharmaceutical active substance (see FIG. 3) is received.

Package 30 can comprise a notch 40 at at least one point, for example in an edge region, for easier opening.

FIG. 3 is a longitudinal section through package 30 of FIG. 2 along section plane III-III of FIG. 2. Section plane III-III is oriented orthogonally to the drawing plane of FIG. 2.

The distribution of layers within film-composite sheets 32 and 33 is no longer depicted separately in FIG. 3 in the longitudinal section through sheets 32 and 33. That distribution corresponds to the layer distribution of film composite 10 as depicted in FIG. 1. The two COC layers 12 of the respective film-composite sheets 32 and 33 are arranged facing toward one another and are fused to one another along sealed seam 34. A transdermal patch 39, constituting a planar carrier 38 of a pharmaceutical active substance, is received in carrier receiving space 36 that is constituted radially inside sealed seam 34.

Carrier receiving space 36 is thus radially externally delimited by sealed seam 34 and orthogonally thereto by the two film-composite sheets 32 and 33.

Sealed seam 34 extends, in a thickness direction of the respective film-composite sheets 32 and 33, not only through the respective COC layers 12 that also serve as sealing layers but also, beyond those COC layers 12, into polyethylene layers 14. Sealed seam 34 is thus constituted by COC layers 12 (which are in contact with one another before sealing) of the two film-composite sheets 32 and 33 and by material of polyethylene layers 14 which are located, from the viewpoint of the contact point of the two COC layers 12 before sealed seam 34 is produced, behind the respective COC layers 12. Because the material of COC layers 12, like the material of polyethylene layers 14, is an olefin, the materials of the two layers 12 and 14 are mutually compatible and can blend with one another in sealed seam 34.

While considerable emphasis has been placed on the preferred embodiments of the invention illustrated and described herein, it will be appreciated that other embodiments, and equivalences thereof, can be made and that many changes can be made in the preferred embodiments without departing from the principles of the invention. Furthermore, the embodiments described above can be combined to form yet other embodiments of the invention of this application. Accordingly, it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation.

ABSTRACT OF THE DISCLOSURE

a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, 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 provision is made that the polyethylene layer encompasses metallocene polyethylene.

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Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Filer:	Gregory Stamm Vickers/Loni Clay
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Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
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Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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RCE- 1ST REQUEST	1801	1	1360	1360
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First Named Inventor/Applicant Name:	Manuella Herb
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37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		TRO45953_AmendmentC.pdf	133047 195f4263401a98c49b74df1185d1ee29033e18f4	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment Submitted/Entered with Filing of CPA/RCE	1	1
	Claims	2	5
	Specification	6	6
	Applicant Arguments/Remarks Made in an Amendment	7	13

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Information:

2	Affidavit-traversing rejectns or objectns rule 132	TRO45953_Declaration.pdf	250306 8cf7eb2f0c07713f24c132725ee09aaf141efc66	no	4

Warnings:

Information:

3	Request for Continued Examination (RCE)	TRO45953_RCE.pdf	1349931 160da6df1f51a40f56b511d3e85e2fbd7e38ae75	no	3

Warnings:

Information:

4		TRO45953_SubSpecClean.pdf	93051 e56b8a07663bb6b20f2c5e7dc06e90973f83b1eb	yes	15

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**

	Specification		1		14
	Abstract		15		15
Warnings:					
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5	Specification	TRO45953_SubSpecMarked.pdf	93441 0205ebf2b8c2ba245ac897d9777b986fea94f25f	no	15
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	38214 7fc239b7aaa1810b62372819bb0794c55f35c80e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1957990		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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,

RANKIN, HILL & CLARK LLP

By /Gregory S. Vickers/
Gregory S. Vickers, Reg. No. 45180

23755 Lorain Road, Suite 200
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(440) 614-0604

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	

DECLARATION UNDER 37 CFR 1.132

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

I, Manuella Herb hereby declare and state:

1. I am the <Senior Manager Product Development> for the Applicant of this application, namely, Huhtamaki Flexible Packaging Germany GmbH & Co. KG.

2. I have worked in the packaging industry for over 22 years and have significant experience in packaging and material designs for packaging.

3. I am one of the inventors of the film composite for packaging transdermal patches and package made of such a film of the above-identified patent application.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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 in 11. 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.

12. While Osborn comprehensively lists the many different kinds of polyethylene that there 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.

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.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements and the like may jeopardize the validity of this document, declares that s/he is properly authorized to execute this document on behalf of the applicant; and all statements made of his/her own knowledge are true and all statements made on information and belief are believed to be true.

Name: Manuella Herb

Title Senior Manager Product Development
Huhtamaki Flexible Packaging Germany GmbH & Co. KG.

Date: 24.09.2021

Huhtamaki Flexible Packaging
Germany GmbH & Co. KG
97671 Rorsberg

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/516,792	Filing Date 07/19/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	08/12/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CAROLYN E THOMAS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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.

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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.

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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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

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EXAMINER
YU, HONG

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 16/516,792	Applicant(s) Herb et al.	
	Examiner HONG YU	Art Unit 1612	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 03/11/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 16-37 is/are pending in the application.

5a) Of the above claim(s) 35-37 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 16-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

DETAILED ACTION

Status of claims

Applicant's affirmation of election of invention I in the reply filed on 03/11/2021 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-15 have been canceled and claims 35-37 have been withdrawn. Claims 16-34 are under examination in the instant office action.

Rejections withdrawn

Applicant's amendments and arguments filed on 03/11/2021 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant's amendments have overcome the claim objections of claim 18 and of claim 21 from the previous Office Action. The following rejections and/or objections are either reiterated or newly applied. They

constitute the complete set of rejections and/or objections presently being applied to the instant application.

Rejections remained

The following rejections of the claims are remained for reasons of record and the following. The text of the section of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn et al. (US 2015/0225151 A1) in view of Torradas et al. (US 2017/0136747 A1).

Osborn et al. teach a flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches comprising

an article contact layer having at least 90 wt. % of a norbornene ethylene copolymer (COC) or derivative thereof;

a polyolefin bulk layer including PE;

a first intermediate adhesive layer;

an oxygen barrier layer including aluminum foil;

a second intermediate adhesive layer; and

an exterior protective layer comprising a polymer selected from the group consisting of paper, polyamide, polyolefin, blends or derivatives thereof and

PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)

exemplified a film comprising OPET (biaxially oriented polyester terephthalate) /PE/LDPE/EVA/Al Foil base layer with three-layer coextrusion of EAA, LDPE, and an

80:20 wt % blend of LDPE:mLLDPE in example 2 and EAA, LDPE, and COC in example 5 which were extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film of

OPET/PE/ LDPE/EAA/Al foil/EAA/LDPE/LDPE:mLLDPE and a total thickness of 3.04 mils (77.2 microns) in example 2 and

0.92 mil (23.37 μm) OPET (the thickness of plastic layer in the instant claims 33 and 34)/PE/0.42 mil (10.67 μm) LDPE/0.1 mil (2.54 μm) EAA/0.35 mil (8.85 μm) All foil/0.17 mil (4.32 μm) EAA/0.65 mil (16.51 μm) LDPE/0.43 mil (10.92 μm) COC and a total thickness of 3.0 mils (76 microns) in example 5;

all layers can have the thickness of less than mils and any increment of 0.1 or 0.01 mil there between which includes 0.4 mil (10.16 μm) (the instant claims 22 and 25) and 1.5 mil (25.4 μm) (the thickness of paper layer in the instant claims 22 and 25) (entire reference, especially abstract, figure 1, paragraph 6-12, 15, 16, 20-28, 40, 41, 46, 47, 49, 50, 51, 53, 54, 57, 68, 69, 71, 72, 78, 93, 97, and 100, and claims 1-5).

Since Osborn et al. teach the adhesive, PE, and COC layers being coextruded which is the same as the method of producing the acrylic acid, PE, and COC layers (2nd paragraph on page 5), the thickness value (claims 23, 24, 26, and 27) of the adhesive, PE, and COC layers taught by Osborn et al. teach would be the same as those of the acrylic acid, PE, and COC layers of the claimed film.

Osborn et al. do not specify: i) an embodiment with the layer next to COC being m-LLDPE; and ii) the weight/unit area of paper and plastic layers (claims 33 and 34).

The 1st deficiency is cured by the teachings of both m-LLDPE and LDPE being suitable PEs and PEs being in all layers, or, alternatively, cured by Torradas et al. who teach a multilayered film, with a total thickness of < about 250 μm, for packing food, including liquid food, drug, etc., comprising

an external layer such as aluminum or PE as a good barrier to moisture permeation including MC-PE with the external layer being optionally protective coated;

one or more inner layers including barrier layers of COC;

a structure layer which can be an external layer, and/or inner layer, and barrier layer such as PE made by metallocene catalyst system for both structure and barrier functions;

one or more adhesive layers such as Elvaloy AC (the claimed ethylene acrylate copolymer in claim 21) between the outside structure layer to an inner layer with the thickness of adhesive layer being 2-10 μm (entire reference, especially abstract, paragraph 92, 93, 95, 99-101, 106, 107119, 121, 122, 126, 127, 131, 136, 137, 140, 202, 222, and 240). A structure layer which can be an external layer, and/or inner layer, and barrier layer is interpreted as a structure can be a barrier layer between external layer and inner layer.

Although none of the examples in Osborn et al. teach the layer next to COC being m-LLDPE recited in the instant claims, it would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the general teachings both m-LLDPE and LDPE being suitable PEs and PEs being in all layers and LDPE layer next to COC layer to replace the LDPE next to COC in example 5 with m-LLDPE. The specific combination of features claimed is disclosed within the broad

generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients (PEs) from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Alternatively, It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Osborn et al. and Torradas et al. to specify the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. is MC-PE. PE made by metallocene catalyst system as a structure layer for both structure and barrier functions was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying it flows from its having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

The 2nd deficiency is cured by the rational that it is routine optimization to determine the optimum weight/unit area for each layer.

Osborn et al. do not specifically teach weight unit of the paper layer and plastic layer (external layers) claimed by applicant. While the layer thicknesses of the paper layer and plastic layer are within those of the claimed film, the PET plastic and the paper are known packaging layer materials for achieve the same protective effect and would be reasonable to assume that they are the similar materials with the similar density and thus would result in the similar weight/unit area.

Or alternatively, weight/unit area of the paper layer and plastic layer in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize or, alternatively obvious to try to reach another workable product or process. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal weight/unit area in order to best achieve the desired results of protective effect.

Response to Applicants' arguments:

Applicants argue 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 in comparison to regular LDPE while Osborn et al. merely teach the existence of mLLDPE (paragraph 15 and 27), and teach mLLDPE being used in comparative example (76, 78, and 97).

However, this argument is not deemed persuasive. First of all, metallocene C8 LLDPE is not recited in claim 16, rather metallocene polyethylene is recited.

Secondly, it is well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the submitted knowledge in the art, to a person of ordinary skill in the art. Although Osborn et al. do not teach incorporating mLLDPE in example 5; Osborn et al. teaching polyolefin bulk layer (abstract and paragraph 49) while polyolefin bulk layer includes polyethylene and polyethylene includes mLLDPE (paragraph 20-29); using LLDPE in any of the interior, exterior,

intermediate or tie layers in paragraph 57 and examples of preferred materials includes LLDPE in paragraph 66 while LLDPE including mLLDPE in paragraph 27 and 28; and mLLDPE for use in the present invention in paragraph 78.

Lastly, applicant merely argues 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 in comparison to regular LDPE and nothing has been shown otherwise. From MPEP 716.01(c) II: The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Respectfully, applicants' arguments are not persuasive. The predictable and expected result of the claimed composition remains predictable and expected in the absence of evidence to the contrary. Accordingly, the claims remain rejected for at least these reasons and the reasons of record.

Claims 16, 17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) in view of Osborn et al. (US 2015/0225151 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify an embodiment with PE being MC-PE.

This deficiency is cured by the rational that it would have obvious to have selected various combinations of various disclosed ingredients (MC-PE) from within a

prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Although Torradas et al. do not specify the PE layer next to COC being MC-PE recited in the instant claims, it would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the general teachings of MC-PE being one of the PEs and having PE in the structure layer which is between the external layer and the inner layer, i.e., 100% MC-PE. The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients (PEs) from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Response to Applicants' arguments:

Argument regarding the 103 rejection is basically the same as the above 103 rejection, thus the response discussed above applies here as well and is not persuasive for reason discussed above.

Claims 18-20 and 22-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1), as applied to claims 16, 17, and 21, in view of Osborn et al. (US 2015/0225151 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify: i) MC-PE being MC-LLDPE catalyzed by hexene (C_6) or 1-octene (C_8) (claims 18-20); ii) the thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers (claims 22-27); and iii) the limitations of the further layers outside the metal layer (protective layers) in claims 28-34.

These deficiency is cured by Osborn et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Osborn et al. to specify MC-PE in the film taught by Torradas et al. being MC-LLDPE catalyzed by hexene (C_6) or 1-octene (C_8) and the claimed thicknesses and the film taught by Torradas et al. having the claimed thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with MC-PE being MC-LLDPE catalyzed by hexene (C_6) or 1-octene (C_8) (claims 18-20); the claimed thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers of the instant claims 22-27; and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been

used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments:

Argument regarding the 103 rejection is basically the same as the above 1st 103 rejection, thus the response discussed above applies here as well and is not persuasive for reason discussed above.

Claims 16-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toft et al. (US 2005/0181154 A1) in view of Osborn et al. (US 2015/0225151 A1) and Torradas et al. (US 2017/0136747 A1).

Toft et al. teach a packing laminate for food as illustrated in figure 1 below comprising, from exterior to food contacting interior,

item 12 being a heat sealable such as PE,

item 11 being a core of paperboard with item 14 being an intermediate layer of thermoplastic of about 23-27 g/m^2 LDPE (the claimed further layers made of plastic and/or paper in claims 28-30) bonding item 11 to

item 13 which is an aluminum foil,

item 15-1 being an adhesive layer of EAA (the instant claim 21),

item 15-2 being a barrier layer of a blend of COC and m-LLDPE, and

item 15-3 being a PE-MC layer a blend of 60-70% by weight of m-LLDPE (the instant claim 18) prepared by copolymerization of C_{4-8} α-olefins including 1-hexene (C_6) or 1-octene (C_8) (the instant claims 19 and 20) and 30-40% by weight of LDPE (the

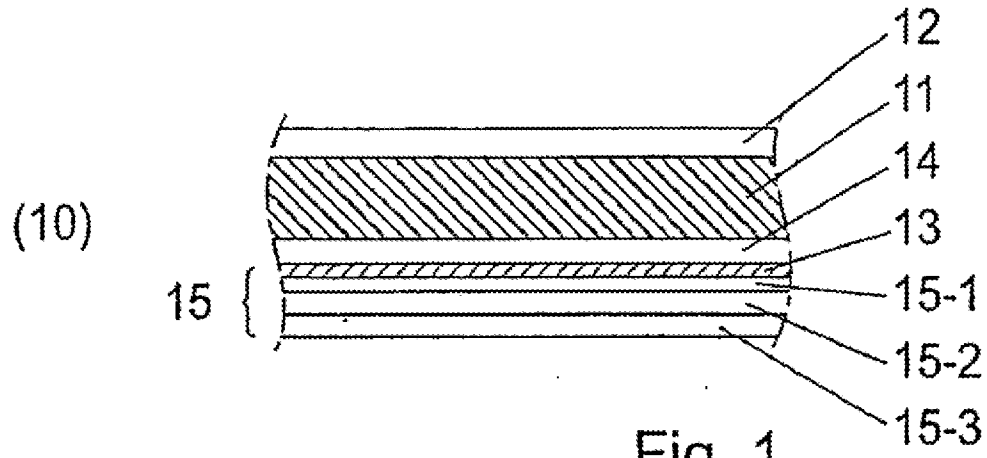


Fig. 1

instant claim 17)

(entire reference, espcially abstract, figure 1, paragraph 46-53, 55, 56, 60, 79-81, and 83, and claims 1-3, 6, 7, and 9).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **[for manufacturing a package for planar carriers of pharmaceutical active substances]**; however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Furthermore, according to Torradas et al. a multilayered film can be used for both packing food, including liquid food, and drug.

Toft et al. do not teach: i) the innermost layer 15-2 and 15-3 being the opposite order; ii) the thicknesses and thickness values of Al external layer, COC inner layer, PE-

MC structure layer, and the adhesive layers (claims 22-27); and iii) the limitations of the further layers outside the metal layer (protective layers) in claims 31-34.

The 1st deficiency is cured by Osborn et al. whose teachings are discussed above and applied in the same manner and Torradas et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al., Osborn et al., and Torradas et al. to exchange the COC layer and MC-PE layer in the film taught by Toft et al. with the innermost layer being COC and MC-PE being the layer before it. OCO as the innermost layer and PE next to it according to Osborn et al. and MC-PE being one of the PE before the innermost layer according to Torradas et al. was well known to a person of ordinary skill in the art at the time of the invention. The motivation for exchanging the COC layer and MC-PE layer in the film taught by Toft et al. flows from its having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

The 2nd deficiency is cured by Osborn et al. whose teachings are discussed above.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al. and Osborn et al. to specify the claimed thicknesses and the film taught by Toft et al. having the claimed thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery

patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Response to Applicants' arguments:

Argument regarding the 103 rejection is basically the same as the above 1st 103rejection, thus the response discussed above applies here as well and is not persuasive for reason discussed above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on 9 am - 5:30 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, Applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HONG YU/
Primary Examiner, Art Unit 1612

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

CPC - Searched*		
Symbol	Date	Examiner
B32B 15/$, B32B 27/$	11/16/2020	HY

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
east search: inventor and assignee search and keyword search	11/16/2020 11/17/2020 11/18/2020	HY
google search	11/16/2020	HY
global dossier	11/16/2020	HY
Updated east search	05/11/2021	HY
google search	05/11/2021	HY
global dossier	05/11/2021	HY

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/HONG YU/ Primary Examiner, Art Unit 1612	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

/HONG YU/ Primary Examiner, Art Unit 1612	

Global Dossier

Office

US

Type

Application

16516792

0 2

US 16516792 4 Members in Patent Family (2 currently shown) ()

« ()

IP Office Type

All IP5 Offices

- EPO
- SIPO
- KIPO
- JPO
- USPTO

Non-IP5 Offices

()	Office	Application	Applicant	Title	App. Date	Priority #	Pub. # ()	Pub. Date
()	EP	19186607	1) Huhtamaki Flexible Packaging Germany GmbH & Co. KG,	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES AND PACKAGING FROM SUCH A FILM COMPOSITE	07/16/2019	DE 102018212303 DE 102018125195	EP 3599090 A1 ()	01/29/2020

Most Recent Documents

Date	Document Description ()	Options
07/21/2020	Letter accompanying subsequently filed items ()	•••
07/21/2020	Reply to invitation to file a copy of priority search results ()	•••
07/21/2020	Priority search results ()	•••

Office Actions

Date	Document Description ()
12/05/2019	European search opinion ()

All Documents | Classification and Citation | View All Office Actions

()	Office	Application	Applicant	Title	App. Date	Priority #	Pub. # ()	Pub. Date
()	US	16516792 View Dossier ()	1) Herb, Manuella 2) Dorn, Michael 3) Stroh, Thomas	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	07/19/2019	DE 102018212303 DE 102018125195	US 20200031107 A1 ()	01/30/2020

FEDERAL GOVERNMENT

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	58,580	(b32b15/$ and b32b27/$).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57
L2	33,136	L1 and (metal or foil or aluminium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57
L3	417	L2 and (Metallocene near10 polyethylene or PE-MC or pe-m or m-PE or mc-pe or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57
L4	129	L3 and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57
L5	129	L4 and polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57
L6	113	L5 and ((laminate or laminating or layer or coat or coating or film or package or packaging).ti. or (laminate or laminating or layer or coat or coating or film or package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57
L7	31	L6 and (acrylic or polyacrylic or poly(acrylic acid)) with (adhesive or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57
L8	31	L7 and (polyethylene or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2021/05/11 12:57

EAST Search History (Interference)

<This search history is empty>

5/11/2021 1:11:32 PM
C:\Users\hyu1\Documents\EAST\Workspaces\16516792.wsp

Web Search History

date, time	web site	search string
5/11/2021 1:12:50 PM	Google	packaging AND metallocene polyethylene AND metal foil AND adhesive

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/516,792	Filing Date 07/19/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	03/11/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LINDA HUMES/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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
P.O. Box 1450
Alexandria, VA 22313-1450

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,

RANKIN, HILL & CLARK LLP

By /Gregory S. Vickers/
Gregory S. Vickers, Reg. No. 45180

23755 Lorain Road, Suite 200
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(440) 614-0604

Electronic Patent Application Fee Transmittal

Application Number:	16516792
Filing Date:	19-Jul-2019
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Filer:	Gregory Stamm Vickers/Loni Clay
Attorney Docket Number:	TRO-45953

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	1251	1	220	220
Miscellaneous:				
			Total in USD ($)	**220**

Electronic Acknowledgement Receipt

EFS ID:	42151760
Application Number:	16516792
International Application Number:	
Confirmation Number:	2546
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Customer Number:	75626
Filer:	Gregory Stamm Vickers/Loni Clay
Filer Authorized By:	Gregory Stamm Vickers
Attorney Docket Number:	TRO-45953
Receipt Date:	11-MAR-2021
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37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		TRO45953_AmendmentB.pdf	126632 1bbbca1ad30ffe51c69452bf4d37211639e3fe64	yes	12

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	5
Applicant Arguments/Remarks Made in an Amendment	6	12

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30950 5555043b11793623b0031586d6024217abf3e3d7	no	2

Warnings:

Information:

Total Files Size (in bytes):	157582

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,792	07/19/2019	Manuella Herb	TRO-45953	2546

75626 7590 11/20/2020

RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
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EXAMINER
YU, HONG

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
11/20/2020	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 16/516,792	Applicant(s) Herb et al.	
	Examiner HONG YU	Art Unit 1612	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 07/19/2019.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 16-37 is/are pending in the application.

5a) Of the above claim(s) 35-37 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 16-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 07/19/.2019, 12/17/2019.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

DETAILED ACTION

Claims 16-37 are pending, claims 1-15 are canceled in this application. This application claims foreign priority to DE 10 2018 212 303.9, filed on 07/24/2018 in Germany and to DE 10 2018 125 195.5, filed on 10/11/2018 in Germany.

Election/Restrictions

During a telephone conversation with Gregory S. Vickers on restriction on 07/15/2020, a provisional election was made to prosecute the invention of I, claims 16-34. Affirmation of this election must be made by applicant in replying to this office action. Claim 35-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions and species.

Claims 16-34 will presently be examined to the extent they read on the elected subject matter of record.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 16-34, drawn to 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 (PE) layer encompassing metallocene polyethylene (MC-PE), and a COC layer made of cycloolefin copolymer (COC) with an exposed surface, classified in B32B 27/327.

II. Claims 35-37, drawn to a package for a planar carrier of pharmaceutical active substances encompassing two said film-composite sheets with the two film-composite sheets 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 the COC layers, classified in B32B 2439/80.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as wrapping sheet for food without two sheets sealed together and the inventions are deemed patentably distinct because there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

In the instance application, the inventions require different search queries as well are likely to raise different non-prior are issues under 35 USC 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Multiple Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claim 18 is objected in the recitation the acronym “LLDPE”. Use of the full terminology at the first occurrence would obviate this objection.

Claim 21 is objected to because of the following informalities: 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. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn et al. (US 2015/0225151 A1) in view of Torradas et al. (US 2017/0136747 A1).

Osborn et al. teach a flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches comprising

an article contact layer having at least 90 wt. % of a norbornene ethylene copolymer (COC) or derivative thereof;

a polyolefin bulk layer including PE;

a first intermediate adhesive layer;

an oxygen barrier layer including aluminum foil;

a second intermediate adhesive layer; and

an exterior protective layer comprising a polymer selected from the group consisting of paper, polyamide, polyolefin, blends or derivatives thereof and

PE including LDPE, m-LLDPE being catalyzed by hexene (C_6) or 1-octene (C_8)

exemplified a film comprising OPET (biaxially oriented polyester terephthalate) /PE/LDPE/EVA/Al Foil base layer with three-layer coextrusion of EAA, LDPE, and an 80:20 wt % blend of LDPE:mLLDPE in example 2 and EAA, LDPE, and COC in example 5 which were extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film of

OPET/PE/ LDPE/EAA/Al foil/EAA/LDPE/LDPE:mLLDPE and a total thickness of 3.04 mils (77.2 microns) in example 2 and

0.92 mil (23.37 μm) OPET (the thickness of plastic layer in the instant claims 33 and 34)/PE/0.42 mil (10.67 μm) LDPE/0.1 mil (2.54 μm) EAA/0.35 mil (8.85 μm) All

foil/0.17 mil (4.32 μm) EAA/0.65 mil (16.51 μm) LDPE/0.43 mil (10.92 μm) COC and a total thickness of 3.0 mils (76 microns) in example 5;

all layers can have the thickness of less than mils and any increment of 0.1 or 0.01 mil there between which includes 0.4 mil (10.16 μm) (the instant claims 22 and 25) and 1.5 mil (25.4 μm) (the thickness of paper layer in the instant claims 22 and 25) (entire reference, especially abstract, figure 1, paragraph 6-12, 15, 16, 20-28, 40, 41, 46, 47, 49, 50, 51, 53, 54, 57, 68, 69, 71, 72, 78, 93, 97, and 100, and claims 1-5).

Since Osborn et al. teach the adhesive, PE, and COC layers being coextruded which is the same as the method of producing the acrylic acid, PE, and COC layers (2nd paragraph on page 5), the thickness value (claims 23, 24, 26, and 27) of the adhesive, PE, and COC layers taught by Osborn et al. teach would be the same as those of the acrylic acid, PE, and COC layers of the claimed film.

Osborn et al. do not specify: i) an embodiment with the layer next to COC being m-LLDPE; and ii) the weight/unit area of paper and plastic layers (claims 33 and 34).

The 1st deficiency is cured by the teachings of both m-LLDPE and LDPE being suitable PEs and PEs being in all layers, or, alternatively, cured by Torradas et al. who teach a multilayered film, with a total thickness of < about 250 μm, for packing food, including liquid food, drug, etc., comprising

an external layer such as aluminum or PE as a good barrier to moisture permeation including MC-PE with the external layer being optionally protective coated;

one or more inner layers including barrier layers of COC;

a structure layer which can be an external layer, and/or inner layer, and barrier layer such as PE made by metallocene catalyst system for both structure and barrier functions;

one or more adhesive layers such as Elvaloy AC (the claimed ethylene acrylate copolymer in claim 21) between the outside structure layer to an inner layer with the thickness of adhesive layer being 2-10 μm (entire reference, especially abstract, paragraph 92, 93, 95, 99-101, 106, 107119, 121, 122, 126, 127, 131, 136, 137, 140, 202, 222, and 240). A structure layer which can be an external layer, and/or inner layer, and barrier layer is interpreted as a structure can be a barrier layer between external layer and inner layer.

Although none of the examples in Osborn et al. teach the layer next to COC being m-LLDPE recited in the instant claims, it would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the general teachings both m-LLDPE and LDPE being suitable PEs and PEs being in all layers and LDPE layer next to COC layer to replace the LDPE next to COC in example 5 with m-LLDPE. The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients (PEs) from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

Alternatively, It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Osborn et al. and Torradas et al. to specify the PE (LDPE) layer next to the innermost COC layer in the film taught by Osborn et al. is MC-PE. PE made by metallocene catalyst system as a structure layer for both structure and barrier functions was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying it flows from its having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

The 2nd deficiency is cured by the rational that it is routine optimization to determine the optimum weight/unit area for each layer.

Osborn et al. do not specifically teach weight unit of the paper layer and plastic layer (external layers) claimed by applicant. While the layer thicknesses of the paper layer and plastic layer are within those of the claimed film, the PET plastic and the paper are known packaging layer materials for achieve the same protective effect and would be reasonable to assume that they are the similar materials with the similar density and thus would result in the similar weight/unit area.

Or alternatively, weight/unit area of the paper layer and plastic layer in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize or, alternatively obvious to try to reach another workable product or process. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal weight/unit area in order to best achieve the desired results of protective effect.

Claims 16, 17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1) in view of Osborn et al. (US 2015/0225151 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify an embodiment with PE being MC-PE.

This deficiency is cured by the rational that it would have obvious to have selected various combinations of various disclosed ingredients (MC-PE) from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Although Torradas et al. do not specify the PE layer next to COC being MC-PE recited in the instant claims, it would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the general teachings of MC-PE being one of the PEs and having PE in the structure layer which is between the external layer and the inner layer, i.e., 100% MC-PE. The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients (PEs) from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Claims 18-20 and 22-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Torradas et al. (US 2017/0136747 A1), as applied to claims 16, 17, and 21, in view of Osborn et al. (US 2015/0225151 A1).

The teachings of Torradas et al. are discussed above and applied in the same manner.

Torradas et al. do not specify: i) MC-PE being MC-LLDPE catalyzed by hexene (C_6) or 1-octene (C_8) (claims 18-20); ii) the thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers (claims 22-27); and iii) the limitations of the further layers outside the metal layer (protective layers) in claims 28-34.

These deficiency is cured by Osborn et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Torradas et al. and Osborn et al. to specify MC-PE in the film taught by Torradas et al. being MC-LLDPE catalyzed by hexene (C_6) or 1-octene (C_8) and the claimed thicknesses and the film taught by Torradas et al. having the claimed thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery patches with MC-PE being MC-LLDPE catalyzed by hexene (C_6) or 1-octene (C_8) (claims 18-20); the claimed thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers of the instant claims 22-27; and the claimed limitations of the protective layer in

the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Claims 16-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toft et al. (US 2005/0181154 A1) in view of Osborn et al. (US 2015/0225151 A1) and Torradas et al. (US 2017/0136747 A1).

Toft et al. teach a packing laminate for food as illustrated in figure 1 below comprising, from exterior to food contacting interior,

item 12 being a heat sealable such as PE,

item 11 being a core of paperboard with item 14 being an intermediate layer of thermoplastic of about 23-27 g/m^2 LDPE (the claimed further layers made of plastic and/or paper in claims 28-30) bonding item 11 to

item 13 which is an aluminum foil,

item 15-1 being an adhesive layer of EAA (the instant claim 21),

item 15-2 being a barrier layer of a blend of COC and m-LLDPE, and

item 15-3 being a PE-MC layer a blend of 60-70% by weight of m-LLDPE (the instant claim 18) prepared by copolymerization of C_{4-8} α-olefins including 1-hexene (C_6) or 1-octene (C_8) (the instant claims 19 and 20) and 30-40% by weight of LDPE (the

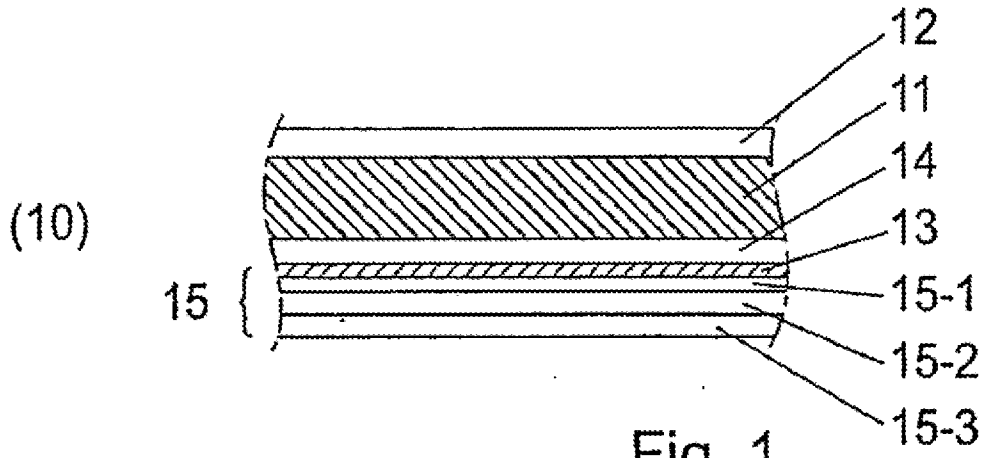


Fig. 1

instant claim 17)

(entire reference, espcially abstract, figure 1, paragraph 46-53, 55, 56, 60, 79-81, and 83, and claims 1-3, 6, 7, and 9).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **[for manufacturing a package for planar carriers of pharmaceutical active substances]**; however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Furthermore, according to Torradas et al. a multilayered film can be used for both packing food, including liquid food, and drug.

Toft et al. do not teach: i) the innermost layer 15-2 and 15-3 being the opposite order; ii) the thicknesses and thickness values of Al external layer, COC inner layer, PE-

MC structure layer, and the adhesive layers (claims 22-27); and iii) the limitations of the further layers outside the metal layer (protective layers) in claims 31-34.

The 1st deficiency is cured by Osborn et al. whose teachings are discussed above and applied in the same manner and Torradas et al. whose teachings are discussed above and applied in the same manner.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al., Osborn et al., and Torradas et al. to exchange the COC layer and MC-PE layer in the film taught by Toft et al. with the innermost layer being COC and MC-PE being the layer before it. OCO as the innermost layer and PE next to it according to Osborn et al. and MC-PE being one of the PE before the innermost layer according to Torradas et al. was well known to a person of ordinary skill in the art at the time of the invention. The motivation for exchanging the COC layer and MC-PE layer in the film taught by Toft et al. flows from its having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

The 2nd deficiency is cured by Osborn et al. whose teachings are discussed above.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Toft et al. and Osborn et al. to specify the claimed thicknesses and the film taught by Toft et al. having the claimed thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers and the claimed limitations of the protective layer in claims 28-34. A flexible, multilayer packaging film suitable for packaging transdermal drug delivery

patches with the claimed thicknesses and thickness values of Al external layer, COC inner layer, PE-MC structure layer, and the adhesive layers of the instant claims 22-27 and the claimed limitations of the protective layer in the instant claims 28-34 was well known to a person of ordinary skill in the art at the time of the invention. The motivation for specifying them flows from their having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on 9 am - 5:30 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, Applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HONG YU/
Primary Examiner, Art Unit 1612

Notice of References Cited	Application/Control No. 16/516,792	Applicant(s)/Patent Under Reexamination Herb et al.	
	Examiner HONG YU	Art Unit 1612	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20050181154-A1	08-2005	Toft, Nils	C08L23/08	428/34.2
*	B	US-20170136747-A1	05-2017	TORRADAS; JOSE MARIA	B32B27/08	1/1
	C					
	D					
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	I					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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	S					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,792	Herb et al.
	Examiner	Art Unit
	HONG YU	1612

CPC - Searched*		
Symbol	Date	Examiner
B32B 15/$, B32B 27/$	11/16/2020	HY

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
east search: inventor and assignee search and keyword search	11/16/2020 11/17/2020 11/18/2020	HY
google search	11/16/2020	HY
global dossier	11/16/2020	HY

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/HONG YU/ Primary Examiner, Art Unit 1612	

Receipt date: 07/19/2019

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2019-07-19
First Named Inventor	Manuella Herb
Art Unit	
Examiner Name	
Attorney Docket Number	TRO-45953

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20070160789	A1	2007-07-12	MERICAL et al.	
	2	20150225151	A1	2015-08-13	OSBORN et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2017114922	WO	A1	2017-07-06	DANAPAK FLEXIBLES A/S		

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Receipt date: 07/19/2019

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2019-07-19
	First Named Inventor	Manuella Herb
	Art Unit	
	Examiner Name	
	Attorney Docket Number	TRO-45953

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	German Search Report for corresponding DE 10 2018 125 195.5 mailed 2019-02-25, 10 pgs.	

