



Huhtamaki Flexible Packaging Germany GmbH & Co. KG

v.

Adapa Flexibles Denmark Slagelse A/S, f/k/a Danapak Flexibles A/S

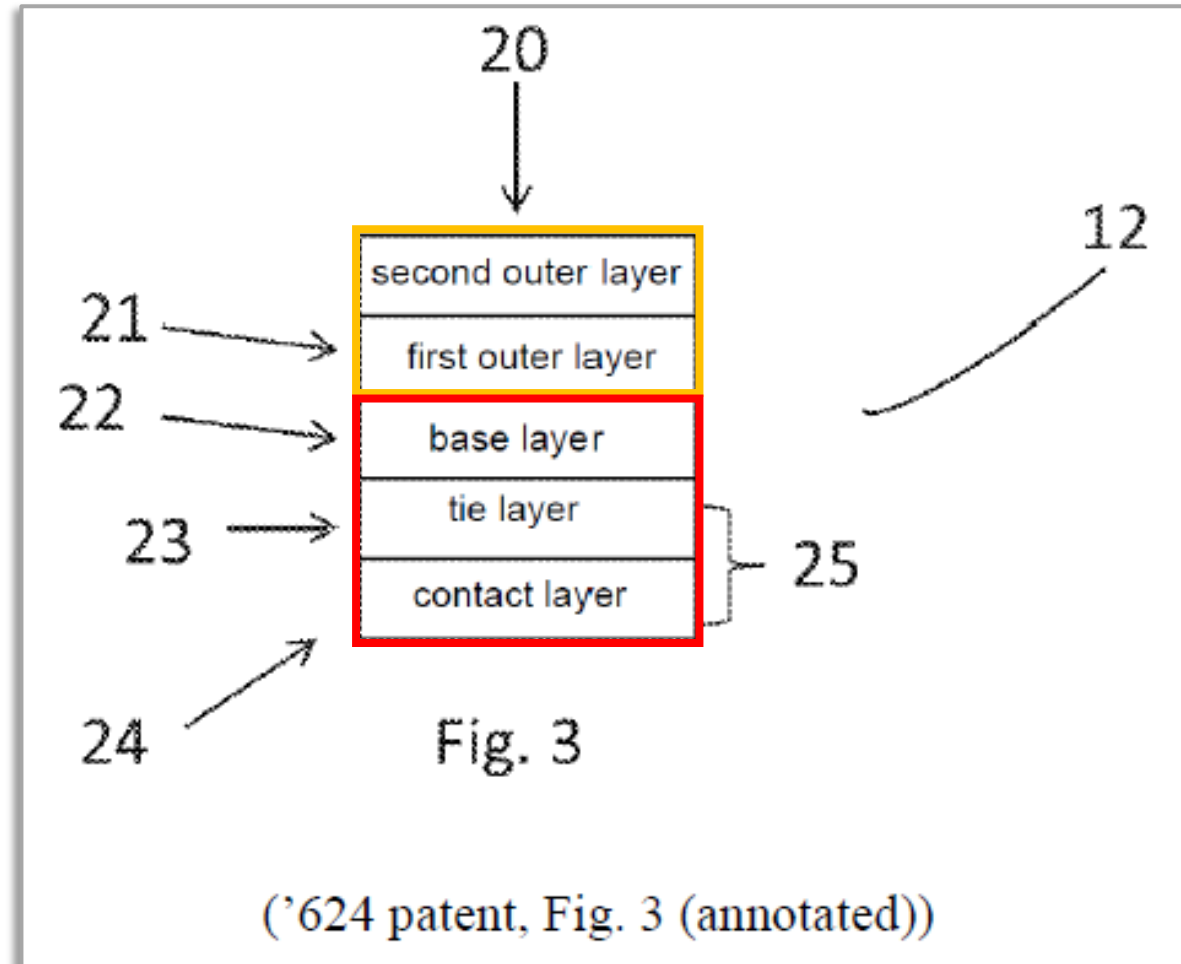
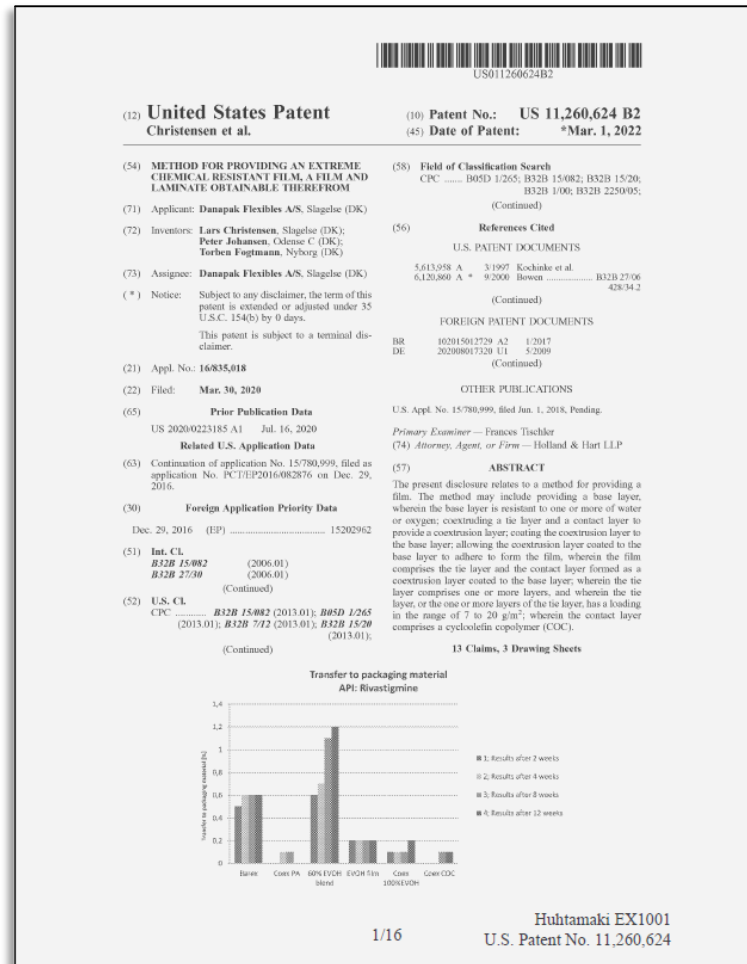
Petitioner's Demonstratives

April 12, 2024

Instituted Grounds

	Statutory Basis	Challenged Claims	Asserted References
Ground 1	35 U.S.C. § 112(b)	1–13	
Ground 2	35 U.S.C. § 103	1–13	Riis
Ground 3	35 U.S.C. § 103	1–13	Riis, Wypych, Tatarka

US 11,260,624 – Method for Providing an Extreme Chemical Resistant Film, a Film and Laminate Obtainable Therefrom



US 11,260,624 – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:

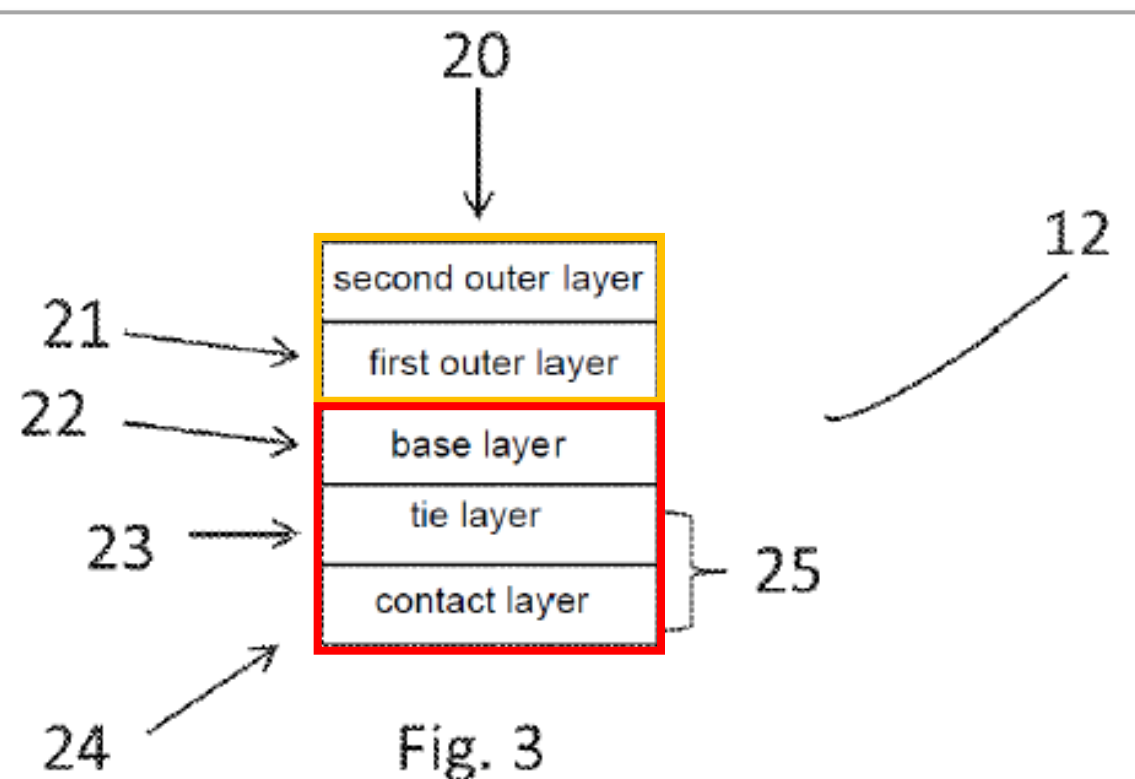
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;

coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);

coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer comprising the aluminum; and

allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of: the base layer comprising the aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,

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.



