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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

<i>Index of Claims</i> 	Application/Control No. 16/835,018	Applicant(s)/Patent Under Reexamination Christensen et al.
	Examiner FRANCES TISCHLER	Art Unit 1765

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	02/01/2021	05/17/2021							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
	13	N	N							
	14	N	N							
	15	N	N							
	16	N	N							
	17	N	N							
	18	N	N							
	19	N	N							
	20	N	N							

Search Notes 	Application/Control No. 16/835,018	Applicant(s)/Patent Under Reexamination Christensen et al.
	Examiner FRANCES TISCHLER	Art Unit 1765

CPC - Searched*		
Symbol	Date	Examiner
B05D1/265 OR B32B15/082 OR B32B15/20 OR B32B1/00 OR B32B2250/05 OR B32B2307/714 OR B32B2307/7244 OR B32B2307/7265 OR B32B2323/00 OR B32B2398/20 OR B32B2439/00 OR B32B27/08 OR B32B27/306 OR B32B27/308 OR B32B27/32 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/153 OR B32B7/12	02/01/2021	/FT/
updated search	05/17/2021	/FT/

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.

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<i>Search Notes</i> 	Application/Control No. 16/835,018	Applicant(s)/Patent Under Reexamination Christensen et al.
	Examiner FRANCES TISCHLER	Art Unit 1765

Search Notes		
Search Notes	Date	Examiner
East text search; inventor and company search; classification search, codes shown above; combination of East text search and classification search; combination of East text search and inventor search; combination of East text search and company search; considered/examined all IDS; searched google scholar and google patent and IP.com; search terms included, for instance: (cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud\$5 and (ethylene adj acrylic)	02/01/2021	/FT/
updated search	05/17/2021	/FT/

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

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 17:13
S2	1	"6120860".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:07
S4	1	"20040234790".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:10
S5	1	"20050106344".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:11
S6	1	"6790496".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:12
S7	1	"20050037162".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:47
S8	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:50
S9	3	((("DANAPAK") near3 ("FLEXIBLES") near3 ("A/S"))).AS,AANM.	USPAT	NEAR	ON	2021/01/31 19:50
S10	142	((("DANAPAK") near3 ("FLEXIBLES"))).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:51
S11	350,512	(B05D1/265 OR B32B15/082 OR B32B15/20 OR B32B1/00 OR B32B2250/05 OR B32B2307/714 OR B32B2307/7244 OR B32B2307/7265 OR B32B2323/00 OR B32B2398/20 OR B32B2439/00 OR B32B27/08 OR B32B27/306 OR B32B27/308 OR B32B27/32 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/153 OR B32B7/12).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:53

S12	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud\$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:55
S13	14	("20090208685" "20110158564" "20150225151" "20160325534" "20170158400" "5613958" "6670423" "6891018" "6921563" "8703283" "8722164" "9452593" "9487918" "9663281").PN.	US-PGPUB; USPAT	NEAR	ON	2021/01/31 19:57
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S15	0	S12 and S14	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S16	0	S12 and S13	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S17	3	S12 and S8	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S18	3	S12 and S10	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S19	21	S12 and S11	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:01
S20	0	S12 and S2	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S21	0	S12 and S3	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S22	0	S12 and S4	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S23	0	S12 and S5	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S24	0	S12 and S6	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02

S25	0	S12 and S7	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
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S33	145	((("DANAPAK") near3 ("FLEXIBLES"))).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/17 16:33

S34	309	((("CHRISTENSEN") near3 ("Lars"))) OR ((("JOHANSEN") near3 ("Peter"))) OR ((("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/05/17 16:33
S35	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud\$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/17 16:34
S36	4	S35 and S33	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/17 16:35
S37	3	S35 and S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/17 16:35

EAST Search History (Interference)

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5/18/2021 7:35:46 AM

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/835,018		Filing Date 03/30/2020		☐ To be Mailed			
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)		(Column 2)							
FOR		NUMBER FILED		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	05/10/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 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".								/ANNIE C SINGLETON/			
*** 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

In re application of:

Christensen et al.

For: A METHOD FOR PROVIDING AN
EXTREME CHEMICAL RESISTANT
FILM, A FILM AND LAMINATE
OBTAINABLE THEREFROM

Application No.: 16/835,018

Filed: March 30, 2020

Docket No.: P006DK.WO.US.01
(87942.0014)

Customer No.: 26582

Confirmation No.: 7472

Examiner: Frances Tischler

Art Unit: 1765

AMENDMENT**CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being filed
via EFS-Web with the United States Patent and
Trademark Office on: May 10, 2021.

By: / Wendy Nishida /
Wendy Nishida

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

Commissioner:

In response to the non-final Office Action dated February 9, 2021, please enter the
following amendments and remarks:

Amendments to the Claims begin on page 2.**Remarks begin on page 5.**

Electronic Acknowledgement Receipt

EFS ID:	42677121
Application Number:	16835018
International Application Number:	
Confirmation Number:	7472
Title of Invention:	METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM
First Named Inventor/Applicant Name:	Lars Christensen
Customer Number:	26582
Filer:	Paul M. Schramm/Wendy Nishida
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P006DK.WO.* (87942.0014)
Receipt Date:	10-MAY-2021
Filing Date:	30-MAR-2020
Time Stamp:	19:41:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P006DanapakFlexibles.pdf	134650	yes	11
			dc032b31873b55be0e89a3ef0ee622ff484b4664		

Multipart Description/PDF files in .zip description			
Document Description		Start	End
Applicant Arguments/Remarks Made in an Amendment		5	11
Claims		2	4
Amendment/Req. Reconsideration-After Non-Final Reject		1	1

Warnings:

Information:

Total Files Size (in bytes):	134650
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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.

REMARKS

Status of the Claims

Before this Amendment, claims 1–12 were present for examination and claims 13–20 were previously withdrawn from consideration. In this Amendment: claims 1 and 4–7 are amended; no claims are canceled; and no new claims are added. Therefore, claims 1–12 are present for examination, and claim 1 is the independent claim. Support for the amendments to the claims may be found throughout the Specification as filed including at least at Paragraphs [0040] and [0116], as well as Figures 1 and 2. No new matter is added with these amendments.

In the non-final Office Action dated February 9, 2021 (“Office Action”): claims 1–12 were rejected under 35 U.S.C. § 102 over U.S. Patent Publication No. 2005/0037162 to Adams (“Adams”); claims 1–12 were rejected under 35 U.S.C. § 103 over U.S. Patent Publication No. 2005/0037162 to Adams (“Adams”); claims 1–12 were rejected under 35 U.S.C. § 103 over U.S. Patent No. 6,120,860 to Bowen et al. (“Bowen”) and Adams; claims 1–12 were rejected for non-statutory double patenting over U.S. Patent Application No. 16,425,067 to Johansen et al. (“Johansen”); claims 1–12 were rejected for non-statutory double patenting over U.S. Patent Application No. 16,780,999 to Gu et al. (“Gu”); and claims 1 and 4–7 were objected to for certain informalities. Applicant respectfully requests reconsideration.

Double Patenting

It appears that the Office Action incorrectly listed U.S. Patent Application No. 16,780,999 to Gu et al. (“Gu”) instead of U.S. Patent Application No. 15,780,999 to Christensen et al. (“Christensen”). Without conceding the merits of the rejection—and solely to expedite prosecution—Applicant has addressed the rejection in view of Christensen. The Office Action rejected claims 1–12 on the ground of non-statutory obviousness-type double patenting over claims 1–20 of Johansen and claims 1–36 Christensen. *See* Office Action, pp. 9 and 10. The Office Action states that the filing of a terminal disclaimer would overcome the double patenting rejection. *See id.*, p. 8.

Applicant has submitted an electronic terminal disclaimer with this response. Applicant submits this terminal disclaimer to expedite allowance of the pending claims and does not

concede the merits of the double patenting rejection or any determination regarding whether claims 1–12 are patentably distinct over claims 1–20 of Johansen and claims 1–36 Christensen.

Applicant believes that the terminal disclaimer overcomes the double patenting rejection, and accordingly requests that the double patenting rejection of claims 1–12 be withdrawn.

Objections to the Claims

The Office Action objected to claims 1 and 4–7 for certain informalities. *See* Office Action, p. 2.

Without conceding the merits of the objection—and solely to expedite prosecution—Applicant has amended claims 1 and 4–7 to recite “g/m².”

Accordingly, Applicant requests that the objection to the claims be withdrawn.

35 U.S.C. § 102 & § 103

The Office Action rejected claims 1–12 under 35 U.S.C. § 102 over Adams or alternatively, under 35 U.S.C. § 103 over Adams. The Office Action further rejected claims 1–12 under 35 U.S.C. § 103 over the stated combinations of Adams and Bowen.

Factual findings made by the Office are the “necessary underpinnings to establish obviousness.” MPEP § 2141(II). The Office must set forth “the relevant teachings of the prior art relied upon.” MPEP § 2142. In *KSR International Co. v. Teleflex Inc.*, the Supreme Court noted that the analysis supporting a rejection under 35 U.S.C. § 103 must be made explicit. *See* 550 U.S. 398, 418 (2007); MPEP § 2142. “[O]bviousness [also] requires a suggestion of all limitations in a claim.” *In re Wada and Murphy*, Appeal 2007-3733 (citing *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)).

Independent Claim 1

Without conceding the merits of the rejection of independent claim 1 under 35 U.S.C. § 102 and § 103—and solely to expedite prosecution—Applicant has amended independent claim 1. For example, independent claim 1 has been amended to recite, in part, “coextruding a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin

copolymer (COC) to provide a coextrusion layer” and “coating the coextrusion layer directly to the base layer.”

35 U.S.C. § 102

Specifically, Adams does not disclose “coextruding a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer,” as recited in amended independent claim 1.

Adams is generally directed to “a laminate structure having improved resistance to the migration of essential oils, aromas and flavors and improved oxygen barriers characteristics for beverage packing.” Adams, Abstract. At the portions cited by the Office Action, Adams describes “suitable polyolefins for use in sublayers include, but are not limited to, LDPE, HDPE, LLDPE, polypropylene, cyclic olefin copolymers (COC), and blends thereof.” *Id.*, ¶ [0023]. Adams further describes that “the laminate structure of FIG. 2 comprises . . . a tie layer 13 with or without filler [that] is applied adjacent the barrier layer 12 and an interior layer or food contact layer containing filler 14 [that] is applied onto the tie layer.” *Id.*, ¶ [0030]. However, a food contact layer *containing filler* is not the same as “wherein the contact layer *consists of a cycloolefin copolymer (COC)*,” as recited in amended independent claim 1 (emphasis added). Rather, Adams describes that “the particular filler useful for blending into food contact, sublayer(s) and tie layer can be inorganic or organic material.” *Id.*, ¶ [0012]. Therefore, Adams does not disclose “coextruding a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer,” as recited in amended independent claim 1.

In addition, Adams does not disclose “coating the coextrusion layer directly to the base layer,” as recited in amended independent claim 1. At the portions cited by the Office Action, Adams describes “applying the tie layer and other layers can be achieved by either coextrusion or by standard lamination of extrusion laminations processes.” *Id.*, ¶ [0028]. Adams further describes that “the laminate structure of FIG. 2 comprises . . . a tie layer 13 with or without filler [that] is applied adjacent the barrier layer 12 and an interior layer or food contact layer containing filler 14 [that] is applied onto the tie layer.” *Id.*, ¶ [0030]. However, applying a food contact layer *containing filler* to the tie layer is not the same as “coating the coextrusion layer

directly to the base layer,” as recited in amended independent claim 1 (emphasis added). That is, Adams describes a method for applying the tie layer to the base layer and applying the contact layer to the tie layer. However, as discussed above, Adams does not teach or suggest “wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer.” It therefore follows that Adams does not disclose “. . . wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer [and] coating the coextrusion layer *directly to the base layer,*” as recited in amended independent claim 1 (emphasis added).

Therefore, for at least these reasons, amended independent claim 1 is allowable over Adams.

Accordingly, Applicant requests that the rejection of independent claim 1 under 35 U.S.C. § 102 be withdrawn.

35 U.S.C. § 103

In addition, Adams and Bowen—alone or in any combination—do not teach or suggest “coextruding a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer,” as recited in amended independent claim 1.

As discussed above, Adams does not disclose “coextruding a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer,” as recited in amended independent claim 1. Bowen does not overcome the deficiencies of Adams, nor does the Office Action indicate otherwise. Therefore, Bowen does not teach or suggest “coextruding a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer,” as recited in amended independent claim 1.

In addition, Adams and Bowen—alone or in any combination—do not teach or suggest “coating the coextrusion layer directly to the base layer,” as recited in amended independent claim 1. As discussed above, Adams does not disclose “coating the coextrusion layer directly to the base layer,” as recited in amended independent claim 1.

Bowen does not overcome the deficiencies of Adams. Bowen is generally directed to “multilayer film structures and packages.” Bowen, Abstract. At the portions cited by the Office

Action, Bowen describes “a tie can be between the flexible barrier material and the sealant.” *Id.*, col. 4, ll. 43-44. Bowen further describes that “EVA/tie/nylon/tie/EVA or, more generally, sealant/tie/nylon/tie/sealant . . . can be formed as a coextrusion which is then adhered to the second layer element.” *Id.*, col. 4, ll. 47-50. However, the coextrusion does not include a cycloolefin copolymer (COC) much less “coating the coextrusion layer directly to the base layer,” as recited in amended independent claim 1. Therefore, Bowen does not teach or suggest “. . . wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer [and] coating the coextrusion layer *directly to* the base layer,” as recited in amended independent claim 1 (emphasis added).