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EXAMINER SIGNATURE

Examiner Signature	/HONG YU/	Date Considered	11/17/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Y/

Receipt date: 07/19/2019

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Application Number	
Filing Date	2019-07-19
First Named Inventor	Manuella Herb
Art Unit	
Examiner Name	
Attorney Docket Number	TRO-45953

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gregory S. Vickers/	Date (YYYY-MM-DD)	2019-07-19
Name/Print	Gregory S. Vickers	Registration Number	45180

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Receipt date: 07/19/2019

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Y/

Receipt date: 12/17/2019

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16516792
Filing Date	2019-07-19
First Named Inventor	Manuella Herb
Art Unit	1783
Examiner Name	
Attorney Docket Number	TRO-45953

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20180354702	A1	2018-12-13	LIU et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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Receipt date: 12/17/2019

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	Art Unit	1783
	Examiner Name	
	Attorney Docket Number	TRO-45953

	1	European Search Report for corresponding EP 19 18 6607 mailed 2019-12-05, 6 pgs.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/HONG YU/	Date Considered	11/17/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Signature	/Gregory S. Vickers/	Date (YYYY-MM-DD)	2019-12-15
Name/Print	Gregory S. Vickers	Registration Number	45180

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Web Search History

date, time	web site	search string
11/16/2020 12:01:07 PM	Google	metallocene polyethalene
11/16/2020 12:22:44 PM	Google	Cyclic olefin

(http://www.uspto.gov)

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Global Dossier

Office

US

Type

Application

16516792

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US 16516792 4 Members in Patent Family (2 currently shown) ()

« ()

IP Office Type

- [x] All IP5 Offices
  - [x] EPO
  - [x] SIPO
  - [x] KIPO
  - [x] JPO
  - [x] USPTO
- [ ] Non-IP5 Offices

()	Office ()	Application ()	Applicant	Title ()	App. Date ()	Priority #
()	EP	19186607 View Dossier ()	1) Huhtamaki Flexible Packaging Germany GmbH & Co. KG,	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES AND PACKAGING FROM SUCH A FILM COMPOSITE	07/16/2019	DE 1020182123 DE 1020181251
()	US	16516792 View Dossier ()	1) Herb, Manuella 2) Dorn, Michael 3) Stroh, Thomas	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	07/19/2019	DE 1020182123 DE 1020181251

(http://www.uspto.gov/)

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FEDERAL GOVERNMENT

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1517	1	"16516792" and metal	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 11:37
S1518	135,177	(b32b15/$).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 11:42
S1519	940	(b32b15/$ and b32b27/327).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 11:56
S1520	5	(b32b15/16 and b32b27/327).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 11:56
S1521	380	S1519 and polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 11:59
S1522	222	S1521 and (acrylic or polyacrylic or adhesive or poly(acrylic acid))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 11:59
S1523	103	S1522 and (Metallocene near5 polyethylene or PE-MC)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:08

S1524	103	S1523 and (layer or coat or coating or metal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:09
S1525	103	S1522 and (Metallocene near5 polyethylene or PE-MC or pe-m)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:19
S1526	103	S1525 and (layer or coat or coating or metal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:20
S1527	29	S1526 and (cycloolefin or Cyclic near5 olefin or coc)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:22
S1528	29	S1526 and (cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:24
S1529	4	"20070160789"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:48
S1530	2	"20070160789".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:48
S1532	103	S1525 and (layer or coat or coating or metal or foil)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:49

S1533	29	S1532 and (cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:49
S1534	4	S1529 and (layer or coat or coating or metal or foil)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:53
S1535	3	S1534 and (acrylic or polyacrylic or adhesive or poly(acrylic acid))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:53
S1536	3	S1535 and (cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene or polyethylene or copolymer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 12:59
S1537	3	S1535 and (cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene or polyethylene or copolymer or polyolefin or polyolefinic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:00
S1538	54,750	(b32b15/$ and b32b27/$).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:29
S1539	29,065	S1538 and (metal or foil)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:30
S1540	871	S1539 and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:31

S1541	746	S1540 and (acrylic or polyacrylic or adhesive or poly(acrylic acid) or adhere or adhered)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:31
S1542	711	S1541 and (polyethylene or polyolefin or polyolefinic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:32
S1543	710	S1542 and (layer or coat or coating or film)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:33
S1544	683	S1541 and polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:34
S1545	683	S1544 and (polyethylene or polyolefin or polyolefinic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:34
S1546	683	S1545 and (layer or coat or coating or film)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:34
S1547	3	"20070160789" and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 13:56
S1548	10	wo "2015123211"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 14:40

S1549	590	S1546 and ((layer or coat or coating or film or package or packaging).ti. or (layer or coat or coating or film or package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 14:45
S1550	224	S1546 and ((package or packaging).ti. or (package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 14:45
S1551	87	S1546 and (Metallocene near5 polyethylene or PE-MC or pe-m)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 14:59
S1552	42	S1551 and ((package or packaging).ti. or (package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 14:59
S1553	77	S1551 and ((layer or coat or coating or film or package or packaging).ti. or (layer or coat or coating or film or package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 15:06
S1554	88	S1546 and (Metallocene near5 polyethylene or PE-MC or pe-m or m-PE or mc-pe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 15:31
S1555	43	S1554 and ((package or packaging).ti. or (package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 15:31
S1556	54,750	(b32b15/$ and b32b27/$).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:25

S1557	31,378	S1556 and (metal or foil or aluminium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:25
S1558	387	S1557 and (Metallocene near10 polyethylene or PE-MC or pe-m or m-PE or mc-pe or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:26
S1559	112	S1558 and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:26
S1560	112	S1559 and polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:27
S1561	100	S1560 and ((laminate or laminating or layer or coat or coating or film or package or packaging).ti. or (laminate or laminating or layer or coat or coating or film or package or packaging).ab.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:27
S1562	99	S1561 and (acrylic or polyacrylic or adhesive or poly(acrylic acid) or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:28
S1563	27	S1561 and (acrylic or polyacrylic or poly(acrylic acid)) with (adhesive or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:29
S1564	387	S1557 and (Metallocene near10 polyethylene or metallocene polyethylene or PE-MC or pe-m or m-PE or mc-pe or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:33

S1565	6	S1563 and metallocene polyethylene	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 19:34
S1566	27	S1563 and (polyethylene or mLLDPE)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 20:21
S1567	27	S1563 and (polyethylene or mLLDPE or metallocene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 20:33
S1568	27	S1563 and (polyethylene or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 21:17
S1569	10	wo "2015123211"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 21:31
S1570	4	S1569 and (metallocene polyethylene or PE-MC or pe-m or m-PE or mc-pe or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 21:31
S1571	4	S1570 and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 21:32
S1572	4	S1571 and (acrylic or polyacrylic or adhesive or poly(acrylic acid) or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 21:32

S1573	4	S1572 and (metal or foil or aluminium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/16 21:32
S1574	3	("20180354702" | "20070160789" | "20150225151").PN.	US-PGPUB; USPAT	ADJ	ON	2020/11/17 08:32
S1575	7	wo "2017114922"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:34
S1576	0	"20200223185" and (metallocene polyethylene or PE-MC or pe-m or m-PE or mc-pe or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:36
S1577	2	"20200223185" and (cyclo-olefin or cycloolefin or Cyclic near5 olefin or coc or Ethylene-norbornene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:36
S1578	2	S1577 and (acrylic or polyacrylic or adhesive or poly(acrylic acid) or adhere or adhered or adhesion)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:36
S1579	2	S1578 and (metal or foil or aluminium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:36
S1580	2	"20200223185" and (polyethylene or metallocene polyethylene or PE-MC or pe-m or m-PE or mc-pe or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:38
S1581	2	S1580 and S1579	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	ADJ	ON	2020/11/17 08:39

			DERWENT; IBM_TDB			
S1582	2	"20200223185" and (pe or polyethylene or metallocene polyethylene or PE-MC or pe-m or m-PE or mc-pe or mLLDPE or metallocene or mpe)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:45
S1583	2	S1582 and S1579	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/17 08:46
S1584	2	"20050181154" and thickness	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/18 09:12
S1585	1	"16516792" and thickness value	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2020/11/18 14:38

EAST Search History (Interference)

<This search history is empty>

11/19/2020 10:11:28 AM
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/516,792	07/19/2019	Manuella Herb	TRO-45953

CONFIRMATION NO. 2546

75626
RANKIN, HILL & CLARK LLP
23755 LORAIN ROAD, SUITE 200
NORTH OLMSTED, OH 44070

PUBLICATION NOTICE



Title:FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

Publication No.US-2020-0031107-A1
Publication Date:01/30/2020

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Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16516792
Filing Date	2019-07-19
First Named Inventor	Manuella Herb
Art Unit	1783
Examiner Name	
Attorney Docket Number	TRO-45953

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1	20180354702	A1	2018-12-13	LIU et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16516792
	Filing Date	2019-07-19
	First Named Inventor	Manuella Herb
	Art Unit	1783
	Examiner Name	
	Attorney Docket Number	TRO-45953

	1	European Search Report for corresponding EP 19 18 6607 mailed 2019-12-05, 6 pgs.

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16516792
	Filing Date	2019-07-19
	First Named Inventor	Manuella Herb
	Art Unit	1783
	Examiner Name	
	Attorney Docket Number	TRO-45953

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gregory S. Vickers/	Date (YYYY-MM-DD)	2019-12-15
Name/Print	Gregory S. Vickers	Registration Number	45180

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Acknowledgement Receipt

EFS ID:	38033039
Application Number:	16516792
International Application Number:	
Confirmation Number:	2546
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Customer Number:	75626
Filer:	Gregory Stamm Vickers/Loni Clay
Filer Authorized By:	Gregory Stamm Vickers
Attorney Docket Number:	TRO-45953
Receipt Date:	17-DEC-2019
Filing Date:	19-JUL-2019
Time Stamp:	12:04:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Other Reference-Patent/App/Search documents	TRO45953_ExtendedSearchReport.pdf	197418 6b482ea7a8f5a2bcddfedad3bcf6f582e0630299	no	6

Warnings:

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2	Information Disclosure Statement (IDS) Form (SB08)	TRO45953_SupplDS.pdf	1034322 7c8b819fb4bc35878160 9f6087ea82bca3b8bda9	no	4
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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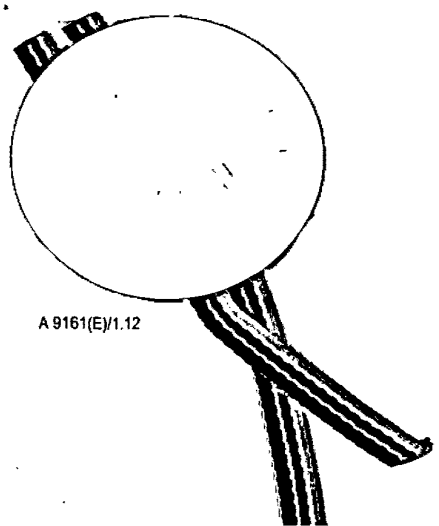
Prioritätsbescheinigung
DE 10 2018 125 195.5
über die Einreichung einer Patentanmeldung

Aktenzeichen:	10 2018 125 195.5
Anmeldetag:	11. Oktober 2018
Anmelder/Inhaber:	Huhtamaki Flexible Packaging Germany GmbH & Co. KG, 87671 Ronsberg, DE
Bezeichnung:	Folienverbund zur Verpackung transdermaler Pflaster und Verpackung aus einem solchen Folienverbund
Priorität:	24. Juli 2018; DE; 10 2018 212 303.9
IPC:	B32B 27/08; A61J 1/00; A61F 13/02; B32B 27/32; B65D 65/40

Die angehefteten Stücke sind eine richtige und genaue Wiedergabe der Teile der am 11. Oktober 2018 eingereichten elektronischen Dokumente dieser Patentanmeldung unabhängig von gegebenenfalls durch das Druckverfahren bedingten Farbabweichungen.

München, den 28. Juni 2019
Deutsches Patent- und Markenamt
Die Präsidentin
Im Auftrag

Kahle



A 9161(E)/1.12

Folienverbund zur Verpackung transdermaler Pflaster und Verpackung aus einem solchen Folienverbund

Beschreibung

Die vorliegende Erfindung betrifft einen Folienverbund zur Herstellung einer Verpackung für flächige Träger von pharmazeutischen Wirkstoffen, wie beispielsweise transdermale Pflaster, umfassend in Richtung von der designierten Außenseite des Folienverbunds zu seiner designierten Innenseite eine Metalllage, eine Acrylsäurehaltige Verbindungslage, eine Polyethylenlage und eine COC-Lage aus Cycloolefin-Copolymer, wobei eine von der Metalllage abgewandte Seite der COC-Lage eine freiliegende Fläche des Folienverbunds ist.

Ein solcher Folienverbund zu dem genannten Zweck einer Herstellung einer Verpackung von pharmazeutischen Wirkstoffträgern ist aus der WO 2015/123211 A1 bekannt. Der gattungsgemäße Folienverbund kommt dabei in unmittelbaren Kontakt mit dem flächigen Träger eines pharmazeutischen Wirkstoffs und damit mit dem pharmazeutischen Wirkstoff selbst. Es handelt sich bei den infrage kommenden pharmazeutischen Wirkstoffen um Wirkstoffe, wie etwa Nikotin, Fentanyl oder Lidocain. Die von diesen pharmazeutischen Wirkstoffen ausgehende Belastung des Folienverbundes ist erheblich. Es ist dabei sicherzustellen, dass zum einen der Folienverbund als solcher über längere Zeit erhalten bleibt, um eine unerwünschte Freisetzung des pharmazeutischen Wirkstoffs des Wirkstoffträgers zu verhindern. Selbst wenn der Folienverbund erhalten bleibt, also beispielsweise nicht unter dem Einfluss des in Verbundlagen diffundierenden pharmazeutischen Wirkstoffs wenigstens abschnittsweise delaminiert, muss zum anderen sichergestellt werden, dass der pharmazeutische Wirkstoff nicht durch den Folienverbund hindurch diffundieren bzw. migrieren kann.

Zur Erhöhung der Diffusions-Barrierewirkung des Folienverbunds gegenüber den durch sie verpackten pharmazeutischen Wirkstoffen ist es bekannt, den Anteil an Cycloolefin-Copolymer (COC) in der in der späteren Verpackung ganz innen liegenden COC-Lage möglichst hoch zu wählen. Mit der Erhöhung des COC-Gehalts in der

COC-Lage wird es jedoch zunehmend schwieriger, die Stabilität des Folienverbunds aufrecht zu erhalten, etwa eine Delamination oder ähnliche Zerfallserscheinungen zu verhindern.

Auch die WO 2017/114922 A1 offenbart Folienverbünde zur Bildung von Verpackungen für flächige pharmazeutische Wirkstoffträger.

Es ist daher Aufgabe der vorliegenden Erfindung, den eingangs genannten Folienverbund mit größtmöglicher chemischer und mechanischer Stabilität gegenüber den zu verpackenden pharmazeutischen Wirkstoffen im Hinblick auf seine Aufgabe einer Bildung einer sicheren, auch kindersicheren Verpackung von flächigen pharmazeutischen Wirkstoffträgern auszubilden.

Diese Aufgabe wird erfindungsgemäß gelöst durch einen Folienverbund der eingangs genannten Art, bei welchem die Polyethylenlage Metallocen-Polyethylen umfasst. Versuche haben nämlich gezeigt, dass bei ansonsten identischen Dimensionen des Folienverbunds die Haftung der COC-Lage an der Polyethylenlage dann erheblich besser ist, wenn die Polyethylenlage Metallocen-Polyethylen aufweist. "Metallocen-Polyethylen" ist dabei Polyethylen, welches unter Verwendung von Metallocen-Katalysatoren in an sich bekannter Weise hergestellt wurde.

Dabei ist der durch die Verwendung von Metallocen-Polyethylen gegenüber herkömmlichem Polyethylen erzielbare Haftungsgewinn in der Haftungswirkung zwischen der COC-Lage und der Polyethylenlage umso größer, je höher der COC-Gehalt in der COC-Lage ist. Da die COC-Lage zur Erzielung einer möglichst hohen Barrierewirkung gegenüber pharmazeutischen Wirkstoffen, die im flächigen Wirkstoffträger gespeichert sind, einen möglichst großen COC-Anteil von wenigstens 95 Gew-%, bevorzugt von wenigstens 99,8 Gew.-% an der Masse der gesamten COC-Lage aufweist, kann mit der vorliegend vorgestellten Verwendung von Metallocen-Polyethylen in der zwischen der Acrylsäule-haltigen Verbindungslage und der COC-Lage angeordneten Polyethylenlage ein besonders großer Haftungsvorteil erzielt werden.

Im Zweifel, etwa wenn mehr als eine Polymerlage des Folienverbunds COC enthält, soll eine COC-Lage nur dann als COC-Lage im Sinne der vorliegenden Anmeldung gelten, wenn sie bezogen auf ihre Lagenmasse mindestens 50 Gew.-% COC enthält. Die genannte Polyethylenlage, die Metallocen-Polyethylen enthält, ist vorzugsweise frei von COC.

Grundsätzlich kann bereits mit vergleichsweise geringen Mengen an Metallocen-Polyethylen eine Verbesserung der Haftung der COC-Lage an der Polyethylenlage erreicht werden. Besonders stark ist die Verbesserung der Haftungswirkung bei ansonsten abmessungsgleichen Vergleichsproben unterschiedlicher Folienverbundflecke dann, wenn der Anteil an Metallocen-Polyethylen am gesamten Polyethylen der Polyethylenlage wenigstens 50 Gew.-% umfasst. Grundsätzlich können also auch sogenannte Polyethylen-Blends zur Bildung der Polyethylenlage verwendet werden, in welchen Metallocen-Polyethylen mit Nicht-Metallocen-Polyethylen vermischt ist.

Wegen der vorteilhaften Haftung erhöhenden Wirkung von Metallocen-Polyethylen ist vorzugsweise dessen Anteil (stets in Gewichtsprozent) am gesamten in der Polyethylenlage enthaltenen Polyethylen möglichst groß, vorzugsweise größer als 90 Gew.-%, besonders bevorzugt größer als 96 Gew.-%.

Dabei hat es sich zur Erhöhung der Haftungswirkung und ebenso der Verarbeitbarkeit des Folienverbunds auf entsprechenden Verarbeitungsmaschinen zu daraus gebildeten Verpackungen als vorteilhaft erwiesen, wenn die Polyethylenlage ein Metallocen-LLDPE umfasst. Vorzugsweise umfasst die Polyethylenlage nur Metallocen-LLDPE als das Metallocen-Polyethylen.

Die Dichte des Metallocen-Polyethylens liegt zur Erzielung guter Laufeigenschaften einer Folienverbundbahn in den oben genannten Verarbeitungsmaschinen vorteilhafterweise in einem Bereich zwischen 0,917 und 0,921 g/m². Zusätzlich oder alternativ weist das Metallocen-Polyethylen zur Erzielung hochfester und hochdichter dauerhafter Siegelnähte einen Schmelzflussindex (MFR) von zwischen 6 und 10 g/10 min. auf, gemessen nach ISO 1133 bei einer Prüftemperatur von 190 °C und bei Ver-

wendung eines Prüfkörpers mit einem Gewicht von 2,16 kg. Denn die Polyethylenlage kann zusätzlich zur COC-Lage als der außen liegenden Barriere- und Siegellage zu einer Siegelverbindung des Folienverbunds beitragen.

Jede Art von Metallocen-Polyethylen in der Polyethylenlage sorgt für eine gewünschte Erhöhung der Haftungswirkung der COC-Lage an der Polyethylenlage, verglichen mit einer Polyethylenlage gleicher Abmessung oder/und gleichen Flächengewichts in dem Folienverbund. Darüber hinaus kann jedoch durch Verwendung unterschiedlicher Typen von Metallocen-Polyethylen die Steifigkeit der Polyethylenlage und damit des Folienverbunds insgesamt beeinflusst werden. Eine vorteilhafte Steifigkeit der Polyethylenlage, bei vorgegebenen Abmessungen derselben, kann dadurch erhalten werden, dass die Polyethylenlage ein Metallocen-Polyethylen C6 oder/und ein Metallocen-Polyethylen C8 umfasst oder aus den genannten Metallocen-Polyethylen-Typen besteht. Dabei liefert Metallocen-Polyethylen C8 nach bisherigen Versuchen bei vorgegebenem Folienverbund und insbesondere bei vorgegebener Abmessung oder/und Flächengewicht der Polyethylenlage das beste Ergebnis hinsichtlich der erzielten Lagensteifigkeit der Polyethylenlage einerseits und der erzielten Verbundsteifigkeit des Folienverbunds insgesamt andererseits.

Aus diesem Grunde ist es nachvollziehbarerweise vorteilhaft, wenn die Polyethylenlage als Metallocen-Polyethylen nur ein Metallocen-Polyethylen C8 umfasst. Gemäß den obigen Darlegungen ist dies besonders bevorzugt ein Metallocen-LLDPE C8.

Die Polyethylenlage ist bevorzugt im Extrusionsverfahren aufgetragen, besonders bevorzugt coextrudiert mit der COC-Lage.

Ein kommerziell verfügbares Metallocen-Polyethylen, welches hervorragend als Polyethylenlage in dem genannten Folienverbund einsetzbar ist, ist das von Dow Chemical Company unter dem Handelsnamen "Elite™ 5811" erhältliche Polyethylen.

Zur Erzielung einer möglichst großen Haftungswirkung des Teilverbunds aus Polyethylenlage und COC-Lage an der Metalllage umfasst die Acrylsäure-haltige Verbin-

dungslage bevorzugt ein Ethylen-Acrylsäure-Copolymer (EAA-Copolymer) oder besteht aus diesem.

Bevorzugt wird auch die Acrylsäure-haltige Verbindungslage durch Extrusion auf die Metalllage aufgetragen. Besonders bevorzugt wird ein Teilverbund aus Acrylsäure-haltiger Verbindungslage, insbesondere EAA-Lage, Polyethylenlage und COC-Lage durch Coextrusion in einem gemeinsamen Extrusionsschritt auf die Metalllage aufgetragen.

Die Metalllage dient als Sauerstoff- und Gasbarriere zum Schutz eines Verpackungsinhalts vor äußeren Einflüssen und überdies als Barriere für pharmazeutische Wirkstoffe und deren Bestandteile, welche durch die COC-Lage, die Polyethylenlage und die Acrylsäure-haltige Verbindungslage hindurch aufgrund von Diffusion die Metalllage erreichen. Bevorzugt ist die Metalllage eine Aluminiumlage.

Bevorzugt weist jede der Lagen aus Acrylsäure-haltiger Verbindungslage, Polyethylenlage und COC-Lage eine Lagendicke im Bereich von etwa 7 µm bis 15µm auf. Dies sorgt zum einen für eine hervorragende Anbindung an die Metalllage. Zum anderen kann in diesem Dickenbereich nicht nur die COC-Lage, sondern auch die Polyethylenlage zur Herstellung einer Siegelverbindung mit der COC-Lage eines gleichartig aufgebauten Folienverbunds dienen. Da in dem genannten Fall auch die unter der COC-Lage gelegenen Polyethylenlage besonders gut und sicher zur Herstellung einer Siegelverbindung beitragen kann, sind die oben angegebenen Werte des Schmelzflussindex (MFR) zur Erzielung hervorragender Siegeleigenschaften des Folienverbunds mit der freiliegenden COC-Lage von großem Vorteil. Vorzugsweise liegen die Dickenwerte der drei, vorzugsweise coextrudierten, Lagen: Acrylsäure-haltige Verbindungslage, Polyethylenlage und COC-Lage, jeweils im Bereich von 9 µm bis 12 µm. Zur Erzielung hervorragender Siegeleigenschaften unter Beteiligung nicht nur der COC-Lage als außenliegende Siegellage, sondern auch der darunterliegenden Polyethylenlage unterscheiden sich vorzugsweise die Lagendicken der Polyethylenlage und der COC-Lage kaum. Auch die Dicke der Acrylsäure-haltigen Verbindungslage unterscheidet sich vorzugsweise kaum von der Dicke der beiden erstgenannten Lagen: Polyethylenlage und COC-Lage, um eine möglichst gute An-

bindung der COC-Lage und der Polyethylenlage an die Metalllage zu erzielen, ohne dabei den Folienverbund unerwünscht dick zu gestalten. Bevorzugt unterscheiden sich die Dickenwerte der genannten Lagen – bezogen auf die dünnste der genannten Lagen – um nicht mehr als 15 %, vorzugsweise um nicht mehr als 11 %. Dann lässt sich ein Dreierverbund aus Acrylsäure-haltiger Verbindungslage, Polyethylenlage und COC-Lage gut coextrudieren, wobei der so entstehende Folienverbund sehr gute Laufeigenschaften auf Verarbeitungsmaschinen zur Verarbeitung des Folienverbunds zu einer Verpackung aufweist und überdies sehr gute Siegeleigenschaften aufweist.

Grundsätzlich kann der Folienverbund so verwendet werden, wie er oben beschrieben ist. Zum weiteren Schutz des Folienverbunds kann dieser auf der von der COC-Lage abgewandten Seite der Metalllage wenigstens eine weitere Lage aus Papier oder/und Kunststoff aufweisen. Dadurch ist die Metalllage eine vollständig innenliegende Lage des Folienverbunds und als solche besser vor äußeren Einflüssen geschützt. Da in der Regel die COC-Lage eine ganz innen liegende Lage einer aus dem Folienverbund gebildeten Verpackung ist, wird durch das Vorsehen der wenigstens einen weiteren Lage die Aufbringung von Produktinformationen auf der zum Verbraucher weisenden Außenseite des Folienverbunds erleichtert, die ansonsten mit erhöhtem Aufwand auf der Metalllage aufgebracht werden müssten.

Die wenigstens eine weitere Lage ist vorzugsweise auf die Metalllage oder auf eine auf dieser bereits vorhandene weitere Lage aufkaschiert. Hierzu wird bevorzugt ein lösungsmittelhaltiger Kaschierkleber mit einem Flächenauftragsgewicht von 2 bis 4 g/m², vorzugsweise mit einem Flächenauftragsgewicht von 3 g/m² verwendet.

Zur leichten Bedruckung und zur Kindersicherung einer aus dem Folienverbund gebildeten Verpackung vor unerwünschtem Öffnen und Freilegen der darin verpackten pharmazeutischen Wirkstoffe weist der Folienverbund bevorzugt auf der von der COC-Lage abgewandten Seite der Metalllage sowohl eine weitere Lage aus Papier als auch eine weitere Lage aus Kunststoff auf. Wegen der besonders einfachen Bedruckbarkeit der Papierlage und damit einer besonders einfachen und kostengünstigen Möglichkeit, den Folienverbund oder/und eine damit gebildete Verpackung

mit Verbraucherinformationen zu versehen, ist bevorzugt die Kunststofflage näher bei der Metalllage gelegen ist als die Papierlage. Bevorzugt ist die Papierlage eine außen liegende Lage des Folienverbunds. Ein auf die Papierlage aufgedruckter Druckauftrag kann durch eine Schutzschicht, wie etwa einen Klarlack, wenigstens teilweise oder bevorzugt vollständig abgedeckt sein.

Zur Sicherung gegen unerwünschtes Aufreißen durch Kinder ist die weitere Lage aus Kunststoff bevorzugt ein biaxial orientierter Kunststoff.

Als Kunststoff für die wenigstens eine weitere Kunststofflage haben sich Polyethylenterephthalat oder/und Polyamid in Versuchen bewährt. Kunststofflagen aus den genannten Kunststoffen sind mechanisch und thermisch ausreichend stabil und stellen besonders in orientierter Form eine weitere Barrierewirkung gegen Diffusion von Gasen und Dämpfen bereit. Die weitere Kunststofflage kann somit in einer Richtung die Metalllage vor chemischen Angriffen von außen schützen und kann in der entgegengesetzten Richtung zusätzlich den pharmazeutischen Wirkstoff oder Bestandteile davon zurückhalten, falls diese die Metalllage überwinden sollten.

Dann, wenn der Folienverbund auf der von der COC-Lage wegweisenden Seite der Metalllage eine weitere Lage aus Papier aufweist, hat diese vorzugsweise eine Dicke von 35 bis 45 µm, besonders bevorzugt von 39 bis 41 µm. Zusätzlich oder alternativ kann die weitere Lage aus Papier ein Flächengewicht von 35 bis 45 g/m², insbesondere von 39 bis 41 g/m² aufweisen.

Dann, wenn der Folienverbund auf der von der COC-Lage wegweisenden Seite der Metalllage eine weitere Lage aus Kunststoff aufweist, hat diese vorzugsweise eine Dicke von 19 bis 27 µm, insbesondere von 22 bis 24 µm. Zusätzlich oder alternativ weist die zusätzliche Lage aus Kunststoff ein Flächengewicht von 28 bis 36 g/m², insbesondere von 31 bis 33 g/m² auf. Diese Werte von Dicken und Flächengewicht bieten einen sehr guten Kompromiss zwischen ausreichender mechanischer Festigkeit, thermischer Stabilität und geringer Gesamtdicke des Folienverbunds.

Da der oben beschriebene Folienverbund besonders geeignet ist zur Herstellung einer Verpackung für einen flächigen Träger von pharmazeutischen Wirkstoffen, wie beispielsweise ein transdermales Pflaster, betrifft die vorliegende Erfindung auch eine solche Verpackung, umfassend zwei Folienverbundflecke aus je einem Folienverbund, wie er oben beschrieben und weitergebildet ist. Die Folienverbundflecke sind unter Bildung eines Träger-Aufnahmeraums mit aufeinander zuweisenden COC-Lagen angeordnet und durch abschnittsweises Siegeln von COC-Lagenbereichen miteinander verbunden. Abschnitte der aufeinander zuweisenden COC-Lagenbereiche sind dabei miteinander gesiegelt, bevorzugt unter Beteiligung der unter den COC-Lagen gelegenen jeweiligen Polyethylenlage mit Metallocen-Polyethylen. Die Siegelnaht umfasst dann bevorzugt eine Mischung aus COC und aus Metallocen-Polyethylen. Die Siegelnaht erstreckt sich dann in Dickenrichtung bis in die Polyethylenlage hinein. Andere Abschnitte der aufeinander zuweisenden COC-Lagenbereiche der beiden Folienverbundflecke liegen einander unverbunden gegenüber. Dann, wenn in der Verpackung ein flächiger Träger von pharmazeutischen Wirkstoffen aufgenommen ist, befindet sich dieser zwischen einander unverbunden gegenüberliegenden Abschnitten je einer COC-Lage eines an der Bildung der Verpackung beteiligten Folienverbundflecks.

Als flächiger Träger von pharmazeutischen Wirkstoffen gilt ein Substrat, welches in seinen beiden zueinander und zur Substrat-Dickenrichtung orthogonalen Hauptersteckungsrichtungen jeweils Abmessungen aufweist, die um wenigstens das 10-Fache, vorzugsweise um wenigstens das 30-Fache, größer sind als die Abmessung des Substrats in Dickenrichtung und welches zur Abgabe eines im Substrat gespeicherten pharmazeutischen Wirkstoffs ausgebildet ist.

Die Verpackung kann raumsparend bei gleichzeitig dauerhaft hoher Abschirmung des darin verpackten pharmazeutischen Wirkstoffs ein Vier-Rand-Siegelbeutel mit um den Träger-Aufnahmeraum umlaufender Siegelnaht sein.

Ein wie oben beschrieben im Träger-Aufnahmeraum der Verpackung aufgenommenen flächiger Wirkstoffträger ist bevorzugt ein transdermales Pflaster. Der pharmazeutische Wirkstoff im Wirkstoffträger umfasst bevorzugt Nikotin oder/und Fentanyl

oder/und Lidocain oder/und einen anderen zur Verabreichung mittels transdermalem Pflaster bekannten Wirkstoff.

Als "designierte" Innen- bzw. Außenseite des Folienverbunds sind jene Seiten des Folienverbunds bezeichnet, die an einer späteren aus dem Folienverbund gebildeten Verpackung einen Abschnitt der Verpackungsinnenseite bzw. der Verpackungsaußenseite bildet.

Bevorzugt weist der Folienverbund nur die in der vorliegenden Anmeldung genannten Lagen auf.

Die vorliegende Erfindung wird nachfolgend anhand der beiliegenden Zeichnungen näher erläutert werden. Es stellt dar:

Figur 1 eine Querschnittsansicht durch eine erfindungsgemäße Ausführungsform eines Folienverbunds der vorliegenden Anmeldung,

Figur 2 eine Draufsicht auf eine unter Beteiligung des Folienverbunds von Figur 1 gebildete Verpackung eines transdermalen Pflasters und

Figur 3 eine Querschnittsansicht der Verpackung von Figur 2 entlang der Schnittebene III-III von Figur 2.

In Figur 1 ist eine erfindungsgemäße Ausführungsform eines Folienverbunds der vorliegenden Anmeldung allgemein mit 10 bezeichnet. Die Darstellung der Figur 1 ist lediglich schematisch. Insbesondere die Dicken der einzelnen Lagen des Folienverbunds 10 sind nicht maßstabsgerecht abgebildet. Der Folienverbund 10 weist auf seiner designierten Innenseite eine COC-Lage 12 auf, welche einen COC-Gehalt von etwa 99,8 Gew.-% aufweist. Der Anteil an COC in der COC-Lage 12 ist möglichst hoch gewählt, um mit der COC-Lage 12 eine möglichst gute Barrierelage gegen Migration und Diffusion von pharmazeutischen Wirkstoffen, wie Nikotin oder/und Fentanyl oder/und Lidocain bereitzustellen. Eine Fläche 12a der COC-Lage 12 bildet

eine freiliegende Außenfläche des Folienverbunds 10. Die COC-Lage 12 weist bevorzugt eine Dicke von 9,8 bis 10,0 µm auf.