('624 patent, Fig. 3 (annotated))

US 11,260,624 – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:

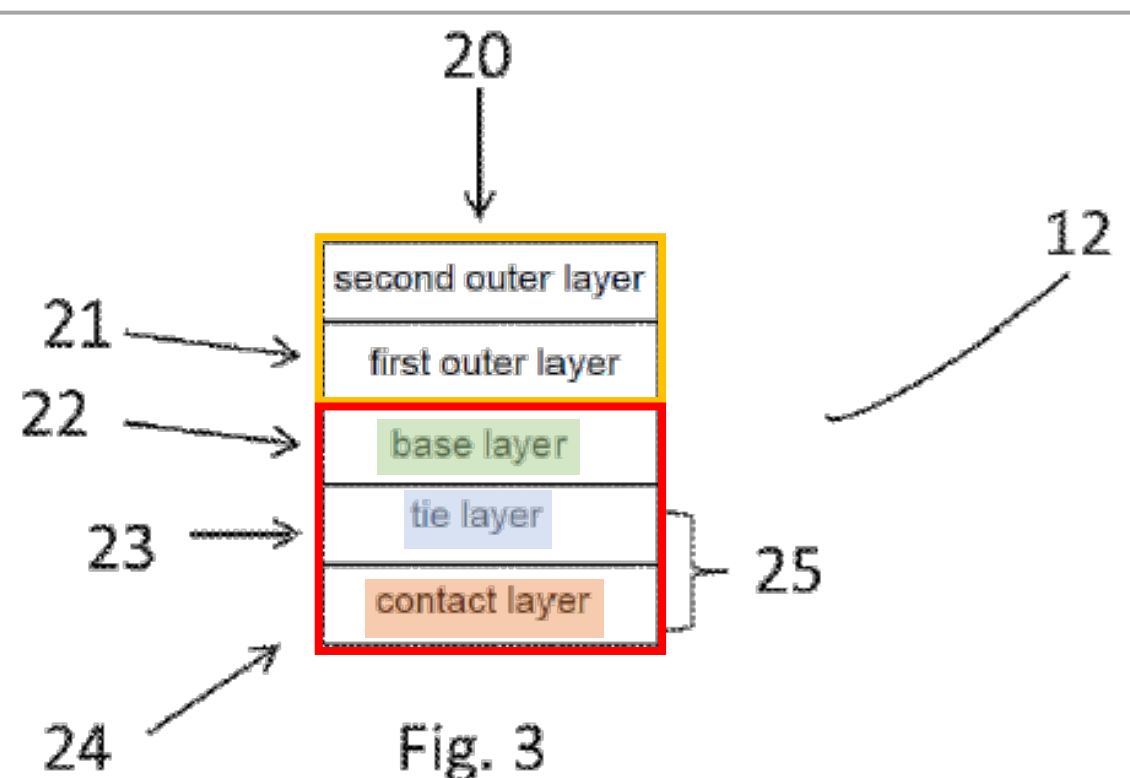
providing a **base layer**, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;

coextruding a **tie layer** and a **contact layer** to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);

coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer comprising the aluminum; and

allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of: the base layer comprising the aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,

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.



(*624 patent, Fig. 3 (annotated))

US 11,260,624 – Claims 8, 11, 12

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

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**.

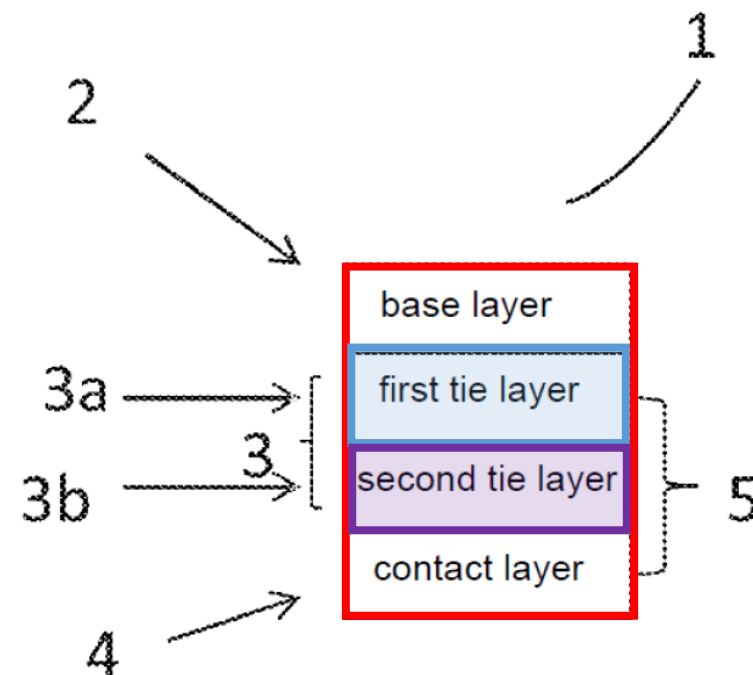
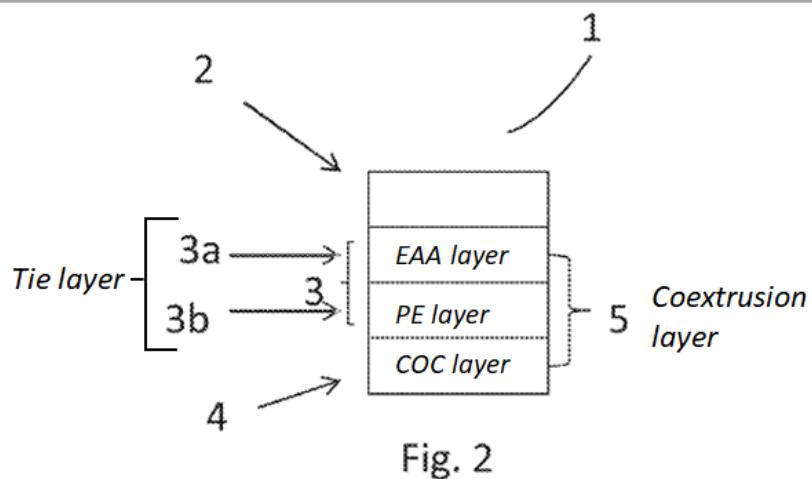


Fig. 2

('624 patent, Fig. 2 (annotated))

EX1001 – '624 Patent - Tie Layers



Paper 1 (Petition), 33

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.

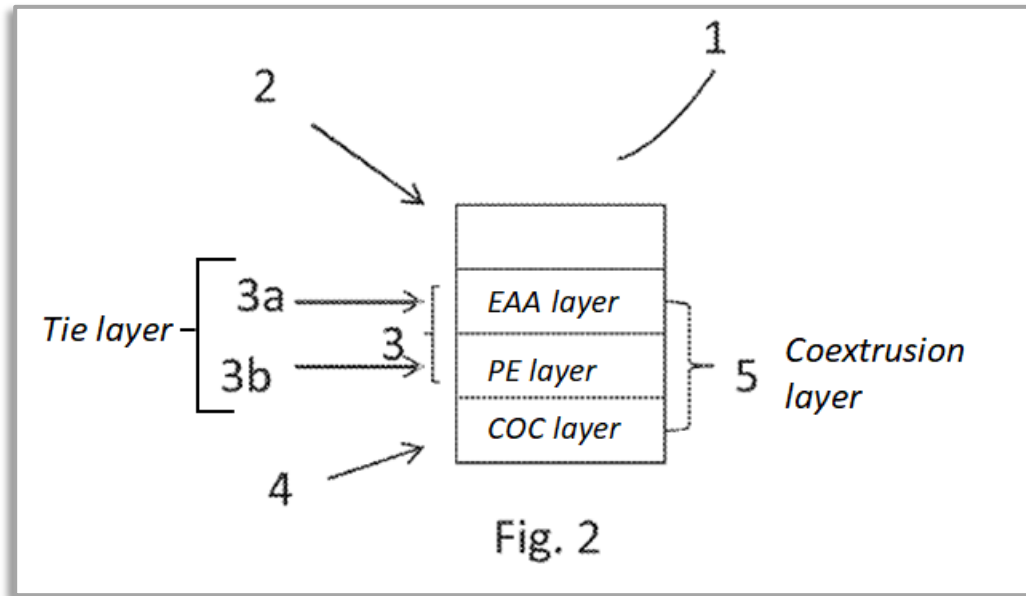
EX1001, 18:57-61

'624 Patent Specification

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.

EX1001, 13:42-46

LDPE as a Tie Layer



13 So low density polyethylene is a type of
14 polyethylene, correct?
15 A That is correct.

EX1032, 100:13-15

Prior Art – Riis (EX1004)

Riis expressly teaches all the limitations of the challenged claims except for the claimed loading ranges and melting points of the polymers. Riis, entitled “Anti-

Paper 1 (Petition), 17

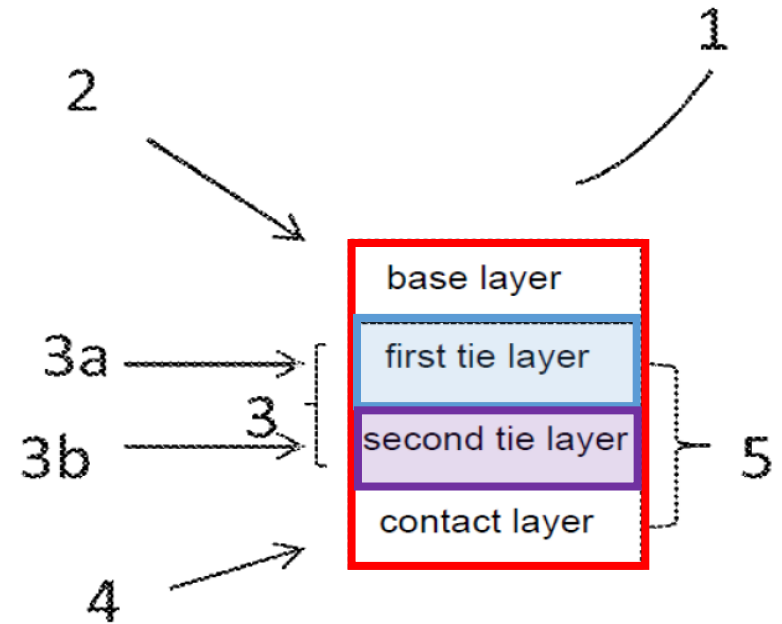


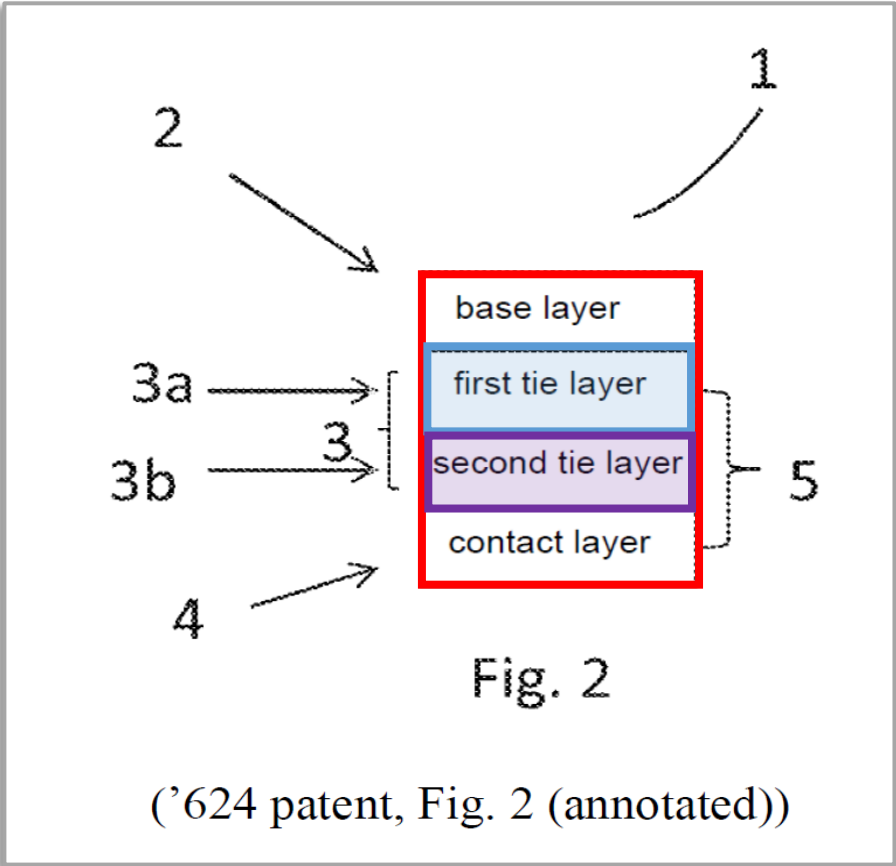
Fig. 2

(’624 patent, Fig. 2 (annotated))