Therefore, for at least these reasons, amended independent claim 1 is allowable over any combination of Adams and Bowen.

Accordingly, Applicant requests that the rejection of independent claim 1 under 35 U.S.C. § 103 be withdrawn.

Dependent Claims 2–12

Dependent claims 2–12 each depend from independent claim 1, and are therefore allowable for at least the same reasons that independent claim 1 is allowable.

Further, Adams and Bowen—alone or in any combination—do not teach or suggest “wherein a melting point of the tie layer differs from a melting point of COC by 30°C or less,” as recited in dependent claim 2. The Office Action concedes, and Applicant agrees, that Adams is silent regarding the loading and melting point of the layers and Bowen in view of Adams is silent regarding the loading and melting point of the layers. *See* Office Action, pp. 4 and 6.

Instead the Office Action states that “since the references disclose the claimed process of making the film and the claimed layers comprising COC and EAA, their loading and melting point values are inherently the same as claimed.” *Id.* The Office Action, however, does not provide explicit analysis to support why the features of dependent claim 2 can be ignored, let alone establish (or even argue) that the melting point values are inherently the same as claimed. Applicant submits that the assertion that the melting point values are inherently the same as claimed is inapplicable in the current application.

The Office bears the initial burden to develop reasons supporting a reliance on inherency. *See MPEP* 2112 (IV). To satisfy this burden, the Office must identify some basis or articulate some reasoning at least tending to show that allegedly inherent subject matter inevitability flows from cited art (e.g., Adams and Bowen). Indeed, the MPEP expressly instructs that “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”

However, Office Action fails to include rationale or evidence at least tending to show that the feature of the melting point values can be inherently the same as claimed. In addition, because Adams and Bowens does not teach or suggest all the features of amended claim 1, the melting points values cannot be inherently the same as claimed. Thus, for at least the foregoing reasons, the assertion that the melting point values are inherently the same as claimed is inapplicable in the current application. Accordingly, the Office Action has failed to establish a *prima facie* case of obviousness for the claimed melting points in view of Adams and Bowen.

Accordingly, for at least these reasons, Applicant requests that the rejection of dependent claims 2–12 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is therefore respectfully requested.

The Commissioner is authorized to charge any fees or underpayments that may be due with this response, or credit any overpayments, to Deposit Account No. 08-2623.

If the Examiner believes a telephone conference would expedite prosecution of this Application, please call the undersigned at (303) 473-2700.

Respectfully submitted,

By: / Paul M. Schramm /
Paul M. Schramm
Reg. No. 62,050

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Salt Lake City, Utah 84147
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Amendments to the Claims

Please enter the following amendments to the claims:

1. (Currently Amended) A method for providing a film, said method comprising:
providing a base layer, wherein the base layer is resistant to one or more of water or oxygen;
coextruding a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin copolymer (COC) to provide a coextrusion layer;
coating the coextrusion layer directly to the base layer; and
allowing the coextrusion layer coated to the base layer to adhere to form the film, wherein the film comprises the tie layer and the contact layer formed as a coextrusion layer coated to the base layer,
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m² g/m²;
~~wherein the contact layer comprises a cycloolefin copolymer (COC).~~
2. (Original) The method according to claim 1, wherein a melting point of the tie layer differs from a melting point of COC by 30°C or less.
3. (Original) The method according to claim 2, wherein the melting point of the tie layer differs from the melting point of COC by a value in the range of 5–15°C.
4. (Currently Amended) The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m² g/m².
5. (Currently Amended) The method according to claim 1, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m² g/m².
6. (Currently Amended) A method according to claim 1, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m² g/m².

7. (Currently Amended) The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers is in the range of 7 to 20 ~~g/m²~~ g/m².

8. (Original) The method according to claim 1, wherein the one or more layers of the tie layer consists of two layers.

9. (Original) The method according to claim 1, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.

10. (Original) The method according to claim 1, wherein at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer.

11. (Original) The method according to claim 1, wherein the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer.

12. (Original) The method according to claim 11, wherein the acrylic acid layer comprises ethylene acrylic acid.

13. (Withdrawn) A film comprising:
a base layer that is resistant to one or more of water or oxygen; and
a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, said tie layer being positioned in between the base layer and the contact layer;
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²;
wherein the contact layer comprises a cycloolefin copolymer (COC).

14. (Withdrawn) The film according to claim 13, wherein a melting point of the tie layer differs from a melting point of COC by 30°C or less.

15. (Withdrawn) The film according to claim 13, wherein the melting point of the tie layer differs from the melting point of COC by a value in the range of 5–15°C.

16. (Withdrawn) The film according to claim 13, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².

17. (Withdrawn) The film according to claim 13, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².

18. (Withdrawn) The film according to claim 12, wherein the coextrusion layer is coextrusion coated to the base layer.

19. (Withdrawn) The film according to claim 12, wherein the tie layer comprises an acrylic acid layer and a polyethylene layer.

20. (Withdrawn) The film layer according to claim 18, wherein the acrylic acid layer comprises ethylene acid.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/835,018	03/30/2020	Lars Christensen	P006DK.WO.* (87942.0014)	7472
26582	7590	02/09/2021	EXAMINER	
HOLLAND & HART, LLP 222 South Main Street, Suite 2200 P.O. Box 11583 SALT LAKE CITY, UT 84147			TISCHLER, FRANCES	
			ART UNIT	PAPER NUMBER
			1765	
			NOTIFICATION DATE	DELIVERY MODE
			02/09/2021	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@hollandhart.com

Office Action Summary	Application No. 16/835,018	Applicant(s) Christensen et al.	
	Examiner FRANCES TISCHLER	Art Unit 1765	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 12/17/20.
☐ 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) 1-20 is/are pending in the application.
5a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-12 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 6/1/20,6/1/20,6/1/20.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

DETAILED ACTION

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.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1 – 12, in the reply filed on 12/17/20 is acknowledged.

Claim Objections

Claims 1 and 4 – 7 are objected to because of the following informalities:

The claims recite g/m2, but should be written as g/m².

Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have

been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 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.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 1 - 12 are rejected under 35 U.S.C. 102(a)(1) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over ADAMS (US 2005/0037162).

ADAMS discloses (see entire document) a process of making a film that provides good oxygen barrier properties ([0004]) [as claimed], the process comprising providing a base layer, referred to as a functional barrier layer, comprising aluminum, polyamide or PET ([0019]) [also reading on the claimed resistant to water or oxygen, since they are

the same layer as recited in the present invention, see for ex. [0033] of the instant Published Application]; coextruding layers onto the base layer to coat said base layer ([0028], [0045], figures), wherein the coextruded layers comprise one or more tie layers and contact layers selected from ethylene acrylic acid (EAA) and cycloolefin copolymer (COC), respectively ([0023], [0024], [0030], table in [0034]), claims 7, 10, 14) [as claimed].

ADAMS is silent regarding the loading and melting point of the layers. However, since ADAMS discloses the claimed process of making the film and the claimed layers comprising COC and EAA, their loading and melting point values are inherently the same as claimed. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.” See MPEP 2112.01. Since the PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). Alternatively, for the loading value, one of ordinary skill in the art would know to vary the process parameters such as the temperature in the extruder, the degree of dryness of the polymers upon extrusion, the thickness of the film, etc., wherein ADAMS discloses target coating weights for the various layers ([0037]) and discloses that constant loading levels are achieved even if one would add fillers to a layer ([0043]), all of which may affect the loading, to achieve ADAMS’ stated objective of making a film comprising a

base layer and coextruded tie and contact layers that provides for good packaging with good oxygen barrier and is effective in minimizing scalping ([0004]), and have thus arrived at the claimed loading.

ADAMS discloses few contact layers to choose from comprising linear polyolefins or cyclic olefin copolymer ([0023]) and few tie layers to choose from comprising ethylene acrylic acid, polyolefins and vinyl acetate ([0024], claim 10). If the genus is small, it can at once envisage each member of the group, then it is anticipated. *In re Petering* 301 F.2d 676, 681 (CCPA 1962). Alternately, it would be obvious to one skilled in the art to choose from ADAMS' small list of tie polymers and contact polymers the combination that produces ADAMS' stated objective of making a film comprising a base layer, and tie and contact layers that provides for good packaging with good oxygen barrier and is effective in minimizing scalping ([0004]), and have thus arrived at the claimed combination of COC of claim 1 and the acrylic acids of claims 10-12.

Claim Rejections - 35 USC § 103

Claims 1 - 12 are rejected under 35 U.S.C. 103 as being unpatentable over BOWEN et al (US 6,120,860) in view of ADAMS (US 2005/0037162).

ADAMS' disclosure is discussed above and is incorporated herein by reference.

BOWEN discloses (see entire document) a process of making a package comprising multilayer film, the process comprising providing a base layer and coextruding a tie layer and a sealant layer to coat the base layer (abstract). The film structure has superior properties for holding aggressive organics, wherein the film comprises high barrier materials (2:48-3:7).

The laminate comprises a first and second layer which can have additional layers (3:40-44).

The adhesive or tie layer can consist of a plurality of layers and is chosen from polyethylene and preferably ethylene acrylic acid (EAA) (3:52-4:10, 4:51-63) [as claimed].

The high barrier material is aluminum or nylon (4:10-16) [thus reading on the claimed water or oxygen resistant, noting that they are the same materials used in the present invention], and further discloses that the high barrier prevents water or moisture to contact the product in the package (5:15-32) [meeting the claimed water resistant layer].

The layers are coextruded and adhered to the core layer (4:49-51) [as claimed].

BOWEN discloses that the sealant or contact layer is selected from polyolefin polymers, polyolefin copolymers or EVA (4:32-42), failing to teach that the olefin copolymer is explicitly a cycloolefin copolymers. However, it would have been obvious to one of ordinary skill in the art to have replaced BOWEN's olefin copolymer with ADAMS' cycloolefin copolymer with the motivation that ADAMS discloses that linear polyolefins and cyclic olefin copolymers are interchangeably used as contact layers ([0023]) in the same field of endeavor disclosed by both references of making a package comprising a multilayered film having a base layer of aluminum or nylon/polyamide, and coextruded a coating film comprising an EAA tie layer and a contact layer onto said base layer.

BOWEN in view of ADAMS is silent regarding the loading and melting point of the layers. However, since the references disclose the claimed process of making the

film and the claimed layers comprising COC and EAA, their loading and melting point values are inherently the same as claimed. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.” See MPEP 2112.01. Since the PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). Alternatively, for the loading value, one of ordinary skill in the art would know to vary the process parameters such as the temperature in the extruder, the degree of dryness of the polymers upon extrusion, the thickness of the film, etc., wherein BOWEN discloses that the layers can be oriented or not (5:55-59), can be laminated, extruded, coextruded, blown extruded extrusion coated, etc., can be made by different apparatuses (6:27-40), and the layers can vary in thickness from 2.0 to 20 mils (6:40-62), all of which may affect the loading, and wherein ADAMS discloses target coating weights for the various layers ([0037]) and discloses that the desired loading levels are achieved even if one would add fillers to a layer ([0043]), to achieve BOWEN’s stated objective of making a film comprising a base layer, and tie and contact layers that provides for high barrier packaging, and have thus arrived at the claimed loading.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 – 12 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 - 20 of copending Application No. 16/425,067 (reference application).

Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims recite the same invention with obvious variants in the language. For instance, the present claims recite that the loading of the contact layer is 4 – 20 g/m² and that of the tie layer is 7 – 20 g/m² while in '067 the loading is claimed as an equation between the loading of the contact layer and the tie layer.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 1 – 12 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 - 36 of copending Application No. 16/780,999 (reference application).

Although the claims at issue are not identical, they are not patentably distinct from each other because '999 recites a relative energy difference value for the contact layer while the present claims are more broadly silent regarding this value, thus fully encompassing '999.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FRANCES TISCHLER whose telephone number is (571)270-5458. The examiner can normally be reached on Monday-Friday, 8:00 AM - 8:00 PM EST, midday flex.

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, James Seidleck can be reached on 571-272-1078. 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 <https://ppair-my.uspto.gov/pair/PrivatePair>. 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.

/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

Notice of References Cited	Application/Control No. 16/835,018		Applicant(s)/Patent Under Reexamination Christensen et al.	
	Examiner FRANCES TISCHLER		Art Unit 1765	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-6120860-A	09-2000	Bowen; William E.	B32B27/06	428/34.2
*	B	US-20050037162-A1	02-2005	Adams, John Peter	B32B27/32	428/34.2
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	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. 16/835,018	Applicant(s)/Patent Under Reexamination Christensen et al.
	Examiner FRANCES TISCHLER	Art Unit 1765

CPC - Searched*		
Symbol	Date	Examiner
B05D1/265 OR B32B15/082 OR B32B15/20 OR B32B1/00 OR B32B2250/05 OR B32B2307/714 OR B32B2307/7244 OR B32B2307/7265 OR B32B2323/00 OR B32B2398/20 OR B32B2439/ 00 OR B32B27/08 OR B32B27/306 OR B32B27/308 OR B32B27/32 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/153 OR B32B7/12	02/01/2021	/FT/

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 text search; inventor and company search; classification search, codes shown above; combination of East text search and classification search; combination of East text search and inventor search; combination of East text search and company search; considered/examined all IDS; searched google scholar and google patent and IP.com; search terms included, for instance: (cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud\$5 and (ethylene adj acrylic)	02/01/2021	/FT/

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<i>Search Notes</i> 	Application/Control No. 16/835,018	Applicant(s)/Patent Under Reexamination Christensen et al.
	Examiner FRANCES TISCHLER	Art Unit 1765

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

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	1	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	001	20090208685-A1	08-20-2009	Rivers et al.	
	002	20110158564-A1	06-30-2011	Krumme	
	003	20150225151-A1	08-13-2015	Osborn et al.	
	004	20170158400-A1	06-08-2017	Priscal et al.	
	005	5613958-A	03-25-1997	Kochinke et al.	
	006	6670423-B2	12-30-2003	Hausmann	
	007	6891018-B2	05-10-2005	Murakami et al.	
	008	6921563-B2	07-26-2005	Goerlitz et al.	
	009	8703283-B2	04-22-2014	Goerlitz et al.	
	010	8722164-B2	05-13-2014	Bekele et al.	
	011	9452593-B2	09-27-2016	Tatarka et al.	
	012	9487918-B2	08-25-2016	Geerdinck et al.	
	013	9663281-B2	05-30-2017	Hall et al.	