Mit der COC-Lage 12 durch Coextrusion verbunden ist eine Polyethylenlage 14. Die Polyethylenlage 14 ist vorzugsweise frei von COC und umfasst wenigstens 50 Gew.-% Metallocen-Polyethylen, bevorzugt Metallocen-LLDPE C8. Im dargestellten Beispiel beträgt der Anteil an Metallocen-LLDPE C8 an der gesamten Polyethylenmasse der Polyethylenlage 14 mehr als 95 Gew.-%. Hierdurch wird eine extrem gute Haftung der COC-Lage 12 an der Polyethylen-Lage 14 und somit ein hoher Schutz vor Delamination erreicht. Die Verwendung von Metallocen-LLDPE des Typs C8 – im Gegensatz zu den ebenfalls möglichen Typen C4 oder C6 – führt bei gleichzeitig hoher Haftung der COC-Lage 12 zu einer Polyethylenlage 14 mit vorteilhaften Steifigkeitseigenschaften. Der Schmelzflussindex MFR der Polyethylenlage 14 beträgt etwa 8 g/10 min., gemessen gemäß ISO 1133 bei einer Prüftemperatur von 190 °C mit einem Prüfgewicht von 2,16 kg. Die Dichte der Polyethylenlage 14 beträgt bevorzugt 0,919 g/m².

Durch den gewählten Wert des Schmelzflussindex kann die Polyethylenlage 14, obwohl sie nicht außenliegende Lage des Folienverbunds 10 ist, an einer Siegelverbindung des Folienverbunds 10 auf der Seite der COC-Lage 12 teilnehmen. Hierdurch werden hohe Siegelfestigkeiten und eine sehr gute Qualität der Siegelnaht erreicht. Die COC-Lage 12 ist nicht nur Barrierelage des Folienverbunds 10, sondern auch dessen siegelfähige Lage.

Die Dicke der Polyethylenlage 14 beträgt im dargestellten Beispiel zwischen 10,8 und 11,0 µm. Somit sind die Polyethylenlage 14 und die COC-Lage 12 etwa gleich dick, wobei die COC-Lage 12 geringfügig dünner sein kann. Auch dieses ausgewogene Dickenverhältnis zwischen Polyethylenlage 14 und COC-Lage 12 trägt zur Erzielung dauerhaft fester und diffusionsdichter Siegelverbindungen bei.

Auf der von der COC-Lage 12 abgewandten Seite ist die Polyethylenlage 14 mit einer Verbindungslage 16 eines Ethylen-Acrylsäure-Copolymers (EAA) verbunden,

um die COC-Lage 12 und die Polyethylenlage 14 mittels der Verbindungslage 16 mit einer Aluminiumlage 18 zu verbinden.

Die im dargestellten Beispiel zwischen 10,6 und 10,8 µm dicke Verbindungslage 16 wurde gemeinsam mit der Polyethylenlage 14 und der COC-Lage 12 coextrudiert und im Wege der Coextrusion auf die Aluminiumlage 18 aufgetragen.

Die als weitere Barrierelage dienende Aluminiumlage 18 ist im dargestellten Beispiel 8 bis 10 µm, vorzugsweise 9 µm dick.

Bereits ein Folienverbund aus den Lagen 12, 14, 16 und 18 ist ein stabiler Verbund, welcher zur Herstellung einer Verpackung für Produkte hervorragend geeignet ist, die pharmazeutische Wirkstoffe enthalten, wie Nikotin, Fentanyl oder Lidocain.

Um den genannten Verbund aus den Lagen 12, 14, 16 und 18 gegen ein unerwünschtes Öffnen bzw. Zerreißen durch neugierige Kinder zu schützen, die so an einen für Kinder gänzlich ungeeigneten verpackten pharmazeutischen Wirkstoff gelangen könnten, ist mittels einer Lage 20 aus lösungsmittelhaltigem Kaschierkleber mit einem Auftragsgewicht von 3 g/m² eine Lage 22 aus biaxial orientiertem Kunststoff, vorzugsweise aus Polyethylenterephthalat oder Polyamid, auf die von der COC-Lage 12 abgewandte Seite der Aluminiumlage 18 aufkaschiert.

Die Lage 22 kann an ihrer von der Aluminiumlage 18 wegweisenden Seite bedruckt sein, um einem Verbraucher Produktinformationen über ein mit dem Folienverbund 10 verpacktes Produkt mitzuteilen. Dann kann die Lage 22 eine der COC-Lage 12 entgegengesetzte außen liegende Lage des Folienverbunds 10 sein.

Anstelle einer Kunststofflage 22 kann die Lage 22 auch eine Papierlage sein.

Im dargestellten Beispiel von Figur 1 weist der Folienverbund 10 zusätzlich zur Kunststofflage 22, verbunden mittels einer weiteren Kaschierkleberlage 24 aus lösungsmittelhaltigem Kaschierkleber, eine außen liegende Papierlage 26 auf.

Die Papierlage 26 kann auf ihrer nach außen weisenden freiliegenden Fläche 26a bedruckt sein. Die Bedruckung kann durch eine Schutzschicht, etwa Klarlack, abgedeckt sein.

Im dargestellten Beispiel weist die Kunststofflage 22 eine Dicke von etwa 22,7 bis 23,3 µm auf. Die Papierlage 26 weist dagegen eine Dicke von etwa 39,5 bis 40,5 µm bei einem Flächengewicht von etwa 40 g/m² auf.

Die Gesamtdicke des Folienverbunds 10 beträgt somit zwischen 108,4 µm und 110,6 µm.

Der Folienverbund 10 weist nicht nur hervorragende Barriereeigenschaften gegen eine Migration und Diffusion von pharmazeutischen Wirkstoffen oder ihren Bestandteilen von der Außenfläche 12a der COC-Lage 12 zur Außenfläche 26a der Papierlage 26 auf. Der Folienverbund 10 hat überdies eine zur Bildung einer Verpackung sehr gut geeignete Steifigkeit und hervorragende Laufeigenschaften auf Verarbeitungsmaschinen zur Verarbeitung des Folienverbunds 10.

In Figur 2 ist eine aus zwei Folienverbundflecken des Folienverbunds 10 von Figur 1 gebildete Verpackung 30 zur Verpackung von flächigen Trägern von pharmazeutischen Wirkstoffen in Draufsicht gezeigt. Wegen der Draufsicht ist nur ein Folienverbundfleck 32 erkennbar. Ein weiterer Folienverbundfleck 33 befindet sich hinter dem in Figur 2 dargestellten Folienverbundfleck 32 und wird durch diesen verdeckt (siehe Figur 3). Man blickt in Figur 2 auf die Außenseite 26a der Papierlage 26 des Folienverbundflecks 32. Als "Folienverbundfleck" im Sinne der vorliegenden Anmeldung gilt jeder vorbestimmte Zuschnitt aus einem Folienverbund, unabhängig von der Art des Zuschnitts. Der Zuschnitt kann daher auch gestanzt oder dergleichen sein.

Die Verpackung 30 ist in Gestalt eines Vier-Rand-Siegelbeutels gebildet, mit einer umlaufenden Siegelnaht 34. Radial innerhalb der Siegelnaht 34 befindet sich ein Träger-Aufnahmeraum 36, in welchem ein flächiger Träger 38 eines pharmazeutischen Werkstoffs (siehe Figur 3) aufgenommen ist.

Als Aufreißhilfe kann die Verpackung 30 an wenigstens einer Stelle, etwa in einem Randbereich, eine Kerbe 40 aufweisen.

Figur 3 zeigt einen Längsschnitt durch die Verpackung 30 von Figur 2 längs der Schnittebene III-III von Figur 2. Die Schnittebene III-III ist orthogonal zur Zeichenebene von Figur 2 orientiert.

In Figur 3 ist im Längsschnitt durch die Folienverbundflecke 32 und 33 die Lagenverteilung innerhalb der Flecke 32 und 33 nicht mehr eigens dargestellt. Sie entspricht der in Figur 1 dargestellten Lagenverteilung des Folienverbunds 10. Die beiden COC-Lagen 12 der jeweiligen Folienverbundflecke 32 und 33 sind aufeinander zuweisend angeordnet und längs der Siegelnaht 34 miteinander verschweißt. In dem radial innerhalb der Siegelnaht 34 gebildeten Träger-Aufnahmeraum 36 ist ein transdermales Pflaster 39 als flächiger Träger 38 eines pharmazeutischen Wirkstoffs aufgenommen. Der Träger-Aufnahmeraum 36 ist somit durch die Siegelnaht 34 nach radial außen begrenzten orthogonal hierzu durch die beiden Folienverbundflecke 32 und 33.

Die Siegelnaht 34 erstreckt sich in Dickenrichtung der jeweiligen Folienverbundflecke 32 und 33 nicht nur über die auch als Siegellage dienenden jeweiligen COC-Lagen 12, sondern über diese COC-Lagen 12 hinaus auch in die Polyethylenlagen 14 hinein. Die Siegelnaht 34 wird somit gebildet durch die sich vor der Siegelung berührenden COC-Lagen 12 der beiden Folienverbundflecke 32 und 33 und durch Material der aus Sicht der Berührstelle der beiden COC-Lagen 12 vor Herstellung des Siegelnaht 34 hinter den jeweiligen COC-Lagen 12 gelegenen Polyethylenlagen 14. Da es sich bei dem Material der COC-Lagen 12 ebenso wie bei dem Material der Polyethylenlagen 14 um ein Olefin handelt, sind die Materialien der beiden Lagen 12 und 14 miteinander kompatibel und können sich in der Siegelnaht 34 mischen.

Ansprüche

1. Folienverbund (10) zur Herstellung einer Verpackung (30) für flächige Träger (38) von pharmazeutischen Wirkstoffen, umfassend in Richtung von der Außenseite (26a) des Folienverbunds (10) zu seiner Innenseite (12a) eine Metalllage (18), eine Acrylsäure-haltige Verbindungslage (16), eine Polyethylenlage (14) und eine COC-Lage (12) aus Cycloolefin-Copolymer, wobei eine von der Metalllage (18) abgewandte Seite (12a) der COC-Lage (12) eine freiliegende Fläche des Folienverbunds (10) ist,
dadurch gekennzeichnet, dass die Polyethylenlage (14) Metallocen-Polyethylen umfasst.

2. Folienverbund (10) nach Anspruch 1,
dadurch gekennzeichnet, dass der Anteil an Metallocen-Polyethylen am gesamten Polyethylen der Polyethylenlage (14) wenigstens 50 Gew.-% umfasst.

3. Folienverbund (10) nach Anspruch 1 oder 2,
dadurch gekennzeichnet, dass die Polyethylenlage (14) ein Metallocen-LLDPE umfasst.

4. Folienverbund (10) nach einem der vorhergehenden Ansprüche,
dadurch gekennzeichnet, dass die Polyethylenlage (14) ein Metallocen-Polyethylen C6 oder/und ein Metallocen-Polyethylen C8 umfasst.

5. Folienverbund (10) nach Anspruch 4,
dadurch gekennzeichnet, dass die Polyethylenlage (14) als Metallocen-Polyethylen nur ein Metallocen-Polyethylen C8 umfasst.

6. Folienverbund (10) nach einem der vorhergehenden Ansprüche,
dadurch gekennzeichnet, dass die Acrylsäure-haltige Verbindungslage (16) ein Ethylen-Acrylsäure-Copolymer umfasst oder aus diesem besteht.

7. Folienverbund (10) nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, dass jede der Lagen (16, 14, 12) aus Acrylsäure-haltiger Verbindungslage (16), Polyethylenlage (14) und COC-Lage (12) eine Lagendicke im Bereich von etwa 7 µm bis 15µm, vorzugsweise im Bereich von 9 µm bis 12 µm aufweist, wobei sich bevorzugt die Dickenwerte der genannten Lagen (16, 14, 12) – bezogen auf die dünnste (12) der genannten Lagen (16, 14, 12) – um nicht mehr als 15 %, vorzugsweise um nicht mehr als 11 % unterscheiden.

8. Folienverbund (10) nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, dass er auf der von der COC-Lage (12) abgewandten Seite der Metalllage (18) wenigstens eine weitere Lage (22, 26) aus Papier oder/und Kunststoff aufweist.

9. Folienverbund (10) nach Anspruch 8, **dadurch gekennzeichnet**, dass er auf der von der COC-Lage (12) abgewandten Seite der Metalllage (18) sowohl eine weitere Lage (26) aus Papier als auch eine weitere Lage (22) aus Kunststoff aufweist, wobei bevorzugt die Kunststofflage (22) näher bei der Metalllage (18) gelegen ist als die Papierlage (26).

10. Folienverbund (10) nach Anspruch 8 oder 9, **dadurch gekennzeichnet**, dass die weitere Lage (22) aus Kunststoff ein biaxial orientierter Kunststoff ist.

11. Folienverbund (10) nach einem der Ansprüche 8 bis 10, **dadurch gekennzeichnet**, dass die weitere Lage (22) aus Kunststoff Polyethylenterephthalat oder/und Polyamid ist.

12. Folienverbund (10) nach einem der Ansprüche 8 bis 11, **dadurch gekennzeichnet**, dass die weitere Lage (26) aus Papier eine Dicke von 35 bis 45 µm, insbesondere von 39 bis 41 µm aufweist, oder/und ein Flächengewicht von 35 bis 45 g/m², insbesondere von 39 bis 41 g/m² aufweist,

oder/und

dass die weitere Lage (22) aus Kunststoff eine Dicke von 19 bis 27 µm, insbesondere von 22 bis 24 µm aufweist oder/und ein Flächengewicht von 28 bis 36 g/m², insbesondere von 31 bis 33 g/m² aufweist.

13. Verpackung (30) für einen flächigen Träger (38) von pharmazeutischen Wirkstoffen, wie beispielsweise ein transdermales Pflaster (39), umfassend zwei Folienverbundflecke (32, 33) aus je einem Folienverbund (10) gemäß einem der vorhergehenden Ansprüche, welche unter Bildung eines Träger-Aufnahmeraums (36) mit aufeinander zuweisenden COC-Lagen (12) angeordnet und durch abschnittsweises Siegeln von COC-Lagenbereichen miteinander verbunden sind.

14. Verpackung (30) nach Anspruch 13,
dadurch gekennzeichnet, dass sie ein Vier-Rand-Siegelbeutel mit um den Träger-Aufnahmeraum (36) umlaufender Siegelnaht (34) ist.

15. Verpackung (30) nach Anspruch 13 oder 14 mit einem im Träger-Aufnahmeraum (36) aufgenommenen flächigen Wirkstoffträger (38), insbesondere transdermalem Pflaster (39), wobei der pharmazeutische Wirkstoff Nikotin oder/und Fentanyl oder/und Lidocain enthält.

Zusammenfassung

Die vorliegende Erfindung betrifft einen Folienverbund (10) zur Herstellung einer Verpackung für flächige Träger von pharmazeutischen Wirkstoffen, wie beispielsweise transdermale Pflaster, umfassend in Richtung von der Außenseite (26a) des Folienverbunds (10) zu seiner Innenseite (12a) eine Metalllage (18), eine Acrylsäure-haltige Verbindungslage (16), eine Polyethylenlage (14) und eine COC-Lage (12) aus Cycloolefin-Copolymer, wobei eine von der Metalllage (18) abgewandte Seite (12a) der COC-Lage (12) eine freiliegende Fläche des Folienverbunds (10) ist. Erfindungsgemäß ist vorgesehen, dass die Polyethylenlage (14) Metallocen-Polyethylen umfasst.

(Fig. 1)

Fig. 1

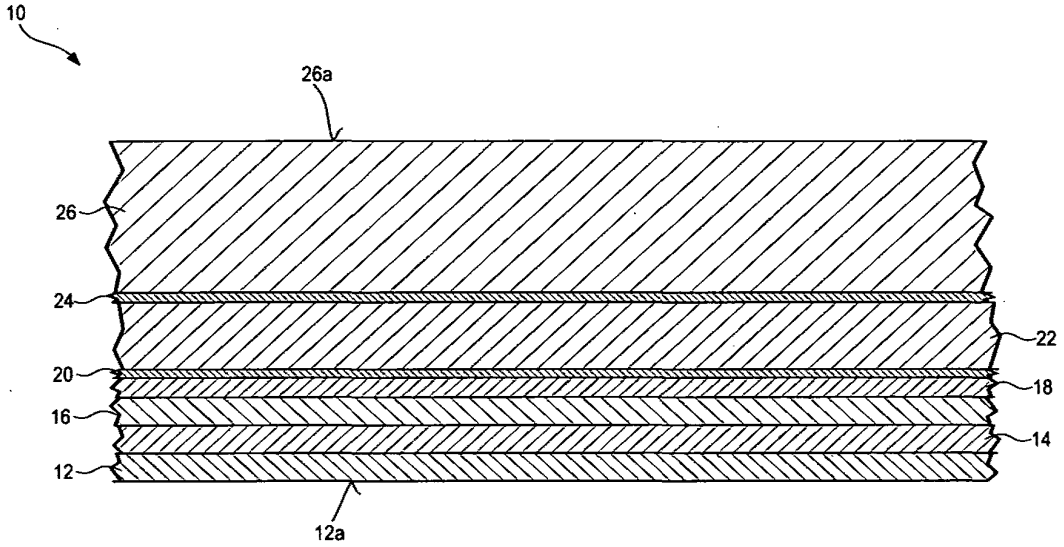


Fig. 2

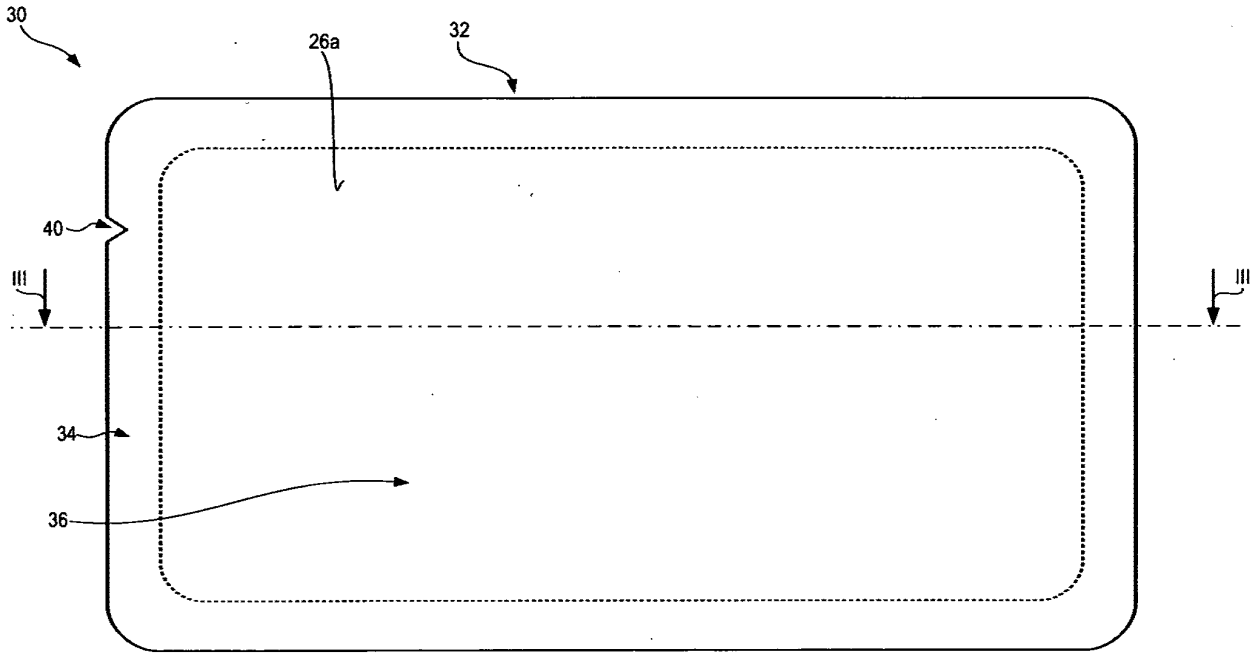
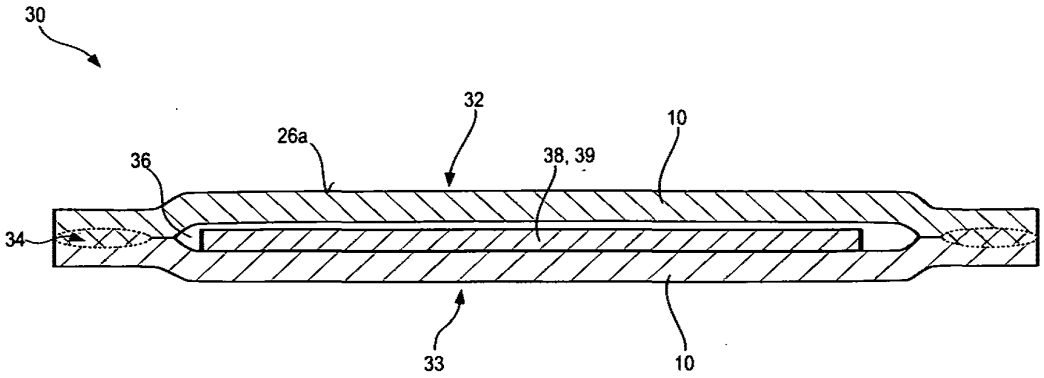


Fig. 3



BUNDESREPUBLIK DEUTSCHLAND

Prioritätsbescheinigung
DE 10 2018 212 303.9
über die Einreichung einer Patentanmeldung

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Anmeldetag:	24. Juli 2018
Anmelder/Inhaber:	Huhtamaki Flexible Packaging Germany GmbH & Co. KG, 87671 Ronsberg, DE
Bezeichnung:	Folienverbund zur Verpackung transdermaler Pflaster und Verpackung aus einem solchen Folienverbund
IPC:	B32B 27/08; B65D 65/40; A61J 1/00; A61F 13/02; B32B 27/32

Die angehefteten Stücke sind eine richtige und genaue Wiedergabe der Teile der am 24. Juli 2018 eingereichten elektronischen Dokumente dieser Patentanmeldung unabhängig von gegebenenfalls durch das Druckverfahren bedingten Farbabweichungen.

München, den 27. Juni 2019
Deutsches Patent- und Markenamt
Die Präsidentin
Im Auftrag

Kahle

A 9161(E)/1.12

Folienverbund zur Verpackung transdermaler Pflaster und Verpackung aus einem solchen Folienverbund

Beschreibung

Die vorliegende Erfindung betrifft einen Folienverbund zur Herstellung einer Verpackung für flächige Träger von pharmazeutischen Wirkstoffen, wie beispielsweise transdermale Pflaster, umfassend in Richtung von der designierten Außenseite des Folienverbunds zu seiner designierten Innenseite eine Metalllage, eine Acrylsäurehaltige Verbindungslage, eine Polyethylenlage und eine COC-Lage aus Cycloolefin-Copolymer, wobei eine von der Metalllage abgewandte Seite der COC-Lage eine freiliegende Fläche des Folienverbunds ist.

Ein solcher Folienverbund zu dem genannten Zweck einer Herstellung einer Verpackung von pharmazeutischen Wirkstoffträgern ist aus der WO 2015/123211 A1 bekannt. Der gattungsgemäße Folienverbund kommt dabei in unmittelbarem Kontakt mit dem flächigen Träger eines pharmazeutischen Wirkstoffs und damit mit dem pharmazeutischen Wirkstoff selbst. Es handelt sich bei den infrage kommenden pharmazeutischen Wirkstoffen um Wirkstoffe, wie etwa Nikotin, Fentanyl oder Lidocain. Die von diesen pharmazeutischen Wirkstoffen ausgehende Belastung des Folienverbundes ist erheblich. Es ist dabei sicherzustellen, dass zum einen der Folienverbund als solcher über längere Zeit erhalten bleibt, um eine unerwünschte Freisetzung des pharmazeutischen Wirkstoffs des Wirkstoffträgers zu verhindern. Selbst wenn der Folienverbund erhalten bleibt, also beispielsweise nicht unter dem Einfluss des in Verbundlagen diffundierenden pharmazeutischen Wirkstoffs wenigstens abschnittsweise delaminiert, muss zum anderen sichergestellt werden, dass der pharmazeutische Wirkstoff nicht durch den Folienverbund hindurch diffundieren bzw. migrieren kann.

Zur Erhöhung der Diffusions-Barrierewirkung des Folienverbunds gegenüber den durch sie verpackten pharmazeutischen Wirkstoffen ist es bekannt, den Anteil an Cycloolefin-Copolymer (COC) in der in der späteren Verpackung ganz innen liegenden COC-Lage möglichst hoch zu wählen. Mit der Erhöhung des COC-Gehalts in der

COC-Lage wird es jedoch zunehmend schwieriger, die Stabilität des Folienverbunds aufrecht zu erhalten, etwa eine Delamination oder ähnliche Zerfallserscheinungen zu verhindern.

Auch die WO 2017/114922 A1 offenbart Folienverbünde zur Bildung von Verpackungen für flächige pharmazeutische Wirkstoffträger.

Es ist daher Aufgabe der vorliegenden Erfindung, den eingangs genannten Folienverbund mit größtmöglicher chemischer und mechanischer Stabilität gegenüber den zu verpackenden pharmazeutischen Wirkstoffen im Hinblick auf seine Aufgabe einer Bildung einer sicheren, auch kindersicheren Verpackung von flächigen pharmazeutischen Wirkstoffträgern auszubilden.

Diese Aufgabe wird erfindungsgemäß gelöst durch einen Folienverbund der eingangs genannten Art, bei welchem die Polyethylenlage Metallocen-Polyethylen umfasst. Versuche haben nämlich gezeigt, dass bei ansonsten identischen Dimensionen des Folienverbunds die Haftung der COC-Lage an der Polyethylenlage dann erheblich besser ist, wenn die Polyethylenlage Metallocen-Polyethylen aufweist. "Metallocen-Polyethylen" ist dabei Polyethylen, welches unter Verwendung von Metallocen-Katalysatoren in an sich bekannter Weise hergestellt wurde.

Dabei ist der durch die Verwendung von Metallocen-Polyethylen gegenüber herkömmlichen Polyethylen erzielbare Haftungsgewinn in der Haftungswirkung zwischen der COC-Lage und der Polyethylenlage umso größer, je höher der COC-Gehalt in der COC-Lage ist. Da die COC-Lage zur Erzielung einer möglichst hohen Barrierewirkung gegenüber pharmazeutischen Wirkstoffen, die im flächigen Wirkstoffträger gespeichert sind, einen möglichst großen COC-Anteil von wenigstens 95 Gew-%, bevorzugt von wenigstens 99,8 Gew.-% an der Masse der gesamten COC-Lage aufweist, kann mit der vorliegend vorgestellten Verwendung von Metallocen-Polyethylen in der zwischen der Acrylsäule-haltigen Verbindungslage und der COC-Lage angeordneten Polyethylenlage ein besonders großer Haftungsvorteil erzielt werden.

Im Zweifel, etwa wenn mehr als eine Polymerlage des Folienverbunds COC enthält, soll eine COC-Lage nur dann als COC-Lage im Sinne der vorliegenden Anmeldung gelten, wenn sie bezogen auf ihre Lagenmasse mindestens 50 Gew.-% COC enthält. Die genannte Polyethylenlage, die Metallocen-Polyethylen enthält, ist vorzugsweise frei von COC.

Grundsätzlich kann bereits mit vergleichsweise geringen Mengen an Metallocen-Polyethylen eine Verbesserung der Haftung der COC-Lage an der Polyethylenlage erreicht werden. Besonders stark ist die Verbesserung der Haftungswirkung bei ansonsten abmessungsgleichen Vergleichsproben unterschiedlicher Folienverbundflecke dann, wenn der Anteil an Metallocen-Polyethylen am gesamten Polyethylen der Polyethylenlage wenigstens 50 Gew.-% umfasst. Grundsätzlich können also auch sogenannte Polyethylen-Blends zur Bildung der Polyethylenlage verwendet werden, in welchen Metallocen-Polyethylen mit Nicht-Metallocen-Polyethylen vermischt ist.

Wegen der vorteilhaften Haftung erhöhenden Wirkung von Metallocen-Polyethylen ist vorzugsweise dessen Anteil (stets in Gewichtsprozent) am gesamten in der Polyethylenlage enthaltenen Polyethylen möglichst groß, vorzugsweise größer als 90 Gew.-%, besonders bevorzugt größer als 96 Gew.-%.

Dabei hat es sich zur Erhöhung der Haftungswirkung und ebenso der Verarbeitbarkeit des Folienverbunds auf entsprechenden Verarbeitungsmaschinen zu daraus gebildeten Verpackungen als vorteilhaft erwiesen, wenn die Polyethylenlage ein Metallocen-LLDPE umfasst. Vorzugsweise umfasst die Polyethylenlage nur Metallocen-LLDPE als das Metallocen-Polyethylen.

Die Dichte des Metallocen-Polyethylens liegt zur Erzielung guter Laufeigenschaften einer Folienverbundbahn in den oben genannten Verarbeitungsmaschinen vorteilhafterweise in einem Bereich zwischen 0,917 und 0,921 g/m². Zusätzlich oder alternativ weist das Metallocen-Polyethylen zur Erzielung hochfester und hochdichter dauerhafter Siegelnähte einen Schmelzflussindex (MFR) von zwischen 6 und 10 g/10 min. auf, gemessen nach ISO 1133 bei einer Prüftemperatur von 190 °C und bei Ver-

wendung eines Prüfkörpers mit einem Gewicht von 2,16 kg. Denn die Polyethylenlage kann zusätzlich zur COC-Lage als der außen liegenden Barriere- und Siegellage zu einer Siegelverbindung des Folienverbunds beitragen.

Jede Art von Metallocen-Polyethylen in der Polyethylenlage sorgt für eine gewünschte Erhöhung der Haftungswirkung der COC-Lage an der Polyethylenlage, verglichen mit einer Polyethylenlage gleicher Abmessung oder/und gleichen Flächengewichts in dem Folienverbund. Darüber hinaus kann jedoch durch Verwendung unterschiedlicher Typen von Metallocen-Polyethylen die Steifigkeit der Polyethylenlage und damit des Folienverbunds insgesamt beeinflusst werden. Eine vorteilhafte Steifigkeit der Polyethylenlage, bei vorgegebenen Abmessungen derselben, kann dadurch erhalten werden, dass die Polyethylenlage ein Metallocen-Polyethylen C6 oder/und ein Metallocen-Polyethylen C8 umfasst oder aus den genannten Metallocen-Polyethylen-Typen besteht. Dabei liefert Metallocen-Polyethylen C8 nach bisherigen Versuchen bei vorgegebenem Folienverbund und insbesondere bei vorgegebener Abmessung oder/und Flächengewicht der Polyethylenlage das beste Ergebnis hinsichtlich der erzielten Lagensteifigkeit der Polyethylenlage einerseits und der erzielten Verbundsteifigkeit des Folienverbunds insgesamt andererseits.

Aus diesem Grunde ist es nachvollziehbarerweise vorteilhaft, wenn die Polyethylenlage als Metallocen-Polyethylen nur ein Metallocen-Polyethylen C8 umfasst. Gemäß den obigen Darlegungen ist dies besonders bevorzugt ein Metallocen-LLDPE C8.

Die Polyethylenlage ist bevorzugt im Extrusionsverfahren aufgetragen, besonders bevorzugt coextrudiert mit der COC-Lage.

Ein kommerziell verfügbares Metallocen-Polyethylen, welches hervorragend als Polyethylenlage in dem genannten Folienverbund einsetzbar ist, ist das von Dow Chemical Company unter dem Handelsnamen "Elite™ 5811" erhältliche Polyethylen.

Zur Erzielung einer möglichst großen Haftungswirkung des Teilverbunds aus Polyethylenlage und COC-Lage an der Metalllage umfasst die Acrylsäure-haltige Verbin-

dungslage bevorzugt ein Ethylen-Acrylsäure-Copolymer (EAA-Copolymer) oder besteht aus diesem.

Bevorzugt wird auch die Acrylsäure-haltige Verbindungslage durch Extrusion auf die Metalllage aufgetragen. Besonders bevorzugt wird ein Teilverbund aus Acrylsäure-haltiger Verbindungslage, insbesondere EAA-Lage, Polyethylenlage und COC-Lage durch Coextrusion in einem gemeinsamen Extrusionsschritt auf die Metalllage aufgetragen.

Die Metalllage dient als Sauerstoff- und Gasbarriere zum Schutz eines Verpackungsinhalts vor äußeren Einflüssen und überdies als Barriere für pharmazeutische Wirkstoffe und deren Bestandteile, welche durch die COC-Lage, die Polyethylenlage und die Acrylsäure-haltige Verbindungslage hindurch aufgrund von Diffusion die Metalllage erreichen. Bevorzugt ist die Metalllage eine Aluminiumlage.

Bevorzugt weist jede der Lagen aus Acrylsäure-haltiger Verbindungslage, Polyethylenlage und COC-Lage eine Lagendicke im Bereich von etwa 7 µm bis 15µm auf. Dies sorgt zum einen für eine hervorragende Anbindung an die Metalllage. Zum anderen kann in diesem Dickenbereich nicht nur die COC-Lage, sondern auch die Polyethylenlage zur Herstellung einer Siegelverbindung mit der COC-Lage eines gleichartig aufgebauten Folienverbunds dienen. Da in dem genannten Fall auch die unter der COC-Lage gelegenen Polyethylenlage besonders gut und sicher zur Herstellung einer Siegelverbindung beitragen kann, sind die oben angegebenen Werte des Schmelzflussindex (MFR) zur Erzielung hervorragender Siegeleigenschaften des Folienverbunds mit der freiliegenden COC-Lage von großem Vorteil. Vorzugsweise liegen die Dickenwerte der drei, vorzugsweise coextrudierten, Lagen: Acrylsäure-haltige Verbindungslage, Polyethylenlage und COC-Lage, jeweils im Bereich von 9 µm bis 12 µm. Zur Erzielung hervorragender Siegeleigenschaften unter Beteiligung nicht nur der COC-Lage als außenliegende Siegellage, sondern auch der darunterliegenden Polyethylenlage unterscheiden sich vorzugsweise die Lagendicken der Polyethylenlage und der COC-Lage kaum. Auch die Dicke der Acrylsäure-haltigen Verbindungslage unterscheidet sich vorzugsweise kaum von der Dicke der beiden erstgenannten Lagen: Polyethylenlage und COC-Lage, um eine möglichst gute An-

bindung der COC-Lage und der Polyethylenlage an die Metalllage zu erzielen, ohne dabei den Folienverbund unerwünscht dick zu gestalten. Bevorzugt unterscheiden sich die Dickenwerte der genannten Lagen – bezogen auf die dünnste der genannten Lagen – um nicht mehr als 15 %, vorzugsweise um nicht mehr als 11 %. Dann lässt sich ein Dreierverbund aus Acrylsäure-haltiger Verbindungslage, Polyethylenlage und COC-Lage gut coextrudieren, wobei der so entstehende Folienverbund sehr gute Laufeigenschaften auf Verarbeitungsmaschinen zur Verarbeitung des Folienverbunds zu einer Verpackung aufweist und überdies sehr gute Siegeleigenschaften aufweist.