Paper 1 (Petition), 9 (annotated)

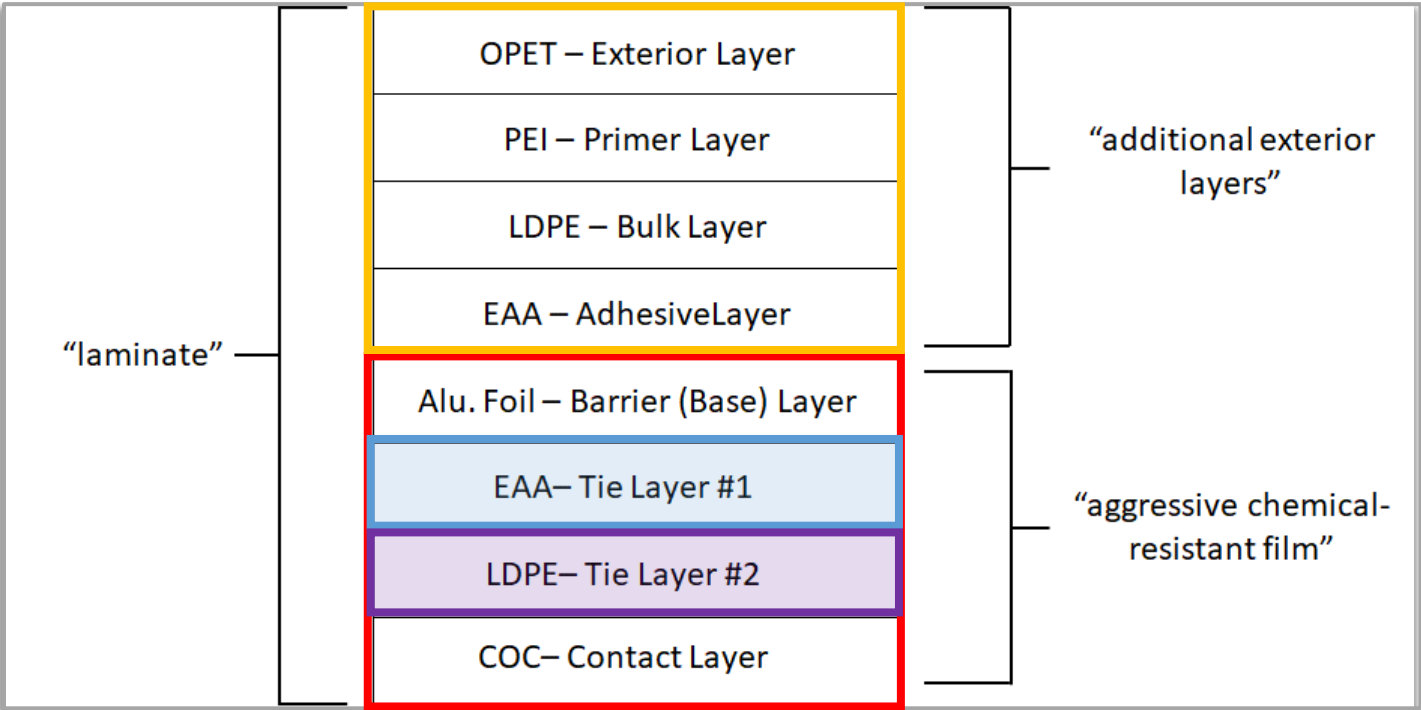
Prior Art – Riis (EX1004)

'624 Patent



Paper 1 (Petition), 9 (annotated)

Riis (EX1004)



Paper 1 (Petition), 38 (annotated)
EX1004, Fig. 1, ¶174

Riis – Aggressive Chemical Resistance – “Scalping”

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	
coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer comprising the aluminum; and	
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,	
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/m ² .	

Riis (EX1004)

This disclosure, among other things, relates to films for packaging products containing a pharmaceutical active agent. The films resist migration of chemicals, such as pharmacological active agents or excipients, between the product and the film. Thus, the films are anti-scalping

EX1004, ¶10005

The product contacting layers of the films described herein include at least 90 wt. % of an ethylene norbornene copolymer having a glass transition temperature in a range from 50°C to 138°C. Layers having such properties were found to resist migration of nicotine and fentanyl.

EX1004, ¶10006

In some embodiments, the pharmaceutical active agent is selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine.

EX1004, ¶10011

Methods of Manufacture

The inventive monolayer or multilayer film may be made by conventional processes. These processes to produce flexible films may include e.g. cast or blown film processes.

Riis – Aluminum Foil Barrier Layer

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	
coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer comprising the aluminum; and	
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,	
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/m ² .	

Riis (EX1004)

Barrier Layers

If included, a barrier layer preferably functions both as a gas barrier layer, and as a moisture barrier layer, although these functions may be provided by separate layers. A gas barrier layer is preferably an oxygen barrier layer, and is preferably a core layer positioned between and protected by surface layers. For example, an oxygen barrier layer can be in contact with a first

EX1004, ¶¶58-59

known to those of skill in the art. Suitable moisture barrier layers include aluminum foil, PVDC, or polyolefins such as LDPE or LLDPE. It is desirable that the thickness of the barrier layer be

EX1004, ¶62

An oxygen barrier layer of a film may comprise aluminum foil, or EVOH, although oxygen barrier layers comprising polyvinylidene chloride-vinyl chloride copolymer (PVDC or VDC-VC) or vinylidene chloride-methylacrylate copolymer (VDC-MA) as well as blends thereof, can also be used. One suitable EVOH barrier material is a 44 mol % EVOH resin E151B sold by

EX1004, ¶63

Riis – Coextrusion Layer – Tie & Contact Layers

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	✓
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	✓
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	✓
coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer comprising the aluminum; and	
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,	
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/m ² .	

Riis (EX1004)

Tie Layers

In addition to the exterior layer, the interior layer, and intermediate layer such as a barrier layer, a multilayer packaging film can further comprise one or more adhesive layers, also known in the art as "tie layers," which can be selected to promote the adherence of adjacent layers to one another in a multilayer film and prevent undesirable delamination. A multifunctional layer is

EX1004, ¶¶70-71

Multilayer films can comprise any suitable number of tie or adhesive layers of any suitable composition. Various adhesive layers are formulated and positioned to provide a desired level of adhesive between specific layers of the film according to the composition of the layers contacted by the tie layers.

EX1004, ¶72

The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example, polyamides, polystyrenes, styrenic copolymers e.g. styrene-butadiene copolymer, polyolefins, and in particular members of the polyethylene family such as LLDPE, VLDPE, HOPE, LDPE, ethylene vinyl ester copolymer or ethylene alkyl acrylate copolymer,

EX1004, ¶74

Riis – Coextrusion Layer – Tie & Contact Layers

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	✓
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	✓
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	✓
coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer comprising the aluminum; and	
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,	
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/m ² .	

Riis (EX1004)

Article Contact/Heat Sealing Layers

The films described herein have a product contact layer containing ethylene norbornene copolymer, which is a cyclic olefin copolymer (COC). COCs are commercially available from Topas as an amorphous, transparent copolymer of ethylene with norbornene made by

EX1004, ¶¶51-52

layer to facilitate formation of hermetically sealed packages. The article contact layer comprises at least 90 wt.% of ethylene norbornene COC, more preferably at least 95 wt. %, and most preferably 100 wt. %. It may be blended with up to 10 wt. %, preferably up to 5 wt. % and more

EX1004, ¶55

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer/0.42 mil

EX1004, ¶174

Riis – Coextruding Contact Layer to Base Layer

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	✓
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	✓
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	✓
coating the <u>coextrusion layer consisting of the tie layer and the COC of the contact layer</u> directly to the base layer comprising the aluminum; and	✓
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,	
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/m ² .	

Riis (EX1004)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil

EX1004, ¶174

Patent Owner’s Response (Paper 21) disputes Riis disclosing a coextrusion layer “consisting of” the tie layer and COC layer (red underlining).

Riis – Coextruding Contact Layer to Base Layer

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	✓
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	✓
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	✓
coating the <u>coextrusion layer consisting of the tie layer and the COC of the contact layer</u> directly to the base layer comprising the aluminum; and	✓
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	✓
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,	
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/m ² .	

'624 Patent

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.

EX1001(13:15-18)

Riis (EX1004)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer/0.42 mil

EX1004, ¶174

Spontak Dec. (EX1003)

it to adhere to form an aggressive chemical-resistant film. Indeed, a POSITA would have understood that the three-layer coextrusion and base layer of Example 5 would have cooled subsequent to coextrusion, causing the coextrusion layer and base layer to adhere. As recognized by the '624 patent, the coextrusion

EX1003, ¶140

Riis – Coextruding Contact Layer to Base Layer

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	✓
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	✓
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	✓
coating the <u>coextrusion layer consisting of the tie layer and the COC of the contact layer</u> directly to the base layer comprising the aluminum; and	✓
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	✓
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, <u>and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,</u>	✓
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/m ² .	

Riis (EX1004)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer/0.42 mil

Spontak Dec. (EX1003)

EX1004, ¶174

'624 patent, Riis's three-layer coextrusion "sealant film" along with the aluminum foil base layer forms an "aggressive chemical-resistant film." Thus, Riis teaches this limitation.

EX1003, ¶146

layer consisting of COC." Ex. 1001, Claim 1 and 13. The plain language of the

claims requires only "the base layer comprising the aluminum." EX. 1001, claim 1 and 13. Thus, the composition of the base layer is therefore open-ended. Riis

Riis – Coextruding Contact Layer to Base Layer

'624 Patent – Claim 1

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:	✓
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	✓
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	✓
coating the <u>coextrusion layer consisting of the tie layer and the COC of the contact layer</u> directly to the base layer comprising the aluminum; and	✓
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	✓
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, <u>and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,</u>	✓
wherein the tie layer comprises one or more layers, and <u>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.</u>	✓

Riis (EX1004)

0.35 mil foil0.17 mil EAA0.65 mil LD/PE0.43 mil COC

EX1004, ¶174

Spontak Dec. (EX1003)

As taught in Riis, a 0.17 mil layer of EAA, which has a density of 0.94 g/cm³, has a “loading” as that term is used in the '624 patent, of 4.06 g/m². A 0.65 mil layer of Dow 4012 (LDPE), which has a density of 0.918 g/cm³, has a loading of 15.16 g/m². These are both consistent with sources of density like those in Wypych, which provides a density of EAA as 0.92-0.96 g/cm³, which with a 0.17 mil layer has a “loading,” as that term is used in the '624 patent, of at least 3.97 g/m²-4.15 g/m². Further consistent with Wypych, a 0.65 mil layer of Dow 4012 (LDPE), which has a density of 0.915-0.929 g/cm³, has a loading of 15.11 g/m²-15.34 g/m².