Examiner Signature	/FRANCES TISCHLER/	Date Considered	02/01/2021
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If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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				Application Number	16/835,018
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				Art Unit	-
				Examiner Name	-
Sheet	2	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	014	BR-102015012729-A2	01-17-2017	Bemis Co. Inc.		☒
	015	DE-102012113026-A1	06-26-2014	SCHOTT AG		☒
	016	DE-102013113718 A1	06-11-2015	Buergofol GmbH		☒
	017	DE-202008017320-U1	05-28-2009	Alcan Technology & Management AG		☐
	018	EP-1364777-B1	08-03-2005	Ticona GmbH		☐
	019	EP-1475228-B1	07-26-2017	Mitsubishi Polyester Film GmbH		☒
	020	EP-1525092-B1	05-23-2007	Cryovac, Inc.		☐
	021	EP-1769908-A1	04-04-2007	Safta S.p.A		☐
	022	EP-1775122-B1	09-03-2014	Curwood, Inc.		☐
	023	EP-2349867-B1	10-11-2017	Cryovac, Inc.		☐
	024	EP-2907769-B1	09-27-2017	BPI.FORMIPAC		☐
	025	EP-2939667-A1	11-04-2015	NIPRO Patch Co., Ltd.		☐
	026	EP-2986450-B1	01-30-2019	Goglio S.p.A.		☐
	027	EP-3000750-A1	03-30-2016	Fujimori Kogyo Co., Ltd.		☐
	028	EP-3112384-B1	07-18-2018	SABIC Global Technologies B.V.		☐
	029	EP-3144127-B1	01-31-2018	SCHOTT Schweiz AG		☒
	030	EP-3210907-B1	07-17-2019	Kyodo Printing Co., Ltd.		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	02/01/2021
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				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	3	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	031	EP-3360530-A1	08-15-2018	Mitsubishi Gas Chemical Company, Inc.		☐
	032	WO-1995007816-A1	03-23-1995	The Dow Chemical Company		☐
	033	WO-2001064786-A1	09-07-2001	Ticona GmbH		☒
	034	WO-2005097486-A1	10-20-2005	Curwood, Inc.		☐
	035	WO-2010047906-A1	04-29-2010	ExxonMobil Oil Company		☐
	036	WO-2010075946-A1	07-08-2010	Huhtamaki Forcchheim		☒
	037	WO-20121192271A1	09-13-2012	Surface Medical Inc.		☐
	038	WO-2013028398-A1	02-28-2013	Avery Dennison Corporation		☐
	039	WO-2013034273-A1	03-14-2013	Siegfried Ltd.		☐
	040	WO-2013116445-A1	08-08-2013	E.I. Dupont de Nemours and Company		☐
	041	WO-2014023995-A1	02-13-2014	Probiotal S.p.A.		☐
	042	WO-2015097208-A1	07-02-2015	Solvay Specialty Polymers Italy S.p.A.		☐
	043	WO-2015118215-A1	08-13-2015	Tampereen Patenttitoimisto Oy		☐
	044	WO-2015123211-A1	08-20-2015	Bemis Company, Inc.		☐
	045	WO-2015187173-A1	12-10-2015	Perfecseal, Inc.		☐
	046	WO-2015187174-A1	12-10-2015	Perfecseal, Inc.		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	02/01/2021
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			Art Unit	-	
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Sheet	4	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

FOREIGN PATENT DOCUMENTS

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	047	WO-2015199637-A1	12-30-2015	Perfecseal, Inc.		☐
	048	WO-2016076844-A1	05-19-2016	Bemis Company, Inc.		☐
	049	WO-2016164794-A1	10-13-2016	PolyOne Corporation		☐
	050	WO-2016190081-A1	12-01-2016	Dexerials Corporation		☒
	051	WO-2016194555-A1	12-08-2016	Polyplastics Co., Ltd.		☒
	052	WO-2016200363-A1	12-15-2016	Bemis Company, Inc.		☐
	053	WO-2017034560-A1	03-02-2017	Bemis Company, Inc.		☐
	054	WO-2017063087-A1	04-20-2017	Macro Technology Inc.		☐
	055	WO-2017087032-A1	05-26-2017	SiO2 Medical Products, Inc.		☐
	056	WO-2017100182-A1	06-15-2017	Bemis Company, Inc.		☐
	057	WO-2017100358-A1	06-15-2017	Bemis Company, Inc.		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	02/01/2021
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				Filing Date	03-30-2020
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				Art Unit	-
				Examiner Name	-
Sheet	5	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T ²
			☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	02/01/2021
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				Art Unit	-
				Examiner Name	-
Sheet	6	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

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.

- ☐ 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	/Paul M. Schramm/	Date (YYYY-MM-DD)	2020-06-01
Name/Print	Paul M. Schramm	Registration Number	62,050

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.**

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.

PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Christensen et al.

Application No.: 16/835,018

Filed: March 30, 2020

For: A METHOD FOR PROVIDING AN
EXTREME CHEMICAL RESISTANT FILM, A
FILM AND LAMINATE OBTAINABLE
THEREFROM

Docket No.: P006DK.WO.US.01 (87942.0014)

Customer No.: 26582

Confirmation No.: 7472

Examiner: not yet assigned

Art Unit: not yet assigned

**INFORMATION DISCLOSURE
STATEMENT****CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is
being filed via EFS-Web with the United
States Patent and Trademark Office
on June 1, 2020.

By: /Sherry Soares/
Sherry Soares

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

Commissioner:

Pursuant to the duty of disclosure set forth at 37 CFR §1.56 and the requirements for filing an Information Disclosure Statement set forth at 37 CFR §§1.97-1.98, enclosed is Form PTO/SB/08 (hereinafter "the Form") with a list of all items being submitted for consideration by the Office. A legible copy of each item listed in the Form that is not a U.S. patent or a published U.S. patent application, and not identified as being cumulative, is enclosed.

The disclosure of the remaining documents identified on the Form is not to be construed as an admission that any of the documents, alone or in any combination, is considered to be material to patentability as defined in 37 CFR §1.56(b). Moreover, the disclosure of these documents is not to be construed as an admission that any of the documents are prior art as to the above-identified application.

Application No. 16/835,018
Docket No. P006DK.WO.US.01 (87942.0014)
IDS dated June 1, 2020

PATENT

Applicant(s) request consideration of the references listed on the attached Form PTO/SB/08a. Under 35 USC § 120 and § 121, this application relies on the earlier filing date of the following U.S. Patent Application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
15/780,999	June 1, 2018	Pending

Foreign and Non-Patent Literature document(s) listed on the attached Form PTO/SB/08a were submitted to and/or cited by the Office in the above-listed prior application and, therefore, pursuant to 37 CFR § 1.98(d), copies are not provided in this application.

Applicants believe that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such a fee from the undersigned's Deposit Account No. 08-2623. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

/Paul M. Schramm/

Paul M. Schramm
Reg. No. 62,050

HOLLAND AND HART LLP
P.O. Box 11583
Salt Lake City, UT 84147
Tel: 303-473-2700
Fax: 303-473-2720

/FRANCES TISCHLER/

02/01/2021

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 17:13
S2	1	"6120860".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:07
S4	1	"20040234790".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:10
S5	1	"20050106344".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:11
S6	1	"6790496".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:12
S7	1	"20050037162".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:47
S8	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:50
S9	3	((("DANAPAK") near3 ("FLEXIBLES") near3 ("A/S"))).AS,AANM.	USPAT	NEAR	ON	2021/01/31 19:50
S10	142	((("DANAPAK") near3 ("FLEXIBLES"))).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:51
S11	350,512	(B05D1/265 OR B32B15/082 OR B32B15/20 OR B32B1/00 OR B32B2250/05 OR B32B2307/714 OR B32B2307/7244 OR B32B2307/7265 OR B32B2323/00 OR B32B2398/20 OR B32B2439/00 OR B32B27/08 OR B32B27/306 OR B32B27/308 OR B32B27/32 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/153 OR B32B7/12).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:53

S12	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud\$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:55
S13	14	("20090208685" "20110158564" "20150225151" "20160325534" "20170158400" "5613958" "6670423" "6891018" "6921563" "8703283" "8722164" "9452593" "9487918" "9663281").PN.	US-PGPUB; USPAT	NEAR	ON	2021/01/31 19:57
S14	1	"20160325534".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:58
S15	0	S12 and S14	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S16	0	S12 and S13	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S17	3	S12 and S8	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S18	3	S12 and S10	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S19	21	S12 and S11	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:01
S20	0	S12 and S2	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S21	0	S12 and S3	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S22	0	S12 and S4	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S23	0	S12 and S5	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S24	0	S12 and S6	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02

S25	0	S12 and S7	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S26	25	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud\$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 08:55
S27	1	((cycloolefin or COC) and layer and coextrud\$5 and (ethylene adj acrylic)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:20
S28	302	((("CHRISTENSEN") near3 ("Lars")) OR ((("JOHANSEN") near3 ("Peter"))) OR ((("FOGTMANN") near3 ("Torben")))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S29	3	((cycloolefin or COC) and layer and coextrud\$5 and (ethylene adj acrylic)) and S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S30	142	((("DANAPAK") near3 ("FLEXIBLES"))).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S31	4	((cycloolefin or COC) and layer and coextrud\$5 and (ethylene adj acrylic)) and S30	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21

EAST Search History (Interference)

<This search history is empty>

2/1/2021 7:20:28 PM

C:\Users\ftischler\Documents\EAST\Workspaces\16835018.wsp

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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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	1	of	4	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	001	20160325534-A1	11-10-2016	Hu et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	002	WO-2017114922-A1	07-06-2017	Danapak Flexibles A/S		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	02/01/2021
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. 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 2 hours 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, 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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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	2	of	4	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T ²
			☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	02/01/2021
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	16/835,018		
		Filing Date	03-30-2020		
		First Named Inventor	Christensen et al.		
		Art Unit	-		
		Examiner Name	-		
Sheet	3	of	4	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

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.

- ☐ 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	/Paul M. Schramm/	Date (YYYY-MM-DD)	2020-06-01
Name/Print	Paul M. Schramm	Registration Number	62,050

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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.

Bibliographic Data

Application No: 16/835,018

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /FRANCES TISCHLER/

Examiner's Signature

Initials

Title:

METHOD FOR PROVIDING AN EXTREME CHEMICAL
RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE
THEREFROM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
03/30/2020	427	1765	P006DK.WO.* (87942.0014)
RULE			

APPLICANTS

Danapak Flexibles A/S, Slagelse, DENMARK

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Peter Johansen, Odense C, DENMARK

Torben Fogtmann, Nyborg, DENMARK

CONTINUING DATA

This application is a CON of 15780999 06/01/2018

15780999 is a 371 of PCT/EP2016/082876 12/29/2016

FOREIGN APPLICATIONS

EPO EP15202962.5 12/29/2016

IF REQUIRED, FOREIGN LICENSE GRANTED**

04/08/2020

STATE OR COUNTRY

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HOLLAND & HART, LLP

222 South Main Street, Suite 2200

P.O. Box 11583

SALT LAKE CITY, UT 84147

UNITED STATES

FILING FEE RECEIVED

\$1,720

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/835,018		Filing Date 03/30/2020		☐ To be Mailed					
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO													
APPLICATION AS FILED - PART I													
		(Column 1)	(Column 2)										
FOR		NUMBER FILED	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), (l), 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	12/17/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)						
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 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.							SLIE						
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".							/SONYA M WILLIAMS/						
*** 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.													

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Christensen et al.

For: A METHOD FOR PROVIDING AN
EXTREME CHEMICAL RESISTANT
FILM, A FILM AND LAMINATE
OBTAINABLE THEREFROM

Application No.: 16/835,018

Filed: March 30, 2020

Docket No.: P006DK.WO.US.01
(87942.0014)

Customer No.: 26582

Confirmation No.: 7472

Examiner: Betelhem Shewareged

Art Unit: 1785

**RESPONSE TO RESTRICTION
REQUIREMENT****CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being filed
via EFS-Web with the United States Patent and
Trademark Office on: December 17, 2020.

By: / Wendy Nishida /
Wendy Nishida

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

Commissioner:

In response to the restriction requirement dated November 18, 2020, please enter the
following remarks:

A Listing of the Claims begins on page 2.

Remarks begin on page 5.