Grundsätzlich kann der Folienverbund so verwendet werden, wie er oben beschrieben ist. Zum weiteren Schutz des Folienverbunds kann dieser auf der von der COC-Lage abgewandten Seite der Metalllage wenigstens eine weitere Lage aus Papier oder/und Kunststoff aufweisen. Dadurch ist die Metalllage eine vollständig innenliegende Lage des Folienverbunds und als solche besser vor äußeren Einflüssen geschützt. Da in der Regel die COC-Lage eine ganz innen liegende Lage einer aus dem Folienverbund gebildeten Verpackung ist, wird durch das Vorsehen der wenigstens einen weiteren Lage die Aufbringung von Produktinformationen auf der zum Verbraucher weisenden Außenseite des Folienverbunds erleichtert, die ansonsten mit erhöhtem Aufwand auf der Metalllage aufgebracht werden müssten.

Die wenigstens eine weitere Lage ist vorzugsweise auf die Metalllage oder auf eine auf dieser bereits vorhandene weitere Lage aufkaschiert. Hierzu wird bevorzugt ein lösungsmittelhaltiger Kaschierkleber mit einem Flächenauftragsgewicht von 2 bis 4 g/m², vorzugsweise mit einem Flächenauftragsgewicht von 3 g/m² verwendet.

Zur leichten Bedruckung und zur Kindersicherung einer aus dem Folienverbund gebildeten Verpackung vor unerwünschtem Öffnen und Freilegen der darin verpackten pharmazeutischen Wirkstoffe weist der Folienverbund bevorzugt auf der von der COC-Lage abgewandten Seite der Metalllage sowohl eine weitere Lage aus Papier als auch eine weitere Lage aus Kunststoff auf. Wegen der besonders einfachen Bedruckbarkeit der Papierlage und damit einer besonders einfachen und kostengünstigen Möglichkeit, den Folienverbund oder/und eine damit gebildete Verpackung

mit Verbraucherinformationen zu versehen, ist bevorzugt die Kunststofflage näher bei der Metalllage gelegen ist als die Papierlage. Bevorzugt ist die Papierlage eine außen liegende Lage des Folienverbunds. Ein auf die Papierlage aufgedruckter Druckauftrag kann durch eine Schutzschicht, wie etwa einen Klarlack, wenigstens teilweise oder bevorzugt vollständig abgedeckt sein.

Zur Bereitstellung einer gezielten Rissführung eines einmal in den Folienverbund eingeleiteten Risses, beispielsweise zum Öffnen einer unter Beteiligung des Folienverbunds gebildeten Verpackung, ist die weitere Lage aus Kunststoff bevorzugt ein orientierter, besonders bevorzugt ein biaxial orientierter Kunststoff.

Als Kunststoff für die wenigstens eine weitere Kunststofflage haben sich Polyethylenterephthalat oder/und Polyamid in Versuchen bewährt. Kunststofflagen aus den genannten Kunststoffen sind mechanisch und thermisch ausreichend stabil und stellen besonders in orientierter Form eine weitere Barrierewirkung gegen Diffusion von Gasen und Dämpfen bereit. Die weitere Kunststofflage kann somit in einer Richtung die Metalllage vor chemischen Angriffen von außen schützen und kann in der entgegengesetzten Richtung zusätzlich den pharmazeutischen Wirkstoff oder Bestandteile davon zurückhalten, falls diese die Metalllage überwinden sollten.

Dann, wenn der Folienverbund auf der von der COC-Lage wegweisenden Seite der Metalllage eine weitere Lage aus Papier aufweist, hat diese vorzugsweise eine Dicke von 35 bis 45 µm, besonders bevorzugt von 39 bis 41 µm. Zusätzlich oder alternativ kann die weitere Lage aus Papier ein Flächengewicht von 35 bis 45 g/m², insbesondere von 39 bis 41 g/m² aufweisen.

Dann, wenn der Folienverbund auf der von der COC-Lage wegweisenden Seite der Metalllage eine weitere Lage aus Kunststoff aufweist, hat diese vorzugsweise eine Dicke von 19 bis 27 µm, insbesondere von 22 bis 24 µm. Zusätzlich oder alternativ weist die zusätzliche Lage aus Kunststoff ein Flächengewicht von 28 bis 36 g/m², insbesondere von 31 bis 33 g/m² auf. Diese Werte von Dicken und Flächengewicht bieten einen sehr guten Kompromiss zwischen ausreichender mechanischer Festigkeit, thermischer Stabilität und geringer Gesamtdicke des Folienverbunds.

Da der oben beschriebene Folienverbund besonders geeignet ist zur Herstellung einer Verpackung für einen flächigen Träger von pharmazeutischen Wirkstoffen, wie beispielsweise ein transdermales Pflaster, betrifft die vorliegende Erfindung auch eine solche Verpackung, umfassend zwei Folienverbundflecke aus je einem Folienverbund, wie er oben beschrieben und weitergebildet ist. Die Folienverbundflecke sind unter Bildung eines Träger-Aufnahmeraums mit aufeinander zuweisenden COC-Lagen angeordnet und durch abschnittsweises Siegeln von COC-Lagenbereichen miteinander verbunden. Abschnitte der aufeinander zuweisenden COC-Lagenbereiche sind dabei miteinander gesiegelt, bevorzugt unter Beteiligung der unter den COC-Lagen gelegenen jeweiligen Polyethylenlage mit Metallocen-Polyethylen. Die Siegelnaht umfasst dann bevorzugt eine Mischung aus COC und aus Metallocen-Polyethylen. Die Siegelnaht erstreckt sich dann in Dickenrichtung bis in die Polyethylenlage hinein. Andere Abschnitte der aufeinander zuweisenden COC-Lagenbereiche der beiden Folienverbundflecke liegen einander unverbunden gegenüber. Dann, wenn in der Verpackung ein flächiger Träger von pharmazeutischen Wirkstoffen aufgenommen ist, befindet sich dieser zwischen einander unverbunden gegenüberliegenden Abschnitten je einer COC-Lage eines an der Bildung der Verpackung beteiligten Folienverbundflecks.

Als flächiger Träger von pharmazeutischen Wirkstoffen gilt ein Substrat, welches in seinen beiden zueinander und zur Substrat-Dickenrichtung orthogonalen Haupterstreckungsrichtungen jeweils Abmessungen aufweist, die um wenigstens das 10-Fache, vorzugsweise um wenigstens das 30-Fache, größer sind als die Abmessung des Substrats in Dickenrichtung und welches zur Abgabe eines im Substrat gespeicherten pharmazeutischen Wirkstoffs ausgebildet ist.

Die Verpackung kann raumsparend bei gleichzeitig dauerhaft hoher Abschirmung des darin verpackten pharmazeutischen Wirkstoffs ein Vier-Rand-Siegelbeutel mit um den Träger-Aufnahmeraum umlaufender Siegelnaht sein.

Ein wie oben beschrieben im Träger-Aufnahmeraum der Verpackung aufgenommenen flächiger Wirkstoffträger ist bevorzugt ein transdermales Pflaster. Der pharma-

zeutische Wirkstoff im Wirkstoffträger umfasst bevorzugt Nikotin oder/und Fentanyl oder/und Lidocain oder/und einen anderen zur Verabreichung mittels transdermalem Pflaster bekannten Wirkstoff.

Als "designierte" Innen- bzw. Außenseite des Folienverbunds sind jene Seiten des Folienverbunds bezeichnet, die an einer späteren aus dem Folienverbund gebildeten Verpackung einen Abschnitt der Verpackungsinnenseite bzw. der Verpackungsaußenseite bildet.

Bevorzugt weist der Folienverbund nur die in der vorliegenden Anmeldung genannten Lagen auf.

Die vorliegende Erfindung wird nachfolgend anhand der beiliegenden Zeichnungen näher erläutert werden. Es stellt dar:

Figur 1 eine Querschnittsansicht durch eine erfindungsgemäße Ausführungsform eines Folienverbunds der vorliegenden Anmeldung,

Figur 2 eine Draufsicht auf eine unter Beteiligung des Folienverbunds von Figur 1 gebildete Verpackung eines transdermalen Pflasters und

Figur 3 eine Querschnittsansicht der Verpackung von Figur 2 entlang der Schnittebene III-III von Figur 2.

In Figur 1 ist eine erfindungsgemäße Ausführungsform eines Folienverbunds der vorliegenden Anmeldung allgemein mit 10 bezeichnet. Die Darstellung der Figur 1 ist lediglich schematisch. Insbesondere die Dicken der einzelnen Lagen des Folienverbunds 10 sind nicht maßstabsgerecht abgebildet. Der Folienverbund 10 weist auf seiner designierten Innenseite eine COC-Lage 12 auf, welche einen COC-Gehalt von etwa 99,8 Gew.-% aufweist. Der Anteil an COC in der COC-Lage 12 ist möglichst hoch gewählt, um mit der COC-Lage 12 eine möglichst gute Barrierelage gegen Migration und Diffusion von pharmazeutischen Wirkstoffen, wie Nikotin oder/und Fentanyl oder/und Lidocain bereitzustellen. Eine Fläche 12a der COC-Lage 12 bildet

eine freiliegende Außenfläche des Folienverbunds 10. Die COC-Lage 12 weist bevorzugt eine Dicke von 9,8 bis 10,0 µm auf.

Mit der COC-Lage 12 durch Coextrusion verbunden ist eine Polyethylenlage 14. Die Polyethylenlage 14 ist vorzugsweise frei von COC und umfasst wenigstens 50 Gew.-% Metallocen-Polyethylen, bevorzugt Metallocen-LLDPE C8. Im dargestellten Beispiel beträgt der Anteil an Metallocen-LLDPE C8 an der gesamten Polyethylenmasse der Polyethylenlage 14 mehr als 95 Gew.-%. Hierdurch wird eine extrem gute Haftung der COC-Lage 12 an der Polyethylen-Lage 14 und somit ein hoher Schutz vor Delamination erreicht. Die Verwendung von Metallocen-LLDPE des Typs C8 – im Gegensatz zu den ebenfalls möglichen Typen C4 oder C6 – führt bei gleichzeitig hoher Haftung der COC-Lage 12 zu einer Polyethylenlage 14 mit vorteilhaften Steifigkeitseigenschaften. Der Schmelzflussindex MFR der Polyethylenlage 14 beträgt etwa 8 g/10 min., gemessen gemäß ISO 1133 bei einer Prüftemperatur von 190 °C mit einem Prüfgewicht von 2,16 kg. Die Dichte der Polyethylenlage 14 beträgt bevorzugt 0,919 g/m².

Durch den gewählten Wert des Schmelzflussindex kann die Polyethylenlage 14, obwohl sie nicht außenliegende Lage des Folienverbunds 10 ist, an einer Siegelverbindung des Folienverbunds 10 auf der Seite der COC-Lage 12 teilnehmen. Hierdurch werden hohe Siegelfestigkeiten und eine sehr gute Qualität der Siegelnaht erreicht. Die COC-Lage 12 ist nicht nur Barrierelage des Folienverbunds 10, sondern auch dessen siegelfähige Lage.

Die Dicke der Polyethylenlage 14 beträgt im dargestellten Beispiel zwischen 10,8 und 11,0 µm. Somit sind die Polyethylenlage 14 und die COC-Lage 12 etwa gleich dick, wobei die COC-Lage 12 geringfügig dünner sein kann. Auch dieses ausgewogene Dickenverhältnis zwischen Polyethylenlage 14 und COC-Lage 12 trägt zur Erzielung dauerhaft fester und diffusionsdichter Siegelverbindungen bei.

Auf der von der COC-Lage 12 abgewandten Seite ist die Polyethylenlage 14 mit einer Verbindungslage 16 eines Ethylen-Acrylsäure-Copolymers (EAA) verbunden,

um die COC-Lage 12 und die Polyethylenlage 14 mittels der Verbindungslage 16 mit einer Aluminiumlage 18 zu verbinden.

Die im dargestellten Beispiel zwischen 10,6 und 10,8 µm dicke Verbindungslage 16 wurde gemeinsam mit der Polyethylenlage 14 und der COC-Lage 12 coextrudiert und im Wege der Coextrusion auf die Aluminiumlage 18 aufgetragen.

Die als weitere Barrierelage dienende Aluminiumlage 18 ist im dargestellten Beispiel 8 bis 10 µm, vorzugsweise 9 µm dick.

Bereits ein Folienverbund aus den Lagen 12, 14, 16 und 18 ist ein stabiler Verbund, welcher zur Herstellung einer Verpackung für Produkte hervorragend geeignet ist, die pharmazeutische Wirkstoffe enthalten, wie Nikotin, Fentanyl oder Lidocain.

Um den genannten Verbund aus den Lagen 12, 14, 16 und 18 gegen ein unerwünschtes Öffnen bzw. Zerreißen durch neugierige Kinder zu schützen, die so an einen für Kinder gänzlich ungeeigneten verpackten pharmazeutischen Wirkstoff gelangen könnten, ist mittels einer Lage 20 aus lösungsmittelhaltigem Kaschierkleber mit einem Auftragsgewicht von 3 g/m² eine Lage 22 aus biaxial orientiertem Kunststoff, vorzugsweise aus Polyethylenterephthalat oder Polyamid, auf die von der COC-Lage 12 abgewandte Seite der Aluminiumlage 18 aufkaschiert.

Die Lage 22 kann an ihrer von der Aluminiumlage 18 wegweisenden Seite bedruckt sein, um einem Verbraucher Produktinformationen über ein mit dem Folienverbund 10 verpacktes Produkt mitzuteilen. Dann kann die Lage 22 eine der COC-Lage 12 entgegengesetzte außen liegende Lage des Folienverbunds 10 sein.

Anstelle einer Kunststofflage 22 kann die Lage 22 auch eine Papierlage sein.

Im dargestellten Beispiel von Figur 1 weist der Folienverbund 10 zusätzlich zur Kunststofflage 22, verbunden mittels einer weiteren Kaschierkleberlage 24 aus lösungsmittelhaltigem Kaschierkleber, eine außen liegende Papierlage 26 auf.

Die Papierlage 26 kann auf ihrer nach außen weisenden freiliegenden Fläche 26a bedruckt sein. Die Bedruckung kann durch eine Schutzschicht, etwa Klarlack, abgedeckt sein.

Im dargestellten Beispiel weist die Kunststofflage 22 eine Dicke von etwa 22,7 bis 23,3 µm auf. Die Papierlage 26 weist dagegen eine Dicke von etwa 39,5 bis 40,5 µm bei einem Flächengewicht von etwa 40 g/m² auf.

Die Gesamtdicke des Folienverbunds 10 beträgt somit zwischen 108,4 µm und 110,6 µm.

Der Folienverbund 10 weist nicht nur hervorragende Barriereeigenschaften gegen eine Migration und Diffusion von pharmazeutischen Wirkstoffen oder ihren Bestandteilen von der Außenfläche 12a der COC-Lage 12 zur Außenfläche 26a der Papierlage 26 auf. Der Folienverbund 10 hat überdies eine zur Bildung einer Verpackung sehr gut geeignete Steifigkeit und hervorragende Laufeigenschaften auf Verarbeitungsmaschinen zur Verarbeitung des Folienverbunds 10.

In Figur 2 ist eine aus zwei Folienverbundflecken des Folienverbunds 10 von Figur 1 gebildete Verpackung 30 zur Verpackung von flächigen Trägern von pharmazeutischen Wirkstoffen in Draufsicht gezeigt. Wegen der Draufsicht ist nur ein Folienverbundfleck 32 erkennbar. Ein weiterer Folienverbundfleck 33 befindet sich hinter dem in Figur 2 dargestellten Folienverbundfleck 32 und wird durch diesen verdeckt (siehe Figur 3). Man blickt in Figur 2 auf die Außenseite 26a der Papierlage 26 des Folienverbundflecks 32. Als "Folienverbundfleck" im Sinne der vorliegenden Anmeldung gilt jeder vorbestimmte Zuschnitt aus einem Folienverbund, unabhängig von der Art des Zuschnitts. Der Zuschnitt kann daher auch gestanzt oder dergleichen sein.

Die Verpackung 30 ist in Gestalt eines Vier-Rand-Siegelbeutels gebildet, mit einer umlaufenden Siegelnaht 34. Radial innerhalb der Siegelnaht 34 befindet sich ein Träger-Aufnahmeraum 36, in welchem ein flächiger Träger 38 eines pharmazeutischen Werkstoffs (siehe Figur 3) aufgenommen ist.

Als Aufreißhilfe kann die Verpackung 30 an wenigstens einer Stelle, etwa in einem Randbereich, eine Kerbe 40 aufweisen.

Figur 3 zeigt einen Längsschnitt durch die Verpackung 30 von Figur 2 längs der Schnittebene III-III von Figur 2. Die Schnittebene III-III ist orthogonal zur Zeichenebene von Figur 2 orientiert.

In Figur 3 ist im Längsschnitt durch die Folienverbundflecke 32 und 33 die Lagenverteilung innerhalb der Flecke 32 und 33 nicht mehr eigens dargestellt. Sie entspricht der in Figur 1 dargestellten Lagenverteilung des Folienverbunds 10. Die beiden COC-Lagen 12 der jeweiligen Folienverbundflecke 32 und 33 sind aufeinander zuweisend angeordnet und längs der Siegelnaht 34 miteinander verschweißt. In dem radial innerhalb der Siegelnaht 34 gebildeten Träger-Aufnahmeraum 36 ist ein transdermales Pflaster 39 als flächiger Träger 38 eines pharmazeutischen Wirkstoffs aufgenommen. Der Träger-Aufnahmeraum 36 ist somit durch die Siegelnaht 34 nach radial außen begrenzten orthogonal hierzu durch die beiden Folienverbundflecke 32 und 33.

Die Siegelnaht 34 erstreckt sich in Dickenrichtung der jeweiligen Folienverbundflecke 32 und 33 nicht nur über die auch als Siegellage dienenden jeweiligen COC-Lagen 12, sondern über diese COC-Lagen 12 hinaus auch in die Polyethylenlagen 14 hinein. Die Siegelnaht 34 wird somit gebildet durch die sich vor der Siegelung berührenden COC-Lagen 12 der beiden Folienverbundflecke 32 und 33 und durch Material der aus Sicht der Berührstelle der beiden COC-Lagen 12 vor Herstellung des Siegelnaht 34 hinter den jeweiligen COC-Lagen 12 gelegenen Polyethylenlagen 14. Da es sich bei dem Material der COC-Lagen 12 ebenso wie bei dem Material der Polyethylenlagen 14 um ein Olefin handelt, sind die Materialien der beiden Lagen 12 und 14 miteinander kompatibel und können sich in der Siegelnaht 34 mischen.

Ansprüche

1. Folienverbund (10) zur Herstellung einer Verpackung (30) für flächige Träger (38) von pharmazeutischen Wirkstoffen, umfassend in Richtung von der Außenseite (26a) des Folienverbunds (10) zu seiner Innenseite (12a) eine Metalllage (18), eine Acrylsäure-haltige Verbindungslage (16), eine Polyethylenlage (14) und eine COC-Lage (12) aus Cycloolefin-Copolymer, wobei eine von der Metalllage (18) abgewandte Seite (12a) der COC-Lage (12) eine freiliegende Fläche des Folienverbunds (10) ist,
dadurch gekennzeichnet, dass die Polyethylenlage (14) Metallocen-Polyethylen umfasst.

2. Folienverbund (10) nach Anspruch 1,
dadurch gekennzeichnet, dass der Anteil an Metallocen-Polyethylen am gesamten Polyethylen der Polyethylenlage (14) wenigstens 50 Gew.-% umfasst.

3. Folienverbund (10) nach Anspruch 1 oder 2,
dadurch gekennzeichnet, dass die Polyethylenlage (14) ein Metallocen-LLDPE umfasst.

4. Folienverbund (10) nach einem der vorhergehenden Ansprüche,
dadurch gekennzeichnet, dass die Polyethylenlage (14) ein Metallocen-Polyethylen C6 oder/und ein Metallocen-Polyethylen C8 umfasst.

5. Folienverbund (10) nach Anspruch 4,
dadurch gekennzeichnet, dass die Polyethylenlage (14) als Metallocen-Polyethylen nur ein Metallocen-Polyethylen C8 umfasst.

6. Folienverbund (10) nach einem der vorhergehenden Ansprüche,
dadurch gekennzeichnet, dass die Acrylsäure-haltige Verbindungslage (16) ein Ethylen-Acrylsäure-Copolymer umfasst oder aus diesem besteht.

7. Folienverbund (10) nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, dass jede der Lagen (16, 14, 12) aus Acrylsäure-haltiger Verbindungslage (16), Polyethylenlage (14) und COC-Lage (12) eine Lagendicke im Bereich von etwa 7 µm bis 15µm, vorzugsweise im Bereich von 9 µm bis 12 µm aufweist, wobei sich bevorzugt die Dickenwerte der genannten Lagen (16, 14, 12) – bezogen auf die dünnste (12) der genannten Lagen (16, 14, 12) – um nicht mehr als 15 %, vorzugsweise um nicht mehr als 11 % unterscheiden.

8. Folienverbund (10) nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, dass er auf der von der COC-Lage (12) abgewandten Seite der Metalllage (18) wenigstens eine weitere Lage (22, 26) aus Papier oder/und Kunststoff aufweist.

9. Folienverbund (10) nach Anspruch 8, **dadurch gekennzeichnet**, dass er auf der von der COC-Lage (12) abgewandten Seite der Metalllage (18) sowohl eine weitere Lage (26) aus Papier als auch eine weitere Lage (22) aus Kunststoff aufweist, wobei bevorzugt die Kunststofflage (22) näher bei der Metalllage (18) gelegen ist als die Papierlage (26).

10. Folienverbund (10) nach Anspruch 8 oder 9, **dadurch gekennzeichnet**, dass die weitere Lage (22) aus Kunststoff ein orientierter, vorzugsweise biaxial orientierter Kunststoff ist.

11. Folienverbund (10) nach einem der Ansprüche 8 bis 10, **dadurch gekennzeichnet**, dass die weitere Lage (22) aus Kunststoff Polyethylenterephthalat oder/und Polyamid ist.

12. Folienverbund (10) nach einem der Ansprüche 8 bis 11, **dadurch gekennzeichnet**, dass die weitere Lage (26) aus Papier eine Dicke von 35 bis 45 µm, insbesondere von 39 bis 41 µm aufweist, oder/und ein Flächengewicht von 35 bis 45 g/m², insbesondere von 39 bis 41 g/m² aufweist,

oder/und
dass die weitere Lage (22) aus Kunststoff eine Dicke von 19 bis 27 µm, insbesondere von 22 bis 24 µm aufweist oder/und ein Flächengewicht von 28 bis 36 g/m², insbesondere von 31 bis 33 g/m² aufweist.

13. Verpackung (30) für einen flächigen Träger (38) von pharmazeutischen Wirkstoffen, wie beispielsweise ein transdermales Pflaster (39), umfassend zwei Folienverbundflecke (32, 33) aus je einem Folienverbund (10) gemäß einem der vorhergehenden Ansprüche, welche unter Bildung eines Träger-Aufnahmeraums (36) mit aufeinander zuweisenden COC-Lagen (12) angeordnet und durch abschnittsweises Siegeln von COC-Lagenbereichen miteinander verbunden sind.

14. Verpackung (30) nach Anspruch 13,
dadurch gekennzeichnet, dass sie ein Vier-Rand-Siegelbeutel mit um den Träger-Aufnahmeraum (36) umlaufender Siegelnaht (34) ist.

15. Verpackung (30) nach Anspruch 13 oder 14 mit einem im Träger-Aufnahmeraum (36) aufgenommenen flächigen Wirkstoffträger (38), insbesondere transdermalem Pflaster (39), wobei der pharmazeutische Wirkstoff Nikotin oder/und Fentanyl oder/und Lidocain enthält.

Zusammenfassung

Die vorliegende Erfindung betrifft einen Folienverbund (10) zur Herstellung einer Verpackung für flächige Träger von pharmazeutischen Wirkstoffen, wie beispielsweise transdermale Pflaster, umfassend in Richtung von der Außenseite (26a) des Folienverbunds (10) zu seiner Innenseite (12a) eine Metalllage (18), eine Acrylsäure-haltige Verbindungslage (16), eine Polyethylenlage (14) und eine COC-Lage (12) aus Cycloolefin-Copolymer, wobei eine von der Metalllage (18) abgewandte Seite (12a) der COC-Lage (12) eine freiliegende Fläche des Folienverbunds (10) ist. Erfindungsgemäß ist vorgesehen, dass die Polyethylenlage (14) Metallocen-Polyethylen umfasst.

(Fig. 1)

Fig. 1

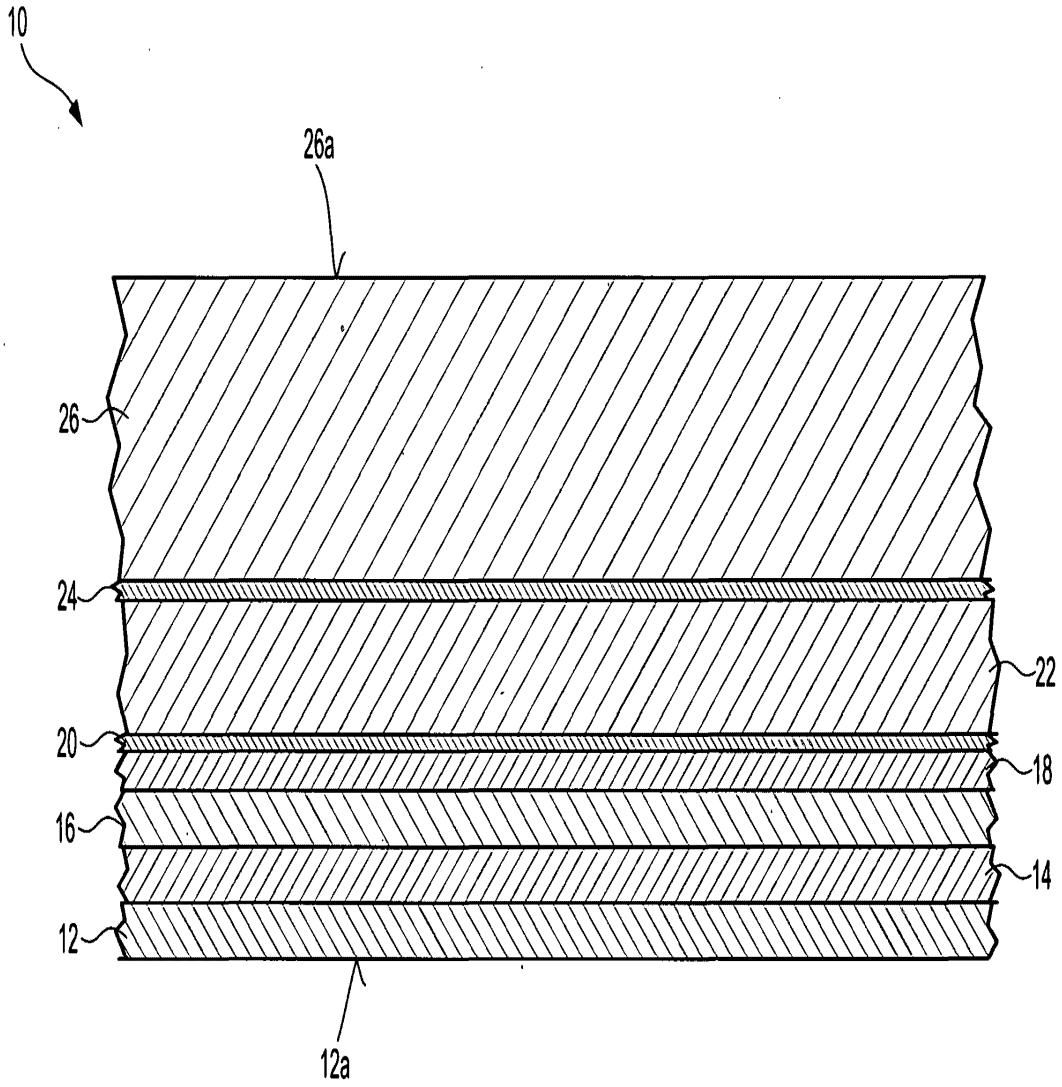


Fig. 2

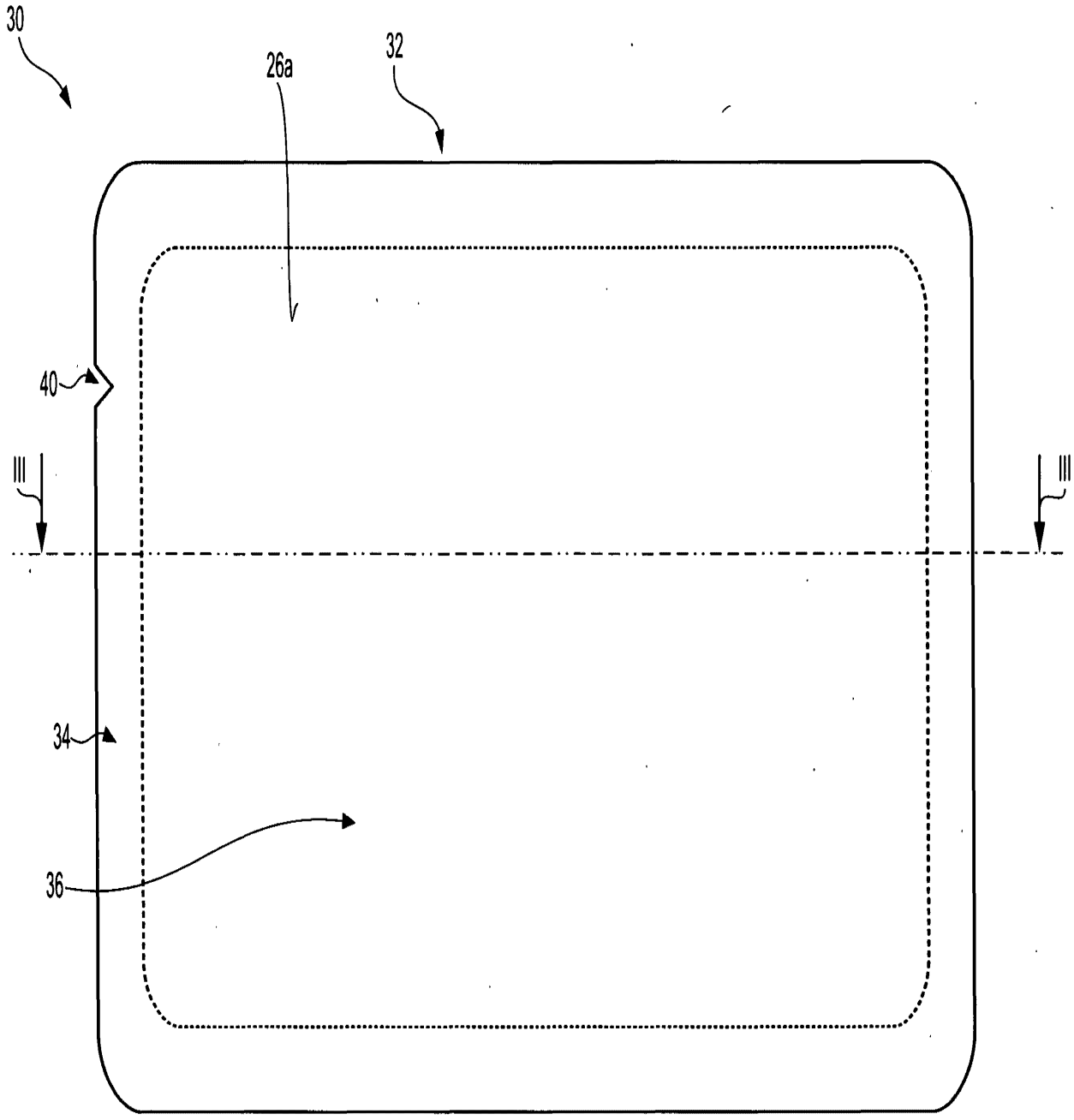
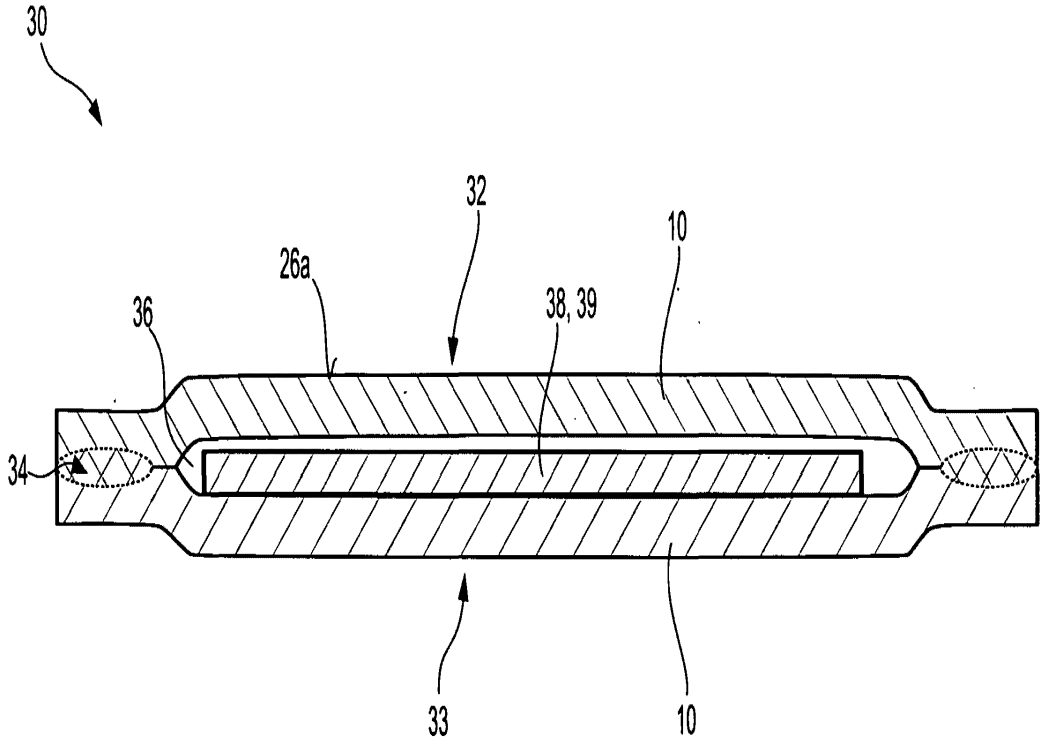


Fig. 3



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Application No.	:	16/516,792	Confirmation No. 2546
Inventor(s)	:	Manuella Herb et al.	
Filed	:	July 19, 2019	
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Docket No.	:	TRO-45953	
Customer No.	:	075626	

SUBMISSION OF PRIORITY DOCUMENT

Commissioner for Patents
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Alexandria, VA 22313-1450

Sir:

Enclosed are certified copies of German Patent Application Nos. 10 2018 212 303.9 and 10 2018 125 195.5; the priority of which have been claimed in the above-identified application.