EX1003, ¶156

Riis – Motivation to Combine & Expectation of Success



Spontak Dec. (EX1003)

160. In view of Riis's disclosures regarding Example 5, a skilled artisan would have been motivated to follow Riis's disclosure to recreate the film of Example 5 and would have had a reasonable expectation of doing so to arrive at the claimed invention.

EX1003, ¶160

Riis Example 5 – 0.92 mil OPET/ Primer/0.42 mil LDPE/0.1 mil EAA/0.35 mil Al. Foil/0.17 mil EAA/0.65 mil LDPE/0.43 mil COC

thickness of 3.0 mils (76 microns). The inventive film is well suited to package articles for collecting or administering a physiologically active substance such as transdermal drug delivery patches, or oral dissolvable thin strips and has advantageous moisture barrier, oxygen barrier, and low scalping properties as discussed below. The resultant multilayer film was tested for

EX1004, ¶0174

Riis – Motivation to Combine & Expectation of Success



Spontak Dec. (EX1003)

164. In view of Riis's teachings of how to produce the film of Example 5 and its experimental data demonstrating the successful anti-scalping properties of the film of Example 5, a POSITA would have had a reasonable expectation of success of arriving at the claimed invention. EX1004, ¶¶[00159]-[00197]. This expectation of success would have been further reinforced by Merial's teaching that similar film structures that use COC for the product contacting layer may be used with pharmaceutical products and Jester's discussion of prior-art films employing COC being "suitable for packaging food and drugs." Ex. 1013, 12:3-17 Ex. 1014, ¶¶[0004], [0008].

EX1003, ¶164

Riis – Motivation to Combine & Expectation of Success

Ex. No.	Sealant Layer	Ave. Sealant Thickness (mil)	Nicotine Direct Contact Test Amount of Eluted Nicotine (mg)					Nicotine Vapor Test Amount of Eluted Nicotine (mg)				
			Day 1	Day 2	Day 8	Day 15	Day 31	Day 1	Day 2	Day 8	Day 15	Day 31
1	Ionomer	1.0	17.1	15.3	16.7	24.0	22.0	8.5	11.9	15.8	25.2	23.7
2	LDPE:mLLDPE 80:20 wt.% blend	0.43	10.5	10.8	13.3	17.0	15.8	5.76	7.85	11.5	17.2	16.2
3	APET	2	12.6	10.5	12.0	13.1	11.2	1.73	2.47	Leak in Pouch	Leak in Pouch	2.3
4	polyacrylonitrile	1.5	0.05	0.00	0.00	0.03	0.03	0.21	0.36	0.49	0.70	1.08
5	COC	0.43	2.08	3.47	1.42	3.12	2.03	0.94	1.26	1.95	2.42	1.26

EX1004, ¶176, Table 2

Melting Points of COC & Tie Layer

'624 Patent – Claims 2 & 3

2. The method according to claim 1, wherein a melting point of the tie layer differs from the 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.	

Spontak Dec. (EX1003)

167. Use of EAA, LDPE, and ethylene norbornene copolymer (COC) would result in a chemical-resistant film wherein the melting point of the tie layer differs from the melting point of the COC by 30°C or less. As noted above for the “loading”

Polymer	Melting Point
EAA	75-112°C
LDPE	105-115°C
Ethylene norbornene copolymer (COC)	60-125°C

EX1003, ¶167, 169

Riis – Contact Layer (COC) – Loading Range

'624 Patent – Claims 4-7

4. The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m ² .	✓
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/m ² .	
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/m ² .	
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/m ² .	

Riis (EX1004)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil LDPEI0.1 mil EANO.35 mil foil0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶10174

Spontak Dec. (EX1003)

converting g/cm² to g/m². Here, a 0.43 mil layer of Topas 8007F-400, which had a density of 1.02 g/cm³, would have had a loading of 11.14 g/m². And even if a

EX1003, ¶172

Riis – Tie Layer Loading Range

'624 Patent – Claims 4-7

4. The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m ² .	✓
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/m ² .	✓
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/m ² .	
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/m ² .	

Riis (EX1004)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil LDPE10.1 mil EAA0.35 mil foil10.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶10174

Spontak Dec. (EX1003)

179. Thus, a tie layer consisting of a 0.17 mil layer of EAA and a 0.65 mil layer of LDPE has a “loading” of 19.22 g/m², or as broad as from 19.08 g/m²-19.49 g/m².

EX1003, ¶179

Riis – Tie Layer Loading Range

'624 Patent – Claims 4-7

4. The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m ² .	✓
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/m ² .	✓
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/m ² .	✓
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/m ² .	✓

Riis (EX1004)

0.35 mil foil0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC

EX1004, ¶174

Spontak Dec. (EX1003)

As taught in Riis, a 0.17 mil layer of EAA, which has a density of 0.94 g/cm³, has a “loading” as that term is used in the '624 patent, of 4.06 g/m². A 0.65 mil layer of Dow 4012 (LDPE), which has a density of 0.918 g/cm³, has a loading of 15.16 g/m². These are both consistent with sources of density like those in Wypych, which provides a density of EAA as 0.92-0.96 g/cm³, which with a 0.17 mil layer has a “loading,” as that term is used in the '624 patent, of at least 3.97 g/m²-4.15 g/m². Further consistent with Wypych, a 0.65 mil layer of Dow 4012 (LDPE), which has a density of 0.915-0.929 g/cm³, has a loading of 15.11 g/m²-15.34 g/m².

EX1003, ¶156

Riis – Tie Layer(s)

'624 Patent – Claims 8-12

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.	

Riis (EX1004)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil LDPEI0.1 mil EAA0.35 mil foil0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶10174

In addition to the exterior layer, the interior layer, and intermediate layer such as a barrier layer, a multilayer packaging film can further comprise one or more adhesive layers, also known in the art as "tie layers," which can be selected to promote the adherence of adjacent layers to one another in a multilayer film and prevent undesirable delamination. A multifunctional layer is

EX1004, ¶10071

Riis – Tie Layer(s)

'624 Patent – Claims 8-12

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.	

Riis (EX1004)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil LDPEI0.1 mil EANO.35 mil foill0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶10174

Riis – Tie Layer(s)

'624 Patent – Claims 8-12

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.	✓

Riis – Ex. 5

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil

EX1004, ¶174

The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example, polyamides, polystyrenes, styrenic copolymers e.g. styrene-butadiene copolymer, polyolefins, and in particular members of the polyethylene family such as LLDPE, VLDPE, HOPE, LDPE, ethylene vinyl ester copolymer or ethylene alkyl acrylate copolymer,

EX1004, ¶74

EAA-Copolymer of ethylene with acrylic acid

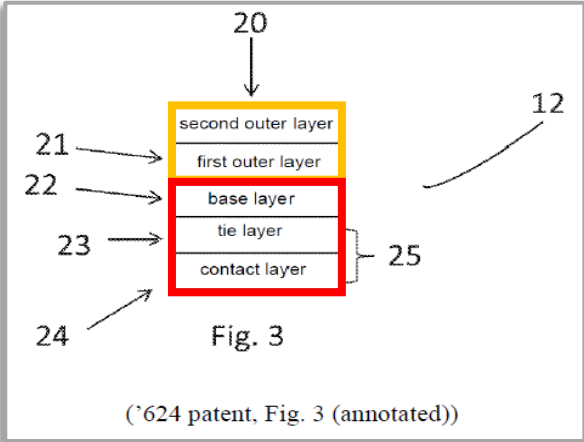
EX1004, ¶18

Riis – Coextruding Contact Layer to Base Layer

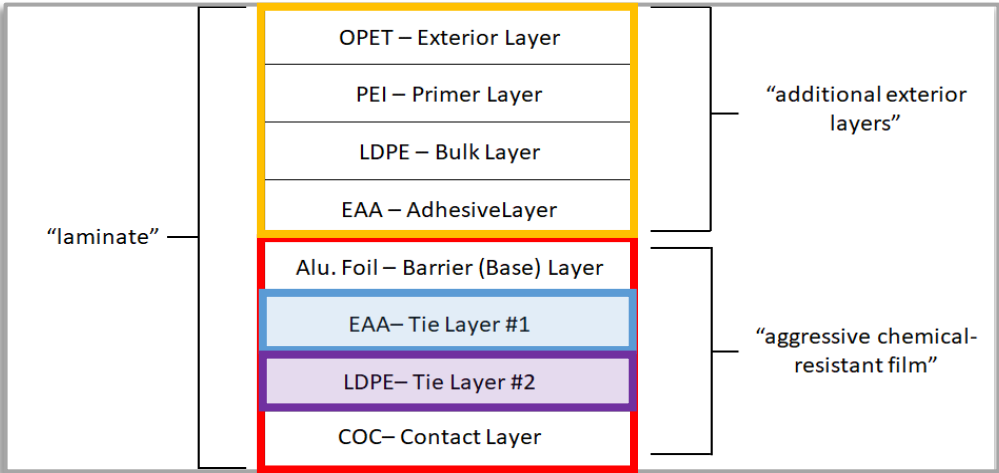
'624 Patent – Claim 13

1. A method for providing a laminate , wherein the laminate comprises an aggressive chemical-resistant film, said method comprising:	✓
providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;	✓
coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	✓
coating the <u>coextrusion layer consisting of the tie layer and the COC of the contact layer directly</u> to the base layer comprising the aluminum; and	✓
allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,	✓
wherein the aggressive chemical-resistant film consists of: the base layer comprising aluminum, and <u>the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC</u> , wherein the aggressive chemical resistant film is resistant to a chemical selected ~~from~~ nicotine, fentanyl, rivastigmine, or lidocaine,	✓
wherein the tie layer comprises one or more layers, and wherein the <u>tie layer, or the one or more layers of the tie layer</u> , has a loading in <u>the range of 7 to 20 g/m².</u>	✓

'624 Patent – Fig. 3 (annotated)



Riis – Fig. 1 (annotated)



Huhtamaki

Ground 3: Riis, Wypych, Tatarka

Riis in combination with Wypych & Tatarka

- Ground 2 – Riis discloses commercial examples of polymers that can be used in making the disclosed films
- Ground 3 – A skilled artisan would look to Wypych and Tatarka to determine properties and characteristics for making a film as disclosed in Riis.

235. In view of Riis's disclosures regarding exemplary polymers used in Example 5, a skilled artisan would have been motivated to look to Wypych and Tatarka in order to learn more about the properties and characteristics of exemplary polymers and to find suitable commercial sources to obtain polymers for a desired film attribute.

EX1003, ¶235

Dr. McCarthy's Misinterpretations



“PRIMARY PURPOSE” – Unsupported by documentary evidence

97. With reference to the above discussion of the disclosure Riis (including the correspondence between the six-layer film described in FIG. 1 of Riis and the eight-layer film disclosed in example 5 of Riis) and the knowledge of one skilled in the art at the time of the '624 Patent, one skilled in the art would understand the primary purposes of the layers of the eight-layer film to be as follows.