Listing of Claims

1. (Original) A method for providing a film, said method comprising:
providing a base layer, wherein the base layer is resistant to one or more of water or oxygen;
coextruding a tie layer and a contact layer to provide a coextrusion layer;
coating the coextrusion layer to the base layer;
allowing the coextrusion layer coated to the base layer to adhere to form the film,
wherein the film comprises the tie layer and the contact layer formed as a coextrusion layer coated to the base layer,
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²;
wherein the contact layer comprises a cycloolefin copolymer (COC).
2. (Original) The method according to claim 1, wherein a melting point of the tie layer differs from a melting point of COC by 30°C or less.
3. (Original) The method according to claim 2, wherein the melting point of the tie layer differs from the melting point of COC by a value in the range of 5–15°C.
4. (Original) The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m².
5. (Original) The method according to claim 1, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².
6. (Original) A method according to claim 1, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².
7. (Original) The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers is in the range of 7 to 20 g/m².

8. (Original) The method according to claim 1, wherein the one or more layers of the tie layer consists of two layers.

9. (Original) The method according to claim 1, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.

10. (Original) The method according to claim 1, wherein at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer.

11. (Original) The method according to claim 1, wherein the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer.

12. (Original) The method according to claim 11, wherein the acrylic acid layer comprises ethylene acrylic acid.

13. (Withdrawn) A film comprising:
a base layer that is resistant to one or more of water or oxygen; and
a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, said tie layer being positioned in between the base layer and the contact layer;
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²;
wherein the contact layer comprises a cycloolefin copolymer (COC).

14. (Withdrawn) The film according to claim 13, wherein a melting point of the tie layer differs from a melting point of COC by 30°C or less.

15. (Withdrawn) The film according to claim 13, wherein the melting point of the tie layer differs from the melting point of COC by a value in the range of 5–15°C.

16. (Withdrawn) The film according to claim 13, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².

17. (Withdrawn) The film according to claim 13, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².

18. (Withdrawn) The film according to claim 12, wherein the coextrusion layer is coextrusion coated to the base layer.

19. (Withdrawn) The film according to claim 12, wherein the tie layer comprises an acrylic acid layer and a polyethylene layer.

20. (Withdrawn) The film layer according to claim 18, wherein the acrylic acid layer comprises ethylene acid.

REMARKS

The Office Action dated November 18, 2020 (“Restriction Requirement”) requested restriction of the claims to one of the following groups:

- Group I Claims 1–12; and
- Group II Claims 13–20

Restriction Requirement

In response, Applicant hereby elects claims 1–12 of Group I, without traverse, for examination on the merits.

Applicant files this response solely to facilitate prosecution. As such, Applicant reserves the right to pursue claims of broader or similar scope as originally filed in this application, a continuation application, or other application after allowance of the present application. Any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter.

CONCLUSION

Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is therefore respectfully requested.

The Commissioner is authorized to charge any fees or underpayments that may be due with this response, or credit any overpayments, to Deposit Account No. 08-2623.

If the Examiner believes a telephone conference would expedite prosecution of this Application, please call the undersigned at (303) 473-2700.

Respectfully submitted,

By: / Paul M. Schramm /
Paul M. Schramm
Reg. No. 62,050

Holland & Hart LLP
P.O. Box 11583
Salt Lake City, Utah 84147
Tel: 303-473-2700
Fax: 303-473-2720

Electronic Acknowledgement Receipt

EFS ID:	41412344
Application Number:	16835018
International Application Number:	
Confirmation Number:	7472
Title of Invention:	METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM
First Named Inventor/Applicant Name:	Lars Christensen
Customer Number:	26582
Filer:	Paul M. Schramm/Wendy Nishida
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P006DK.WO.* (87942.0014)
Receipt Date:	17-DEC-2020
Filing Date:	30-MAR-2020
Time Stamp:	10:04:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P006Danapak.pdf	97436	yes	6
			fc713cb503ef64bdf830acdd73431cda7f38094b		

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Response to Election / Restriction Filed	1	1	
Claims	2	4	
Applicant Arguments/Remarks Made in an Amendment	5	6	

Warnings:

Information:

Total Files Size (in bytes):	97436
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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.
16/835,018	03/30/2020	Lars Christensen	P006DK.WO.* (87942.0014)	7472
26582	7590	11/18/2020	EXAMINER	
HOLLAND & HART, LLP 222 South Main Street, Suite 2200 P.O. Box 11583 SALT LAKE CITY, UT 84147			SHEWAREGED, BETELHEM	
			ART UNIT	PAPER NUMBER
			1785	
			NOTIFICATION DATE	DELIVERY MODE
			11/18/2020	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@hollandhart.com

Notice of Pre-AIA or AIA Status

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

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to method of making, classified in 427/385.5.

II. Claims 13-20, drawn to film, classified in 428/340.

The inventions are independent or distinct, each from the other because:

3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, (i.e., forming the tie layer and the contact layer onto the base layer by lamination method instead of coextrusion coating).
4. Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries).

5. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a 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.**

6. 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 upon the elected invention.

7. 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 or pre-AIA 35 U.S.C. 103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that

identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Correspondence

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BETELHEM SHEWAREGED whose telephone number is (571)272-1529. The examiner can normally be reached on Monday -Friday 7am-4:30pm.

10. 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>.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Ruthkosky can be reached on 571-272-1291. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. 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 <https://ppair-my.uspto.gov/pair/PrivatePair>. 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.

BS
November 14, 2020

/BETELHEM SHEWAREGED/
Primary Examiner
Art Unit 1785



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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/835,018	03/30/2020	Lars Christensen	P006DK.WO.* (87942.0014)

CONFIRMATION NO. 7472

26582
HOLLAND & HART, LLP
222 South Main Street, Suite 2200
P.O. Box 11583
SALT LAKE CITY, UT 84147

PUBLICATION NOTICE



OC000000118511691

Title:METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM

Publication No.US-2020-0223185-A1

Publication Date:07/16/2020

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	1	of	4	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	001	20160325534-A1	11-10-2016	Hu et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	002	WO-2017114922-A1	07-06-2017	Danapak Flexibles A/S		☐

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. 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 2 hours 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, 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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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	2	of	4	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,calendar,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T ²
			☐

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO <h2 style="margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="margin: 0;">(Use as many sheets as necessary)</p>				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
				Attorney Docket Number	P006DK.WO.US.01 (87942.0014)
Sheet	3	of	4		

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.
- ☐ 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	/Paul M. Schramm/	Date (YYYY-MM-DD)	2020-06-01
Name/Print	Paul M. Schramm	Registration Number	62,050

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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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.
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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.
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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.



(51) International Patent Classification:

B32B 7/12 (2006.01) **B32B 27/08** (2006.01)
B32B 15/08 (2006.01) **B32B 27/30** (2006.01)
B32B 15/082 (2006.01) **B32B 27/32** (2006.01)
B32B 15/085 (2006.01) **B32B 27/36** (2006.01)
B32B 15/20 (2006.01)

(21) International Application Number:

PCT/EP20 16/082876

(22) International Filing Date:

29 December 2016 (29. 12.2016)

(25) Filing Language:

English

(26) Publication Language:

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(30) Priority Data:

15202962.5 29 December 2015 (29. 12.2015) EP

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(74) Agent: **AWAPATENT A/S**; Rigersgade 11, Denmark,
 13 16 Copenhagen K (DK).

(81) Designated States (unless otherwise indicated, for every
 kind of national protection available): AE, AG, AL, AM,
 AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
 BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM,
 DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
 HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN,
 KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA,
 MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG,
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 TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN,
 ZA, ZM, ZW.

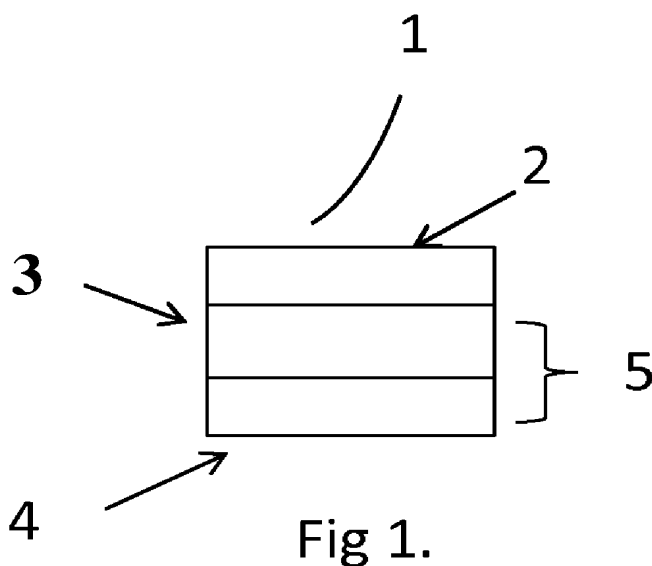
(84) Designated States (unless otherwise indicated, for every
 kind of regional protection available): ARIPO (BW, GH,
 GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,
 TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,
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 GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a
 patent (Rule 4.1 7(H))

[Continued on nextpage]

(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 lay-
 er, such as a metal foil, as well as films and laminates ob-
 tained by the method and uses of the films and laminates to
 pack aggressive chemical substances such as nicotine, lido-
 caine, fentanyl and rivastigmine.

Published:

— 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
5 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 ob-
tained by the method and uses of the films and laminates to wrap aggressive
chemical substances such as nicotine, fentanyl, lidocaine and rivastigmine.

10 **Background of the invention**

In the pharmaceutical industry substances, including highly aggres-
sive 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 en-
15 sure 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 aggres-
sive towards its environment and highly volatile. These properties are prob-
lematic for the consumer safety and product durability if not addressed, be-
20 cause 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
25 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;
- 30 - 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 polyacrylonitrile (PAN) based film, which
is sold for example as resins under the trademark Barex®, which is manufac-
35 tured *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
5 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,
10 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-
15 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.

20 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,
25 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

30 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 packag-
35 ings 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:

- 5 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
- 10 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 >
- 15 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

20 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 homogenous 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

25 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

35

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.

5 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 CM. Hansen : "Hansen Solubility Parameters, A User's Handbook", CRC Press, Boca Raton, 1999.

10 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

15

The HSP distance, R_a , between polymer and the aggressive chemical substance is given by:

$$R_a^2 = 4(\Delta \delta_D)^2 + \Delta \delta_P^2 + \Delta \delta_H^2$$

20 The Δ indicates the difference in the given parameter for the aggressive substance and the polymer.

The relation between the HSP distance, R_a and RED is given as:

$$RED = R_a/R_o$$

25 Where R_o 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

30 RED = 1 the polymer and the aggressive chemical substance will partially dissolve

RED > 1 the polymer and the aggressive chemical substance will not dissolve

35 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
5 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
10 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, silicon or aluminium oxide coated polyesters, and/or fluoro polymers.

15 According to the invention water and/or oxygen resistance is preferably encompassing materials having an oxygen transfer rate (OTR) equal to or below $1 \text{ cm}^3/\text{m}^2/24\text{hr}/\text{bar}$ according to ASTM standard D3985 at 23°C and 0% RH and/or water (or moisture) vapor transfer rate (WVTR) equal to or below $1 \text{ g}/\text{m}^2/24\text{hr}$ according to ASTM standard F1249 at 38°C and 90%RH,
20 preferably both the WVTR and the OTR are below $0.01 \text{ g}/\text{m}^2/24\text{hr}$ or $0.01 \text{ cm}^3/\text{m}^2/24\text{hr}/\text{bar}$ 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
25 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.

30 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
35 adhesion between the base layer and the coextrusion layer. The tie layer

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
5 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
10 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
15 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
20 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.

25 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
30 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
35 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
5 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.

10 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
15 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 trade-names EVAL® C109B sold by Kuraray, Sellar PA 3426 R sold by Dupont®, 6013M-07 sold by Topas®.

20 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
25 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, lidocaine and rivastigmine.

30 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
35 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 nominal 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, silicon oxide coated polyesters, and/or fluoropolymers.

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
- 5 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.

10

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.

15 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.

20 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.

25

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.

30

In a further embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine.

35 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
5 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;

10 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
15 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
20 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
25 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
30 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
35 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.

5 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.

10 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.

15 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%,
20 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

25 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.

30 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
35 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 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
5 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,
10 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
15 packaging compounds 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.

20 **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.

25 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.

30 Figure 5 shows the amount of lidocaine 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

35 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
5 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
10 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.

15 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.

20 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
25 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
30 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
35 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
5 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
10 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.

15 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.

20 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
25 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
30 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
35 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-
5 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.

10 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.

15 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
20 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
25 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
30 (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.

35 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, silicon or aluminium oxide coated polyesters, and/or fluoro 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 methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third
5 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
10 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
15 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.

20

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
25 bonding properties. The methodology of determining HSP values, interaction radius and RED values are described in CM. 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
30 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 rivastigmine, 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 sol-
- 5 ubility is assessed based on the visual observation of 0.5 g of the chemical substance in a vial with 5 cm³ 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
- 10 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.
- 15 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.

25

Table 3: The composition of the 6 wrappings was as 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/m² and the loading of the contact layer was 8-12 g/m².

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

10 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.

15

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 exam- ple 1
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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;
- 5 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,
- 10 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

15 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 poly-

20 esters, and/or fluoro 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 meth-

25 acrylate, and more preferably a maleic anhydride.

30

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

35

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
5 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/m² and/or the contact layer has a loading in the range of 4 to 20 g/m² and the loading of the film is not more than 40 g/m².

10. 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, lidocaine and rivastigmine

11. A method according to claim 10, wherein the composition is a patch.

15 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.

20 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
25 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

30 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
35 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 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/m² and/or the contact layer has a loading in the range of 4 to 20 g/m² and the loading of the film is not more than 40 g/m².

16. A laminate for packing an aggressive chemical substance said laminate comprising at least

10 - 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
15 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
20 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.

25 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
30 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,
35 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
5 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
10 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.

15 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
20 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,
25 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.