Respectfully submitted,

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Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Assignment For Published Patent Application

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A proper domestic benefit claim must be provided in an Application Data Sheet in order to constitute a claim for domestic benefit. See 37 CFR 1.76 and 1.78.

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)
GERMANY 10 2018 212 303.9 07/24/2018
GERMANY 10 2018 125 195.5 10/11/2018

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/516,792**

Projected Publication Date: 01/30/2020

Non-Publication Request: No

Early Publication Request: No

Title

FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

Preliminary Class

428

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/516,792

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	660
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	* 2			OR	x 100 =	200
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 460 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1920

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

PTO/AIA/80 (07-12)
Approved for use through 11/30/2014. OMB 0651-0035
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I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

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OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

☒ The address associated with Customer Number: 75626

OR

☐	Firm or Individual Name			
	Address			
	City		State	Zip
	Country			
	Telephone		Email	

Assignee Name and Address: Huhtamaki Flexible Packaging Germany GmbH & Co. KG
Heinrich-Nicolaus-Strasse 6
87671 Ronsberg
Germany

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	ppa. [signature]	Date	13/02/2015
Name	Manfred Merz	Telephone	
Title	General Manager BU Food & Beverage		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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REMARKS

If clarification of the amendment or application is desired, or if issues are present which the Examiner believes may be quickly resolved, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

This Amendment does not include new matter.

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,

RANKIN, HILL & CLARK LLP

By /Gregory S. Vickers/
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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. (New) 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. (New) 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. (New) The film composite according to Claim 16, wherein the polyethylene layer encompasses a metallocene LLDPE.

19. (New) 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. (New) The film composite according to Claim 19, wherein the polyethylene layer encompasses only a C8 metallocene polyethylene as a metallocene polyethylene.

21. (New) The film composite according Claim 16, wherein the acrylic-acid-containing joining layer encompasses or is made of an ethylene-acrylic acidEAA copolymer.

22. (New) 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. (New) 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. (New) 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. (New) 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. (New) 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. (New) 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. (New) 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. (New) The film composite according to Claim 28, wherein the at least one further layer includes a paper layer and a plastic layer.

30. (New) The film composite according to Claim 29, wherein the plastic layer is located closer to the metal layer than the paper layer.

31. (New) 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. (New) 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. (New) 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. (New) 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. (New) 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. (New) 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. (New) 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	Not Yet Assigned	Confirmation No. N/A
Inventor(s)	:	Manuella Herb et al.	
Filed	:	Herewith	
TC/A.U.	:	N/A	
Examiner	:	N/A	
Title	:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	
Docket No.	:	TRO-45953	
Customer No.	:	075626	

PRELIMINARY AMENDMENT "A"

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

Prior to calculating the filing fee and prior to substantive examination of the above-identified patent application, please amend the 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	Not Yet Assigned	Confirmation No. N/A
Inventor(s)	:	Manuella Herb et al.	
Filed	:	Herewith	
TC/A.U.	:	N/A	
Examiner	:	N/A	
Title	:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	
Docket No.	:	TRO-45953	
Customer No.	:	075626	

SUBSTITUTE SPECIFICATION
(Filed under §1.125(b))

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

Sir:

Enclosed herewith is a substitute specification for filing in the above-identified application. The undersigned hereby certifies that the substitute specification includes no new matter. A marked-up copy of the substitute specification showing the matter being added to and the matter being deleted from the specification of record is also included.

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,

RANKIN, HILL & CLARK LLP

By /Gregory S. Vickers/
Gregory S. Vickers, Reg. No. 45180

23755 Lorain Road, Suite 200
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(440) 614-0604

ABSTRACT OF THE DISCLOSURE

a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, 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 provision is made that the polyethylene layer encompasses metallocene polyethylene.

SUBSTITUTE SPECIFICATION - CLEAN

FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

The present invention relates to a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, encompassing, in a direction from the designated outer side of the film composite toward its designated 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.

BACKGROUND OF THE INVENTION

A film composite of this kind, for the aforesaid purpose of manufacturing a package for pharmaceutical active-substance carriers, is known from WO 2015/123211 A1. The film composite of the species comes into direct contact with the planar carrier of a pharmaceutical active substance, and thus with the pharmaceutical active substance itself. The relevant pharmaceutical active substances are active substances such as nicotine, fentanyl, or lidocaine. The stress on the film composite produced by these pharmaceutical active substances is considerable. It is necessary to ensure in this context on the one hand that the film composite survives as such over the long term in order to prevent undesired release of the pharmaceutical active substance of the active-substance carrier. Even if the film composite survives, i.e., does not at least locally delaminate, for example, under the influence of the pharmaceutical active substance diffusing into composite layers, it is necessary on the other hand to ensure that the pharmaceutical active substance cannot diffuse or migrate through the film composite.

In order to increase the diffusion barrier effect of the film composite with respect to the pharmaceutical active substances packaged by it, it is known to select the proportion of cycloolefin copolymer (COC) in the COC layer that is innermost in the subsequent

package to be as high as possible. As the COC concentration in the COC layer rises, however, it becomes increasingly difficult to maintain the stability of the film composite, for example to prevent delamination or similar disintegration phenomena.

WO 2017/114922 A1 also discloses film composites for creating packages for planar pharmaceutical active substance carriers.

SUMMARY OF THE INVENTION

An object of the present invention is therefore to embody the film composite recited initially with the greatest possible chemical and mechanical stability with regard to the pharmaceutical active substances that are to be packaged, in light of its purpose of constituting a safe, including childproof, package for planar pharmaceutical active-substance carriers.

This object is achieved according to the present invention by a film composite of the kind recited initially in which the polyethylene layer encompasses metallocene polyethylene. The reason is that experiments have shown that given otherwise identical dimensions for the film composite, adhesion of the COC layer to the polyethylene layer is considerably better when the polyethylene layer encompasses metallocene polyethylene. "Metallocene polyethylene" in this context is polyethylene that has been manufactured in known fashion using metallocene catalysts.

The higher the COC concentration in the COC layer, the greater the gain in adhesion, in terms of the adhesive effect between the COC layer and the polyethylene layer, which is achievable by the use of metallocene polyethylene as compared with conventional polyethylene. Because the COC layer comprises a COC proportion that is as high as possible (at least 95 wt%, preferably at least 99.8 wt%, of the mass of the COC as a whole) in order to achieve a maximum barrier effect with respect to pharmaceutical active substances that are stored in the planar active-substance carrier, a particularly significant adhesion advantage can be achieved with the utilization, as presented here, of

metallocene polyethylene in the polyethylene layer arranged between the acrylic-acid-containing joining layer and the COC layer.

In doubtful cases, for example if more than one polymer layer of the film composite contains COC, a COC layer is to be considered a "COC layer" for purposes of the present Application only if it contains at least 50 wt% COC in terms of its layer mass. The aforesaid polyethylene layer that contains metallocene polyethylene is preferably devoid of COC.

In principle, an improvement in the adhesion of the COC layer to the polyethylene layer can already be achieved with comparatively small quantities of metallocene polyethylene. In a context of comparative samples of different film-composite sheets that are otherwise dimensionally identical, the improvement in the adhesive effect is particularly large if the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer is at least 50 wt%. It is therefore also possible in principle to use so-called polyethylene blends, in which metallocene polyethylene is blended with non-metallocene polyethylene, to constitute the polyethylene layer.

Because of the advantageous adhesion-enhancing effect of metallocene polyethylene, the proportion thereof (always in percent by weight) in terms of the total polyethylene contained in the polyethylene layer is preferably as high as possible, preferably higher than 90 wt%, particularly preferably higher than 96 wt%.

It has proven to be advantageous, in order to enhance the adhesion effect and also the processability of the film composite on corresponding processing machines to produce packages constituted therefrom, if the polyethylene layer encompasses a metallocene LLDPE. The polyethylene layer preferably encompasses only metallocene LLDPE as the metallocene polyethylene.

In order to achieve good running properties for a film-composite web in the aforementioned processing machines, the density of the metallocene polyethylene is advantageously in a range between 0.917 and 0.921 g/m^2. In order to achieve permanent

sealed seams with high strength and high density, the metallocene polyethylene additionally or alternatively has a melt flow index (melt flow rate, MFR) of between 6 and 10 g/10 min., measured per ISO 1133 at a test temperature of 190°C and using a test element having a weight of 2.16 kg. This is because in addition to the COC, the polyethylene layer, constituting the external barrier layer and sealing layer, can contribute to sealed join of the film composite.

Any type of metallocene polyethylene in the polyethylene layer provides a desired enhancement of the adhesion effect of the COC layer on the polyethylene layer, compared with a polyethylene layer of the same dimensions and/or the same weight per unit area in the film composite. In addition, however, the rigidity of the polyethylene layer, and thus of the film composite as a whole, can be influenced by using different types of metallocene polyethylene. Advantageous rigidity of the polyethylene layer, in a context of predefined dimensions thereof, can be obtained by the fact that the polyethylene layer encompasses a C6 metallocene polyethylene and/or a C8 metallocene polyethylene, or is made of the aforesaid types of metallocene polyethylene. According to previous experiments, for a predefined film composite and in particular for a predefined dimension and/or weight per unit area of the polyethylene layer, C8 metallocene polyethylene offers the best results in terms of achieving on the one hand layer rigidity of the polyethylene layer and on the other hand composite rigidity of the film composite.

It is understandably advantageous for that reason if the polyethylene layer encompasses only a C8 metallocene polyethylene as a metallocene polyethylene. Based on what is stated above, it is particularly preferably a C8 metallocene LLDPE.

The polyethylene layer is preferably applied using the extrusion method, particularly preferably coextruded with the COC layer.

A commercially available metallocene polyethylene that is outstandingly applicable as a polyethylene layer in the aforesaid film composite is the polyethylene obtainable from the Dow Chemical Company under the trade name "Elite™ 5811."

In order to achieve the greatest possible adhesion effect for the partial composite, made up of a polyethylene layer and COC layer, on the metal layer, the acrylic-acid-containing joining layer preferably encompasses or is made of an ethylene-acrylic acid (EAA) copolymer.

The acrylic-acid-containing joining layer is preferably also applied onto the metal layer by extrusion. Particularly preferably, a partial composite made up of an acrylic-acid-containing joining layer, in particular an EAA layer; a polyethylene layer; and a COC layer is applied onto the metal layer by coextrusion in one collective extrusion step.

The metal layer serves as an oxygen barrier and gas barrier to protect package contents from external influences, and furthermore as a barrier for pharmaceutical active substances and constituents thereof which reach the metal layer as a result of diffusion through the COC layer, the polyethylene layer, and the acrylic-acid-containing joining layer.

Preferably each of the layers, from among the acrylic-acid-containing joining layer, polyethylene layer, and COC layer, has a layer thickness in the range from approximately 7 µm to 15 µm. On the one hand this ensures outstanding attachment to the metal layer; on the other hand, in this thickness range not only the COC layer but also the polyethylene layer can serve to produce a sealed join to the COC layer of a film composite of similar construction. Because, in the instance recited, the polyethylene layer located below the COC layer can also contribute in particularly effective and reliable fashion to production of a sealing join, the values indicated above for the melt flow index (MFR) are highly advantageous in terms of achieving outstanding sealing properties for the film composite having the exposed COC layer. The thickness values of the three, preferably coextruded layers (acrylic-acid-containing joining layer, polyethylene layer, and COC layer) are preferably each in the range from 9 µm to 12 µm. In order to achieve outstanding sealing properties with the involvement not only of the COC layer as an external sealing layer but also the polyethylene layer located therebelow, there is preferably little difference

between the layer thicknesses of the polyethylene layer and of the COC layer. In order to achieve optimum attachment of the COC layer and the polyethylene layer to the metal layer without thereby making the film composite undesirably thick, the thickness of the acrylic-acid-containing joining layer also preferably differs little from the thickness of the two layers recited above (polyethylene layer and COC layer). The thickness values of the aforesaid layers, referred to the thinnest of the aforesaid layers, preferably differ by no more than 15%, preferably by no more than 11%. A triple composite made up of an acrylic-acid-containing joining layer, a polyethylene layer, and a COC layer can then easily be coextruded, the resulting film composite then exhibiting very good running properties on processing machines for processing the film composite to yield a package, and furthermore exhibiting very good sealing properties.

In principle, the film composite can be used as it is described above. For further protection of the film composite it can have, on that side of the metal layer which faces away from the COC layer, at least one further layer made of paper and/or plastic. As a result, the metal layer is a completely internal layer of the film composite, and as such is better protected from external influences. Because the COC layer as a rule is an entirely internally located layer of a package constituted from the film composite, provision of the at least one further layer simplifies the application of product information onto the outer side of the film composite which faces toward the consumer, which information would otherwise need to be applied, with greater complexity, onto the metal layer.

The at least one further layer is preferably laminated onto the metal layer or onto a further layer already present thereon. A solvent-containing laminating adhesive having a coating weight per unit area of 2 to 4 g/m^2, preferably having a coating weight per unit area of 3 g/m^2, is preferably used for this.

For easy imprinting and for child safety of a package constituted from the film composite, in order to prevent undesired opening and exposure of the pharmaceutical active substances packaged therein, the film composite preferably comprises, on that side of the metal layer which faces away from the COC layer, both a further layer made of paper

and a further layer made of plastic. Because of the particular easy imprintability of the paper layer and thus a particularly simple and inexpensive capability for equipping the film composite, and/or a package constituted therewith, with consumer information, the plastic layer is preferably located closer to the metal layer than is the paper layer. The paper layer is preferably an external layer of the film composite. A imprint printed onto the paper layer can be at least partly, or preferably completely, covered by a protective layer, for example a clear lacquer.

To protect against undesired tearing by children, the further layer made of plastic is preferably a biaxially oriented plastic.

In experiments, polyethylene terephthalate and/or polyamide have proven successful as a plastic for the at least one further plastic layer. Plastic layers made of the aforesaid plastics have sufficient mechanical and thermal stability and, especially in oriented form, provide a further barrier effect against diffusion of gases and vapors. The further plastic layer can thus, in one direction, protect the metal layer from chemical attack from outside, and in the opposite direction can additionally retain the pharmaceutical active substance, or constituents thereof, if they happen to pass through the metal layer.

When the film composite has a further layer made of paper on that side of the metal layer which faces away from the COC layer, that paper layer preferably has a thickness of 35 to 45 µm, particularly preferably 39 to 41 µm. Additionally or alternatively, the further layer made of paper can have a weight per unit area of 35 to 45 g/m^2, in particular 39 to 41 g/m^2.

When the film composite has, on that side of the metal layer which faces away from the COC layer, a further layer made of plastic, the latter layer preferably has a thickness of 19 to 27 µm, in particular 22 to 24 µm. Additionally or alternatively, the additional layer made of plastic has a weight per unit area of 28 to 36 g/m^2, in particular 31 to 33 g/m^2. These values for thickness and weight per unit area offer a very good compromise among

sufficient mechanical strength, thermal stability, and low overall thickness for the film composite.

Because the above-described film composite is particularly suitable for manufacturing a package for a planar carrier of pharmaceutical active substances, for example a transdermal patch, the present invention also relates to such a package encompassing two film-composite sheets each made of a film composite as described and refined above. The film-composite sheets are arranged with mutually facing COC layers to form a carrier receiving space, and are joined to one another by local sealing of COC layer regions. Portions of the mutually facing COC layer regions are sealed to one another, preferably with participation of the polyethylene layer that has metallocene polyethylene and is located below the COC layers. The sealed seam then preferably encompasses a mixture of COC and metallocene polyethylene. The sealed seam then extends, in a thickness direction, into the polyethylene layer. Other portions of the mutually facing COC layer regions of the two film-composite sheets are located unjoinedly opposite one another. When a planar carrier of pharmaceutical active substances is received in the package, said carrier is located between respective oppositely located portions, unjoined to one another, of a COC layer of a film-composite sheet involved in the constitution of the package.

A "planar carrier of pharmaceutical active substances" is understood to be a substrate that respectively has, in its two principal directions of extent that are orthogonal to one another and to the substrate thickness direction, dimensions that are at least 10 times, preferably at least 30 times, greater than the dimension of the substrate in a thickness direction, and that is embodied to release a pharmaceutical active substance stored in the substrate.

To save space while providing durably effective shielding of the pharmaceutical active substance packaged therein, the package can be a four-side-sealed pouch having a sealed seam surrounding the carrier receiving space.

A planar active-substance carrier received in the carrier receiving space of the package as described above is preferably a transdermal patch. The pharmaceutical active substance in the active-substance carrier preferably encompasses nicotine and/or fentanyl and/or lidocaine and/or another known active substance for administration by means of a transdermal patch.

The "designated" internal or external side of the film composite refers respectively to that side of the film composite which respective constitutes, on a package subsequently constituted from the film composite, a portion of the inner side or the outer side of the package.

The film composite preferably comprises only the layers recited in the present Application.

These and other objects, aspects, features and advantages of the invention will become apparent to those skilled in the art upon a reading of the Detailed Description of the invention set forth below taken together with the drawings which will be described in the next section.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take physical form in certain parts and arrangement of parts, a preferred embodiment of which will be described in detail and illustrated in the accompanying drawings which form a part hereof and wherein:

FIG. 1 is a cross-sectional view through an embodiment according to the present invention of a film composite of the present Application;

FIG. 2 is a plan view of a package, constituted with participation of the film composite of FIG. 1, of a transdermal patch; and

FIG. 3 is a cross-sectional view of the package of FIG. 2 along section plane III-III of FIG. 2.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawings wherein the showings are for the purpose of illustrating preferred and alternative embodiments of the invention only and not for the purpose of limiting the same, in FIG. 1, an embodiment according to the present invention of a film composite of the present Application is labeled in general with the number 10. The depiction in FIG. 1 is merely schematic. In particular, the thicknesses of the individual layers of film composite 10 are not illustrated accurately to scale. Film composite 10 has on its designated inner side a COC layer 12 that has a COC content of approximately 99.8 wt%. The proportion of COC in COC layer 12 is selected to be as high as possible in order to provide, with COC layer 12, an optimum barrier layer against migration and diffusion of pharmaceutical active substances such as nicotine and/or fentanyl and/or lidocaine. A surface 12a of COC layer 12 constitutes an exposed outer surface of film composite 10. COC layer 12 preferably has a thickness of 9.8 to 10.0 µm.

A polyethylene layer 14 is joined to COC layer 12 by coextrusion. Polyethylene layer 14 is preferably devoid of COC, and encompasses at least 50 wt% metallocene polyethylene, preferably C8 metallocene LLDPE. In the example depicted, the proportion of C8 metallocene LLDPE in terms of the total polyethylene mass of polyethylene layer 14 is more than 95 wt%. Extremely good adhesion of COC layer 12 to polyethylene layer 14, and thus good protection from delamination, are thereby achieved. The use of C8 metallocene LLDPE, as opposed to the C4 or C6 types that are also possible, results not only in good adhesion of COC layer 12 to a polyethylene layer 14 but also in a polyethylene layer 14 having advantageous rigidity properties. The melt flow index (MFR) of polyethylene layer 14 is approximately 8 g/10 min., measured per ISO 1133 at a test temperature of 190°C using a test weight of 2.16 kg. The density of polyethylene layer 14 is preferably 0.919 g/m^2.

Thanks to the value selected for the melt flow index, although polyethylene layer 14 is not an external layer of film composite 10 it can participate in a sealed join of film composite 10 on COC layer 12 side. High sealing strength values, and a very high-quality sealed

seam, are thereby achieved. COC layer 12 is not only a barrier layer of film composite, but also its sealable layer.

In the example depicted, the thickness of polyethylene layer 14 is between 10.8 and 11.0 µm. Polyethylene layer 14 and COC layer 12 are thus of approximately equal thickness; COC layer 12 can be slightly thinner. This balanced thickness relationship between polyethylene layer 14 and COC layer 12 also contributes to the attainment of permanently strong and diffusion-proof sealed joins.

On the side facing away from COC layer 12, polyethylene layer 14 is joined to a joining layer 16 made of an ethylene-acrylic acid (EAA) copolymer, in order to join COC layer 12 and polyethylene layer 14, by means of joining layer 16, to an aluminum layer 18.

Joining layer 16, which is between 10.6 and 10.8 µm thick in the example depicted, has been coextruded together with polyethylene layer 14 and COC layer 12, and applied onto aluminum layer 18 in the course of coextrusion.

Aluminum layer 18, which serves as a further barrier layer, is 8 to 10 µm thick, preferably 9 µm thick, in the example depicted.

A film composite made up of layers 12, 14, 16, and 18 is already a stable composite that is outstandingly suitable for manufacturing a package for products that contain pharmaceutical active substances such as nicotine, fentanyl, or lidocaine.

In order to protect the aforesaid composite, made up of layers 12, 14, 16, and 18, from being undesirably opened or torn by curious children, who might thereby gain access to a packaged pharmaceutical active substance that is entirely unsuitable for children, a layer 22 made of biaxially oriented plastic, preferably of polyethylene terephthalate or polyamide, is laminated, by means of a layer 20 made of solvent-containing laminating adhesive at an application weight of 3 g/m^2, onto that side of aluminum layer 18 which faces away from COC layer 12.

Layer 22 can be imprinted on its side facing away from aluminum layer 18 product so that information regarding a product that is packaged using film composite 10 can be conveyed to a consumer. Layer 22 can then be an externally located layer, opposite from COC layer 12, of film composite 10.

Layer 22 can also be a paper layer rather than a plastic layer 22.

In the example depicted in FIG. 1 film composite 10 comprises, in addition to plastic layer 22, an externally located paper layer 26 joined by means of a further laminating-adhesive layer 24 made of solvent-containing laminating adhesive.

Paper layer 26 can be imprinted on its outward-facing exposed surface 26a. The imprint can be covered by a protective layer, for example clear lacquer.

In the example depicted, plastic layer 22 has a thickness of approximately 22.7 to 23.3 µm. Paper layer 26, on the other hand, has a thickness of approximately 39.5 to 40.5 µm at a weight per unit area of approximately 40 g/m^2.

The total thickness of film composite 10 is thus between 108.4 µm and 110.6 µm.

Film composite 10 not only has outstanding barrier properties with respect to migration and diffusion of pharmaceutical active substances or constituents thereof from outer surface 12a of COC layer 12 to outer surface 26a of paper layer 26. The rigidity of film composite 10 is furthermore very suitable for constitution of a package, and it has outstanding running properties on processing machines for processing film composite 10.

FIG. 2 is a plan view of a package 30 constituted from two film-composite sheets of film composite 10 of FIG. 1, for packaging planar carriers of pharmaceutical active substances. Because of the plan view, only one film-composite sheet 32 is visible. A further film-composite sheet 33 is located behind film-composite sheet 32 depicted in FIG.

2 and is concealed by it (see FIG. 3). The viewer of FIG. 2 is looking onto outer side 26a of paper layer 26 of film-composite sheet 32. A "film-composite sheet" is understood for purposes of the present Application to mean any predetermined piece cut out of a film composite, regardless of the manner of cutting. The cut-out piece can therefore also be stamped or the like.

Package 30 is configured in the form of a four-side-sealed pouch having a surrounding sealed seam 34. Located radially inside sealed seam 34 is a carrier receiving space 36 in which a planar carrier 38 of a pharmaceutical active substance (see FIG. 3) is received.

Package 30 can comprise a notch 40 at at least one point, for example in an edge region, for easier opening.

FIG. 3 is a longitudinal section through package 30 of FIG. 2 along section plane III-III of FIG. 2. Section plane III-III is oriented orthogonally to the drawing plane of FIG. 2.

The distribution of layers within film-composite sheets 32 and 33 is no longer depicted separately in FIG. 3 in the longitudinal section through sheets 32 and 33. That distribution corresponds to the layer distribution of film composite 10 as depicted in FIG. 1. The two COC layers 12 of the respective film-composite sheets 32 and 33 are arranged facing toward one another and are fused to one another along sealed seam 34. A transdermal patch 39, constituting a planar carrier 38 of a pharmaceutical active substance, is received in carrier receiving space 36 that is constituted radially inside sealed seam 34. Carrier receiving space 36 is thus radially externally delimited by sealed seam 34 and orthogonally thereto by the two film-composite sheets 32 and 33.

Sealed seam 34 extends, in a thickness direction of the respective film-composite sheets 32 and 33, not only through the respective COC layers 12 that also serve as sealing layers but also, beyond those COC layers 12, into polyethylene layers 14. Sealed seam 34 is thus constituted by COC layers 12 (which are in contact with one another before sealing) of the two film-composite sheets 32 and 33 and by material of polyethylene layers 14

which are located, from the viewpoint of the contact point of the two COC layers 12 before sealed seam 34 is produced, behind the respective COC layers 12. Because the material of COC layers 12, like the material of polyethylene layers 14, is an olefin, the materials of the two layers 12 and 14 are mutually compatible and can blend with one another in sealed seam 34.

While considerable emphasis has been placed on the preferred embodiments of the invention illustrated and described herein, it will be appreciated that other embodiments, and equivalences thereof, can be made and that many changes can be made in the preferred embodiments without departing from the principles of the invention. Furthermore, the embodiments described above can be combined to form yet other embodiments of the invention of this application. Accordingly, it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation.

SUBSTITUTE SPECIFICATION - MARKED

FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

The present invention relates to a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, encompassing, in a direction from the designated outer side of the film composite toward its designated 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.

BACKGROUND OF THE INVENTION

A film composite of this kind, for the aforesaid purpose of manufacturing a package for pharmaceutical active-substance carriers, is known from WO 2015/123211 A1. The film composite of the species comes into direct contact with the planar carrier of a pharmaceutical active substance, and thus with the pharmaceutical active substance itself. The relevant pharmaceutical active substances are active substances such as nicotine, fentanyl, or lidocaine. The stress on the film composite produced by these pharmaceutical active substances is considerable. It is necessary to ensure in this context on the one hand that the film composite survives as such over the long term in order to prevent undesired release of the pharmaceutical active substance of the active-substance carrier. Even if the film composite survives, i.e., does not at least locally delaminate, for example, under the influence of the pharmaceutical active substance diffusing into composite layers, it is necessary on the other hand to ensure that the pharmaceutical active substance cannot diffuse or migrate through the film composite.

In order to increase the diffusion barrier effect of the film composite with respect to the pharmaceutical active substances packaged by it, it is known to select the proportion of cycloolefin copolymer (COC) in the COC layer that is innermost in the subsequent

package to be as high as possible. As the COC concentration in the COC layer rises, however, it becomes increasingly difficult to maintain the stability of the film composite, for example to prevent delamination or similar disintegration phenomena.

WO 2017/114922 A1 also discloses film composites for creating packages for planar pharmaceutical active substance carriers.

SUMMARY OF THE INVENTION

~~The~~An object of the present invention is therefore to embody the film composite recited initially with the greatest possible chemical and mechanical stability with regard to the pharmaceutical active substances that are to be packaged, in light of its purpose of constituting a safe, including childproof, package for planar pharmaceutical active-substance carriers.

This object is achieved according to the present invention by a film composite of the kind recited initially in which the polyethylene layer encompasses metallocene polyethylene. The reason is that experiments have shown that given otherwise identical dimensions for the film composite, adhesion of the COC layer to the polyethylene layer is considerably better when the polyethylene layer encompasses metallocene polyethylene. "Metallocene polyethylene" in this context is polyethylene that has been manufactured in known fashion using metallocene catalysts.

The higher the COC concentration in the COC layer, the greater the gain in adhesion, in terms of the adhesive effect between the COC layer and the polyethylene layer, which is achievable by the use of metallocene polyethylene as compared with conventional polyethylene. Because the COC layer comprises a COC proportion that is as high as possible (at least 95 wt%, preferably at least 99.8 wt%, of the mass of the COC as a whole) in order to achieve a maximum barrier effect with respect to pharmaceutical active substances that are stored in the planar active-substance carrier, a particularly significant adhesion advantage can be achieved with the utilization, as presented here, of

metallocene polyethylene in the polyethylene layer arranged between the acrylic-acid-containing joining layer and the COC layer.

In doubtful cases, for example if more than one polymer layer of the film composite contains COC, a COC layer is to be considered a "COC layer" for purposes of the present Application only if it contains at least 50 wt% COC in terms of its layer mass. The aforesaid polyethylene layer that contains metallocene polyethylene is preferably devoid of COC.

In principle, an improvement in the adhesion of the COC layer to the polyethylene layer can already be achieved with comparatively small quantities of metallocene polyethylene. In a context of comparative samples of different film-composite sheets that are otherwise dimensionally identical, the improvement in the adhesive effect is particularly large if the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer is at least 50 wt%. It is therefore also possible in principle to use so-called polyethylene blends, in which metallocene polyethylene is blended with non-metallocene polyethylene, to constitute the polyethylene layer.

Because of the advantageous adhesion-enhancing effect of metallocene polyethylene, the proportion thereof (always in percent by weight) in terms of the total polyethylene contained in the polyethylene layer is preferably as high as possible, preferably higher than 90 wt%, particularly preferably higher than 96 wt%.

It has proven to be advantageous, in order to enhance the adhesion effect and also the processability of the film composite on corresponding processing machines to produce packages constituted therefrom, if the polyethylene layer encompasses a metallocene LLDPE. The polyethylene layer preferably encompasses only metallocene LLDPE as the metallocene polyethylene.

In order to achieve good running properties for a film-composite web in the aforementioned processing machines, the density of the metallocene polyethylene is advantageously in a range between 0.917 and 0.921 g/m^2. In order to achieve permanent

sealed seams with high strength and high density, the metallocene polyethylene additionally or alternatively has a melt flow index (melt flow rate, MFR) of between 6 and 10 g/10 min., measured per ISO 1133 at a test temperature of 190°C and using a test element having a weight of 2.16 kg. This is because in addition to the COC, the polyethylene layer, constituting the external barrier layer and sealing layer, can contribute to sealed join of the film composite.

Any type of metallocene polyethylene in the polyethylene layer provides a desired enhancement of the adhesion effect of the COC layer on the polyethylene layer, compared with a polyethylene layer of the same dimensions and/or the same weight per unit area in the film composite. In addition, however, the rigidity of the polyethylene layer, and thus of the film composite as a whole, can be influenced by using different types of metallocene polyethylene. Advantageous rigidity of the polyethylene layer, in a context of predefined dimensions thereof, can be obtained by the fact that the polyethylene layer encompasses a C6 metallocene polyethylene and/or a C8 metallocene polyethylene, or is made of the aforesaid types of metallocene polyethylene. According to previous experiments, for a predefined film composite and in particular for a predefined dimension and/or weight per unit area of the polyethylene layer, C8 metallocene polyethylene offers the best results in terms of achieving on the one hand layer rigidity of the polyethylene layer and on the other hand composite rigidity of the film composite.

It is understandably advantageous for that reason if the polyethylene layer encompasses only a C8 metallocene polyethylene as a metallocene polyethylene. Based on what is stated above, it is particularly preferably a C8 metallocene LLDPE.

The polyethylene layer is preferably applied using the extrusion method, particularly preferably coextruded with the COC layer.

A commercially available metallocene polyethylene that is outstandingly applicable as a polyethylene layer in the aforesaid film composite is the polyethylene obtainable from the Dow Chemical Company under the trade name "Elite™ 5811."

In order to achieve the greatest possible adhesion effect for the partial composite, made up of a polyethylene layer and COC layer, on the metal layer, the acrylic-acid-containing joining layer preferably encompasses or is made of an ethylene-acrylic acid (EAA) copolymer.

The acrylic-acid-containing joining layer is preferably also applied onto the metal layer by extrusion. Particularly preferably, a partial composite made up of an acrylic-acid-containing joining layer, in particular an EAA layer; a polyethylene layer; and a COC layer is applied onto the metal layer by coextrusion in one collective extrusion step.

The metal layer serves as an oxygen barrier and gas barrier to protect package contents from external influences, and furthermore as a barrier for pharmaceutical active substances and constituents thereof which reach the metal layer as a result of diffusion through the COC layer, the polyethylene layer, and the acrylic-acid-containing joining layer.

Preferably each of the layers, from among the acrylic-acid-containing joining layer, polyethylene layer, and COC layer, has a layer thickness in the range from approximately 7 µm to 15 µm. On the one hand this ensures outstanding attachment to the metal layer; on the other hand, in this thickness range not only the COC layer but also the polyethylene layer can serve to produce a sealed join to the COC layer of a film composite of similar construction. Because, in the instance recited, the polyethylene layer located below the COC layer can also contribute in particularly effective and reliable fashion to production of a sealing join, the values indicated above for the melt flow index (MFR) are highly advantageous in terms of achieving outstanding sealing properties for the film composite having the exposed COC layer. The thickness values of the three, preferably coextruded layers (acrylic-acid-containing joining layer, polyethylene layer, and COC layer) are preferably each in the range from 9 µm to 12 µm. In order to achieve outstanding sealing properties with the involvement not only of the COC layer as an external sealing layer but also the polyethylene layer located therebelow, there is preferably little difference

between the layer thicknesses of the polyethylene layer and of the COC layer. In order to achieve optimum attachment of the COC layer and the polyethylene layer to the metal layer without thereby making the film composite undesirably thick, the thickness of the acrylic-acid-containing joining layer also preferably differs little from the thickness of the two layers recited above (polyethylene layer and COC layer). The thickness values of the aforesaid layers, referred to the thinnest of the aforesaid layers, preferably differ by no more than 15%, preferably by no more than 11%. A triple composite made up of an acrylic-acid-containing joining layer, a polyethylene layer, and a COC layer can then easily be coextruded, the resulting film composite then exhibiting very good running properties on processing machines for processing the film composite to yield a package, and furthermore exhibiting very good sealing properties.