EX2014, ¶97

104. As detailed more fully below, and for the same reasons one of ordinary skill in the art would understand that the 0.42 mil LDPE layer primary serves as a bulk layer in Riis, one skilled in the art would also understand that the 0.65 mil LDPE layer is a primarily serving a bulk purpose and would, thus, refer to the 0.65 mil LDPE layer as a “bulk” layer. *See also*, ¶¶ 94, 156.

EX2014, ¶104

Is the plain and ordinary meaning of tie layer restricted to the layer's primary purpose?

104. As detailed more fully below, and for the same reasons one of ordinary skill in the art would understand that the 0.42 mil LDPE layer primary serves as a bulk layer in Riis, one skilled in the art would also understand that the 0.65 mil LDPE layer is a primarily serving a bulk purpose and would, thus, refer to the 0.65 mil LDPE layer as a "bulk" layer. *See also*, ¶¶ 94, 156.

EX2014, ¶104



Primary Purpose – Subjective Determination

Any assignment of a “primary purpose” by Patent Owner is arbitrary and based solely on subjective intent, not on the layer’s functionality. Dr. McCarthy’s testimony demonstrates the flaw in Patent Owner’s construction:

Q: So the entire definition of primary purpose depends on the person who made the film’s intention for that layer? Is that what you’re saying?

A: Not the person who made the film but the inventor who designed the film.



Paper 027 (Petitioner’s Reply), 6 (quoting EX1032, 126:14-19)

Primary Purpose – Subjective Determination

Dr. McCarthy relies on this subjective intent to opine that Riis's 0.65 mil LDPE layer is not the claimed "tie layer":

Q: Do you agree that as of December 29, 2015, a POSA would have understood that LDPE is a suitable thermoplastic for a tie layer?

A: Again, it would depend on the definition of tie layer. It would not be a multifunctional tie layer, so it wouldn't be suitable for Riis' definition of it.

Q: Would it be suitable for the '624 patent's definition?

A: Possibly.

EX1032, 149:12-21.



PO's Considerations to Determine Primary Purpose

1. The absolute thickness of a layer, the material(s) of the layer, and the thickness of the layer relative to the thickness of the multilayer film. POR, 42.
2. Perform a full test removing the layer at issue and testing the film's overall performance. POR, 53.
3. The absolute peel strength. McCarthy Third Depo. Tr.
4. The context/application of use. McCarthy Third Depo. Tr.

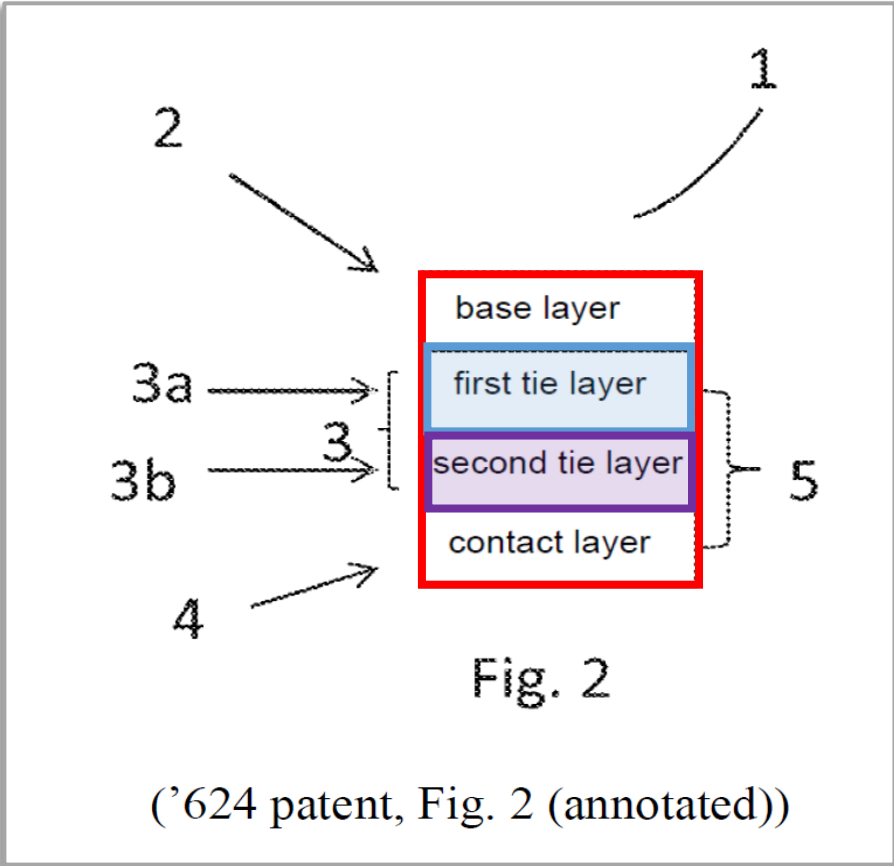
Nevertheless, one skilled in the art would understand whether a polyolefin bulk layer is serving as a "tie" layer, as defined in Riis, to depend on the thickness of the polyolefin layer, the material(s) used for the polyolefin bulk layer, as well as the thickness and materials of the adjacent layers. EX2014 ¶¶ 92–95, 152–162.

Paper 21 (PO Resp.), 42

to a layer based on its primary purpose. To determine whether a layer of a multi-layer film is serving a primary purpose (such as tying two layers together), one skilled in the art could remove that layer and test the multi-layer film to determine whether the performance of the multi-layer film was improved, unchanged, or worsened, in that aspect — e.g., is the adhesion between the two layers improved, unchanged, or worsened. If the performance of the multi-layer film is improved or unchanged, one skilled in the art would understand that the primary purpose of the removed layer is not directed to that aspect. In Riis, if one skilled in the art were to

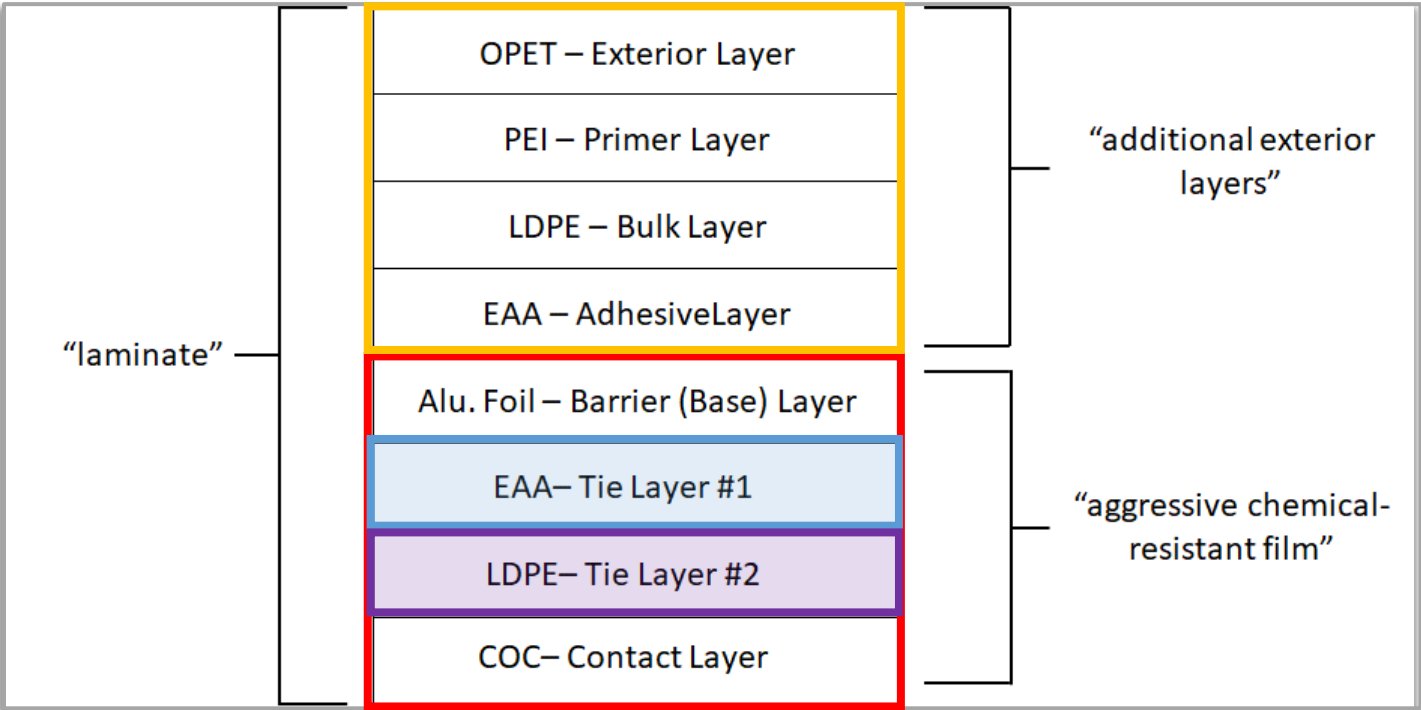
Prior Art – Riis (EX1004)

'624 Patent



Paper 1 (Petition), 9 (annotated)

Riis (EX1004)



Paper 1 (Petition), 38 (annotated)
EX1004, Fig. 1, ¶174

Tie Layer Functionality



3 Q. (BY MR. ROESER) And what are the
4 advantages of having -- I know you just discussed some
5 of them. What are -- what are the advantages of
6 having a thin tie layer in a multilayer film?

7 A. The tie layer serves only one primary
8 purpose, and that is to basically behave as an
9 adhesive, as a glue, if you will.

EX2015, 76:3-9

3 Q. (BY MR. ROESER) Can LDPE serve other
4 functions than just being an adhesive?

5 A. Oh, certainly, certainly. It can have
6 an effect on the bulk properties -- the bulk
7 mechanical properties, but that didn't seem to be of
8 concern here.

EX2015, 113:3-8

16 Q. Is there any other function that an
17 adhesive layer serves other than keeping the
18 multilayers together?

20 A. That is the primary objective. If there
21 are other attributes, and, for example, it can be used
22 to -- as a term that they use in -- in this field,
23 "scalp," if it can be used to capture any diffusing
24 molecules, that would be a plus. If it were able to
25 add any mechanical stability, that would be a plus.

EX2015, 70:16-25

Tie Layer Definition

'624 Patent

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

EX1001 ('624 Patent), 4:35-39

Riis

The term "adhesive layer," or "tie layer," refers to a layer or material placed on one or more layers to promote the adhesion of that layer to another surface. Preferably, adhesive layers are

EX1004 (Riis), ¶20

Tie Layer Definition

McCarthy



16 A Yeah, I think the tie layer would give
17 sufficient adhesion between the base layer and the
18 contact layer.

EX1032, 100:16-18



Spontak

18 Q. All right. So -- in this paragraph,
19 Riis discloses that an adhesive, or tie layer, is used
20 to promote the adhesion of that layer to another
21 surface; is that correct?
22 A. That is generally the idea behind an
23 adhesive layer, yes.