30 25. 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
35 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.

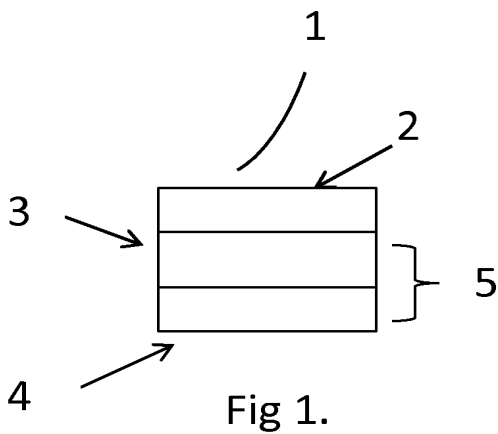
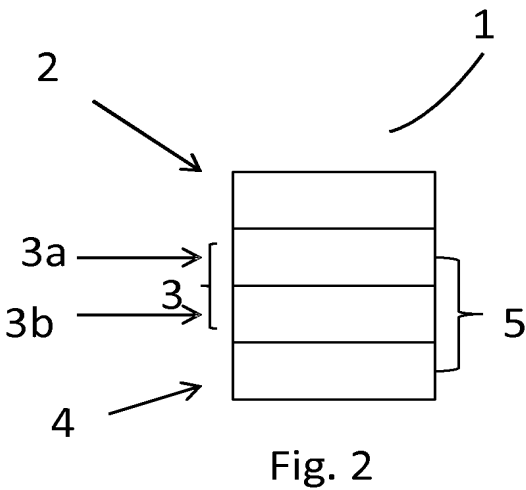
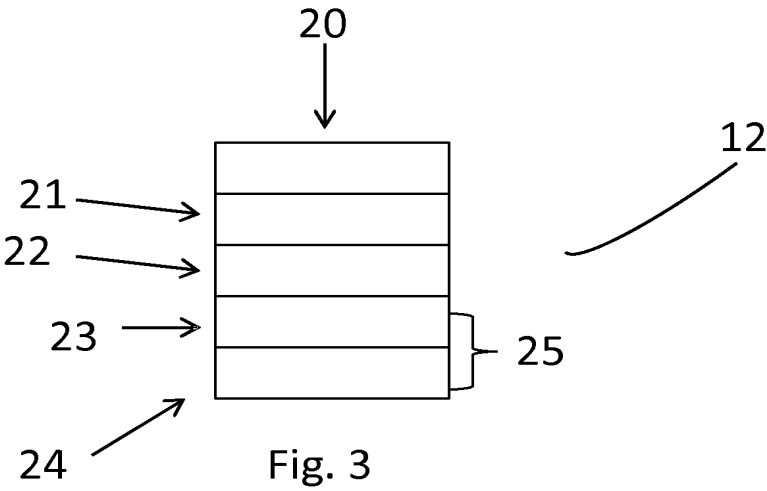
28. A method according to claim 26 and 27, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/-10% in comparison to a Barex® patch as index 100.

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, lidocaine, fentanyl and nicotine.



2/3

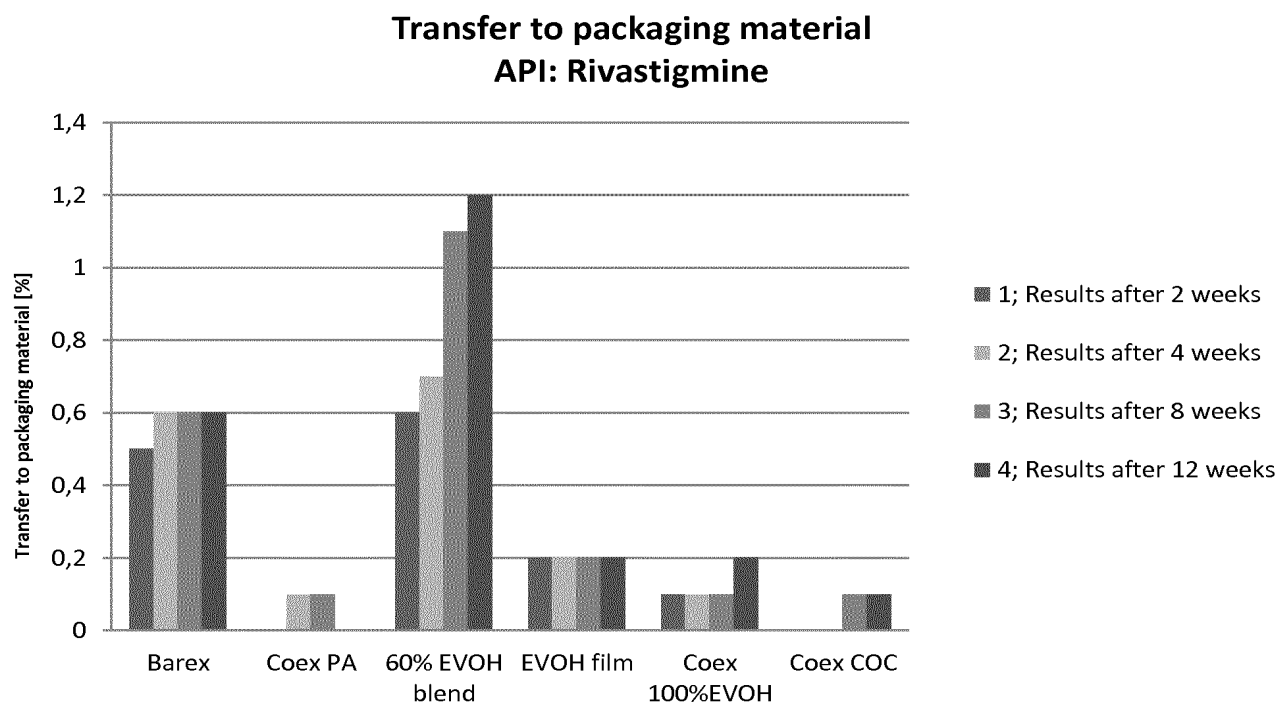


Fig. 4

3/3

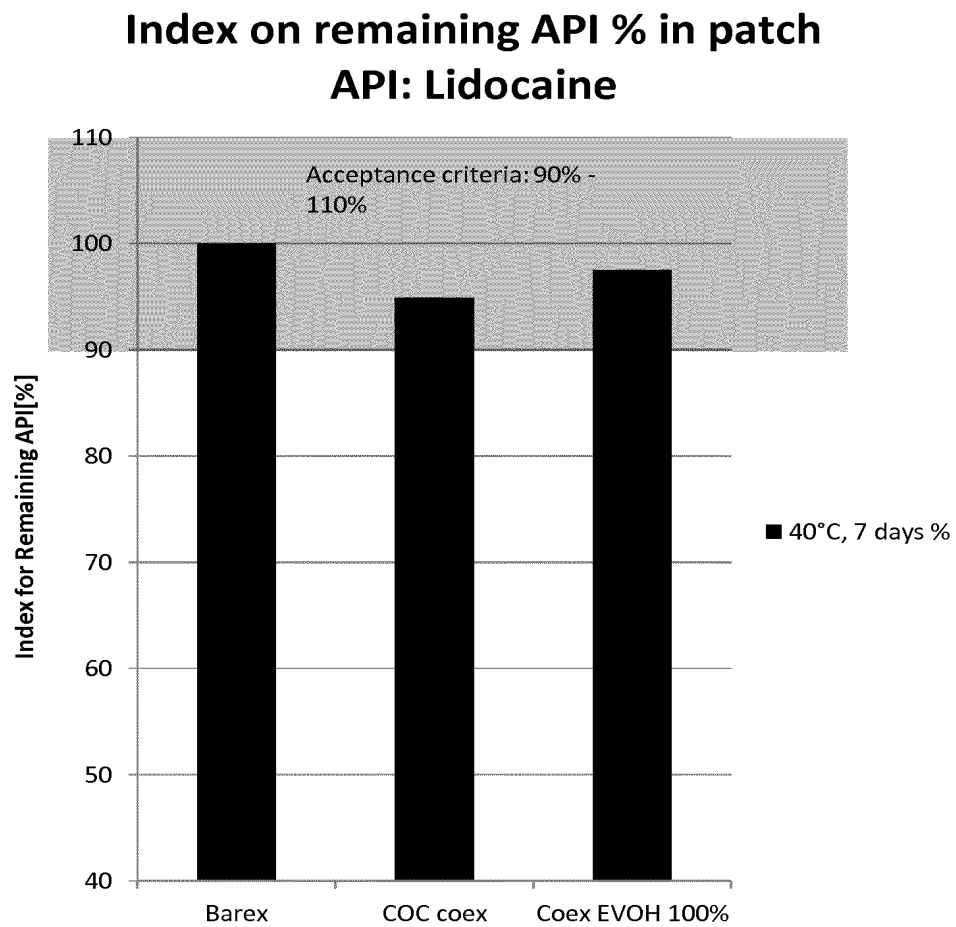


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2016/082876

A. CLASSIFICATION OF SUBJECT MATTER		
INV. B32B7/12	B32B15/08	B32B15/082
B32B27/08	B32B27/30	B32B27/32
ADD.	B32B15/085	B32B15/20
	B32B27/36	
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
☒ Further documents are listed in the continuation of Box C. ☒ 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 "&" document 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/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Mazet, Jean-François

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2016/082876

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/234790 AI (SMITH WILLIAM STUART [US] ET AL) 25 November 2004 (2004-11-25) figure 1 paragraphs [0004] , [0005] claims -----	1-31
X	wo 00/44559 AI (PHARMACIA & UPJOHN AB [SE] ; LEVANDER GUSTAV [SE] ; KARLSSON ANDERS H F) 3 August 2000 (2000-08-03) cited in the application page 2, line 14 - line 20 page 6, line 12 - page 7, line 4 example 1 claims 1,7,8,9 ,13 -----	1-31
A	wo 2005/037539 AI (DU PONT [US] ; MORRIS BARRY ALAN [US] ; TROUILHET YVES M [CH]) 28 April 2005 (2005-04-28) page 11, line 18 - line 32 claims -----	1-31
A	EP 2 939 667 AI (NI PRO PATCH CO LTD [JP]) 4 November 2015 (2015-11-04) claims 6-11 -----	1-31
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A	DATABASE WPI Week 201579 Thomson Scientific, London , GB; AN 2015-71769A XP002759263 , & wo 2015/174502 AI (NICHIBAN KK) 19 November 2015 (2015-11-19) abstract -----	1-31
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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
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us 2005037162	AI	17-02 -2005	AR 045254 AI 19-10-2005 CA 2532720 AI 17-02-2005 CN 1835841 A 20-09-2006 EP 1654115 AI 10-05-2006 JP 2007502219 A 08-02-2007 KR 20060073595 A 28-06-2006 MX PA06001349 A 04-05-2006 PA 8608701 AI 03-03-2005 SV 2005001843 A 16-06-2005 US 2005037162 AI 17-02-2005 WO 2005014283 AI 17-02-2005	
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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
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wo 2015174502	AI	19-11-2015	NONE

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		ZA 9010132 B	30-10 - 1991

Electronic Acknowledgement Receipt

EFS ID:	39589977
Application Number:	16835018
International Application Number:	
Confirmation Number:	7472
Title of Invention:	METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM
First Named Inventor/Applicant Name:	Lars Christensen
Customer Number:	26582
Filer:	Paul M. Schramm/Sherry Soares
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P006DK.WO.* (87942.0014)
Receipt Date:	01-JUN-2020
Filing Date:	30-MAR-2020
Time Stamp:	17:48:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P006DKWOUS01_16835018_ID S1.pdf	279644 83109d4b4f37bb645dcce61d23917f3c5d2 e48ba	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Transmittal Letter	1	2
	Information Disclosure Statement (IDS) Form (SB08)	3	9

Warnings:

Information:

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			1e7727c482997713efa4aa9c2f1a3953027222db		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Transmittal Letter	1	2
	Information Disclosure Statement (IDS) Form (SB08)	3	6

Warnings:

Information:

3	Foreign Reference	FR_WO2017114922A1_Danapak_41pgs.pdf	587640	no	41
			047a961734e446a896d8aca5076ad079d0dbfba1		

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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

In re application of:

Christensen et al.

Application No.: 16/835,018

Filed: March 30, 2020

For: A METHOD FOR PROVIDING AN
EXTREME CHEMICAL RESISTANT FILM, A
FILM AND LAMINATE OBTAINABLE
THEREFROM

Docket No.: P006DK.WO.US.01 (87942.0014)

Customer No.: 26582

Confirmation No.: 7472

Examiner: not yet assigned

Art Unit: not yet assigned

**INFORMATION DISCLOSURE
STATEMENT**
CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is
being filed via EFS-Web with the United
States Patent and Trademark Office
on June 1, 2020.

By: /Sherry Soares/
Sherry Soares

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

Commissioner:

Pursuant to the duty of disclosure set forth at 37 CFR §1.56 and the requirements for filing an Information Disclosure Statement set forth at 37 CFR §§1.97-1.98, enclosed is Form PTO/SB/08 (hereinafter “the Form”) with a list of all items being submitted for consideration by the Office. A legible copy of each item listed in the Form that is not a U.S. patent or a published U.S. patent application, and not identified as being cumulative, is enclosed.

The disclosure of the remaining documents identified on the Form is not to be construed as an admission that any of the documents, alone or in any combination, is considered to be material to patentability as defined in 37 CFR §1.56(b). Moreover, the disclosure of these documents is not to be construed as an admission that any of the documents are prior art as to the above-identified application.