In principle, the film composite can be used as it is described above. For further protection of the film composite it can have, on that side of the metal layer which faces away from the COC layer, at least one further layer made of paper and/or plastic. As a result, the metal layer is a completely internal layer of the film composite, and as such is better protected from external influences. Because the COC layer as a rule is an entirely internally located layer of a package constituted from the film composite, provision of the at least one further layer simplifies the application of product information onto the outer side of the film composite which faces toward the consumer, which information would otherwise need to be applied, with greater complexity, onto the metal layer.

The at least one further layer is preferably laminated onto the metal layer or onto a further layer already present thereon. A solvent-containing laminating adhesive having a coating weight per unit area of 2 to 4 g/m^2, preferably having a coating weight per unit area of 3 g/m^2, is preferably used for this.

For easy imprinting and for child safety of a package constituted from the film composite, in order to prevent undesired opening and exposure of the pharmaceutical active substances packaged therein, the film composite preferably comprises, on that side of the metal layer which faces away from the COC layer, both a further layer made of paper

and a further layer made of plastic. Because of the particular easy imprintability of the paper layer and thus a particularly simple and inexpensive capability for equipping the film composite, and/or a package constituted therewith, with consumer information, the plastic layer is preferably located closer to the metal layer than is the paper layer. The paper layer is preferably an external layer of the film composite. A imprint printed onto the paper layer can be at least partly, or preferably completely, covered by a protective layer, for example a clear lacquer.

To protect against undesired tearing by children, the further layer made of plastic is preferably a biaxially oriented plastic.

In experiments, polyethylene terephthalate and/or polyamide have proven successful as a plastic for the at least one further plastic layer. Plastic layers made of the aforesaid plastics have sufficient mechanical and thermal stability and, especially in oriented form, provide a further barrier effect against diffusion of gases and vapors. The further plastic layer can thus, in one direction, protect the metal layer from chemical attack from outside, and in the opposite direction can additionally retain the pharmaceutical active substance, or constituents thereof, if they happen to pass through the metal layer.

When the film composite has a further layer made of paper on that side of the metal layer which faces away from the COC layer, that paper layer preferably has a thickness of 35 to 45 µm, particularly preferably 39 to 41 µm. Additionally or alternatively, the further layer made of paper can have a weight per unit area of 35 to 45 g/m^2, in particular 39 to 41 g/m^2.

When the film composite has, on that side of the metal layer which faces away from the COC layer, a further layer made of plastic, the latter layer preferably has a thickness of 19 to 27 µm, in particular 22 to 24 µm. Additionally or alternatively, the additional layer made of plastic has a weight per unit area of 28 to 36 g/m^2, in particular 31 to 33 g/m^2. These values for thickness and weight per unit area offer a very good compromise among

sufficient mechanical strength, thermal stability, and low overall thickness for the film composite.

Because the above-described film composite is particularly suitable for manufacturing a package for a planar carrier of pharmaceutical active substances, for example a transdermal patch, the present invention also relates to such a package encompassing two film-composite sheets each made of a film composite as described and refined above. The film-composite sheets are arranged with mutually facing COC layers to form a carrier receiving space, and are joined to one another by local sealing of COC layer regions. Portions of the mutually facing COC layer regions are sealed to one another, preferably with participation of the polyethylene layer that has metallocene polyethylene and is located below the COC layers. The sealed seam then preferably encompasses a mixture of COC and metallocene polyethylene. The sealed seam then extends, in a thickness direction, into the polyethylene layer. Other portions of the mutually facing COC layer regions of the two film-composite sheets are located unjoinedly opposite one another. When a planar carrier of pharmaceutical active substances is received in the package, said carrier is located between respective oppositely located portions, unjoined to one another, of a COC layer of a film-composite sheet involved in the constitution of the package.

A "planar carrier of pharmaceutical active substances" is understood to be a substrate that respectively has, in its two principal directions of extent that are orthogonal to one another and to the substrate thickness direction, dimensions that are at least 10 times, preferably at least 30 times, greater than the dimension of the substrate in a thickness direction, and that is embodied to release a pharmaceutical active substance stored in the substrate.

To save space while providing durably effective shielding of the pharmaceutical active substance packaged therein, the package can be a four-~~edge~~side-sealed pouch having a sealed seam surrounding the carrier receiving space.

A planar active-substance carrier received in the carrier receiving space of the package as described above is preferably a transdermal patch. The pharmaceutical active substance in the active-substance carrier preferably encompasses nicotine and/or fentanyl and/or lidocaine and/or another known active substance for administration by means of a transdermal patch.

The "designated" internal or external side of the film composite refers respectively to that side of the film composite which respective constitutes, on a package subsequently constituted from the film composite, a portion of the inner side or the outer side of the package.

The film composite preferably comprises only the layers recited in the present Application.

~~The present invention will be explained in further detail below with reference to the appended drawings, in which:~~These and other objects, aspects, features and advantages of the invention will become apparent to those skilled in the art upon a reading of the Detailed Description of the invention set forth below taken together with the drawings which will be described in the next section.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take physical form in certain parts and arrangement of parts, a preferred embodiment of which will be described in detail and illustrated in the accompanying drawings which form a part hereof and wherein:

FIG. 1 is a cross-sectional view through an embodiment according to the present invention of a film composite of the present Application;

FIG. 2 is a plan view of a package, constituted with participation of the film composite of FIG. 1, of a transdermal patch; and

FIG. 3 is a cross-sectional view of the package of FIG. 2 along section plane III-III of FIG. 2.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawings wherein the showings are for the purpose of illustrating preferred and alternative embodiments of the invention only and not for the purpose of limiting the same, in~~In~~ FIG. 1, an embodiment according to the present invention of a film composite of the present Application is labeled in general with the number 10. The depiction in FIG. 1 is merely schematic. In particular, the thicknesses of the individual layers of film composite 10 are not illustrated accurately to scale. Film composite 10 has on its designated inner side a COC layer 12 that has a COC content of approximately 99.8 wt%. The proportion of COC in COC layer 12 is selected to be as high as possible in order to provide, with COC layer 12, an optimum barrier layer against migration and diffusion of pharmaceutical active substances such as nicotine and/or fentanyl and/or lidocaine. A surface 12a of COC layer 12 constitutes an exposed outer surface of film composite 10. COC layer 12 preferably has a thickness of 9.8 to 10.0 µm.

A polyethylene layer 14 is joined to COC layer 12 by coextrusion. Polyethylene layer 14 is preferably devoid of COC, and encompasses at least 50 wt% metallocene polyethylene, preferably C8 metallocene LLDPE. In the example depicted, the proportion of C8 metallocene LLDPE in terms of the total polyethylene mass of polyethylene layer 14 is more than 95 wt%. Extremely good adhesion of COC layer 12 to polyethylene layer 14, and thus good protection from delamination, are thereby achieved. The use of C8 metallocene LLDPE, as opposed to the C4 or C6 types that are also possible, results not only in good adhesion of COC layer 12 to a polyethylene layer 14 but also in a polyethylene layer 14 having advantageous rigidity properties. The melt flow index (MFR) of polyethylene layer 14 is approximately 8 g/10 min., measured per ISO 1133 at a test temperature of 190°C using a test weight of 2.16 kg. The density of polyethylene layer 14 is preferably 0.919 g/m^2.

Thanks to the value selected for the melt flow index, although polyethylene layer 14 is not an external layer of film composite 10 it can participate in a sealed join of film composite 10 on COC layer 12 side. High sealing strength values, and a very high-quality sealed seam, are thereby achieved. COC layer 12 is not only a barrier layer of film composite, but also its sealable layer.

In the example depicted, the thickness of polyethylene layer 14 is between 10.8 and 11.0 µm. Polyethylene layer 14 and COC layer 12 are thus of approximately equal thickness; COC layer 12 can be slightly thinner. This balanced thickness relationship between polyethylene layer 14 and COC layer 12 also contributes to the attainment of permanently strong and diffusion-proof sealed joins.

On the side facing away from COC layer 12, polyethylene layer 14 is joined to a joining layer 16 made of an ethylene-acrylic acid (EAA) copolymer, in order to join COC layer 12 and polyethylene layer 14, by means of joining layer 16, to an aluminum layer 18.

Joining layer 16, which is between 10.6 and 10.8 µm thick in the example depicted, has been coextruded together with polyethylene layer 14 and COC layer 12, and applied onto aluminum layer 18 in the course of coextrusion.

Aluminum layer 18, which serves as a further barrier layer, is 8 to 10 µm thick, preferably 9 µm thick, in the example depicted.

A film composite made up of layers 12, 14, 16, and 18 is already a stable composite that is outstandingly suitable for manufacturing a package for products that contain pharmaceutical active substances such as nicotine, fentanyl, or lidocaine.

In order to protect the aforesaid composite, made up of layers 12, 14, 16, and 18, from being undesirably opened or torn by curious children, who might thereby gain access to a packaged pharmaceutical active substance that is entirely unsuitable for children, a layer 22 made of biaxially oriented plastic, preferably of polyethylene terephthalate or

polyamide, is laminated, by means of a layer 20 made of solvent-containing laminating adhesive at an application weight of 3 g/m^2, onto that side of aluminum layer 18 which faces away from COC layer 12.

Layer 22 can be imprinted on its side facing away from aluminum layer 18 product so that information regarding a product that is packaged using film composite 10 can be conveyed to a consumer. Layer 22 can then be an externally located layer, opposite from COC layer 12, of film composite 10.

Layer 22 can also be a paper layer rather than a plastic layer 22.

In the example depicted in FIG. 1 film composite 10 comprises, in addition to plastic layer 22, an externally located paper layer 26 joined by means of a further laminating-adhesive layer 24 made of solvent-containing laminating adhesive.

Paper layer 26 can be imprinted on its outward-facing exposed surface 26a. The imprint can be covered by a protective layer, for example clear lacquer.

In the example depicted, plastic layer 22 has a thickness of approximately 22.7 to 23.3 µm. Paper layer 26, on the other hand, has a thickness of approximately 39.5 to 40.5 µm at a weight per unit area of approximately 40 g/m^2.

The total thickness of film composite 10 is thus between 108.4 µm and 110.6 µm.

Film composite 10 not only has outstanding barrier properties with respect to migration and diffusion of pharmaceutical active substances or constituents thereof from outer surface 12a of COC layer 12 to outer surface 26a of paper layer 26. The rigidity of film composite 10 is furthermore very suitable for constitution of a package, and it has outstanding running properties on processing machines for processing film composite 10.

FIG. 2 is a plan view of a package 30 constituted from two film-composite sheets of film composite 10 of FIG. 1, for packaging planar carriers of pharmaceutical active substances. Because of the plan view, only one film-composite sheet 32 is visible. A further film-composite sheet 33 is located behind film-composite sheet 32 depicted in FIG. 2 and is concealed by it (see FIG. 3). The viewer of FIG. 2 is looking onto outer side 26a of paper layer 26 of film-composite sheet 32. A "film-composite sheet" is understood for purposes of the present Application to mean any predetermined piece cut out of a film composite, regardless of the manner of cutting. The cut-out piece can therefore also be stamped or the like.

Package 30 is configured in the form of a four-~~edge~~side-sealed pouch having a surrounding sealed seam 34. Located radially inside sealed seam 34 is a carrier receiving space 36 in which a planar carrier 38 of a pharmaceutical active substance (see FIG. 3) is received.

Package 30 can comprise a notch 40 at at least one point, for example in an edge region, for easier opening.

FIG. 3 is a longitudinal section through package 30 of FIG. 2 along section plane III-III of FIG. 2. Section plane III-III is oriented orthogonally to the drawing plane of FIG. 2.

The distribution of layers within film-composite sheets 32 and 33 is no longer depicted separately in FIG. 3 in the longitudinal section through sheets 32 and 33. That distribution corresponds to the layer distribution of film composite 10 as depicted in FIG. 1. The two COC layers 12 of the respective film-composite sheets 32 and 33 are arranged facing toward one another and are fused to one another along sealed seam 34. A transdermal patch 39, constituting a planar carrier 38 of a pharmaceutical active substance, is received in carrier receiving space 36 that is constituted radially inside sealed seam 34. Carrier receiving space 36 is thus radially externally delimited by sealed seam 34 and orthogonally thereto by the two film-composite sheets 32 and 33.

Sealed seam 34 extends, in a thickness direction of the respective film-composite sheets 32 and 33, not only through the respective COC layers 12 that also serve as sealing layers but also, beyond those COC layers 12, into polyethylene layers 14. Sealed seam 34 is thus constituted by COC layers 12 (which are in contact with one another before sealing) of the two film-composite sheets 32 and 33 and by material of polyethylene layers 14 which are located, from the viewpoint of the contact point of the two COC layers 12 before sealed seam 34 is produced, behind the respective COC layers 12. Because the material of COC layers 12, like the material of polyethylene layers 14, is an olefin, the materials of the two layers 12 and 14 are mutually compatible and can blend with one another in sealed seam 34.

While considerable emphasis has been placed on the preferred embodiments of the invention illustrated and described herein, it will be appreciated that other embodiments, and equivalences thereof, can be made and that many changes can be made in the preferred embodiments without departing from the principles of the invention. Furthermore, the embodiments described above can be combined to form yet other embodiments of the invention of this application. Accordingly, it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation.

ABSTRACT OF THE DISCLOSURE

~~The present invention relates to a~~a film composite ~~(10)~~ for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, encompassing, in a direction from the outer side ~~(26a)~~ of the film composite ~~(10)~~ toward its inner side ~~(12a)~~: a metal layer ~~(18)~~; an acrylic-acid-containing joining layer ~~(16)~~; a polyethylene layer ~~(14)~~; and a COC layer ~~(12)~~ made of cycloolefin copolymer, a side ~~(12a)~~ of the COC layer ~~(12)~~ which faces away from the metal layer ~~(18)~~ being an exposed surface of the film composite, ~~(10). According to the present invention,~~wherein provision is made that the polyethylene layer ~~(14)~~ encompasses metallocene polyethylene.

~~(FIG. 1)~~

FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

The present invention relates to a film composite for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, encompassing, in a direction from the designated outer side of the film composite toward its designated 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.

A film composite of this kind, for the aforesaid purpose of manufacturing a package for pharmaceutical active-substance carriers, is known from WO 2015/123211 A1. The film composite of the species comes into direct contact with the planar carrier of a pharmaceutical active substance, and thus with the pharmaceutical active substance itself. The relevant pharmaceutical active substances are active substances such as nicotine, fentanyl, or lidocaine. The stress on the film composite produced by these pharmaceutical active substances is considerable. It is necessary to ensure in this context on the one hand that the film composite survives as such over the long term in order to prevent undesired release of the pharmaceutical active substance of the active-substance carrier. Even if the film composite survives, i.e., does not at least locally delaminate, for example, under the influence of the pharmaceutical active substance diffusing into composite layers, it is necessary on the other hand to ensure that the pharmaceutical active substance cannot diffuse or migrate through the film composite.

In order to increase the diffusion barrier effect of the film composite with respect to the pharmaceutical active substances packaged by it, it is known to select the proportion of cycloolefin copolymer (COC) in the COC layer that is innermost in the subsequent package to be as high as possible. As the COC concentration in the COC layer rises,

however, it becomes increasingly difficult to maintain the stability of the film composite, for example to prevent delamination or similar disintegration phenomena.

WO 2017/114922 A1 also discloses film composites for creating packages for planar pharmaceutical active substance carriers.

The object of the present invention is therefore to embody the film composite recited initially with the greatest possible chemical and mechanical stability with regard to the pharmaceutical active substances that are to be packaged, in light of its purpose of constituting a safe, including childproof, package for planar pharmaceutical active-substance carriers.

This object is achieved according to the present invention by a film composite of the kind recited initially in which the polyethylene layer encompasses metallocene polyethylene. The reason is that experiments have shown that given otherwise identical dimensions for the film composite, adhesion of the COC layer to the polyethylene layer is considerably better when the polyethylene layer encompasses metallocene polyethylene. "Metallocene polyethylene" in this context is polyethylene that has been manufactured in known fashion using metallocene catalysts.

The higher the COC concentration in the COC layer, the greater the gain in adhesion, in terms of the adhesive effect between the COC layer and the polyethylene layer, which is achievable by the use of metallocene polyethylene as compared with conventional polyethylene. Because the COC layer comprises a COC proportion that is as high as possible (at least 95 wt%, preferably at least 99.8 wt%, of the mass of the COC as a whole) in order to achieve a maximum barrier effect with respect to pharmaceutical active substances that are stored in the planar active-substance carrier, a particularly significant adhesion advantage can be achieved with the utilization, as presented here, of metallocene polyethylene in the polyethylene layer arranged between the acrylic-acid-containing joining layer and the COC layer.

In doubtful cases, for example if more than one polymer layer of the film composite contains COC, a COC layer is to be considered a "COC layer" for purposes of the present Application only if it contains at least 50 wt% COC in terms of its layer mass. The aforesaid polyethylene layer that contains metallocene polyethylene is preferably devoid of COC.

In principle, an improvement in the adhesion of the COC layer to the polyethylene layer can already be achieved with comparatively small quantities of metallocene polyethylene. In a context of comparative samples of different film-composite sheets that are otherwise dimensionally identical, the improvement in the adhesive effect is particularly large if the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer is at least 50 wt%. It is therefore also possible in principle to use so-called polyethylene blends, in which metallocene polyethylene is blended with non-metallocene polyethylene, to constitute the polyethylene layer.

Because of the advantageous adhesion-enhancing effect of metallocene polyethylene, the proportion thereof (always in percent by weight) in terms of the total polyethylene contained in the polyethylene layer is preferably as high as possible, preferably higher than 90 wt%, particularly preferably higher than 96 wt%.

It has proven to be advantageous, in order to enhance the adhesion effect and also the processability of the film composite on corresponding processing machines to produce packages constituted therefrom, if the polyethylene layer encompasses a metallocene LLDPE. The polyethylene layer preferably encompasses only metallocene LLDPE as the metallocene polyethylene.

In order to achieve good running properties for a film-composite web in the aforementioned processing machines, the density of the metallocene polyethylene is advantageously in a range between 0.917 and 0.921 g/m^2. In order to achieve permanent sealed seams with high strength and high density, the metallocene polyethylene additionally or alternatively has a melt flow index (melt flow rate, MFR) of

between 6 and 10 g/10 min., measured per ISO 1133 at a test temperature of 190°C and using a test element having a weight of 2.16 kg. This is because in addition to the COC, the polyethylene layer, constituting the external barrier layer and sealing layer, can contribute to sealed join of the film composite.

Any type of metallocene polyethylene in the polyethylene layer provides a desired enhancement of the adhesion effect of the COC layer on the polyethylene layer, compared with a polyethylene layer of the same dimensions and/or the same weight per unit area in the film composite. In addition, however, the rigidity of the polyethylene layer, and thus of the film composite as a whole, can be influenced by using different types of metallocene polyethylene. Advantageous rigidity of the polyethylene layer, in a context of predefined dimensions thereof, can be obtained by the fact that the polyethylene layer encompasses a C6 metallocene polyethylene and/or a C8 metallocene polyethylene, or is made of the aforesaid types of metallocene polyethylene. According to previous experiments, for a predefined film composite and in particular for a predefined dimension and/or weight per unit area of the polyethylene layer, C8 metallocene polyethylene offers the best results in terms of achieving on the one hand layer rigidity of the polyethylene layer and on the other hand composite rigidity of the film composite.

It is understandably advantageous for that reason if the polyethylene layer encompasses only a C8 metallocene polyethylene as a metallocene polyethylene. Based on what is stated above, it is particularly preferably a C8 metallocene LLDPE.

The polyethylene layer is preferably applied using the extrusion method, particularly preferably coextruded with the COC layer.

A commercially available metallocene polyethylene that is outstandingly applicable as a polyethylene layer in the aforesaid film composite is the polyethylene obtainable from the Dow Chemical Company under the trade name "Elite™ 5811."

In order to achieve the greatest possible adhesion effect for the partial composite, made up of a polyethylene layer and COC layer, on the metal layer, the acrylic-acid-containing joining layer preferably encompasses or is made of an ethylene-acrylic acid (EAA) copolymer.

The acrylic-acid-containing joining layer is preferably also applied onto the metal layer by extrusion. Particularly preferably, a partial composite made up of an acrylic-acid-containing joining layer, in particular an EAA layer; a polyethylene layer; and a COC layer is applied onto the metal layer by coextrusion in one collective extrusion step.

The metal layer serves as an oxygen barrier and gas barrier to protect package contents from external influences, and furthermore as a barrier for pharmaceutical active substances and constituents thereof which reach the metal layer as a result of diffusion through the COC layer, the polyethylene layer, and the acrylic-acid-containing joining layer.

Preferably each of the layers, from among the acrylic-acid-containing joining layer, polyethylene layer, and COC layer, has a layer thickness in the range from approximately 7 µm to 15 µm. On the one hand this ensures outstanding attachment to the metal layer; on the other hand, in this thickness range not only the COC layer but also the polyethylene layer can serve to produce a sealed join to the COC layer of a film composite of similar construction. Because, in the instance recited, the polyethylene layer located below the COC layer can also contribute in particularly effective and reliable fashion to production of a sealing join, the values indicated above for the melt flow index (MFR) are highly advantageous in terms of achieving outstanding sealing properties for the film composite having the exposed COC layer. The thickness values of the three, preferably coextruded layers (acrylic-acid-containing joining layer, polyethylene layer, and COC layer) are preferably each in the range from 9 µm to 12 µm. In order to achieve outstanding sealing properties with the involvement not only of the COC layer as an external sealing layer but also the polyethylene layer located therebelow, there is preferably little difference between the layer thicknesses of the

polyethylene layer and of the COC layer. In order to achieve optimum attachment of the COC layer and the polyethylene layer to the metal layer without thereby making the film composite undesirably thick, the thickness of the acrylic-acid-containing joining layer also preferably differs little from the thickness of the two layers recited above (polyethylene layer and COC layer). The thickness values of the aforesaid layers, referred to the thinnest of the aforesaid layers, preferably differ by no more than 15%, preferably by no more than 11%. A triple composite made up of an acrylic-acid-containing joining layer, a polyethylene layer, and a COC layer can then easily be coextruded, the resulting film composite then exhibiting very good running properties on processing machines for processing the film composite to yield a package, and furthermore exhibiting very good sealing properties.

In principle, the film composite can be used as it is described above. For further protection of the film composite it can have, on that side of the metal layer which faces away from the COC layer, at least one further layer made of paper and/or plastic. As a result, the metal layer is a completely internal layer of the film composite, and as such is better protected from external influences. Because the COC layer as a rule is an entirely internally located layer of a package constituted from the film composite, provision of the at least one further layer simplifies the application of product information onto the outer side of the film composite which faces toward the consumer, which information would otherwise need to be applied, with greater complexity, onto the metal layer.

The at least one further layer is preferably laminated onto the metal layer or onto a further layer already present thereon. A solvent-containing laminating adhesive having a coating weight per unit area of 2 to 4 g/m^2, preferably having a coating weight per unit area of 3 g/m^2, is preferably used for this.

For easy imprinting and for child safety of a package constituted from the film composite, in order to prevent undesired opening and exposure of the pharmaceutical active substances packaged therein, the film composite preferably comprises, on that side of the metal layer which faces away from the COC layer, both a further layer made

of paper and a further layer made of plastic. Because of the particular easy imprintability of the paper layer and thus a particularly simple and inexpensive capability for equipping the film composite, and/or a package constituted therewith, with consumer information, the plastic layer is preferably located closer to the metal layer than is the paper layer. The paper layer is preferably an external layer of the film composite. A imprint printed onto the paper layer can be at least partly, or preferably completely, covered by a protective layer, for example a clear lacquer.

To protect against undesired tearing by children, the further layer made of plastic is preferably a biaxially oriented plastic.

In experiments, polyethylene terephthalate and/or polyamide have proven successful as a plastic for the at least one further plastic layer. Plastic layers made of the aforesaid plastics have sufficient mechanical and thermal stability and, especially in oriented form, provide a further barrier effect against diffusion of gases and vapors. The further plastic layer can thus, in one direction, protect the metal layer from chemical attack from outside, and in the opposite direction can additionally retain the pharmaceutical active substance, or constituents thereof, if they happen to pass through the metal layer.

When the film composite has a further layer made of paper on that side of the metal layer which faces away from the COC layer, that paper layer preferably has a thickness of 35 to 45 µm, particularly preferably 39 to 41 µm. Additionally or alternatively, the further layer made of paper can have a weight per unit area of 35 to 45 g/m^2, in particular 39 to 41 g/m^2.

When the film composite has, on that side of the metal layer which faces away from the COC layer, a further layer made of plastic, the latter layer preferably has a thickness of 19 to 27 µm, in particular 22 to 24 µm. Additionally or alternatively, the additional layer made of plastic has a weight per unit area of 28 to 36 g/m^2, in particular 31 to 33 g/m^2. These values for thickness and weight per unit area offer a very good compromise

among sufficient mechanical strength, thermal stability, and low overall thickness for the film composite.

Because the above-described film composite is particularly suitable for manufacturing a package for a planar carrier of pharmaceutical active substances, for example a transdermal patch, the present invention also relates to such a package encompassing two film-composite sheets each made of a film composite as described and refined above. The film-composite sheets are arranged with mutually facing COC layers to form a carrier receiving space, and are joined to one another by local sealing of COC layer regions. Portions of the mutually facing COC layer regions are sealed to one another, preferably with participation of the polyethylene layer that has metallocene polyethylene and is located below the COC layers. The sealed seam then preferably encompasses a mixture of COC and metallocene polyethylene. The sealed seam then extends, in a thickness direction, into the polyethylene layer. Other portions of the mutually facing COC layer regions of the two film-composite sheets are located unjoinedly opposite one another. When a planar carrier of pharmaceutical active substances is received in the package, said carrier is located between respective oppositely located portions, unjoined to one another, of a COC layer of a film-composite sheet involved in the constitution of the package.

A "planar carrier of pharmaceutical active substances" is understood to be a substrate that respectively has, in its two principal directions of extent that are orthogonal to one another and to the substrate thickness direction, dimensions that are at least 10 times, preferably at least 30 times, greater than the dimension of the substrate in a thickness direction, and that is embodied to release a pharmaceutical active substance stored in the substrate.

To save space while providing durably effective shielding of the pharmaceutical active substance packaged therein, the package can be a four-edge-sealed pouch having a sealed seam surrounding the carrier receiving space.

A planar active-substance carrier received in the carrier receiving space of the package as described above is preferably a transdermal patch. The pharmaceutical active substance in the active-substance carrier preferably encompasses nicotine and/or fentanyl and/or lidocaine and/or another known active substance for administration by means of a transdermal patch.

The "designated" internal or external side of the film composite refers respectively to that side of the film composite which respective constitutes, on a package subsequently constituted from the film composite, a portion of the inner side or the outer side of the package.

The film composite preferably comprises only the layers recited in the present Application.

The present invention will be explained in further detail below with reference to the appended drawings, in which:

FIG. 1 is a cross-sectional view through an embodiment according to the present invention of a film composite of the present Application;

FIG. 2 is a plan view of a package, constituted with participation of the film composite of FIG. 1, of a transdermal patch; and

FIG. 3 is a cross-sectional view of the package of FIG. 2 along section plane III-III of FIG. 2.

In FIG. 1, an embodiment according to the present invention of a film composite of the present Application is labeled in general with the number 10. The depiction in FIG. 1 is merely schematic. In particular, the thicknesses of the individual layers of film composite 10 are not illustrated accurately to scale. Film composite 10 has on its designated inner side a COC layer 12 that has a COC content of approximately 99.8 wt%. The proportion

of COC in COC layer 12 is selected to be as high as possible in order to provide, with COC layer 12, an optimum barrier layer against migration and diffusion of pharmaceutical active substances such as nicotine and/or fentanyl and/or lidocaine. A surface 12a of COC layer 12 constitutes an exposed outer surface of film composite 10. COC layer 12 preferably has a thickness of 9.8 to 10.0 µm.

A polyethylene layer 14 is joined to COC layer 12 by coextrusion. Polyethylene layer 14 is preferably devoid of COC, and encompasses at least 50 wt% metallocene polyethylene, preferably C8 metallocene LLDPE. In the example depicted, the proportion of C8 metallocene LLDPE in terms of the total polyethylene mass of polyethylene layer 14 is more than 95 wt%. Extremely good adhesion of COC layer 12 to polyethylene layer 14, and thus good protection from delamination, are thereby achieved. The use of C8 metallocene LLDPE, as opposed to the C4 or C6 types that are also possible, results not only in good adhesion of COC layer 12 to a polyethylene layer 14 but also in a polyethylene layer 14 having advantageous rigidity properties. The melt flow index (MFR) of polyethylene layer 14 is approximately 8 g/10 min., measured per ISO 1133 at a test temperature of 190°C using a test weight of 2.16 kg. The density of polyethylene layer 14 is preferably 0.919 g/m^2.

Thanks to the value selected for the melt flow index, although polyethylene layer 14 is not an external layer of film composite 10 it can participate in a sealed join of film composite 10 on COC layer 12 side. High sealing strength values, and a very high-quality sealed seam, are thereby achieved. COC layer 12 is not only a barrier layer of film composite, but also its sealable layer.

In the example depicted, the thickness of polyethylene layer 14 is between 10.8 and 11.0 µm. Polyethylene layer 14 and COC layer 12 are thus of approximately equal thickness; COC layer 12 can be slightly thinner. This balanced thickness relationship between polyethylene layer 14 and COC layer 12 also contributes to the attainment of permanently strong and diffusion-proof sealed joins.

On the side facing away from COC layer 12, polyethylene layer 14 is joined to a joining layer 16 made of an ethylene-acrylic acid (EAA) copolymer, in order to join COC layer 12 and polyethylene layer 14, by means of joining layer 16, to an aluminum layer 18.

Joining layer 16, which is between 10.6 and 10.8 µm thick in the example depicted, has been coextruded together with polyethylene layer 14 and COC layer 12, and applied onto aluminum layer 18 in the course of coextrusion.

Aluminum layer 18, which serves as a further barrier layer, is 8 to 10 µm thick, preferably 9 µm thick, in the example depicted.

A film composite made up of layers 12, 14, 16, and 18 is already a stable composite that is outstandingly suitable for manufacturing a package for products that contain pharmaceutical active substances such as nicotine, fentanyl, or lidocaine.

In order to protect the aforesaid composite, made up of layers 12, 14, 16, and 18, from being undesirably opened or torn by curious children, who might thereby gain access to a packaged pharmaceutical active substance that is entirely unsuitable for children, a layer 22 made of biaxially oriented plastic, preferably of polyethylene terephthalate or polyamide, is laminated, by means of a layer 20 made of solvent-containing laminating adhesive at an application weight of 3 g/m^2, onto that side of aluminum layer 18 which faces away from COC layer 12.

Layer 22 can be imprinted on its side facing away from aluminum layer 18 product so that information regarding a product that is packaged using film composite 10 can be conveyed to a consumer. Layer 22 can then be an externally located layer, opposite from COC layer 12, of film composite 10.

Layer 22 can also be a paper layer rather than a plastic layer 22.

In the example depicted in FIG. 1 film composite 10 comprises, in addition to plastic layer 22, an externally located paper layer 26 joined by means of a further laminating-adhesive layer 24 made of solvent-containing laminating adhesive.

Paper layer 26 can be imprinted on its outward-facing exposed surface 26a. The imprint can be covered by a protective layer, for example clear lacquer.

In the example depicted, plastic layer 22 has a thickness of approximately 22.7 to 23.3 µm. Paper layer 26, on the other hand, has a thickness of approximately 39.5 to 40.5 µm at a weight per unit area of approximately 40 g/m^2.

The total thickness of film composite 10 is thus between 108.4 µm and 110.6 µm.

Film composite 10 not only has outstanding barrier properties with respect to migration and diffusion of pharmaceutical active substances or constituents thereof from outer surface 12a of COC layer 12 to outer surface 26a of paper layer 26. The rigidity of film composite 10 is furthermore very suitable for constitution of a package, and it has outstanding running properties on processing machines for processing film composite 10.

FIG. 2 is a plan view of a package 30 constituted from two film-composite sheets of film composite 10 of FIG. 1, for packaging planar carriers of pharmaceutical active substances. Because of the plan view, only one film-composite sheet 32 is visible. A further film-composite sheet 33 is located behind film-composite sheet 32 depicted in FIG. 2 and is concealed by it (see FIG. 3). The viewer of FIG. 2 is looking onto outer side 26a of paper layer 26 of film-composite sheet 32. A "film-composite sheet" is understood for purposes of the present Application to mean any predetermined piece cut out of a film composite, regardless of the manner of cutting. The cut-out piece can therefore also be stamped or the like.

Package 30 is configured in the form of a four-edge-sealed pouch having a surrounding sealed seam 34. Located radially inside sealed seam 34 is a carrier receiving space 36 in which a planar carrier 38 of a pharmaceutical active substance (see FIG. 3) is received.

Package 30 can comprise a notch 40 at at least one point, for example in an edge region, for easier opening.

FIG. 3 is a longitudinal section through package 30 of FIG. 2 along section plane III-III of FIG. 2. Section plane III-III is oriented orthogonally to the drawing plane of FIG. 2.

The distribution of layers within film-composite sheets 32 and 33 is no longer depicted separately in FIG. 3 in the longitudinal section through sheets 32 and 33. That distribution corresponds to the layer distribution of film composite 10 as depicted in FIG. 1. The two COC layers 12 of the respective film-composite sheets 32 and 33 are arranged facing toward one another and are fused to one another along sealed seam 34. A transdermal patch 39, constituting a planar carrier 38 of a pharmaceutical active substance, is received in carrier receiving space 36 that is constituted radially inside sealed seam 34. Carrier receiving space 36 is thus radially externally delimited by sealed seam 34 orthogonally thereto by the two film-composite sheets 32 and 33.

Sealed seam 34 extends, in a thickness direction of the respective film-composite sheets 32 and 33, not only through the respective COC layers 12 that also serve as sealing layers but also, beyond those COC layers 12, into polyethylene layers 14. Sealed seam 34 is thus constituted by COC layers 12 (which are in contact with one another before sealing) of the two film-composite sheets 32 and 33 and by material of polyethylene layers 14 which are located, from the viewpoint of the contact point of the two COC layers 12 before sealed seam 34 is produced, behind the respective COC layers 12. Because the material of COC layers 12, like the material of polyethylene layers 14, is an olefin, the materials of the two layers 12 and 14 are mutually compatible and can blend with one another in sealed seam 34.

CLAIMS

1. A film composite (10) for manufacturing a package (30) for planar carriers (38) of pharmaceutical active substances, encompassing, in a direction from the outer side (26a) of the film composite (10) toward its inner side (12a): a metal layer (18); an acrylic-acid-containing joining layer (16); a polyethylene layer (14); and a COC layer (12) made of cycloolefin copolymer, a side (12a) of the COC layer (12) which faces away from the metal layer (18) being an exposed surface of the film composite (10),

wherein the polyethylene layer (14) encompasses metallocene polyethylene.