EX2015, 69:158-23,

'624 Patent – Tie Layer functionality

'624 Patent provides multiple functionalities for a tie layer

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

EX1001 ('624 Patent), 4:35-39

EX1004 - Riis – Tie layer functionality

“Riis” provides LDPE having multiple functions as a layer

The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example, polyamides, polystyrenes, styrenic copolymers e.g. styrene-butadiene copolymer, polyolefins, and in particular members of the polyethylene family such as LLDPE, VLDPE, HDPE, LDPE, ethylene vinyl ester copolymer or ethylene alkyl acrylate copolymer,

EX1004, ¶0074

A bulk layer may be provided to provide additional functionality such as stiffness or heat sealability or to improve machinability, cost, flexibility, barrier properties, etc. Preferred bulk layers comprise one or more polyolefins such as polyethylene, ethylene-alpha olefin copolymers (EAO), polypropylene, polybutene, ethylene copolymers having a majority amount by weight of

1 is shown for purposes of example. In some embodiments, a polyolefin bulk layer can serve as an adhesive or tie layer.

EX1004, ¶0065

EX1004, ¶135

Riis – Tie layer functionality

“Riis” provides LDPE having multiple functions as a layer

The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example, polyamides, polystyrenes, styrenic copolymers e.g. styrene-butadiene

properties); *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804 (Fed. Cir. 1989) (a prior art reference is relied upon for all that it teaches). Dr. McCarthy advances this

Paper 27 (Petitioner’s Reply), 5

(EAO), polypropylene, polybutene, ethylene copolymers having a majority amount by weight of

1 is shown for purposes of example. In some embodiments, a polyolefin bulk layer can serve as an adhesive or tie layer.

EX1004, ¶10065

EX1004, ¶135

Dr. McCarthy's Misinterpretations

Riis explicitly discloses LDPE can be a tie layer

The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example, polyamides, polystyrenes, styrenic copolymers e.g. styrene-butadiene copolymer, polyolefins, and in particular members of the polyethylene family such as LLDPE, VLDPE, HDPE, LDPE, ethylene vinyl ester copolymer or ethylene alkyl acrylate copolymer,

EX1004, ¶174

Riis Example 5 – no “bulk layer” mentioned

base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer/0.42 mil LDPE/0.1 mil EAA/0.35 mil foil/0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of 3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶174

Primary Purpose is not Restrictive

the layer. Such a construction is overly narrow; “[c]ommon sense teaches [] that familiar items may have obvious uses *beyond their primary purposes*.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) (emphasis added). No documentary

Paper 27 (Petitioner’s Reply), 5

Here, all that is required of the claimed tie layer is to provide sufficient adhesion between layers. EX1001, 4:35-46; EX1004, ¶[0020]. Riis discloses exactly that—LDPE can provide adhesive functionality in a multilayer film. EX1004, ¶¶[0069],

Paper 27 (Petitioner’s Reply), 7

LDPE is Adhesive to EAA and COC

EX1004, ¶[00135]. Even Dr. McCarthy admitted that Riis's 0.65 mil LDPE layer provides the requisite adhesion to function as the claimed "tie layer":

Q: First I want to understand, the EAA layer that is .17 mil is adhered on one side to the aluminum foil and on the other side to the .65-mil LDPE layer, correct?

A. That is correct.

Q. And then I want to look at this polyethylene layer. So this .65-mil LDPE layer is adhered on one side to the .17-mil EAA layer and on the other side to the .43-mil COC layer, correct?

A: That is correct.

Paper 27 (Petitioner's Reply), 7

LDPE & EAA are Recognized in the Prior Art as Tie Layers

Indeed, it was well known in the art that LDPE functions as a tie layer. For example, in PGR2022-00001, Dr. McCarthy relied on a textbook authored by Morris, which he described as “a 709-page text that covers a wide range of topics related to multilayer structures, including their designs, selection of their materials, and their methods of manufacturing as a primary reference.” EX1029, ¶45. Morris teaches

(2) a tie-layer adhesive, and (3) a structural layer. EX1036, 72¹, Table 4.2. Indeed, under the heading “Tie Resins and Adhesives,” Morris describes LDPE as “the workhorse resin used to bond to aluminum foil, paper, and other substrates in extrusion lamination.” EX1036, 89.

Paper 27 (Petitioner’s Reply), 9

Consider also:

- **EX1013 (Merical)** – identifying LDPE and EAA as tie layers for coextrusion to a barrier layer and sealant layer. EX1013, 9:22-28; Paper 1 (Petition), 44
- **EX1015 (Liu)** – identifying a film using LDPE and EAA as tie layer for coextrusion onto a Al. Foil layer and modified COC layer. EX1015, ¶¶0098-0104; Paper 1 (Petition), 44

Patent Owner – Reliance on Preferred Embodiments

Patent Owner and Dr. McCarthy

- Rely on **preferred** embodiments of tie layers
- “Multifunctional” tie layers are only **preferred** in Riis
- Disclosure of **preferred** tie layer thicknesses in Riis
- Failure to appreciate Riis for **all that it teaches**

Tie Layers

In addition to the exterior layer, the interior layer, and intermediate layer such as a barrier layer, a multilayer packaging film can further comprise one or more adhesive layers, also known in the art as "tie layers," which can be selected to promote the adherence of adjacent layers to one another in a multilayer film and prevent undesirable delamination. A multifunctional layer is

EX1004, ¶10071

Patent Owner – Relative Thickness Determines Primary Purpose

Patent Owner and Dr. McCarthy

- **Preferred embodiment** having 2% to 10% of overall thickness renders LDPE of Example 5 a bulk layer
- It logically follows that a tie layer, if increased in thickness beyond 2% to 10% of overall film thickness becomes a bulk layer
- It logically follows that a bulk layer, if decreased to a range of 2% to 10% of overall film thickness becomes a tie layer.

Therefore, one skilled in the art would find the combined thickness of the .17 mil EAA layer and .65 mil LDPE layer to be inconsistent with Riis's disclosure in paragraph [0071] of a layer that primarily serves as a tie layer being between 2% and 10% of the overall thickness of the eight-layer film. EX2014 ¶ 158.

Riis discloses the '624 Claimed Loading Ranges

1. A method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:

providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;

coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);

coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer comprising the aluminum; and

allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of: the base layer comprising the aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,

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.

- Dr. McCarthy agreed that the LDPE of Riis' Example 5 adheres COC to EAA. (EX1032, 176:9-19)
- The loading range of LDPE in Riis' Example 5 is 15.11 g/m² – 15.34 g/m² (EX1003, ¶156)

EAA, LDPE, and COC. *In re Clarke*, 809 F. App'x 787, 791-92, 794 (Fed. Cir. 2020) (finding that “[a]ny difference [between the prior art and the claims] resides merely in the language [the prior art] uses to describe the structure rather than in the structure itself.”). Dr. McCarthy agrees that Riis is teaching a POSITA to make

Paper 27 (Petitioner's Reply), 16

Patent Owner cannot establish “Teaching Away”

Teaching away requires that a reference criticize, discredit, or otherwise discourage the solution claimed. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

A mere preference does not constitute a teaching away from non-preferred alternatives. *UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679, 692 (Fed. Cir. 2023);

see also Bayer Pharma AG v. Watson Labs., Inc., 874 F.3d 1316, 1327-28 (Fed. Cir. 2017) (finding that where an option is less favored, but is nonetheless a workable option, does not rise to the level of “teaching away”). Even Riis cautions against limiting its disclosure in such a manner. EX1004, ¶45 (explaining the use of “preferred” or “preferably” “does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the inventive technology”).

Patent Owner cannot establish “Teaching Away”

“is preferred.” POR, 51. It is axiomatic to the law of obviousness that preferred embodiments do not constitute a teaching away from a broader disclosure or even non-preferred embodiments. *In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971)

Paper 27 (Petitioner’s Reply), 15

EX1001, 6:1-3


TOPAS and MSM make progress on Barex

11/20/2012 9:22 AM

TOPAS © Commercial Alternative to Barex TPOA3









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Topic Advanced Polymers

TOPAS Advanced Polymers

Polymers used to help create soft, flexible, and durable products for a wide range of applications. TOPAS Advanced Polymers is a leading manufacturer of high-performance polymers for a wide range of applications. TOPAS Advanced Polymers is a leading manufacturer of high-performance polymers for a wide range of applications.

One potential replacement for discontinu

— and another is on the way.

One potential replacement for discontinu

— and another is on the way.

Ineos Group in October 2014 announced Barex polyoxymethylene (PAN) resin at its only global plant in L. patches in the world left by Barex, which was known as pharmaceutical and food packaging films.

"We're pleased to announce that our industry-leading [cyclic] resins of many health-care suppliers who seek a replacement Advanced Polymers President Timothy Kneale said in a Nov. based in Frankfurt, Germany, and operates in North America.

"PAN and COC come from the opposite ends of the polymer properties when it comes to barrier/permeation performance resistance," Kneale added.

TOPAS officials added that their firm has been working closely and "has specified COC in a wide range of pharmaceutical pouches and patches." The pharmaceutical packaging through its use in semi-rigid and container applications, Kneale

<https://www.plasticstoday.com/articles/2014/11/18/MSM-and-TOPAS-make-progress-on-Barex-r>

<https://topas.com/company/news/topas-coc-commercial-alternative-to-barex-tpoa3>

<https://www.uspatent.gov>

TOPAS® COC is Commercial Alternative to Barex

Packaging Companies Adopt COC for Broad Range of Applications
 FLORENCE, Ky., November 18, 2013 — TOPAS® cyclic olefin copolymer from TOPAS is already identified as a successful alternative to Barex® polyoxymethylene (PAN) in the announced closure of Ineos' line Barex plant in Ohio. Working closely with top packaging has specified COC in a wide range of pharmaceutical packages such as medical patches that require applications that require strong chemical resistance.

"We're pleased to announce that our industry-leading COC is filling the needs of many who seek a replacement for Barex® materials," said Timothy Kneale, president of TOPAS Polymers, Inc. "PAN and COC come from the opposite ends of the polymer: spectral properties when it comes to barrier/permeation performance and strong chemical resist. The pharmaceutical packaging industry is already familiar with COC through its use in container applications, according to Kneale. While not a full-fledged replacement for PAN, COC chemical resistance and low adsorption rates, exhibiting low reactivity with medical-grade contents such as insulin for patches. For example, COC's resistance to methyl acetate and better than PETG. COC's adsorption of insulin is less than that of PETG and ethylene vinyl alcohol (EVOH). TOPAS' converter customers have developed innovative nicotine patch packaging for the commercial industry.

COC is known for its high purity and excellent heat sealing behavior, and comes with broad regulatory compliance for food contact and medical uses. Unlike PAN, TOPAS COC can hold common thermoplastic processing methods including mono- and multi-layer film, extrusion coating, along with injection and extrusion blow molding.