Applicant(s) request consideration of the references listed on the attached Form PTO/SB/08a. Under 35 USC § 120 and § 121, this application relies on the earlier filing date of the following U.S. Patent Application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
15/780,999	June 1, 2018	Pending

Foreign and Non-Patent Literature document(s) listed on the attached Form PTO/SB/08a were submitted to and/or cited by the Office in the above-listed prior application and, therefore, pursuant to 37 CFR § 1.98(d), copies are not provided in this application.

Applicants believe that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such a fee from the undersigned's Deposit Account No. 08-2623. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

/Paul M. Schramm/

Paul M. Schramm
Reg. No. 62,050

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Salt Lake City, UT 84147
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Fax: 303-473-2720

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	1	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	001	20090208685-A1	08-20-2009	Rivers et al.	
	002	20110158564-A1	06-30-2011	Krumme	
	003	20150225151-A1	08-13-2015	Osborn et al.	
	004	20170158400-A1	06-08-2017	Priscal et al.	
	005	5613958-A	03-25-1997	Kochinke et al.	
	006	6670423-B2	12-30-2003	Hausmann	
	007	6891018-B2	05-10-2005	Murakami et al.	
	008	6921563-B2	07-26-2005	Goerlitz et al.	
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	010	8722164-B2	05-13-2014	Bekele et al.	
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	013	9663281-B2	05-30-2017	Hall et al.	

Examiner Signature		Date Considered	
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				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
				Attorney Docket Number	P006DK.WO.US.01 (87942.0014)
Sheet	2	of	7		

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	014	BR-102015012729-A2	01-17-2017	Bemis Co. Inc.		☒
	015	DE-102012113026-A1	06-26-2014	SCHOTT AG		☒
	016	DE-102013113718 A1	06-11-2015	Buergofol GmbH		☒
	017	DE-202008017320-U1	05-28-2009	Alcan Technology & Management AG		☐
	018	EP-1364777-B1	08-03-2005	Ticona GmbH		☐
	019	EP-1475228-B1	07-26-2017	Mitsubishi Polyester Film GmbH		☒
	020	EP-1525092-B1	05-23-2007	Cryovac, Inc.		☐
	021	EP-1769908-A1	04-04-2007	Safta S.p.A		☐
	022	EP-1775122-B1	09-03-2014	Curwood, Inc.		☐
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	024	EP-2907769-B1	09-27-2017	BPI.FORMIPAC		☐
	025	EP-2939667-A1	11-04-2015	NIPRO Patch Co., Ltd.		☐
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	027	EP-3000750-A1	03-30-2016	Fujimori Kogyo Co., Ltd.		☐
	028	EP-3112384-B1	07-18-2018	SABIC Global Technologies B.V.		☐
	029	EP-3144127-B1	01-31-2018	SCHOTT Schweiz AG		☒
	030	EP-3210907-B1	07-17-2019	Kyodo Printing Co., Ltd.		☐

Examiner Signature		Date Considered	
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				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	3	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	031	EP-3360530-A1	08-15-2018	Mitsubishi Gas Chemical Company, Inc.		☐
	032	WO-1995007816-A1	03-23-1995	The Dow Chemical Company		☐
	033	WO-2001064786-A1	09-07-2001	Ticona GmbH		☒
	034	WO-2005097486-A1	10-20-2005	Curwood, Inc.		☐
	035	WO-2010047906-A1	04-29-2010	ExxonMobil Oil Company		☐
	036	WO-2010075946-A1	07-08-2010	Huhtamaki Forcchheim		☒
	037	WO-20121192271A1	09-13-2012	Surface Medical Inc.		☐
	038	WO-2013028398-A1	02-28-2013	Avery Dennison Corporation		☐
	039	WO-2013034273-A1	03-14-2013	Siegfried Ltd.		☐
	040	WO-2013116445-A1	08-08-2013	E.I. Dupont de Nemours and Company		☐
	041	WO-2014023995-A1	02-13-2014	Probiotal S.p.A.		☐
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	043	WO-2015118215-A1	08-13-2015	Tampereen Patenttitoimisto Oy		☐
	044	WO-2015123211-A1	08-20-2015	Bemis Company, Inc.		☐
	045	WO-2015187173-A1	12-10-2015	Perfecseal, Inc.		☐
	046	WO-2015187174-A1	12-10-2015	Perfecseal, Inc.		☐

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	4	of	7	Attorney Docket Number	P006DK.WO.US.01 (87942.0014)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	047	WO-2015199637-A1	12-30-2015	Perfecseal, Inc.		☐
	048	WO-2016076844-A1	05-19-2016	Bemis Company, Inc.		☐
	049	WO-2016164794-A1	10-13-2016	PolyOne Corporation		☐
	050	WO-2016190081-A1	12-01-2016	Dexerials Corporation		☒
	051	WO-2016194555-A1	12-08-2016	Polyplastics Co., Ltd.		☒
	052	WO-2016200363-A1	12-15-2016	Bemis Company, Inc.		☐
	053	WO-2017034560-A1	03-02-2017	Bemis Company, Inc.		☐
	054	WO-2017063087-A1	04-20-2017	Macro Technology Inc.		☐
	055	WO-2017087032-A1	05-26-2017	SiO2 Medical Products, Inc.		☐
	056	WO-2017100182-A1	06-15-2017	Bemis Company, Inc.		☐
	057	WO-2017100358-A1	06-15-2017	Bemis Company, Inc.		☐

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
Sheet	5	of	7	Attorney Docket Number P006DK.WO.US.01 (87942.0014)	

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T ²
			☐

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO <h2 style="margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="margin: 0;">(Use as many sheets as necessary)</p>				Complete if Known	
				Application Number	16/835,018
				Filing Date	03-30-2020
				First Named Inventor	Christensen et al.
				Art Unit	-
				Examiner Name	-
				Attorney Docket Number	P006DK.WO.US.01 (87942.0014)
Sheet	6	of	7		

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.

- ☐ 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	/Paul M. Schramm/	Date (YYYY-MM-DD)	2020-06-01
Name/Print	Paul M. Schramm	Registration Number	62,050

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.**

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

In re application of:

Christensen et al.

Application No.: 16/835,018

Filed: March 30, 2020

For: A METHOD FOR PROVIDING AN
EXTREME CHEMICAL RESISTANT FILM, A
FILM AND LAMINATE OBTAINABLE
THEREFROM

Docket No.: P006DK.WO.US.01 (87942.0014)

Customer No.: 26582

Confirmation No.: 7472

Examiner: not yet assigned

Art Unit: not yet assigned

**INFORMATION DISCLOSURE
STATEMENT**
CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is
being filed via EFS-Web with the United
States Patent and Trademark Office
on June 1, 2020.

By: /Sherry Soares/
Sherry Soares

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

Commissioner:

Pursuant to the duty of disclosure set forth at 37 CFR §1.56 and the requirements for filing an Information Disclosure Statement set forth at 37 CFR §§1.97-1.98, enclosed is Form PTO/SB/08 (hereinafter “the Form”) with a list of all items being submitted for consideration by the Office. A legible copy of each item listed in the Form that is not a U.S. patent or a published U.S. patent application, and not identified as being cumulative, is enclosed.

The disclosure of the remaining documents identified on the Form is not to be construed as an admission that any of the documents, alone or in any combination, is considered to be material to patentability as defined in 37 CFR §1.56(b). Moreover, the disclosure of these documents is not to be construed as an admission that any of the documents are prior art as to the above-identified application.

Applicants believe that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such a fee from the undersigned's Deposit Account No. 08-2623. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

/Paul M. Schramm/

Paul M. Schramm
Reg. No. 62,050

HOLLAND AND HART LLP
P.O. Box 11583
Salt Lake City, UT 84147
Tel: 303-473-2700
Fax: 303-473-2720



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
16/835,018	03/30/2020	2811	1720	P006DK.WO.* (87942.0014)	20	2

CONFIRMATION NO. 7472

FILING RECEIPT



0000000116083584

26582
HOLLAND & HART, LLP
222 South Main Street, Suite 2200
P.O. Box 11583
SALT LAKE CITY, UT 84147

Date Mailed: 04/09/2020

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.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Lars Christensen, Slagelse, DENMARK;
Peter Johansen, Odense C, DENMARK;
Torben Fogtmann, Nyborg, DENMARK;

Applicant(s)

Danapak Flexibles A/S, Slagelse, DENMARK;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/780,999
which is a 371 of PCT/EP2016/082876 12/29/2016

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.)
EUROPEAN PATENT OFFICE (EPO) 15202962.5 12/29/2016 No Access Code Provided

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 04/08/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/835,018**

Projected Publication Date: 07/16/2020

Non-Publication Request: No

Early Publication Request: No

Title

METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM

Preliminary Class

257

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative,

page 2 of 4

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 16/835,018	
APPLICATION AS FILED - PART I							
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)	OR	RATE(\$)	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), (l), 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(j))	20	minus 20 = *			OR	x 100 =	0.00
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	1720
APPLICATION AS AMENDED - PART II							
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)	OR	RATE(\$)
	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))					OR	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					OR	
				TOTAL ADD'L FEE		TOTAL ADD'L FEE	
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)	OR	RATE(\$)
	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))					OR	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					OR	
				TOTAL ADD'L FEE		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.							

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UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>		Attorney Docket No. P006DK.WO.US.01 (87942.0014)	
		First Named Inventor Christensen et al.	
		Title A METHOD FOR PROVIDING AN EXTREME CHEMICAL ...	
		Priority Mail Express® Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
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<ol style="list-style-type: none"> 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 33] 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 2] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) <ol style="list-style-type: none"> 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) <div style="margin-left: 20px;"> ☐ Landscape Table on CD </div> 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) <ol style="list-style-type: none"> a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: <ol style="list-style-type: none"> i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies 	ACCOMPANYING APPLICATION PAPERS <ol style="list-style-type: none"> 10. ☒ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☐ 37 CFR 3.73(c) Statement ☐ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449) <div style="margin-left: 20px;">☐ Copies of citations attached</div> 14. ☐ Preliminary Amendment 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: _____ _____ _____ _____
---	---

***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).
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS			
☒ The address associated with Customer Number: 26582 OR ☐ Correspondence address below			
Name _____			
Address _____			
City	State	Zip Code	
Country	Telephone	Email	
Signature /Paul M. Schramm/		Date March 30, 2020	
Name (Print/Type) Paul M. Schramm		Registration No. (Attorney/Agent) 62,050	

This collection of information is required by 37 CFR 1.53(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.

**A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A
FILM AND LAMINATE OBTAINABLE THEREFROM**

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 15/780,999, entitled “A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM,” filed 1 June 2018, which is a 371 national phase filing of International Application No. PCT/EP2016/082876, entitled “A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM”, filed 29 December 2016, and claims the benefit of European Patent Application No. 15202962.5, entitled “A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM”, filed 29 December 2015. Each of these references is incorporated by reference herein for all purposes.

BACKGROUND

[0002] The present disclosure 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.

[0003] 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.

[0004] 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.

[0005] A known polymer that fulfils the requirements of extreme chemical resistance and inert properties is a polyacrylonitrile (PAN) based film, which is sold for example as resins under the trademark Barex®, which is manufactured for example 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 price 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.

[0006] 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 dicarboxylate 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.

[0007] 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.

[0008] 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

[0009] With this background it is an object of the present disclosure to provide solutions that meet one or more of the needs described above, that is, for example 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.

[0010] 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.

[0011] It has surprisingly been found that when coextruding the tie layer and the contact layer according to the disclosure, 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 co-extrusion also results in a better adherence of the various layers resulting in a homogenous film in which the layers do not separate.

[0012] 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 disclosure 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.

[0013] A polymer candidate for use as a contact layer in the present disclosure 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 disclosure 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.

[0014] 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.

[0015] 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.

[0016] The HSP distance, R_a , between polymer and the aggressive chemical substance is given by:

$$R_a^2 = 4(\Delta \delta_D)^2 + \Delta \delta_P^2 + \Delta \delta_H^2.$$

[0017] The Δ indicates the difference in the given parameter for the aggressive substance and the polymer.

[0018] The relation between the HSP distance, R_a and RED is given as:

$$RED = R_a/R_o$$

where R_o 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.

[0019] 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.

[0020] The resulting RED value is used to give an indication of the likelihood of dissolution or not.

[0021] All values can be calculated using the Hansen Solubility Parameter in Practice by (HSPiP) Software, commercially available at <http://hansen-solubility.com>.

[0022] Contact layer polymers according to the disclosure 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 disclosure as is supported by the examples provided here with.

[0023] 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 fluoro polymers.

[0024] According to the disclosure water and/or oxygen resistance is preferably encompassing materials having an oxygen transfer rate (OTR) equal to or below 1 cm³/m²/24hr/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/m²/24hr according to ASTM standard F1249 at 38°C and 90%RH, preferably both the WVTR and the OTR are below 0.01 g/m²/24hr or 0.01 cm³/m²/24hr/bar respectively.

[0025] According to the disclosure, 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.

[0026] In embodiments where the contact layer is hygroscopic the base layer is preferably made of a metal foil, preferably aluminum.

[0027] 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.

[0028] According to the disclosure the tie layer is selected to provide sufficient adhesion between the base layer and the coextrusion layer. The tie layer 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 disclosure 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.

[0029] 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.

[0030] In a further embodiment all the layers are coextruded with the contact layer for a simplified processing and for ensuring homogeneity of the layers.

[0031] 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.

[0032] According to the disclosure 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.

[0033] Hence, in the context of the present disclosure 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.

[0034] 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).

[0035] 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.