2. The film composite (10) according to Claim 1, wherein the proportion of metallocene polyethylene in terms of the total polyethylene of the polyethylene layer (14) is at least 50 wt%.

3. The film composite (10) according to Claim 1 or 2, wherein the polyethylene layer (14) encompasses a metallocene LLDPE.

4. The film composite (10) according to one of the preceding claims, wherein the polyethylene layer (14) encompasses a C6 metallocene polyethylene and/or a C8 metallocene polyethylene.

5. The film composite (10) according to Claim 4, wherein the polyethylene layer (14) encompasses only a C8 metallocene polyethylene as a metallocene polyethylene.

6. The film composite (10) according to one of the preceding claims, wherein the acrylic-acid-containing joining layer (16) encompasses or is made of an ethylene-acrylic acid (EAA) copolymer.

7. The film composite (10) according to one of the preceding claims, wherein each of the layers (16, 14, 12), from among the acrylic-acid-containing joining layer (16), polyethylene layer (14), and COC layer (12), has a layer thickness in the range from approximately 7 µm to 15 µm, preferably in the range from 9 µm to 12 µm, the thickness values of the aforesaid layers (16, 14, 12), referred to the thinnest (12) of the aforesaid layers (16, 14, 12), differing by no more than 15%, preferably by no more than 11%.

8. The film composite (10) according to one of the preceding claims, wherein it comprises, on that side of the metal layer (18) which faces away from the COC layer (12), at least one further layer (22, 26) made of paper and/or plastic.

9. The film composite (10) according to Claim 8, wherein it comprises, on that side of the metal layer (18) which faces away from the COC layer (12), both a further layer (26) made of paper and a further layer (22) made of plastic, the plastic layer (22) preferably being located closer to the metal layer (18) than is the paper layer (26).

10. The film composite (10) according to Claim 8 or 9, wherein the further layer (22) made of plastic is a biaxially oriented plastic.

11. The film composite (10) according to one of Claims 8 to 10, wherein the further layer (22) made of plastic is polyethylene terephthalate and/or polyamide.

12. The film composite (10) according to one of Claims 8 to 11, wherein the further layer (26) made of paper has a thickness of 35 to 45 µm, in particular 39 to 41 µm, and/or a weight per unit area of 35 to 45 g/m^2, in particular 39 to 41 g/m^2; and/or

the further layer (22) made of plastic has a thickness of 19 to 27 µm, in particular 22 to 24 µm, and/or a weight per unit area of 28 to 36 g/m^2, in particular 31 to 33 g/m^2.

13. A package (30) for a planar carrier (38) of pharmaceutical active substances, for example a transdermal patch (39), encompassing two film-composite sheets (32, 33), each made of a film composite (10) in accordance with one of the preceding claims, which are arranged with mutually facing COC layers (12) to form a carrier receiving space (36) and are joined to one another by local sealing of COC layer regions.

14. The package (30) according to Claim 13, wherein it is a four-edge-sealed pouch having a sealed seam (34) surrounding the carrier receiving space (36).

15. The package (30) according to Claim 13 or 14, having a planar active-substance carrier (38), in particular a transdermal patch (39), received in the carrier receiving space (36), the pharmaceutical active substance containing nicotine and/or fentanyl and/or lidocaine.

ABSTRACT

The present invention relates to a film composite (10) for manufacturing a package for planar carriers of pharmaceutical active substances, for example transdermal patches, encompassing, in a direction from the outer side (26a) of the film composite (10) toward its inner side (12a): a metal layer (18); an acrylic-acid-containing joining layer (16); a polyethylene layer (14); and a COC layer (12) made of cycloolefin copolymer, a side (12a) of the COC layer (12) which faces away from the metal layer (18) being an exposed surface of the film composite (10). According to the present invention, provision is made that the polyethylene layer (14) encompasses metallocene polyethylene.

(FIG. 1)

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	Application Number	
	Filing Date	2019-07-19
	First Named Inventor	Manuella Herb
	Art Unit	
	Examiner Name	
	Attorney Docket Number	TRO-45953

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2019-07-19
	First Named Inventor	Manuella Herb
	Art Unit	
	Examiner Name	
	Attorney Docket Number	TRO-45953

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The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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SIGNATURE

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Name/Print	Gregory S. Vickers	Registration Number	45180

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	TRO-45953
First Named Inventor	Manuella Herb
Title	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES...
Priority Mail Express® Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [✔] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [ ] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✔] **Specification** [*Total Pages* 17] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [✔] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 3]
6. **Inventor's Oath or Declaration** [*Total Pages* 3] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [✔] Newly executed (original or copy)
   b. [ ] A copy from a prior application (37 CFR 1.63(d))
7. [✔] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
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ACCOMPANYING APPLICATION PAPERS

10. [✔] **Assignment Papers** (cover sheet & document(s))
    Name of Assignee: Huhtamaki Flexible Packaging Germany GmbH & Co. KG
11. [✔] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [✔] **Power of Attorney**
12. [✔] **English Translation Document** (*if applicable*)
13. [✔] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [✔] Copies of citations attached
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15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. [ ] **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. [ ] **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [✔] **Other:** Substitute Specification - Marked; Substitute Specification - Clean; Specification Letter; German Search Report

Note*: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must be included in an Application Data Sheet (ADS).
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Name (Print/Type)	Gregory S. Vickers	Registration No. (Attorney/Agent)	45180

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

[Continued on next page]

(54) Title: A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM

(57) Abstract: The present invention relates to a method for providing an extreme chemical resistant film whereby a tie layer and a contact layer are coextruded with a base layer, such as a metal foil, as well as films and laminates obtained by the method and uses of the films and laminates to pack aggressive chemical substances such as nicotine, lidocaine, fentanyl and rivastigmine.

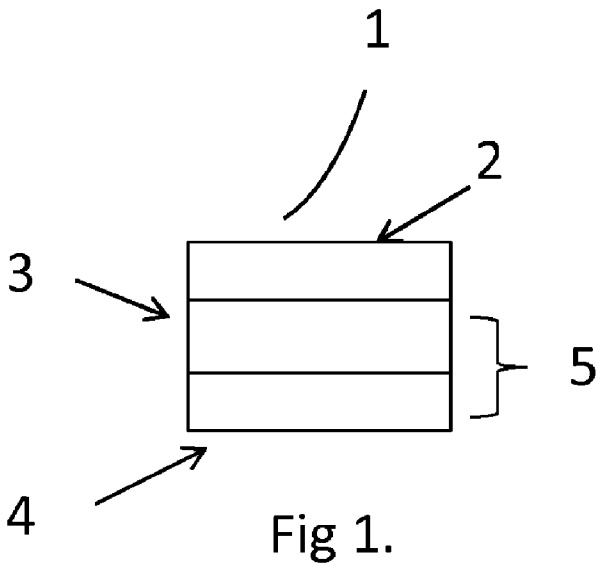


Fig 1.

WO 2017/114922 A1

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— *with international search report (Art. 21(3))*

A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM

The present invention relates to a method for providing an extreme chemical resistant film whereby a tie layer and a contact layer are coextruded with a base layer, such as a metal foil, as well as films and laminates obtained by the method and uses of the films and laminates to wrap aggressive chemical substances such as nicotine, fentanyl, lidocaine and rivastigmine.

Background of the invention

In the pharmaceutical industry substances, including highly aggressive substances such as nicotine, fentanyl, rivastigmine and lidocaine, are packed as tablets in inhalers, patches etc. resulting in special requirements for the packing, laminate, or film for sealing these substances in order to ensure that no adverse degradation takes place.

One common example is the problem relating to the packaging of nicotine, in particular as nicotine patches, because nicotine is highly aggressive towards its environment and highly volatile. These properties are problematic for the consumer safety and product durability if not addressed, because it is important that the amount of nicotine in, for example a tablet, gum or a patch is stable and complies with the product specification. Further, it is important to avoid adverse reactions between the packaging and the pharmaceutical substance. Additionally, from a business perspective a long stable shelf time is highly desirable. Thus, the chemical requirements of a packaging, film or laminate are typically:

- Resistance towards highly aggressive substances such as nicotine.
- Inert properties for ensuring that chemical compounds do not migrate from the exterior environment of for example a laminate, through the laminate getting into contact with a sealed substance;
- Possibly ensuring that the packaging is child proof to increase safety of potentially hazardous compounds.

A known polymer that fulfils the requirements of extreme chemical resistance and inert properties is a polyactyllonitrile (PAN) based film, which is sold for example as resins under the trademark Barex®, which is manufactured *i.a.* by the company Ineos. Barex® is widely used and approved for

drugs and food applications and is used because it is a good barrier towards oxygen, nitrogen and carbon dioxide compared to other common polymers, and because it has excellent chemical resistance towards different functional groups such as hydrocarbons, ketones, esters, alcohols, bases and acids and/or pharmaceuticals such as nicotine. Furthermore, extruded Barex® resin is heat stable and therefore weldable at a temperature around 160 - 220°C, which makes it possible to use in flexible packagings. However, Barex® is sold at a high prize due to the difficulties in the production and subsequent extrusion to film resulting in a high loss of material. Furthermore, the water and oxygen resistance of Barex® is not satisfactory for all purposes.

Another solution can be found in WO 00/44559 disclosing a material for packaging nicotine containing products (e.g. patches, tablets, lozenges, nasal spray), wherein the material comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers. Further, it is disclosed that a polymeric film is combined with other barrier materials in a laminate to further improve the barrier characteristic of the laminate. The preferred material for a laminate is aluminium due to its good oxygen and water barrier properties.

In addition to the barrier properties, in particular for pharmaceuticals, it is important that the concentration of the substances is stable and reliable, which also poses requirements of the packaging and laminates in terms of inertness and permeability.

Hence, given the increased market and demands for packagings, there is an instant need for finding solutions for packaging, of in particular highly aggressive substances and pharmaceuticals, which fulfil all the requirements while still being economical.

Summary of the invention

With this background it is an object of the present invention to provide solutions that meet one or more of the needs described above, that is, *i.a.* provide impermeability and inertness to a packaging. Furthermore, it is an object to provide a laminate that is weldable at temperatures suitable for the manufacture of flexible wrappings, such as for use in preparing packagings for patches. It is a further object to provide methods and products that

are cost efficient without compromising the quality of the products.

Accordingly, in a first aspect this is solved by a method for providing, e.g. an aggressive chemical resistant, film, said method comprising the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide the, e.g. aggressive chemical resistant, film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards an aggressive chemical of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred between 1 to 2.

It has surprisingly been found that when coextruding the tie layer and the contact layer according to the invention, the respective layers can be thinner while maintaining the overall mechanical and chemical robustness of the final film and laminates and wrappings made with the film. The coextrusion also results in a better adherence of the various layers resulting in a homogonous film in which the layers do not separate.

While it was previously believed that usable polymers should be hydrophobic (in order to repel water from the surroundings), the present inventors have found that by providing the film according to the invention where the coextrusion layer comprises a tie layer and a contact layer, and where the contact layer comprises a polymer having a relative energy difference (RED) value in the range 0.8 to 10 relative to the aggressive substance, it has surprisingly turned out that the desired effect of the laminate being inert to aggressive compounds, such as nicotine, rivastigmine and lidocaine, while still providing a barrier to external factors such as water/moist and oxygen, is obtained.

A polymer candidate for use as a contact layer in the present invention is selected by calculating the RED value, which is generally used to predict the solubility of a polymer in a particular solvent, or the compatibility of

two polymers in a blend.In the present invention the RED values for various polymer/solvent systems have been calculated, wherein the polymer is the polymer forming the contact layer, and the solvent is an aggressive chemical substance such as nicotine, rivastigmine, fentanyl and lidocaine etc.

The RED value for the polymer and the aggressive chemical substance is calculated by using the theory of the Hansen solubility Parameters (HSP), which is described in C.M. Hansen: "Hansen Solubility Parameters, A User's Handbook", CRC Press, Boca Raton, 1999.

The HSP system between the polymer and the aggressive chemical substance is described by parameters set up in a 3 dimensional coordinate system:

- δ_D for dispersion cohesion energy
- δ_P for dipolar cohesion energy
- δ_H for hydrogen bonding cohesion energy

The HSP distance, Ra, between polymer and the aggressive chemical substance is given by:

$$Ra^2 = 4(\Delta \delta_D)^2 + \Delta \delta_P{}^2 + \Delta \delta_H{}^2$$

The Δ indicates the difference in the given parameter for the aggressive substance and the polymer.

The relation between the HSP distance, Ra and RED is given as:

$$RED = Ra/Ro$$

Where Ro is the interaction radius, which determines the radius of the sphere in Hansen space, and the center are the three Hansen parameters. All values are calculated or determined with empiric data and it is known to the person skilled in the art how to calculate the values.

The obtained RED value indicates whether or not the polymer is likely to dissolve in the aggressive chemical substance or not:

RED < 1 the polymer and the aggressive chemical substance will dissolve

RED = 1 the polymer and the aggressive chemical substance will partially dissolve

RED > 1 the polymer and the aggressive chemical substance will not dissolve

The resulting RED value is used to give an indication of the likelihood of dissolution or not.

All values can be calculated using the Hansen Solubility Parameter in Practice by (HSPiP) Software, commercially available at http://hansen-solubility.com.

Contact layer polymers according to the invention surprisingly turned out to have a RED value in the range from 0.8 and higher, preferably, 0.8 to 10 and more preferred 0.8 to 5 and most preferred 1 to 2. It is highly unexpected that polymers which in theory range from being soluble to insoluble with an aggressive substance to be packed fulfill the requirements set for films according to the invention as is supported by the examples provided here with.

The base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluro polymers.

According to the invention water and/or oxygen resistance is preferably encompassing materials having an oxygen transfer rate (OTR) equal to or below 1 $cm^3/m^2/24hr/bar$ according to ASTM standard D3985 at 23°C and 0% RH and/or water (or moisture) vapor transfer rate (WVTR) equal to or below 1 $g/m^2/24hr$ according to ASTM standard F1249 at 38°C and 90%RH, preferably both the WVTR and the OTR are below 0.01 $g/m^2/24hr$ or 0.01 $cm^3/m^2/24hr/bar$ respectively.

According to the invention, the base layer of the film is selected to provide a number of properties to the film and a laminate and packaging comprising the film. The base layer may give desired barrier and support properties to the final laminate. Furthermore, the base layer may in one embodiment be a gas and water impermeable base layer, more preferably a water and/or oxygen resistant base layer.

In embodiments where the contact layer is hygroscopic the base layer is preferably made of a metal foil, preferably aluminum.

Aluminum is price competitive, a superior barrier of all gases and moisture and furthermore similar to other metal-like materials aluminium has good dead-fold properties, i.e. it does not unfold once folded, it reflects radiant heat, and gives a decorative appeal to laminates and packages.

According to the invention the tie layer is selected to provide sufficient adhesion between the base layer and the coextrusion layer. The tie lay-

er may give melt strength and support the coextrusion coating of both the tie layer and the contact layer. It is preferred that the melting profile of the tie layer polymers and the contact layer polymers are in the same range to provide optimal films that do not separate. Preferably both layers comprise polymers that melt at the operating temperature of the process of the invention and even more preferred the melting profiles (i.e. melting points) should differ with less than 30°C, preferably with 0-15°C, such as 5-15°C.

In one embodiment the tie layer is made of 1, 2, 3, 4 or 5 layers. In this way, the properties of the film and resulting laminates and packagings may be improved to accommodate the specific chemical and physical properties of the contact layer and/or the base layer.

In a further embodiment all the layers are coextruded with the contact layer for a simplified processing and for ensuring homogeneity of the layers.

In a further embodiment the tie layer is constituted of one layer where the layer is made of a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride. Most preferably the tie layer has a melting profile similar to that of the contact layer.

According to the invention the contact layer must be chemically resistant to the aggressive substance and excipient if present ultimately to be packed. Further it must show an extreme low absorption of the aggressive substances migrating through the film or laminate. The degree of absorption for a given substances is typically dictated by the manufacturer of the substance but often the accepted values lie in the range of 0 to 1 % (w/w). For some products up to 10 % (W/W) is acceptable typically for products with a low initial API content. The absorption is calculated as the weight of API in packaging relative to the initial weight of the API in the commercial product.

Hence, in the context of the present invention aggressive chemical resistant film means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks. Typically, the degree of uptake is complete after 12 weeks or less.

In one preferred embodiment the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer (COC), a polyamide (PA), or, an ethylene vinyl alcohol (EVOH).

In a further embodiment the tie layer and contact layer comprise the same polymer, such as a cyclic olefin copolymer (COC), a polyamide (PA), or, an ethylene vinyl alcohol (EVOH) the latter being particularly preferred.

The HSP and RED Values calculated using http://hansen-solubility.com, mentioned above resulted in the following values for the preferred polymers according to the invention using lidocaine/rivastigmine as solvent (API):

Table 1: HSP and RED values for preferred polymers according to the invention

Polymer	D	P	H	RED value (chi)
Lidocaine/ Rivastigmine	18.1	8.2	6.1	-
PA 66	16	11	24	1.72
COC	18	3	2	1.32
EVOH	20.5	10.5	12.3	1.12

It has surprisingly been shown that when the contact layer comprises any of the polymers from the group above, having a relatively low RED (i.e. between 1 and 2) value a chemical resistant film and also laminate may be obtained even though the mentioned polymers chemically represent different polymer types. Tests have shown that the resistance of laminates in which the film is coated with the preferred polymers shows results unexpectedly superior to those of laminates coated/laminated with Barex®.

EVOH is normally used in laminates due to the superior oxygen barrier properties of EVOH. However, EVOH is known to be very hydrophilic and hydroscopic (i.e. has a high WVTR), hence it is surprising that a EVOH polymer is usable in the context of the present invention where water resistance is a desired property. Also, PA has typically been used in laminates due to the superior mechanical properties like tear strength or as a barrier. As for EVOH it is unexpected that PA may be used as a contact layer and/or co-extrusion layer (i.e tie and contact layer) for providing a chemical resistant film due to the hydrophilic nature of PA.

Because of the hydrophilic nature of PA and EVOH, in a preferred embodiment, the film obtained according to the invention may be tightly packed in a moisture barrier, in particular if it has to be stored. The film or laminate according to the invention may be packed immediately after manufacture of the chemical resistant film or laminate and should be kept safely packed until further use, for example in a packing line.

COC has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates. Without the wish to be bound by any theory this is believed to be due to the stress which the polymer is subjected to during an extrusion process. The stress causes irregular heating and melting within the COC, resulting in the final film or laminate to be unacceptable from a visual point of view for use in various packaging industries. Hence, it is very surprising that the inventors of the present invention have succeeded in providing a coextrusion layer comprising COC as a contact layer for sealing aggressive substances. The inventors have found that an improved processing of COC is obtained when COC is coextruded with a tie layer having a glass transition temperature higher than or equal to that of a COC polymer such as a terpolymer of ethylene, acrylic ester and maleic anhydride. In another embodiment of the invention the tie layer has a melting point that differs from COC with 30°C or less, preferably with 0-15°C, such as 5-15°C.

In a further embodiment, the melting point of the tie layer is at least the same as COC, preferably 5 to 30 °C higher, more preferably 15 to 30 °C higher than COC.

To obtain a satisfactory coextrusion layer it is important that the polymer constituting a contact layer and a copolymer constituting a tie layer are compatible with respect to the melting characteristic of the polymers and the copolymer. As an effect of having been able to process a chemical resistant laminate with a coextrusion layer laminated to a base layer, thin laminates may be obtained, and generally improved process ability during the manufacture of the laminates or wrappings are achieved.

Consequently, in one embodiment the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m2 and/or the contact layer has a loading in the range of 4 to 20 g/m2 and the loading of the laminate is not more than 40 g/m2.

In terms of the invention loading means the amount of polymer left, in the layer when the film has dried.

In a particular embodiment the contact layer of the coextrusion layer is made from a blend of at least two polymers. Using blends can be a means for reducing the costs and for adapting the physical and chemical properties of the co-extrusion process, such as reducing or increasing the melting temperature to comply with the profile of the tie layer(s) and the polarity of the blend to improve the adhesion properties of the layers and hence the robustness of the final product.

In a preferred embodiment the contact layer consists of one polymer type. Experiments showed that using one type of polymer resulted in improved resistance of the film and laminate towards the chemical substance to be packed.

According to an embodiment, in any of the blends or homo layers at least one of or all the polymer(s) forming the contact layer of the coextrusion layer is a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol. Each of the polymers are commercial available for example under the tradenames EVAL® C109B sold by Kuraray, Selar PA 3426 R sold by Dupont®, 6013M-07 sold by Topas®.

In one embodiment the cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol makes up at least 50% w/w of the blend, preferably at least 60% w/w, more preferably at least 80% w/w, most preferably at least 95% w/w.

The adhering of step iv) preferably occurs instantly for example by cooling the co-extrudate in cooling cylinders during the lamination process.

According to the invention a chemical resistant film has various applications. In an embodiment of the invention, the film is used to wrap a composition comprising a chemical selected from nicotine, fentanyl, lidocine and rivastigmine.

In a particular embodiment of the invention, wherein the composition is provided as a patch, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/- 10% in comparison to a Barex® patch as index 100.

In a further aspect of the invention an aggressive chemical resistant film is provided, said film comprising at least a base layer, which is water

and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and whereby the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2. Films according to the invention are resistant to aggressive chemical substances.

the term "aggressive chemical resistant film" means a film which when in contact with an aggressive substance does not allow more than 10 %, such as 5% w/w or 1.5% w/w based on the nomial content of the aggressive chemical to migrate to the packaging material.

In one embodiment the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, polyamide, polyvinylidene chloride, silicium oxide coated polyesters, and/or fluropolymers.

In a further embodiment the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride.

In a particular embodiment the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

In yet an embodiment the tie layer and the contact layer is the same material.

In a further embodiment the film is heat sealable. A heat sealable film or laminate is a laminate that is capable of sealing to itself during heat sealing without creating any deformation of films or laminates, which is highly undesired, especially, during the final wrapping of the product. The deformation is undesirable in relation to quality assurance, where any deformation must be noted and explained, which is highly labor intensive. Furthermore, the legislation in many countries is very strict. Hence, film and/or laminates with any deformation are not allowable for packing active ingredients.

In yet another aspect the invention relates to a laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;

- an aggressive chemical resistant film as described above comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer said coextrusion layer comprising a tie layer wherein the base layer side of the film is facing the first outer layer.

In one embodiment the first outer layer may be made from a material selected from but not limited to paper, polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or combinations. It is preferred that the first outer layer is a combination of materials when polyester based sheets are used.

In an embodiment the first outer layer and the film are laminated to provide the packaging in one piece. Laminating the first outer layer to the film provides a strong laminate, which is easy to wrap, and, it is ensured that the individual parts of the laminate do not fall apart.

In another embodiment the laminate further comprises a second outer layer facing the exterior side of the first outer layer, preferably the second outer layer is a paper layer. The paper layer is typically printed with the name, color and/or logo of the product and manufacturer of the product. It is also contemplated that the first outer layer is printed.

It is also contemplated that an adhesive agent may be applied between the second and first outer layers. The adhesive layer may be the same or different from the tie layer. Additional suitable adhesives are adhesives approved for use in packaging products for human use and are well known to the skilled person. A suitable adhesive may be selected from but is not limited to polyurethane based adhesives, epoxy based adhesives, or acrylic based adhesives.

The laminate of the present invention must be inert and impermeable to the aggressive chemical substance which the laminate is wrapped around. Hence, in an embodiment of the invention a maximum of 10%, preferably a maximum of 5%, even more preferably a maximum of 1.5%, most preferably a maximum 0.5% of the aggressive chemical is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

In a further embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine. These compounds are known as aggressive chemicals/compounds and re-

quire specialized packaging.

Hence, the invention also contemplates an aggressive chemical substance packed in a laminate or packaging as explained above and a method for providing the packaging the chemical substance, said method comprising the steps of:

a) providing a base layer

b) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

c) coating the coextrusion layer to the base layer;

d) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide a chemical resistant film comprising the tie layer and the contact layer formed as an coextrusion layer coated to the base layer;

e) providing a highly aggressive substance to the contact layer side of the film; and

f) sealing the chemical resistant film, preferably by heat sealing, in such a way to provide a hollow interior space for sealing the highly aggressive substance, said hollow space having an interior side and an exterior side, wherein the interior side of the film is the contact layer of the coextrusion layer and the exterior side of the film is the base layer.

In a preferred embodiment the highly aggressive substance is selected from the group consisting of nicotine, lidocaine, rivastigmine, and fentanyl.

It is also contemplated that a first outer layer may be applied to the film; the first outer layer is made of a mechanically wear resistant material and typically serves to protect from children being able to break the sealed film, laminate or wrapping.

A packaging should preferably comply with International standards such as 16 CFR §1700.20 (for USA) and ISO 8317 (2003) corresponding to DIN EN ISO 8317 (2004) (for Europe).

A "packaging" is in the context of the invention intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate

It is also contemplated that a second outer layer may be applied to the film and/or laminate; the second outer layer is typically a paper layer.

The paper layer is typically printed with the logo or colors etc. of the supplier of the product. The second outer layer is preferably applied when there is a first outer layer.

It is contemplated that the first and/or second outer layer is laminated to the film before steps e) and f) for example in one combined coextrusion and laminating step.

In yet another aspect, the invention provides the use of a polymer having a RED value of > 0.8, preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a base layer which is water and/or oxygen resistant coated to a, optionally co-extruded, layer comprising a tie layer and the contact layer.

In a further embodiment the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

Specific films according to the invention comprise but are not limited to base layer/tie-layer/contact-layer (the latter two coextruded) EAA/PE/COC, EAA/EMA/COC, EAA/terpolymer/COC, terpolymer/PE/COC, EAA/terpolymer/EVOH, EAA/terpolymer/PA, or EAA/PA.

Specific films according to the invention that are resistant to nicotine comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, AL/EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride.

In a further embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

Specific films according to the invention resistant to rivastigmine

comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, AL/EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride.

In a further embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

Specific films according to the invention resistant to lidocaine comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, AL/terpolymer of EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride

In a further embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

Specific films according to the invention resistant to fentanyl comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%,

Al/EVOH/EVOH, AL/terpolymer of EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride

In a further embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

The invention should not be restricted to the above combinations. Further combinations are within the scope of the invention.

In another aspect of the invention is provided a method for providing an aggressive chemical resistant film said film being resistant to nicotine, rivastigmine and/or and lidocaine, and wherein said method comprises the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards nicotine, rivastigmine and/or lidocaine of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

It has surprisingly been shown that films provided from polymers having a red value between 0.8 and 10 relative to rivastigmine, lidocaine and/or nicotine and coextruded as stipulated above have superior resistance to said chemical substances.

In a further aspect of the invention is provided a method for provid-

ing an aggressive chemical resistant film against nicotine, rivastigmine and/or and lidocaine, said method comprising the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

It has surprisingly been shown that polymers of cyclic olefin copolymer, polyamide and ethylene vinyl alcohol, when coextruded, provide a resistant film, which performs at least as well as films known in the prior art for packaging compunds such as nicotine, lidocaine and rivastigmine.

Conveniently, the polymers used in the present invention have the advantage of being easy accessible thereby providing a more cost efficient production.

Figures

Figures 1 is a cross section of an embodiment of a chemical resistant film according to the invention

Figure 2 is a cross section of another embodiment of a chemical resistant film according to the invention.

Figure 3 is a cross section of a laminate according to the invention.

Figure 4 shows the results of an absorption study of rivastigmine as API wrapped in laminates according to the invention as compared to a commercial available laminate with the commercial available polymer film Barex® after storing for 2, 4, 8 and 12 weeks at 40°C.

Figure 5 shows the amount of licodaine remaining in a patch after 7 days at 40°C for embodiments of the laminate according to the invention and in comparison, with a commercial available Barex® laminate.

Detailed description

The invention will now be described in greater details. Each specific

embodiment and variation of features applies equally to each aspect of the invention unless specifically stated otherwise.

The film, laminate and packaging according to the present invention is intended to be used in packaging highly aggressive substances such as nicotine, rivastigmine, fentanyl or lidocaine, however, the invention should not be limited to these specific substances.

The term "film" according to the invention contemplates a product comprising a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or a base layer laminated with a tie layer and a contact layer.

Where the contact layer is laminated, for example using an EVOH film, the contact layer and tie layer may be either coextruded, or, the contact film layer may be laminated to the base layer optionally with an intermediate tie layer or the tie and contact layers may be the same material.

The term "laminate" according to the invention contemplates the film to which a further layer is laminated, such as a first outer layer.

A "packaging" is in the context of the invention intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate.

The term "highly aggressive substance" should be understood as a substance which is both very reactive with metals, acids, bases or functional groups such as ketones, alcohols, hydro carbons and/or esters, and/or, volatile but also easily migrates through barriers. Similarly, the term "aggressive chemical resistant film" means a film which when in contact with an aggressive substance does not allow more than 1.5 % w/w of nominal content to migrate to the packaging material or that 90-110% w/w of the aggressive chemical substance remains in the product when compared to Barex® as index 100.

Therefore, the films, laminates or packagings applicable for packing highly aggressive substances should have both chemical-resistant properties but also limit the migration of the aggressive substance through the film, laminate or packaging. The aggressive substance according to the invention is also or alternatively susceptible to degradation when exposed to ambient conditions, such as oxygen and water, it is volatile and able to migrate or a combination. Specifically, the aggressive substance is selected from but not

limited to nicotine, oils, such as spearmint and peppermint oil, licodaine, fentanyl or rivastigmine.

The term "oxygen and water resistant" as used in the context of the present invention contemplates material for which the oxygen transfer rate (OTR) and/or water vapor transfer rate (WVTR) is no more than 1 preferably no more than 0.1 as also indicated above. The term WVTR may also be referred to as the moisture vapor transfer rate (MVTR). WVTR and MVTR are equivalent.

The term "mechanically wear resistant layer" as used for the first outer layer in the context of the present invention should be a material which is suitable for the manufacture of a flexible packaging. The mechanically wear resistant layer may be chosen from materials such as polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets or combinations.

Further, the mechanically wear resistant material can be provided as a film that is biaxially oriented to give the film higher seal strength. The term "biaxial oriented" should be understood such that the provided polymer film has been stretched in both a longitudinal and a transverse direction during manufacturing.

The term "exterior side" should be understood in its broadest term. The term exterior environment is used for defining the direction opposite of the side that is facing the highly aggressive substance to be sealed by a laminate or packaging of the present invention. This means that the term exterior environment is independent on whether additional layers are coated, laminated or otherwise attached to the film. Thus, the word is used for specifying which direction a side of a layer is facing.

The various embodiments of the invention will now be illustrated with references to the figures and examples.

With reference to figure 1 a film of the invention will now be described in greater detail. The extreme chemical resistant film, 1, is obtained by providing a base layer, 2. A coextrusion layer, 5, comprising a tie layer, 3, and a contact layer, 4, is coated to one side of the base layer, 2, according to the method of the invention and is allowed to adhere. The base layer, 2, and the coextrusion layer, 5, define the film according to all the aspects of the invention. Consequently, the film is provided with a base layer side, 2, and a

coextrusion layer side 5, wherein the base layer side, 2, is intended for facing the exterior environment and the coextrusion layer side, 5, is intended for facing the highly aggressive substance to be sealed.

The coextrusion layer may be coated to the aluminium layer by a co-extrusion system generally known in the art to provide the coextrusion layer coated on the first side of the aluminum layer. The coextrusion layer may be applied in an amount of 7-40 g/m3. After coating of the aluminium layer and subsequently cooling, the coextrusion layer is adhered to the side of the tie layer facing away from the aggressive chemical substance.

The coextrusion is preferably performed at a temperature of 240-330°C, more preferred 270 - 300°C and the speed of the application/coating is in the range of 150 to 600 m/min. The equipment suitable for extruding and laminating films and laminates according to the invention may be obtained from Bobst.

When using coextrusion, it is possible to obtain a multi layer which is thinner than multilayer layers provided by sequential film application techniques without compromising the extreme chemical resistance properties of the first laminate. Hence, the present invention does not only provide an extreme chemical resistance laminate, and packaging comprising the same but at the same time the manufacturing process is more cost effective since less polymer, forming the contact layer, has to be used.

Another embodiment of a film in which the tie layer comprises two layers is illustrated in figure 2. The extreme chemical resistant film, 1, is obtained by providing a base layer, 2. The coextrusion layer, 5, comprises a tie layer, 3, comprising a first layer, 3a, and a second layer, 3b, and a contact layer 4. The coextrusion layer is coated onto one side of the base layer, 2, according to the method of the invention and is allowed to dry.

In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b, where the first layer of EAA faces the base layer and second layer of the PE faces the contact layer, 4.

The extreme chemical resistant film according to the invention is intended for use as a component of a packaging suitable for sealing a highly aggressive substance. The film may constitute the packing itself.

To further improve the mechanical wear resistance of the film a first

outer layer may be laminated to the base layer side of the film or simply be wrapped around the film to provide a laminate. Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the invention, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.

The first outer layer, 21, is a mechanically wear resistant layer which adds safety properties to the wrapping ensuring that the wrapping is not inadvertently opened. Hence, the outer layer can also be seen as a child proof layer meaning that the layer is made of a material and is sealable in such a way that it is difficult for children to open. Additionally, the outer layer may be provided with a second outer layer, 20.

The second outer layer, 20, is typically a paper layer, wherein the paper layer is facing the exterior environment; the exterior facing side of the second layer may be printed as desired. The second outer layer, such as the paper layer is added to improve the stiffness of the packaging in addition to providing a printing platform.

Furthermore, it is within the inventive concept of the present invention that an adhesive agent is applied between the first outer layer and the base layer and/or between the first outer layer and the second outer layer. The obtained packaging may then be assembled in such a way that the various layers do not part during handling, printing and/or packaging of the substance to be packed.

After production, the film, laminate or packaging may be stored as rolls ready for use in further lamination or packaging of the aggressive substance to be packed.

In use, the packaging is sealed around the substance to be packed so that the contact layer of the coextrusion layer faces the interior side and the substance, and, the base layer, first outer layer or second outer layer, as applicable, face the exterior side, so as to create a hollow interior for containing the, substance, such as the aggressive substance.

The sealing of the packaging is achieved in such way that the contact layer of the coextrusion layer is facing the aggressive substance so that the remaining part of the package is protected by the contact layer of the coex-

trusion layer. In this way, the aggressive substance is encompassed by the inner side of packaging and will therefore only have direct contact with the contact layer of the coextrusion layer.