TOPAS COC is a key component in a brand range of global Barex® replacement products: healthcare packaging companies including **Bemis Healthcare Packaging**, **Ohlsson**

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EX1004

Huhtamaki

MOTION TO AMEND

Motion to Amend - Substitute Claim 14

A. Proposed substitute claim 14 to replace claim 1, if claim 1 is found unpatentable.

14. (substitute for claim 1, if found unpatentable) A method for providing an aggressive chemical-resistant film, wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, [[or]] and lidocaine, said method comprising:

- providing a base layer, wherein the base layer ~~comprises~~ consists of aluminum and is resistant to one or more of water or oxygen;
- coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);
- coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer ~~comprising~~ consisting of the aluminum; and
- allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of:
 - the base layer ~~comprising~~ consisting of the aluminum, and
 - the coextrusion layer consisting of the tie layer[[.]] and the contact layer consisting of the COC, 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.

Patent Owner's Proposed Amendments:

Claim 14

wherein the base layer consists of aluminum

wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine

Riis – The Base Layer Consists of Aluminum – Claim 14

Preliminary Guidance (Paper 29)

Petitioner. Riis discloses that Figure 1 depicts multilayer film 10 that “may have any number of one or more layers and that the six-layered film depicted in FIG. 1 is shown for purposes of example.” Ex. 1004 ¶ 135. As noted by Petitioner’s expert, an ordinary artisan “would understand that Riis discloses the optional nature of the exterior protective layer and associated adhesive layer” and thus “would understand that Riis discloses leaving off the exterior protective layer and second intermediate adhesive layer from the film [], leaving only a film consisting of a barrier layer consisting of aluminum foil and a three-layer coextrusion of LDPE and EAA tie layers and a COC contact layer.” Ex. 1037 ¶¶ 88–89.

Paper 29 (Prelim. Guidance), 10

Riis (EX1004)

[0066] Abuse-Resistant Outer Layer

[0067] The films described herein may include an outer layer.

adhesive layer 5 is an exterior protective layer 6. It will be understood that a film as described herein may have any number of one or more layers and that the six-layered film depicted in FIG. 1 is shown for purposes of example. In some embodiments, a polyolefin bulk layer can serve as an adhesive or tie layer.

EX1004, ¶¶66-67, 135

The Aggressive Chemical-Resistant Film is Resistant to a Chemical Selected From Nicotine, Fentanyl, Rivastigmine, and Lidocaine

Option One: Riis Renders Meets This Limitation

Preliminary Guidance (Paper 29)

Petitioner. “Treatment of claims reciting alternatives is not governed by the particular format used (e.g., alternatives may be set forth as ‘a material selected from the group consisting of A, B, and C’ or ‘wherein the material is A, B, or C’). MPEP 2117 (citing *Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 Fed. Reg. 7162 (February 9, 2011)); *see also* MPEP 2173.05(h). Thus, as noted by Petitioner’s expert, this recitation requires “chemical-specific resistance to only one chemical of the identified chemicals.” Ex. 1037 ¶ 93.

The Aggressive Chemical-Resistant Film is Resistant to a Chemical Selected From Nicotine, Fentanyl, Rivastigmine, and Lidocaine

Option Two: The Modification with Rivers Renders This Limitation Obvious

Preliminary Guidance (Paper 29)

Nonetheless, even if all chemicals are required, Tohara discloses “a cyclic polyolefin (hereinafter, also referred to as ‘COC’) film capable of suppressing the adsorption of lidocaine *or rivastigmine*.” Ex. 1033 ¶ 89 (emphasis added); Ex. 1037 ¶ 97. We agree with Petitioner’s expert that because both Riis and Tohara disclose COC for suppressing adsorption of lidocaine and Tohara discloses rivastigmine as an alternative to lidocaine, an ordinary artisan “would reasonably expect that incorporating Tohara’s teachings regarding resistance to rivastigmine into the method of fabricating a laminate of Riis (and Wypych) would be successful.” Ex. 1037 ¶ 99.

Motion to Amend - Substitute Claims 18 & 20 for an “Aggressive Chemical Resistant Film”

E. Proposed substitute claim 18 to replace claim 8, if (a) claim 1 is found unpatentable and replaced with substitute claim 14 and (b) claim 8 is found unpatentable.

18. The method according to claim ~~[[1]]~~ 14, wherein:
the one or more layers of the tie layer consists of two layers, and
the aggressive chemical-resistant film is resistant to the chemical
based at least in part on allowing less than 10% of the chemical to migrate into the
aggressive chemical-resistant film.

Motion to Amend - Substitute Claims for an “Aggressive Chemical Resistant Film”

G. Proposed substitute claim 20 to replace claim 11, if (a) claim 1 is found unpatentable and replaced with substitute claim 14 and (b) claim 11 is found unpatentable.

20. The method according to claim ~~[[1]]~~ 14, wherein:
the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer,
the chemical is provided in a first patch, and
the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing 90% to 110% of the chemical in the first patch to migrate into a first pouch formed by the aggressive chemical-resistant film relative to an amount of the chemical in a second patch allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises Barex®.

Dr. Spontak Declaration

66. Rivers teaches packaging films that utilize COC within the sealant layer of the film to minimize scalping of the packaged product, in some cases not more than 1% of the packaged product. EX1035, 2:6-3:12, 4:12-5:2. Rivers ultimately teaches that it is the use of cyclic olefin copolymers in a packaging film that leads to minimal scalping of packaged contents. EX1035, 13:16-25.

Preliminary Guidance – Substitute Claim 18 & 20 for an “Aggressive Chemical Resistant Film”

Petitioner asserts that Riis’s COC contact layers “prevent migration of ‘any suitable pharmaceutical active agent,’” but “Riis does not specifically disclose percentages of API migration.” Opp. 20–21 (citing Ex. 1004 ¶¶ 8–9). Nonetheless, Petitioner asserts that “Rivers teaches that packaging films using COCs as product contact layers allow for as little as 1% scalping of a packaged product.” *Id.* at 21 (citing Ex. 1035, 4:13–5:2, 8:32–9:12, 9:31–10:3 (defining scalping), 25:1–31). According to Petitioner, an ordinary artisan “would have had a reasonable expectation of success in looking to Rivers to verify such anti-scalping properties since both Riis and Rivers are similarly directed to multilayer films used to package volatile products susceptible to degradation and adsorption.” *Id.* at 21–22 (citing Ex. 1037 ¶¶ 152–155; Ex. 1004 ¶ 55; Ex. 1035, 25:1–31, 26:16–27:5). Based on this, Petitioner concludes that “substitute claim 18

Paper 29 (Prelim. Guidance), 17

Petitioner. Riis discloses: “Typical contents for various embodiments of the inventive container may include, for example, transdermal patches, thin strips of dissolvable material for oral administration, as well as articles for collecting or administering a physiologically active substance e.g. a microdiffusion cassette.” Ex. 1004 ¶ 92. Riis also discloses that a layer is considered effective if “an amount of the active agent migrates into the product contacting layer of the film (the test film) is not more than 15% greater than migrates into a substantially similar film having a Barex® product contacting layer (the reference film) when a product containing the pharmaceutical active agent is positioned relative to the test and reference films.” *Id.* ¶ 129. We credit Petitioner’s expert’s opinion that an ordinary artisan “would understand that 10% difference range disclosed by Riis is equivalent to a range of allowing 90–110% migration as compared to the original amount of chemical present in the contained patch product,” and thus, we agree that “Riis teaches the [claimed] ranges based upon the same comparison [that] allow no more than 10% of chemical migration.” Ex. 1037 ¶ 163 (citing Ex. 1004 ¶ 132).

Paper 29 (Prelim. Guidance), 13–14

Motion to Amend - Substitute Claims 16 & 17 for Loading Ranges

C. Proposed substitute claim 16 to replace claim 6, if (a) claim 1 is found unpatentable and replaced with substitute claim 14 and (b) claim 6 is found unpatentable.

16. [[A]] The method according to claim [[1]] 14, wherein a loading of at least a portion of a first layer of the tie layer is in the range of 7 to [[20]] 18 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m².

D. Proposed substitute claim 17 to replace claim 7, if (a) claim 1 is found unpatentable and replaced with substitute claim 14 and (b) claim 7 is found unpatentable.

17. The method according to claim [[1]] 14, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of a first layer of the plurality of layers is in the range of 7 to [[20]] 14 g/m² and a loading of a second layer of the plurality of layers is in the range of 7 to 14 g/m².

Preliminary Guidance – Substitute Claims 16 & 17 for Loading Ranges

Petitioner. As Petitioner's expert explains, loading is determined "by multiplying the thickness of the layer by the mass density to yield an area density." Ex. 1037 ¶ 119 (citing Ex. 1003 ¶ 152). Based on this methodology, we agree with Petitioner's expert that "Holzmuller's preferred and especially preferred ranges overlap substantially with the new claimed range recited in Substitute Claim 16." *Id.* ¶ 125. Our reviewing Court has held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *Wertheim*, 541 F.2d at 267. Because the films of Riis and Holzmuller are similar in structure, function, and polymeric materials considered, we agree with Petitioner's expert that an ordinary artisan "would have a reasonable expectation of success in implementing Holzmuller's teachings into the method of providing a film with the combination of Riis, Wypych, and Tohara" and "that absent any criticality, the specific dimensional ranges in Substitute Claim 16" would have been obvious. *Id.* ¶¶ 127, 130.

Paper 29 (Prelim. Guidance), 15

At this preliminary stage of the proceeding, we agree with Petitioner. As discussed above for claim 16, we agree with the methodology for determining the loading ranges as posited by Petitioner's expert. *See* Ex. 1037 ¶ 133. Using this methodology, we agree with Petitioner's expert that Holzmuller's "ranges overlap substantially with the new claimed range recited in Substitute Claim 17." Ex. 1037 ¶ 146. Thus, we agree with Petitioner's expert's conclusion "that absent any criticality, the specific dimensional ranges in Substitute Claim 17 are obvious," at least "because such ranges were known in the prior art of Holzmuller." *Id.* ¶ 149.

Paper 29 (Prelim. Guidance), 16

Huhtamaki

REVISED MOTION TO AMEND

Revised Motion to Amend – Grounds of Challenge

Ground	Statutory Basis	Prior Art References	Challenged Substitute Claims
1	35 U.S.C. § 103	Riis and Wypych	14, 15, and 20–24
2	35 U.S.C. § 103	Riis, Wypych, and Holzmuller	16–18
3	35 U.S.C. § 103	Riis, Wypych, and Rivers	19

Revised Motion to Amend - Substitute Claim 14

A. Proposed substitute claim 14 to replace claim 1, if claim 1 is found unpatentable.

14. A method for providing an aggressive chemical-resistant film, wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:

providing a base layer, wherein the base layer ~~comprises~~ consists of aluminum and is resistant to one or more of water or oxygen;

coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);

coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer ~~comprising~~ consisting of the aluminum; and

allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of:

the base layer ~~comprising~~ consisting of the aluminum, and

the coextrusion layer consisting of the tie layer[[.]] and the contact layer consisting of the COC, wherein:

the tie layer comprises ~~one or more layers~~ a first layer and a second layer, and wherein the tie layer, or each of the ~~one or more layers~~ first layer of the tie layer and the second layer of the tie layer, has a loading in the range of 7 to 20 g/m².