[0036] 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 disclosure using lidocaine/rivastigmine as solvent (API):

Table 1: HSP and RED values for preferred polymers according to the disclosure

Polymer	D	P	H	RED value (chi)
Lidocaine/ Rivastig- mine	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

[0037] 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®.

[0038] 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 disclosure 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.

[0039] Because of the hydrophilic nature of PA and EVOH, in a preferred embodiment, the film obtained according to the disclosure may be tightly packed in a moisture barrier, in particular if it has to be stored. The film or laminate according to the disclosure 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.

[0040] 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 disclosure 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 disclosure 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.

[0041] 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.

[0042] 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.

[0043] 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.

[0044] In terms of the disclosure loading means the amount of polymer left, in the layer when the film has dried.

[0045] 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.

[0046] 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.

[0047] 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®.

[0048] 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.

[0049] The adhering of step iv) preferably occurs instantly for example by cooling the co-extrudate in cooling cylinders during the lamination process.

[0050] According to the disclosure a chemical resistant film has various applications. In an embodiment of the disclosure, the film is used to wrap a composition comprising a chemical selected from nicotine, fentanyl, lidocaine and rivastigmine.

[0051] In a particular embodiment of the disclosure, 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.

[0052] In a further aspect of the disclosure 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 disclosure are resistant to aggressive chemical substances.

[0053] 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 nominal content of the aggressive chemical to migrate to the packaging material.

[0054] 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 fluoropolymers.

[0055] 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.

[0056] 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.

[0057] In yet an embodiment the tie layer and the contact layer is the same material.

[0058] 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.

[0059] In yet another aspect the disclosure 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.

[0060] 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.

[0061] 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.

[0062] 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.

[0063] 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.

[0064] The laminate of the present disclosure must be inert and impermeable to the aggressive chemical substance which the laminate is wrapped around. Hence, in an embodiment of the disclosure 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.

[0065] 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 require specialized packaging.

[0066] Hence, the disclosure 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.

[0067] In a preferred embodiment the highly aggressive substance is selected from the group consisting of nicotine, lidocaine, rivastigmine, and fentanyl.

[0068] 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.

[0069] 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).

[0070] A “packaging” is in the context of the disclosure intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate.

[0071] 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.

[0072] 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.

[0073] In yet another aspect, the disclosure 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 coextruded, layer comprising a tie layer and the contact layer.

[0074] In a further embodiment the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

[0075] Specific films according to the disclosure 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.

[0076] Specific films according to the disclosure 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.

[0077] In an embodiment of the disclosure, 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.

[0078] In a further embodiment of the disclosure, 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.

[0079] In yet another embodiment of the disclosure, 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.

[0080] Specific films according to the disclosure 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.

[0081] In an embodiment of the disclosure, wherein the film is resistant to rivastigmine 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.

[0082] In a further embodiment of the disclosure, wherein the film is resistant to rivastigmine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

[0083] In yet another embodiment of the disclosure, wherein the film is resistant to rivastigmine 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.

[0084] Specific films according to the disclosure 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.

[0085] In an embodiment of the disclosure, 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.

[0086] In a further embodiment of the disclosure, 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.

[0087] In yet another embodiment of the disclosure, 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.

[0088] Specific films according to the disclosure 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.

[0089] In an embodiment of the disclosure, 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.

[0090] In a further embodiment of the disclosure, 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.

[0091] In yet another embodiment of the disclosure, 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.

[0092] The disclosure should not be restricted to the above combinations. Further combinations are within the scope of the disclosure.

[0093] In another aspect of the disclosure 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.

[0094] 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.

[0095] In a further aspect of the disclosure is provided a method for providing 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.

[0096] 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 compounds such as nicotine, lidocaine and rivastigmine.

[0097] Conveniently, the polymers used in the present disclosure have the advantage of

being easy accessible thereby providing a more cost efficient production.

BRIEF DESCRIPTION OF THE FIGURES

[0098] Figures 1 is a cross section of an embodiment of a chemical resistant film according to the disclosure.

[0099] Figure 2 is a cross section of another embodiment of a chemical resistant film according to the disclosure.

[0100] Figure 3 is a cross section of a laminate according to the disclosure.

[0101] Figure 4 shows the results of an absorption study of rivastigmine as API wrapped in laminates according to the disclosure 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.

[0102] Figure 5 shows the amount of lidocaine remaining in a patch after 7 days at 40°C for embodiments of the laminate according to the disclosure and in comparison, with a commercial available Barex® laminate.

DETAILED DESCRIPTION

[0103] The disclosure will now be described in greater details. Each specific embodiment and variation of features applies equally to each aspect of the disclosure unless specifically stated otherwise.

[0104] The film, laminate and packaging according to the present disclosure is intended to be used in packaging highly aggressive substances such as nicotine, rivastigmine, fentanyl or lidocaine, however, the disclosure should not be limited to these specific substances.

[0105] The term “film” according to the disclosure 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.

[0106] 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.

[0107] The term “laminate” according to the disclosure contemplates the film to which a further layer is laminated, such as a first outer layer.

[0108] A “packaging” is in the context of the disclosure intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate.

[0109] 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.

[0110] 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 disclosure 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.

[0111] The term “oxygen and water resistant” as used in the context of the present disclosure 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.

[0112] The term “mechanically wear resistant layer” as used for the first outer layer in the context of the present disclosure 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.

[0113] 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.

[0114] 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 disclosure. 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.

[0115] The various embodiments of the disclosure will now be illustrated with references to the figures and examples.

[0116] With reference to figure 1 a film of the disclosure 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 disclosure and is allowed to adhere. The base layer, 2, and the coextrusion layer, 5, define the film according to all the aspects of the disclosure. 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.

[0117] The coextrusion layer may be coated to the aluminium layer by a coextrusion 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.

[0118] 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 disclosure may be obtained from Bobst.

[0119] 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 disclosure 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.

[0120] 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 disclosure and is allowed to dry.

[0121] 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.

[0122] The extreme chemical resistant film according to the disclosure is intended for use as a component of a packaging suitable for sealing a highly aggressive substance. The film may constitute the packing itself.

[0123] 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 disclosure, 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.

[0124] 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.

[0125] 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.

[0126] Furthermore, it is within the inventive concept of the present disclosure 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.

[0127] 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.

[0128] 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.

[0129] 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 coextrusion 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.

[0130] In general, the order in which the different layers of the packaging according to the disclosure 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.

[0131] In more details the packaging according to the present disclosure 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.

[0132] 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.

[0133] 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.

[0134] According to all aspects of the disclosure 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, silicon or aluminium oxide coated polyesters, and/or fluoro 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.

[0135] According to all aspects of the disclosure 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 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, such as the commercial product Lotader® 3410 sold by Arkema or Nucrel® 0609HSA sold by Dupont®.

[0136] According to all aspects of the disclosure 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.

[0137] According to all aspects of the disclosure 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.

[0138] The disclosure will now be illustrated in more details with reference to the following non limiting examples.

[0139] RED Calculation

[0140] 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.

[0141] 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 rivastigmine, 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

[0142] For assessing the solubility of Rivastigmine, Lidocaine, fentanyl and nicotine in the solvents an experimental measurement is performed. The solubility is assessed based on the visual observation of 0.5 g of the chemical substance in a vial with 5 cm³ 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.

[0143] Example 1- performance of a laminate according to the disclosure compared to a commercially used laminate.

[0144] A study was conducted to evaluate the performance of four laminates according to the present disclosure as compared to a commercially available laminate product comprising Barex® as the contact layer.

[0145] The wrappings according to the disclosure were compared to the performance of a Barex® laminate currently used in the field.

[0146] 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 disclosure

	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 anhy- dride (Lotader 3410) Contact layer: COC	Al	PE	PET
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*Between the paper/PET, PET/Al, and Al/EVOH film layers an adhesive was applied.

[0147] Laminates 1 to 5 were obtained according to the method of the disclosure. 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/m² and the loading of the contact layer was 8-12 g/m².

[0148] 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.

[0149] The Rivastigmine patches tested were commercially available patches originally containing 9.5 mg API/patch.

[0150] 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.

[0151] 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.

[0152] 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 disclosure.

[0153] From the figure it is clear that the results for laminates according to the disclosure 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.

[0154] 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.

[0155] 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.

[0156] Example 2 - stability test of a chemical substance wrapped in laminates according to the disclosure and wrapped in a prior art product using Barex®.

[0157] Similar to the test described in example 1, laminates according to the disclosure 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
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[0158] 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 disclosure using Barex as index 100.

[0159] 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 disclosure indicates that more lidocaine has disappeared from the patch.

WHAT IS CLAIMED IS:

CLAIMS

1. A method for providing a film, said method comprising:
providing a base layer, wherein the base layer is resistant to one or more of water or oxygen;
coextruding a tie layer and a contact layer to provide a coextrusion layer;
coating the coextrusion layer to the base layer;
allowing the coextrusion layer coated to the base layer to adhere to form the film,
wherein the film comprises the tie layer and the contact layer formed as a coextrusion layer coated to the base layer,
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²;
wherein the contact layer comprises a cycloolefin copolymer (COC).
2. The method according to claim 1, wherein a melting point of the tie layer differs from a melting point of COC by 30°C or less.
3. The method according to claim 2, wherein the melting point of the tie layer differs from the melting point of COC by a value in the range of 5–15°C.
4. The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m².
5. The method according to claim 1, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².
6. A method according to claim 1, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².
7. The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers is in the range of 7 to 20 g/m².

8. The method according to claim 1, wherein the one or more layers of the tie layer consists of two layers.

9. The method according to claim 1, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.

10. The method according to claim 1, wherein at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer.

11. The method according to claim 1, wherein the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer.

12. The method according to claim 11, wherein the acrylic acid layer comprises ethylene acrylic acid.

13. A film comprising:
a base layer that is resistant to one or more of water or oxygen; and
a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, said tie layer being positioned in between the base layer and the contact layer;
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²;
wherein the contact layer comprises a cycloolefin copolymer (COC).

14. The film according to claim 13, wherein a melting point of the tie layer differs from a melting point of COC by 30°C or less.

15. The film according to claim 13, wherein the melting point of the tie layer differs from the melting point of COC by a value in the range of 5–15°C.

16. The film according to claim 13, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².

17. The film according to claim 13, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².

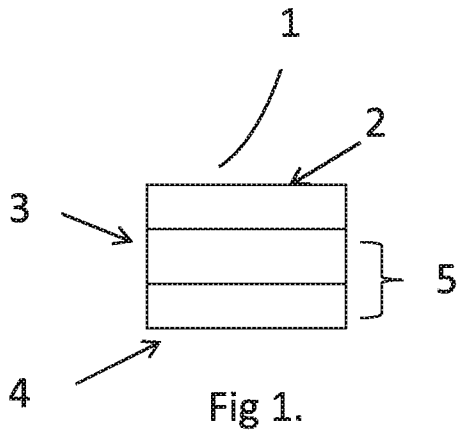
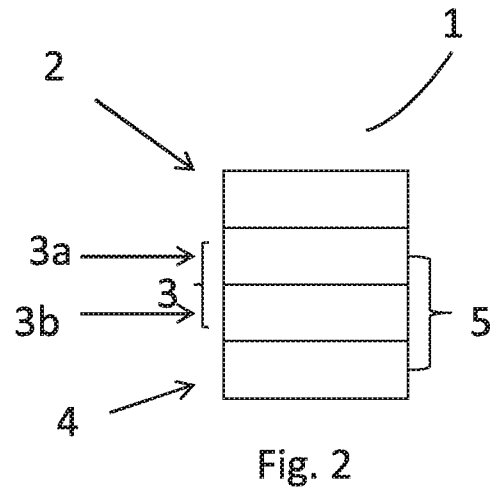
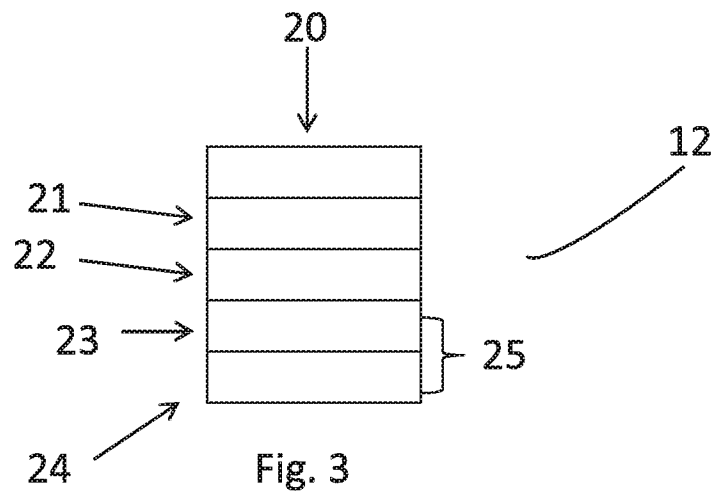
18. The film according to claim 12, wherein the coextrusion layer is coextrusion coated to the base layer.

19. The film according to claim 12, wherein the tie layer comprises an acrylic acid layer and a polyethylene layer.

20. The film layer according to claim 18, wherein the acrylic acid layer comprises ethylene acid.

ABSTRACT

The present disclosure relates to a method for providing a film. The method may include providing a base layer, wherein the base layer is resistant to one or more of water or oxygen; coextruding a tie layer and a contact layer to provide a coextrusion layer; coating the coextrusion layer to the base layer; allowing the coextrusion layer coated to the base layer to adhere to form the film, wherein the film comprises the tie layer and the contact layer formed as a coextrusion layer coated to the base layer; wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²; wherein the contact layer comprises a cycloolefin copolymer (COC).