In general, the order in which the different layers of the packaging according to the invention are applied to the base layer is flexible. Hence, the first outer layer may be applied before the coextrusion layer and the other way around. The order depends on which production line is suitable in a specific situation.

In more details the packaging according to the present invention may in one embodiment be manufactured by obtaining a film comprising a base layer, such as an aluminum layer and a coextrusion layer comprising a biopolymer of ethylene and acrylic acid as a tie layer and EVOH as the contact layer coated to the aluminium as described above. The base layer side of the film may then be provided with an adhesive agent and subsequently laminated to a biaxial orientated PET-film which is the first outer layer, i.e. the mechanically wear resistant layer. The PET-film is further provided with an adhesive agent on the exterior side of the mechanically wear resistant layer and is subsequently laminated to a paper layer for providing the final packaging.

An aggressive substance, such as but not limited to lidocaine, is placed on the contact layer side of the laminate which is welded around the substance, such as to form a pouch with an inner side and an outer side. Accordingly, the interior of the pouch consists of the coextrusion layer, where the contact layer of EVOH facing the aggressive substance thereby protects the rest of the provided packaging and the exterior side is the paper layer.

In general, the lamination procedure for laminating the mechanically wear resistant or paper layer to each other or to the base layer is routine procedure for the person skilled in the art.

According to all aspects of the invention the base layer may be selected from but not limited to a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluro polymers, such as commercial Alu foil from e.g. Hydro, or AlOx coated PET films obtainable from e.g. Toray Films Europe, or SiOx coated PET films obtainable from e.g. Celplast under the tradename Ceramis.

According to all aspects of the invention the tie layer may be made of a material selected from but not limited to a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and meth-acrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride, such as the commercial product Lotader® 3410 sold by Arkema or Nucrel® 0609HSA sold by Dupont®

According to all aspects of the invention the contact layer may be made of a material selected from cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol or mixtures thereof, such as the commercial products EVAL® C109B sold by Kuraray, Selar PA 3426 R sold by Dupont® or COC 6013M-07, COC 8007F-600, or 9506F500 sold by Topas® or EVOH obtainable from Nippon Gohsei under the tradename Soarnel.

According to all aspects of the invention the first outer layer may be made of a material selected from paper, polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or combinations, such as the commercial product F-PAP sold by Flexpet.

The invention will now be illustrated in more details with reference to the following non limiting examples.

RED Calculation

Determination of the HSP values and interaction radius for nicotine, rivastigmine, fentanyl and lidocaine requires that the solubility of the drug is evaluated against at least 16 solvents having a range of polar and hydrogen bonding properties. The methodology of determining HSP values, interaction radius and RED values are described in C.M. Hansen: "Hansen Solubility Parameters, A User's Handbook", CRC Press, 2007, Second Edition and exemplified in EP 2 895 531.

Typical solvents used to determine the HSP may be but is not limited to the solvents present in table 2.

Table 2: Typical solvents used to determine the HSP of a polymer or substance of interest.

Typical solvents used in Determining of HSP of rivagstigmine, lidocaine, fentanyl and nicotine	
Chemical name	Trade Designation or Alternate Name
Acetonitrile	Acetonitrile
Ethylene glycol n-Butyl Ether	Butyl CELLOSOLVE™ Glycol Ether
Dibutyl Ether	Dibutyl Ether
Dimethyl Formamide	Dimethyl Formamide
Dimethyl Sulfoxide	Dimethyl Sulfoxide
Methanol	Methyl alcohol
2-Butanone	Methyl Ethyl Ketone
4-Methyl-2-pentanone	Methyl Isobutyl Ketone
n-Butyl Acetate	n-Butyl Acetate
n-Heptane	n-Heptane
1-Propanol	n-Propyl Alcohol
o-Dichlorobenzene	1,2-Dichlorobenzene
Tetrahydrofuran	Tetrahydrofuran
Toluene	Methylbenzene
Propylene Carbonate	Propylene Carbonate
Water	Water

For assessing the solubility of Rivastigmine, Lidocaine, fentanyl and nicotine in the solvents an experimental measurement is performed. The solubility is assesed based on the visual observation of 0.5 g of the chemical substance in a vial with 5 cm^3 solvent at room temperature. The vial is capped with a polyethylene-lined lid and labeled with the solvent loaded. The vials are placed in a vial shaker at low speed at room temperature. After 24 hours, the samples are removed from the vial shaker, and allowed to sit for 30 min before they are visually rated. The rating is performed by giving each solvent a score being 0 for insoluble and 1 for soluble. The numerical ratings are then entered into the HSPiP software program to obtain the HSP (Hansen solubility parameters). R (radius) values for the compound of relevance, e.g. nicotine, rivastigmine, fentanyl and/or lidocaine is inserted, and a report is

generated. The report lists the final parameters and R values calculated for nicotine, rivastigmine, fentanyl and/or lidocaine. The report also lists the solvents used in the evaluation, their HSP values (taken from a database), the rating of the visual observations, and their RED values with a specific polymer of interest.

Example 1- performance of a laminate according to the invention compared to a commercially used laminate

A study was conducted to evaluate the performance of four laminates according to the present invention as compared to a commercially available laminate product comprising Barex® as the contact layer.

The wrappings according to the invention were compared to the performance of a Barex® laminate currently used in the field.

The test is a resistance test, wherein the migration of rivastigmine to the laminates is evaluated.

Table 3: The composition of the 6 wrappings was a follows, laminates 1 to 5 are laminates according to the invention

	Adhesive/Polymer layer Coextrusion layer	Base layer	First outer layer	Second Outer layer
Commercially used Barex® laminate (prior art)	Adhesive/ Barex® film	Al	PET	Paper
Laminate 1	Tie layer: Bipolymer of ethylene and acrylic acid (Nucrel 0609 HAS) Contact layer: PA (Selar PA 3426R)	Al	PET	
Laminate 2	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 60% (EVAL C109B) and PE 40%	Al	PET	
Laminate 3	Tie and contact layer: EvOH film (EVAL C109B)	Al	PET	
Laminate 4	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 100% (EVAL C109B)	Al	PE	PET
Laminate 5	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: COC	Al	PE	PET

*Between the paper/PET, PET/Al, and Al/EVOH film layers an adhesive was applied.

Laminates 1 to 5 were obtained according to the method of the invention. For laminates 1, 2, 4 and 5 a coextrusion layer was coated to the base layer and in laminate 3 the combined tie and contact layer was laminated to the base layer. For the co-extrusion layers, the loading of the tie layers was between 4-18 g/m^2 and the loading of the contact layer was 8-12 g/m^2.

The resulting laminates were wrapped around a patch containing rivastigmine as API and the migration of the API to the packaging material/wrapping was measured after 2, 4, 8 and 12 weeks at 40 °C. The API in the wrapping was measured by extracting the packaging and analysing the amount of API therein using Mass spectrometry.

The Rivastigmine patches tested were commercially available patches originally containing 9.5 mg API/patch.

The results are shown in figure 4 illustrating the resulting migration of rivastigmine (weight API extracted from the laminate) to the laminate in percentage of the content of the original patches of 9.5 mg.

The columns are denoted 1, 2, 3 and 4 respectively to the order they are shown from left to right in figure 4. Hence column 1 (furthest to the left) for each contact layer polymer used shows the results for the 6 laminates after two weeks. Column 2 shows the results for the 6 laminates after four weeks. Column 3 shows the results for the 6 laminates after 8 weeks, and column 4 shows the results for the 6 laminates after 12 weeks.

The Barex® laminate is a reference known for applicability in the art and comparison were made for evaluating the properties of the laminates according to present invention.

From the figure it is clear that the results for laminates according to the invention obtained by coextrusion of either of EVOH, PA, or COC as well as laminating EVOH provides for an improved chemical resistant laminate compared to the commercially used Barex® laminate, meaning that less migration occurs.

Also, a contact layer, illustrated as laminate 2, of a blend of EVOH and PE was prepared and tested. Though the properties of this blend with rivastigmine as API resulted in a higher migration of the API than Barex®, the rate is still below the limit demanded in the industry and hence, it illustrates that blends as provided in laminate 2 are usable alternatives to

Barex® as well. Surprisingly though the tie/contact layer made of 100% EVOH was markedly superior to the blend.

Also, a contact layer, illustrated as laminate 3, a film of EVOH laminated to aluminum was prepared and tested. Surprisingly, it was shown that the use of EVOH in the form of a film laminated to aluminum provided a chemical resistant laminate.

Example 2 - stability test of a chemical substance wrapped in laminates according to the invention and wrapped in a prior art product using Barex®

Similar to the test described in example 1, laminates according to the invention were prepared as outlined in table 4 below. A lidocaine patch containing 40 mg lidocaine was wrapped in the pouch, packaged and stored at 40°C for seven days.

Table 4: Packagings for lidocaine stability test.

	Barex Commercially used Barex® laminate (prior art)	COC coex same as laminate 5 of example 1	Coex EVOH same as laminate 4 of example 1

Stability of the API is important to ensure that the dose indicated on the packaging is correct. A value of 90% - 110% of the original dose after one week when stored at 40°C using Barex® as index 100 is considered acceptable. Figure 5 illustrates the results of the test where the y-axis indicates the weight decrease of the two laminates according to the invention using Barex as index 100.

As can be seen from figure 5, both inventive laminates have a lower value than the index 100 Barex® comparative product, however with a value within the acceptable limits. The lower %value of the laminates according to the invention indicates that more lidocaine has disappeared from the patch.

C L A I M S

1. A method for providing a, e.g. aggressive chemical resistant, film, said method comprising the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer; and,

wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards an aggressive chemical of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

2. A method according to claim 1, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluro polymers.

3. A method according to any one of the claims 1 to 2, wherein the tie layer is made of 1, 2, 3, 4 or 5 layers.

4. A method according to claim 3, wherein all the layers of the tie layer are coextruded with the contact layer.

5. A method according any one of the preceding claims, wherein the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride.

6. A method according to any one of the claims 1 to 4, wherein the tie layer comprises at least two layers, and wherein the first layer comprises a copolymer according to claim 5 and the at least second or more layer(s) comprises a material selected from EEA, PE, EMA, EAA or a combination.

7. A method according to any one of the preceding claims, wherein

the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

8. A method according to anyone of the preceding claims wherein the contact layer is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

9. A method according to anyone of the preceding claims, wherein the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m^2 and/or the contact layer has a loading in the range of 4 to 20 g/m^2 and the loading of the film is not more than 40 g/m^2.

10. A method according to any of the preceding claims, wherein the film is used to wrap a composition comprising a chemical selected from nicotine, lidocine and rivastigmine

11. A method according to claim 10, wherein the composition is a patch.

12. A method according to claim 10 or 11, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/-10% in comparison to a Barex® patch as index 100.

13. An aggressive chemical resistant film comprising at least a base layer, which is water and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

14. A film according to claim 13, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, such as polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluropolymers; and/or

the tie layer is constituted of one layer and wherein the layer is made of a copolymer, said copolymer comprising a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a third polymer, which third polymer is preferably made of a material selected from glycidyl methacrylate, and more preferably maleic anhydride; and/or

wherein the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

15. A film according to claims 13 or 14, wherein the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m^2 and/or the contact layer has a loading in the range of 4 to 20 g/m^2 and the loading of the film is not more than 40 g/m^2.

16. A laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;

- an aggressive chemical resistant film according to any of claims 13 to 15, said film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, where the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2; and, where the base layer side of the film is facing the first outer layer.

17. A laminate according to claim 16, wherein the laminate further comprises a second outer layer facing the exterior side of the outer layer, preferably the second outer layer is a paper layer.

18. A laminate according to any of the claims 16 to 17, wherein the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine.

19. A laminate according to claim 16, 17, and 18, wherein the laminate is heat sealable.

20. A laminate according to claim 16 to 19, wherein a maximum of 10%, preferably a maximum of 5%, even more preferably a maximum of 2% of the active ingredient is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

21. An aggressive chemical substance packed in a heat sealable laminate, said heat sealable laminate comprising

- a first outer layer made of a mechanically wear resistant material;

- an aggressive chemical resistant film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextru-

sion layer comprising a tie layer and a contact layer, wherein the base layer side of the film is facing the outer layer; and, wherein the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

22. Use of a polymer having a RED value based on Hansens Solubility parameter (HSP) of > 0.8, preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a base layer which is water and/or oxygen resistant, said film is coated to a, optionally coextruded, layer comprising a tie layer and the contact layer.

23. Use according to claim 22, wherein the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

24. A method for providing an aggressive chemical resistant film said film being resistant against nicotine, rivastigmine, fentanyl and/or lidocaine, and wherein said method comprises the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards nicotine, rivastigmine, fentanyl and/or lidocaine of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

25. A method for providing an aggressive chemical resistant film said film being resistant against nicotine, rivastigmine, fentanyl and/or and lidocaine, and wherein said method comprises the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

26. A method according to claim 25, wherein the film is used to wrap a composition comprising a chemical selected from nicotine, lidocaine, fentanyl and rivastigmine

27. A method according to claim 26, wherein the composition is a patch.

28. A method according to claim 26 and 27, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/-10% in comparison to a Barex® patch as index 100.

29 A laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;

- an aggressive chemical resistant film according to claim 25, said film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, where the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

30. A laminate according to claim 29, wherein the laminate is wrapped around a composition comprising the aggressive chemical substance and wherein a maximum of 10% w/w, preferably a maximum of 5% w/w, even more preferably a maximum of 1.5% w/w, most preferably a maximum of 0.5% w/w of the aggressive chemical substance based on nominal content is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

31. A laminate according to claim 30, wherein the aggressive chemical substance is selected from the group consisting of rivastigmine, lidocain, fentanyl and nicotine.

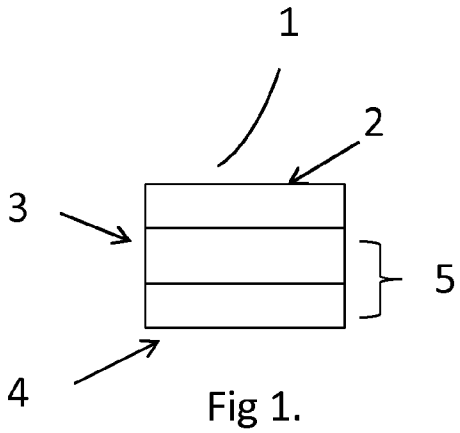


Fig 1.

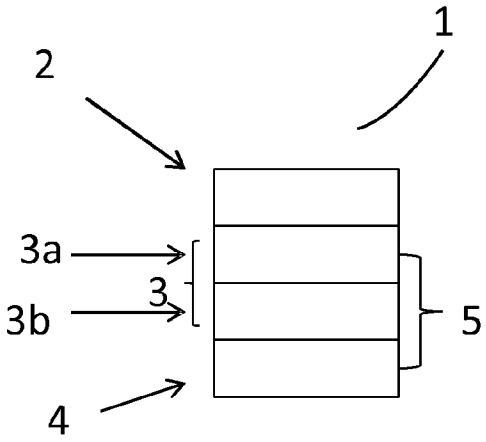


Fig. 2

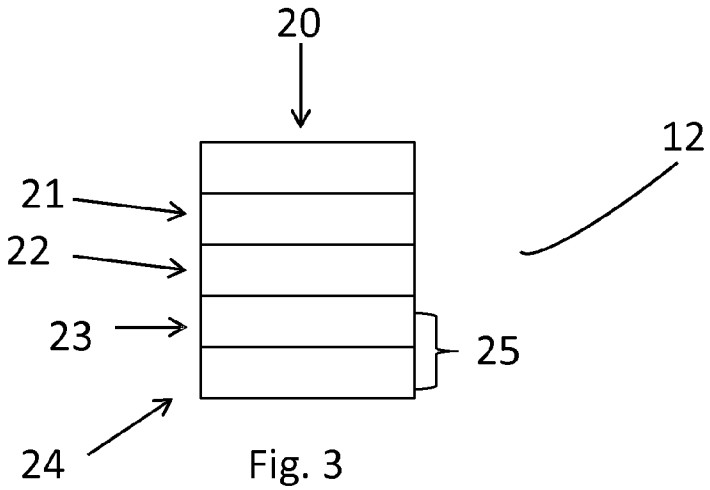


Fig. 3

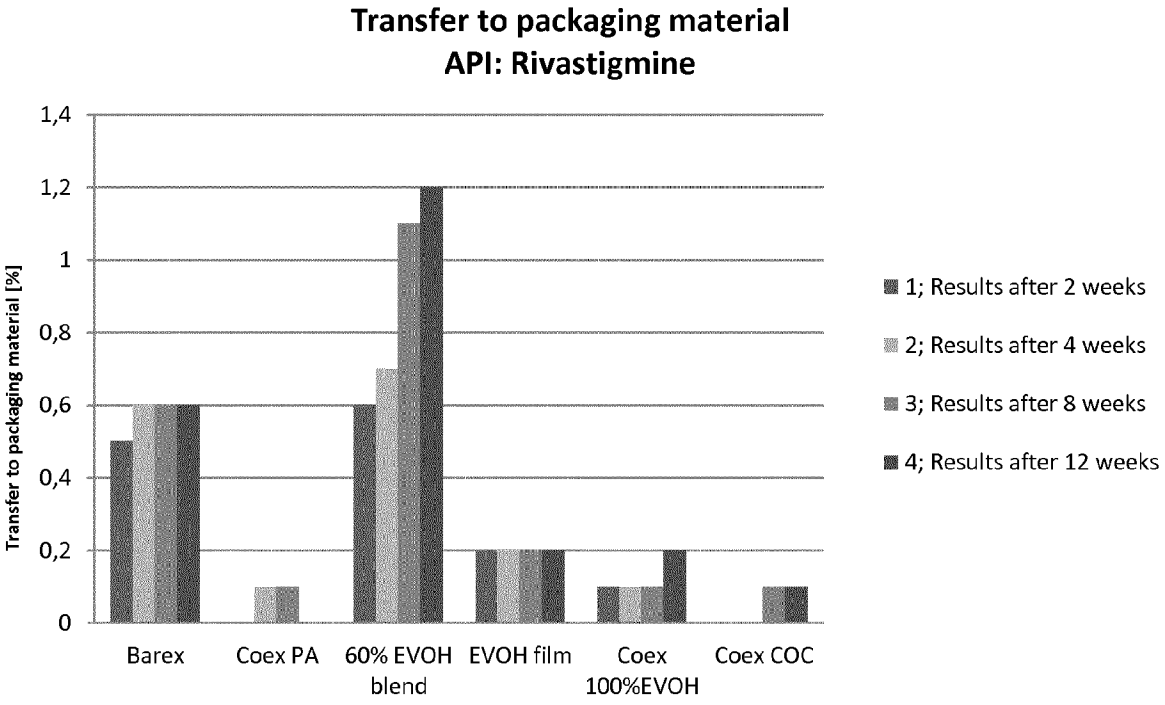

Transfer to packaging material
API: Rivastigmine
Transfer to packaging material [%]
1,4
1,2
1
0,8
0,6
0,4
0,2
0
Barex
Coex PA
60% EVOH blend
EVOH film
Coex 100%EVOH
Coex COC
1; Results after 2 weeks
2; Results after 4 weeks
3; Results after 8 weeks
4; Results after 12 weeks

Fig. 4

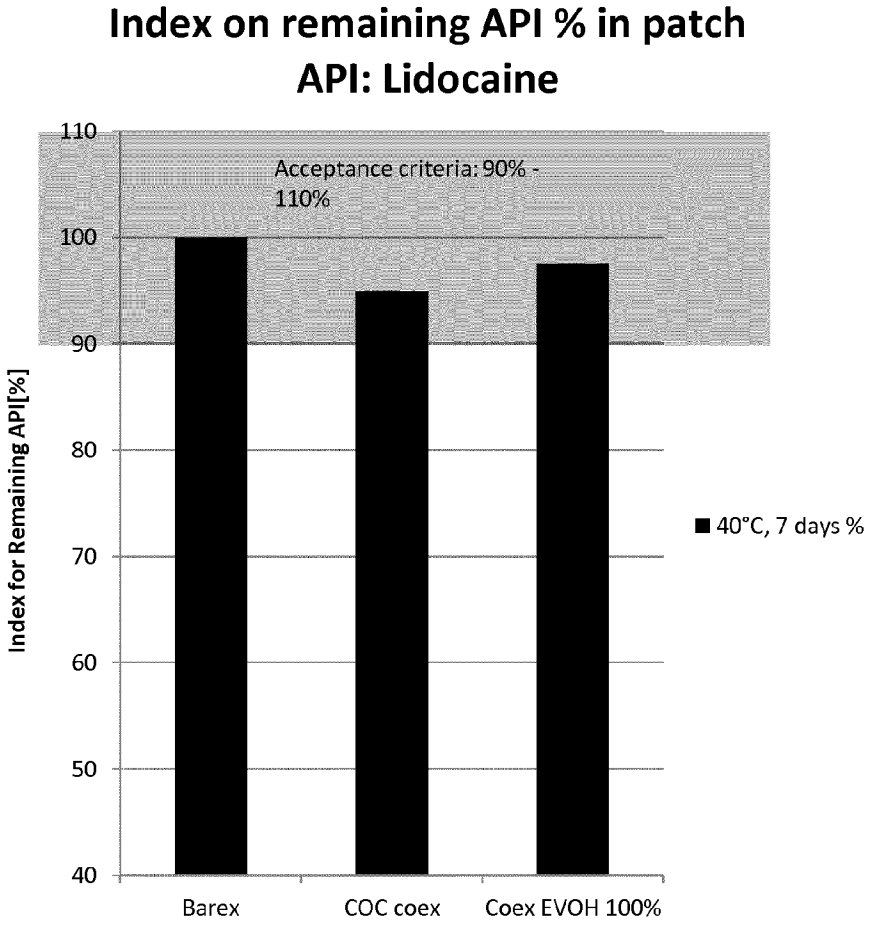

Index on remaining API % in patch
API: Lidocaine
Acceptance criteria: 90% - 110%
110
100
90
80
70
60
50
40
Index for Remaining API[%]
Barex
COC coex
Coex EVOH 100%
40°C, 7 days %

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/082876

A. CLASSIFICATION OF SUBJECT MATTER
INV. B32B7/12 B32B15/08 B32B15/082 B32B15/085 B32B15/20
B32B27/08 B32B27/30 B32B27/32 B32B27/36
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B32B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 120 860 A (BOWEN WILLIAM E [US] ET AL) 19 September 2000 (2000-09-19) column 2, line 24 - column 3, line 8 page 3, line 30 - page 5, line 14 page 5, line 33 - line 44 page 6, line 27 - line 40; claims -----	1-31
X	US 2005/037162 A1 (ADAMS JOHN PETER [US]) 17 February 2005 (2005-02-17) figures paragraphs [0028], [0045] sample E; page 3; table claim -----	1-31
	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" doument member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 March 2017	30/03/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mazet, Jean-François

1

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

International application No
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/082876

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		WO 2005056634 A1	23-06-2005
WO 2015174502 A1	19-11-2015	NONE	
WO 9109731 A1	11-07-1991	AT 166029 T	15-05-1998
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		WO 9109731 A1	11-07-1991
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Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Filer:	Gregory Stamm Vickers/Loni Clay
Attorney Docket Number:	TRO-45953

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	2	100	200
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1920**

Electronic Acknowledgement Receipt

EFS ID:	36632367
Application Number:	16516792
International Application Number:	
Confirmation Number:	2546
Title of Invention:	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE
First Named Inventor/Applicant Name:	Manuella Herb
Customer Number:	75626
Filer:	Gregory Stamm Vickers/Loni Clay
Filer Authorized By:	Gregory Stamm Vickers
Attorney Docket Number:	TRO-45953
Receipt Date:	19-JUL-2019
Filing Date:	
Time Stamp:	14:27:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1920
RAM confirmation Number	072219INTEFSW14280700
Deposit Account	180160
Authorized User	Loni Clay

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Assignee showing of ownership per 37 CFR 3.73	TRO45953_37CFR373.pdf	117730 fb0ed078ca9ee2cc7c553e65e93756d39f9d0cf2	no	3
Warnings:					
Information:					
2	Application Data Sheet	TRO45953_ADS.pdf	1256240 0d8b88e3c11e7298d695b4ac12634e33394b78c6	no	9
Warnings:					
Information:					
3	Oath or Declaration filed	TRO45953_Declarations.pdf	2621791 13a7803b192a7fd0bf38ad26ed366ddba5f76a11	no	3
Warnings:					
Information:					
4	Drawings-only black and white line drawings	TRO45953_Drawings.pdf	27537 e4430338de02d306ad5bbf59ebc562cde283bcf9	no	3
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	TRO45953_IDS.pdf	1034341 1f711a0b7d8538a84c1001e6f276e6214b2876eb	no	4
Warnings:					
Information:					
6	Power of Attorney	TRO45953_POA.pdf	1066041 95a7b3109576a2e0670c435c30601b2a9f89f642	no	1
Warnings:					
Information:					

7		TRO45953_PreliminaryAmendment.pdf	105284 22480cfb3dbfe5a5efc65528a03e09bd9aedfe94	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Abstract	6	6
	Claims	2	5
	Preliminary Amendment	1	1

Warnings:

Information:

8	Other Reference-Patent/App/Search documents	TRO45953_SearchReport.pdf	343370 c1704f5676aa71309ae959afaa292458aa2ce3af	no	10

Warnings:

Information:

9	Translation of Foreign Priority Documents	TRO45953_Specification.pdf	95621 d5652640c74be870482ef23fda90f25b10924373	no	17

Warnings:

Information:

10	Miscellaneous Incoming Letter	TRO45953_SpecificationLetter.pdf	56943 06c9eb12188731ae6d43c22e4f7535a1e2cb016a	no	1

Warnings:

Information:

11		TRO45953_SubSpecClean.pdf	103000 c233719a059f49f6613fcff3391efb3affbcac7f	yes	15

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Abstract	15	15
	Specification	1	14

Warnings:

Information:					
12	Specification	TRO45953_SubSpecMarked.pdf	104090 0a8f4f369b863bd1d8ebd4f25acbf07d1171c0cc	no	15
Warnings:					
Information:					
13	Transmittal of New Application	TRO45953_Transmittal.pdf	299413 824debe02c4d3d5ad359234800b9ed3cc5953e35	no	2
Warnings:					
Information:					
14	Foreign Reference	TRO45953_WO2017114922A1.pdf	1866971 cfca6c09ef5d09d268828f1b6f8d64a4109c3791	no	41
Warnings:					
Information:					
15	Fee Worksheet (SB06)	fee-info.pdf	36886 7f415f54958baaf60061798cdc73552d0b91051e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	9135258		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Huhtamaki Flexible Packaging Germany GmbH & Co. KG

Application No./Patent No.: Not Yet Assigned Filed/Issue Date: July 19, 2019

Titled: FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

Huhtamaki Flexible Packaging Germany GmbH & Co. KG, a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Gregory S. Vickers/	July 19, 2019
Signature	Date
Gregory S. Vickers	45180
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TRO-45953
	Application Number	
Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Manuella		Herb	

Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

City	Görisried	Country of Residence i	DE

Mailing Address of Inventor:

Address 1	Vorderstaig 5
Address 2	
City	Görisried
State/Province	
Postal Code	87657
Country i	DE

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Michael		Dorn	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	Dietmannsried	Country of Residence i	DE

Mailing Address of Inventor:

Address 1	Grüntenweg 16
Address 2	
City	Dietmannsried
State/Province	
Postal Code	87463
Country i	DE

Inventor 3 Remove

Legal Name

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TRO-45953
	Application Number	
Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Thomas		Stroh	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	Memmingen	Country of Residence i	DE

Mailing Address of Inventor:

Address 1	Im Paradies 45		
Address 2			
City	Memmingen	**State/Province**	
Postal Code	87700	**Country** i	DE

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	75626		
Email Address	vickers@rankinhill.com	Add Email	Remove Email
Email Address	clay@rankinhill.com	Add Email	Remove Email

Application Information:

Title of the Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE		
Attorney Docket Number	TRO-45953	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	3	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TRO-45953
	Application Number	
Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	75626		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TRO-45953
	Application Number	
Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
10 2018 212 303.9	DE	2018-07-24	

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
10 2018 125 195.5	DE	2018-10-11	

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TRO-45953
	Application Number	
Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TRO-45953
	Application Number	
Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Huhtamaki Flexible Packaging Germany GmbH & Co. KG		
Mailing Address Information For Applicant:			
Address 1	Heinrich-Nicolaus-Strasse 6		
Address 2			
City	Ronsberg	**State/Province**	
Country	DE	Postal Code	87671
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Gregory S. Vickers/			Date (YYYY-MM-DD)	2019-07-19
First Name	Gregory S.	Last Name	Vickers	Registration Number	45180

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TRO-45953
	Application Number	
Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	FILM COMPOSITE FOR PACKAGING TRANSDERMAL PATCHES, AND PACKAGE MADE OF SUCH A FILM COMPOSITE

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [x] The attached application, or
- [ ] United States application or PCT international application number _____

  filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Manuella Herb Date (Optional): 18 OCT 2019

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____

  filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: Michael Dorn Date (Optional): 18.07.2013

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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- [ ] United States application or PCT international application number _____

  filed on _____.

The above-identified application was made or authorized to be made by me.

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LEGAL NAME OF INVENTOR

Inventor: Thomas Stroh Date (Optional): 18.07.2013

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Fig. 1

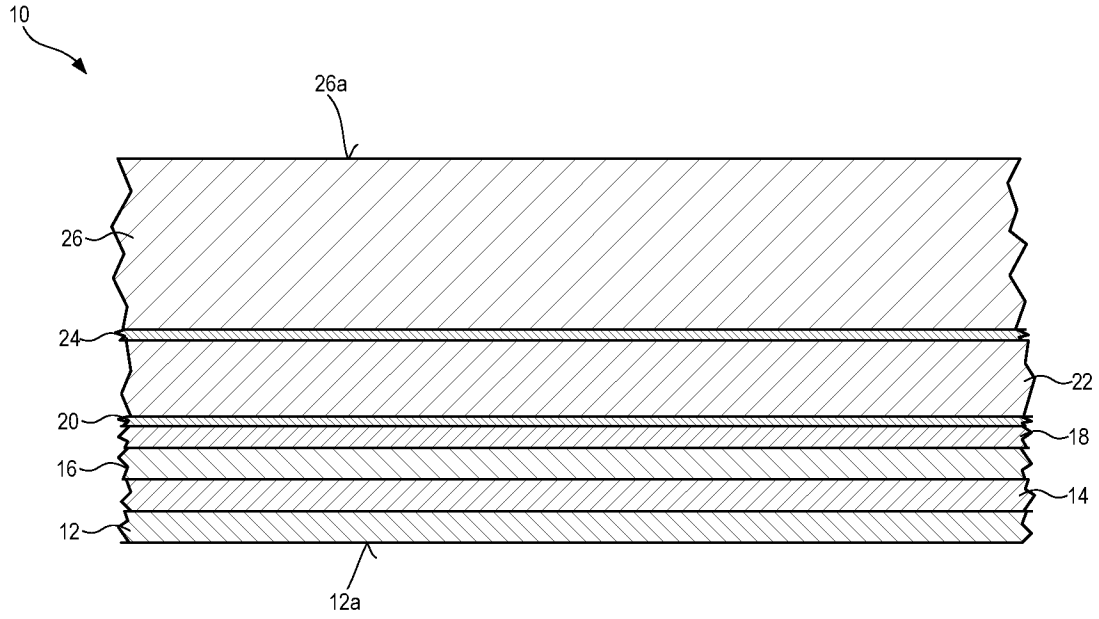


Fig. 2

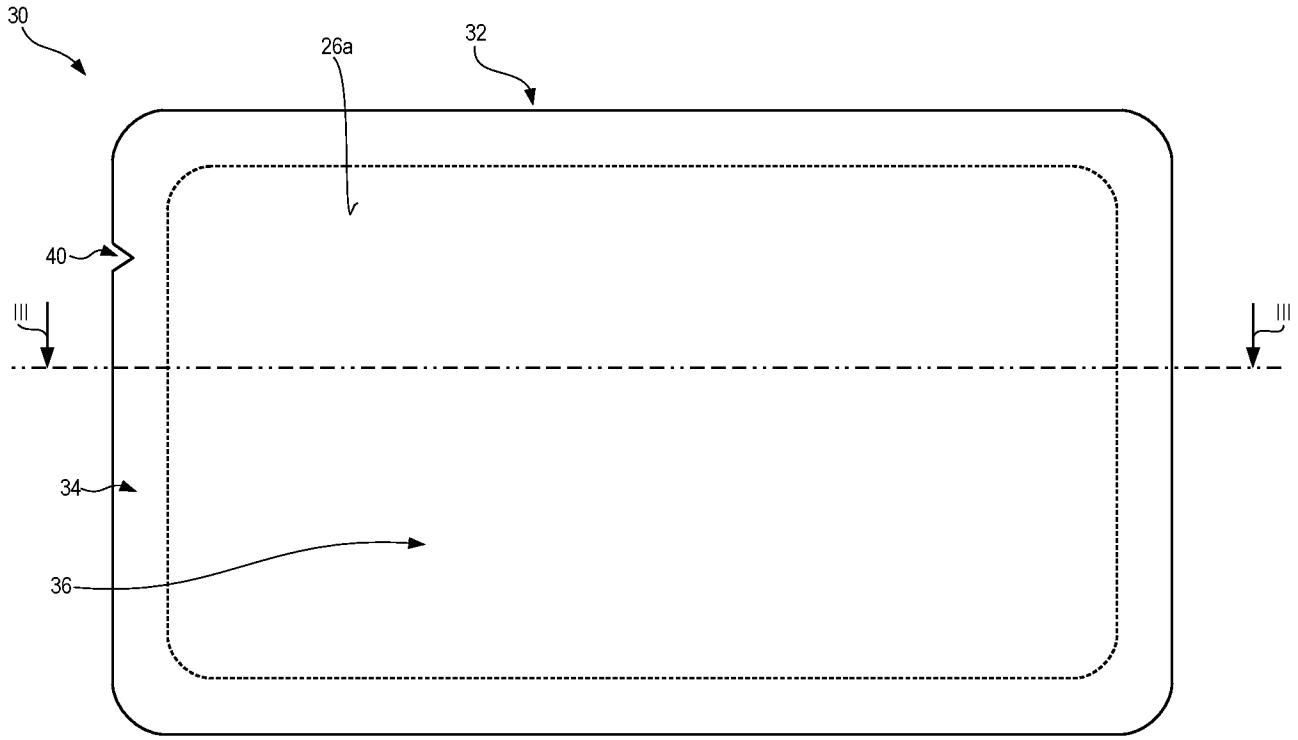


Fig. 3