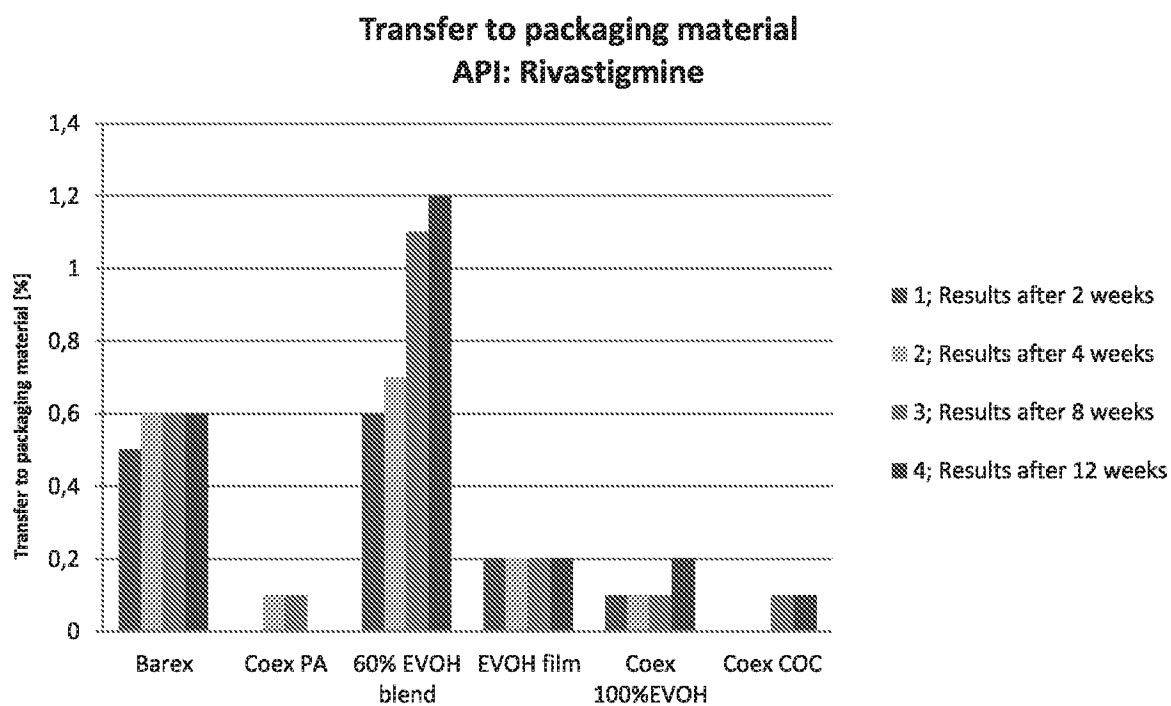


Fig. 4

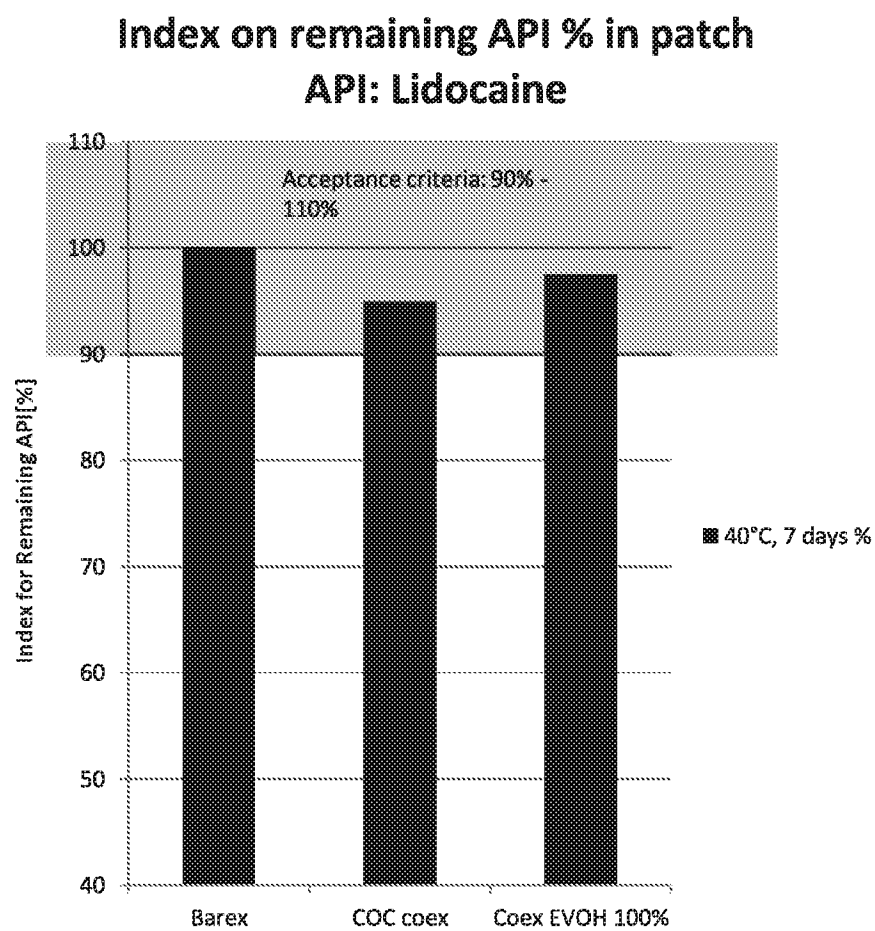


Fig. 5

**DECLARATION FOR UTILITY OR DESIGN APPLICATION
USING AN APPLICATION DATA SHEET
and
ASSIGNMENT**

We, Lars Christensen, Peter Johansen and Torben Foghmann, as the inventors, hereby declare that this declaration is directed to:

Title of Invention: A METHOD FOR PROVIDING AN EXTREME
CHEMICAL RESISTANT FILM, A FILM AND
LAMINATE OBTAINABLE THEREFROM

Filing Date: 01 June 2018

Application No.: 15/780,999

which is a 371 national phase of the below-identified international patent application:

Title of Invention: A METHOD FOR PROVIDING AN EXTREME CHEMICAL
RESISTANT FILM, A FILM AND LAMINATE
OBTAINABLE THEREFROM

Filing Date: 29 December 2016

Application No.: PCT/EP2016/082876

The above-identified applications were made or authorized to be made by us.

We believe that we are the original inventors of a claimed invention in the applications.

We 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.

WHEREAS, Lars Christensen, a citizen of Denmark, residing at Slagelse, Denmark; Peter Johansen, a citizen of Denmark, residing at Odense C, Denmark; and Torben Foghmann, a citizen of Denmark, residing at Nyborg, Denmark; hereinafter referred to as "Assignors," are the inventors described and set forth in the above-identified applications;

WHEREAS, Danapak Flexibles A/S, located at Slagelse, Denmark; hereinafter referred to as "Assignee," is desirous of acquiring an ownership interest in the invention and applications listed above and in any U.S. Letters Patent and Registrations which may be granted on any patent application claiming priority from the same;

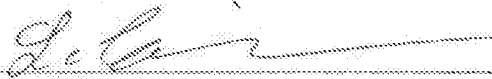
For good and valuable consideration, receipt of which is hereby acknowledged by the Assignors, Assignors have assigned, and by these presents do assign to Assignee all right, title and interest in and to the invention and application and to all foreign counterparts (including patent, utility model and industrial designs), and in and to any Letters Patent and Registrations which may hereafter be granted on any patent application claiming priority from the same in the United States and all countries throughout the world, and to claim the priority from the application as provided by the Paris Convention. The right, title and interest is to be held and enjoyed by Assignee and Assignee's successors and assigns and as fully and

exclusively as it would have been held and enjoyed by the Assignors had this Assignment not been made, for the full term of any Letters Patent and Registrations which may be granted thereon, or of any division, renewal, continuation in whole or in part, substitution, conversion, reissue, prologation or extension thereof.

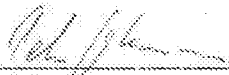
Assignors further agree that Assignors will, without charge to Assignee, but at Assignee's expense, (a) cooperate with Assignee in the prosecution of U.S. Patent applications and foreign counterparts on the invention and any improvements, (b) execute, verify, acknowledge and deliver all such further papers, including applications and instruments of transfer, and (c) perform such other acts as Assignee lawfully may request to obtain or maintain Letters Patent and Registrations for the invention and improvements in any and all countries, and to vest title thereto in Assignee, or Assignee's successors and assigns.

IN TESTIMONY WHEREOF, Assignors have signed their names on the date indicated.

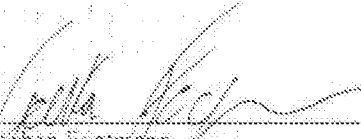
Dated: 08-06-2018


Lars Christensen

Dated: 08.06.2018


Peter Johansen

Dated: 08-06-2018


Torben Fogtmann

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		
<p>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.</p> <p>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.</p>			

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	
	Lars		Christensen		
Residence Information (Select One) ☐ US Residency ☒ Non US Residency ☐ Active US Military Service					
City	Slagelse		Country of Residenceⁱ	DK	
Mailing Address of Inventor:					
Address 1		Østerbro 54			
Address 2					
City	Slagelse		State/Province	DK	
Postal Code	4200		Countryⁱ	DK	
Inventor 2					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Peter		Johansen		
Residence Information (Select One) ☐ US Residency ☒ Non US Residency ☐ Active US Military Service					
City	Odense C		Country of Residenceⁱ	DK	
Mailing Address of Inventor:					
Address 1		Munkebjergvej 3, 2. sal			
Address 2					
City	Odense C		State/Province	DK	
Postal Code	5000		Countryⁱ	DK	
Inventor 3					Remove
Legal Name					

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		

Prefix	Given Name	Middle Name	Family Name	Suffix
	Torben		Fogtmann	
Residence Information (Select One) ☐ US Residency ☒ Non US Residency ☐ Active US Military Service				

City	Nyborg	Country of Residence ⁱ	DK
------	--------	-----------------------------------	----

Mailing Address of Inventor:

Address 1	Hjortevænget 174		
Address 2			
City	Nyborg	State/Province	DK
Postal Code	5800	Country ⁱ	DK

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button.

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	26582		
Email Address	patentdocket@hollandhart.com	<input type="button" value="Add Email"/>	<input type="button" value="Remove Email"/>

Application Information:

Title of the Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		
Attorney Docket Number	P006DK.WO.* (87942.0014)	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	3	Suggested Figure for Publication (if any)	1

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		

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.											
<table border="1"> <tr> <td>Please Select One:</td> <td>☒ Customer Number</td> <td>☐ US Patent Practitioner</td> <td>☐ Limited Recognition (37 CFR 11.9)</td> </tr> <tr> <td>Customer Number</td> <td colspan="3">26582</td> </tr> </table>				Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)	Customer Number	26582		
Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)								
Customer Number	26582										

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	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15780999	2018-06-01
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15780999	a 371 of international	PCT/EP2016/082876	2016-12-29
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		

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).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)
15202962.5	EP	2015-12-29	
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

<p>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.</p> <p>☐ 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.</p>
--

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		

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			
<p>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.</p>			
<input type="button" value="Clear"/>			
☒ Assignee		☐ Legal Representative under 35 U.S.C. 117	
☐ Person to whom the inventor is obligated to assign.		☐ Joint Inventor	
☐ 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: <input type="text"/>			
If the Applicant is an Organization check here. ☒			
Organization Name	Danapak Flexibles A/S		
Mailing Address Information For Applicant:			
Address 1	Strudsbergsvej 3		
Address 2			
City	Slagelse	State/Province	DK
Country	DK	Postal Code	4200
Phone Number		Fax Number	
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		

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.

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		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.

Signature:

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	/Paul M. Schramm/		Date (YYYY-MM-DD)	2020-03-30
First Name	Paul	Last Name	Schramm	Registration Number 62050

Additional Signature may be generated within this form by selecting the Add button.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P006DK.WO.* (87942.0014)
		Application Number	
Title of Invention	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM		

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.**

Electronic Patent Application Fee Transmittal

Application Number:				
Filing Date:				
Title of Invention:	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM			
First Named Inventor/Applicant Name:	Lars Christensen			
Filer:	Paul M. Schramm/Wendy Nishida			
Attorney Docket Number:	P006DK.WO.* (87942.0014)			
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:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1720

Electronic Acknowledgement Receipt

EFS ID:	39012133
Application Number:	16835018
International Application Number:	
Confirmation Number:	7472
Title of Invention:	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM
First Named Inventor/Applicant Name:	Lars Christensen
Customer Number:	26582
Filer:	Paul M. Schramm/Wendy Nishida
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P006DK.WO.* (87942.0014)
Receipt Date:	30-MAR-2020
Filing Date:	
Time Stamp:	19:24:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 1720
RAM confirmation Number	E20203TJ25188467
Deposit Account	082623
Authorized User	Wendy Nishida

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

183/186

358

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		P006DK.pdf	2474790	yes	47
			3dd8a1d908d2c609c8a0ab68a64f7c33ea041447		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Transmittal of New Application		1	1	
	Specification		2	30	
	Claims		31	33	
	Abstract		34	34	
	Drawings-only black and white line drawings		35	37	
	Oath or Declaration filed		38	39	
	Application Data Sheet		40	47	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	35442	no	2
			11966c76af66438943383c06aece04b637da23bb		
Warnings:					
Information:					
Total Files Size (in bytes):			2510232		

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.

SCORE Placeholder Sheet for IFW Content

Application Number: 16835018

Document Date: 03/30/2020

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- Drawing

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