Patent Owner's Proposed Amendments:

- 1. Wherein the base layer consists of aluminum*
- 2. Wherein the tie layer comprises a first layer and a second layer*

the tie layer comprises ~~one or more layers~~ a first layer and a second layer, and wherein the tie layer, or each of the ~~one or more layers~~ first layer of the tie layer and the second layer of the tie layer, has a loading in the range of 7 to 20 g/m².

RMTA– The Two-Layer Tie Layer is Nothing New

Original Claims 1 and 8

Claim 1

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.

Claim 8

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

RMTA Substitute Claim 14

the tie layer comprises ~~one or more layers~~ a first layer and a second layer, and wherein the tie layer, or ~~each of the one or more layers~~ first layer of the tie layer and the second layer of the tie layer, has a loading in the range of 7 to 20 g/m².

Substitute Claim 14 – Obvious

1. Substitute Claim 14

Patent Owner's new revised amendments to substitute claim 14 require the coextrusion layer to include a tie layer having a first layer and a second layer.

RMTA, 17-18. The combination of Riis and Wypych renders amended substitute claim 14 obvious for at least the reasons set forth below, further in view of

Petitioner's Opposition to the Motion to Amend for claim 14, and further in view of

the Petition and Petitioner's Reply regarding original claim 1. Pet. 31-45, 53-64;

Pet. Reply, 4-16, Opp. MTA, 8-11. The limitations for amended substitute claim 14

Paper 36 (Petitioner's Opp. to RMTA), 1-2

Substitute Claim 14 – Obvious

- Riis discloses a base layer consisting of aluminum

Barrier Layers

If included, a barrier layer preferably functions both as a gas barrier layer, and as a moisture barrier layer, although these functions may be provided by separate layers. A gas barrier layer is preferably an oxygen barrier layer, and protected by surface layers. For example,

known to those of skill in the art. Suitable moisture barrier layers include aluminum foil, PVDC, or polyolefins such as LDPE or

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil

LDPE10.1 mil EAN0.35 mil foill0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶10174

EX1004, ¶¶58-59

EX1004, ¶62

An oxygen barrier layer of a film may comprise aluminum foil, or EVOH, although oxygen barrier layers comprising polyvinylidene chloride-vinyl chloride copolymer (PVDC or VDC-VC) or vinylidene chloride-methylacrylate copolymer (VDC-MA) as well as blends thereof, can also be used. One suitable EVOH barrier material is a 44 mol % EVOH resin E151B sold by

EX1004, ¶63

Substitute Claim 14 – Obvious

- Riis discloses a coextrusion layer consisting of a tie layer comprising a first and second layer and a contact layer

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil

LDPE10.1 mil EAA0.35 mil foil0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶10174

The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example, polyamides, polystyrenes, styrenic copolymers e.g. styrene-butadiene copolymer, polyolefins, and in particular members of the polyethylene family such as LLDPE, VLDPE, HOPE, LDPE, ethylene vinyl ester copolymer or ethylene alkyl acrylate copolymer,

EX1004, ¶74

EAA-Copolymer of ethylene with acrylic acid

EX1004, ¶18

Substitute Claim 15 – Obvious

- Riis and Wypych disclose a contact layer having a loading in the range of 4 to 20 g/m²

2. Substitute Claim 15

Substitute claim 15 restates original claim 4. For the same reasons as set forth

in the Petition regarding original claim 4, as well as the arguments in Petitioner's Opposition to the MTA, the combination of Riis and Wypych render substitute claim 15 obvious. *See* Pet. 48–49, 67–68 (citing EX1003, ¶¶171–73, 247–48; EX1004, ¶¶52, 54, 91, 174; EX1005, 7; EX1019, 7); *see also* Opp. MTA, 15–16 (citing EX1004, ¶¶48, 160–74, and EX1037, ¶¶104–09). The RMTA fails to argue the patentability of substitute claim 15 over original claim 4 and fails to specifically address the patentability of substitute claim 15. *See generally* Revised MTA.

Substitute Claim 20 – Obvious

- Riis discloses a coating the coextrusion layer to the base layer by coextrusion coating

3. Substitute Claim 20

Substitute claim 20 restates original claim 9. For the same reasons as set forth in the Petition regarding original claim 9, as well as the reasons set forth in Petitioner's Opposition to the MTA with respect to substitute claim 19, the combination of Riis and Wypych render substitute claim 20 obvious. *See* Pet. 50, 70 (citing EX1003, ¶¶195–96, 254), *see also* Opp. MTA, 22 (citing EX1004, ¶¶135, 157, 174). The RMTA fails to argue the patentability of substitute claim 20 over original claim 9 and fails to specifically address the patentability of substitute claim 20. *See generally* Revised MTA.

Substitute Claim 21 – Obvious

- Riis discloses at least one of the first and second tie layer comprises EAA or PE

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer|0.42 mil

LDPE|0.1 mil EAA|0.35 mil foil|0.17 mil EAA/0.65 mil LD/PE/0.43 mil COC and a total thickness of 3.0 mils (76 microns). The inventive film is well suited to package articles for

EX1004, ¶0174

Substitute Claim 22 – Obvious

- Riis discloses the aggressive chemical is provided in a patch and the film is resistant to the chemical on allowing only 90-110% of migration compared to a film having polyacrylonitrile.

Riis (EX1004)

Typical contents for various embodiments of the inventive container may include, for example, transdermal patches, thin strips of dissolvable material for oral administration, as well as articles for collecting or administering a physiologically active substance e.g. a microdiffusion cassette

EX1004, ¶92

Barex® as a sealing layer. More preferably, the amount of an active pharmaceutical agent that migrates into a film having an ethylene norbornene copolymer as described herein as a sealing layer will be no more than 9% (no more than 8%, no more than 7%, no more than 6%, no more than 5%, no more than 4%, no more than 3%, no more than 2%, or no more than 1%) more than the amount of the pharmaceutical active agent that migrates into film having Barex® as a sealing layer.

EX1004, ¶132

Substitute Claim 23 – Obvious

- Riis discloses the acrylic acid layer comprising EAA.

Petitioner's Opp. to RMTA

6. Substitute Claim 23

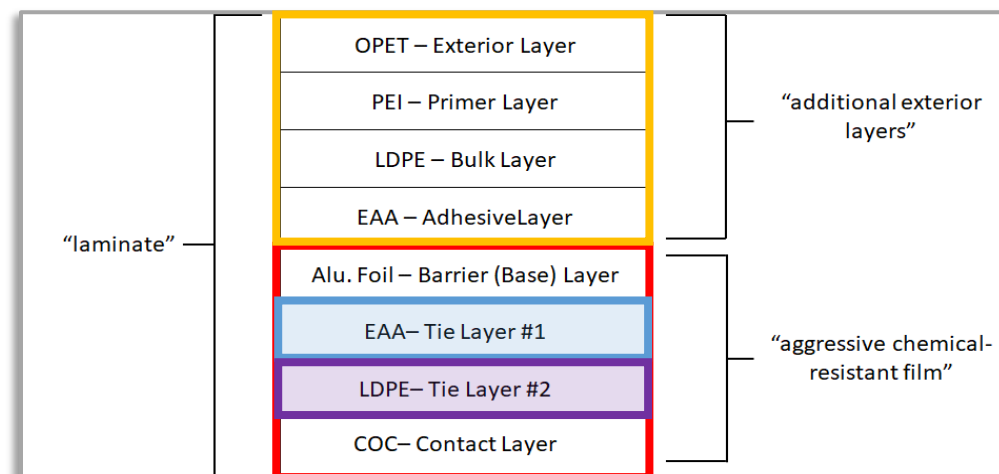
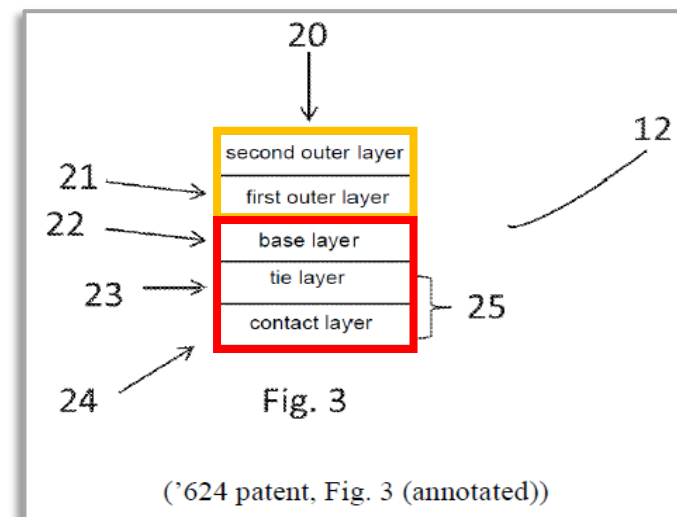
Substitute claim 23 restates original claim 12. For the same reasons as set forth in the Petition regarding original claim 12, the combination of Riis and Wypych render substitute claim 23 obvious. *See* Pet. 50–51, 70 (citing EX1003, ¶¶197–200, 255–58; EX1004, ¶174). The RMTA fails to argue the patentability of substitute claim 23 over original claim 12 and fails to specifically address the patentability of substitute claim 23. *See generally* Revised MTA.

Substitute Claim 24 – Obvious

- Riis discloses the method of providing a “laminate.”
- Riis discloses “consisting of aluminum” and “first and second tie layers” like Substitute Claim 14.

7. Substitute Claim 24

Substitute Claim 24 is similar to substitute claim 14, the difference being the claim is directed to a laminate instead of a film, and the portion of the preamble referring to “the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine” is now in the body of the claim.



Substitute Claims 16, 17, & 18 – Riis, Wypych, and Holzmuller

16. The method according to claim ~~[[1]]~~ 14, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m², and wherein a loading of the first layer of the tie layer is in the range of 1 to 14 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m².

Paper 31 (PO RMTA), 27

Substitute Claims 16, 17, & 18 – Riis, Wypych, and Holzmuller

17. [[A]] The method according to claim [[1]] 14, wherein a loading of ~~at least a portion of~~ the entirety of the tie layer is in the range of 7 to 20 g/m², wherein the first layer of the tie layer is adjacent to the base layer, wherein the second layer of the tie layer is adjacent to the first layer and the contact layer, and wherein a loading of the first layer of the tie layer is in the range of 5 to 19 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m².

Paper 31 (PO RMTA), 27

Substitute Claims 16, 17, & 18 – Riis, Wypych, and Holzmuller

18. The method according to claim ~~[[1]]~~ 14, wherein ~~the one or more layers of~~ the tie layer comprises a plurality of layers consisting of the first layer of the tie layer and the second layer of the tie layer, ~~[[and]]~~ wherein a loading of the ~~plurality of layers~~ first layer of the tie layer is in the range of 7 to 20 g/m² and a loading of the second layer of the tie layer is in the range of 7 to 20 g/m².

Paper 31 (PO RMTA), 28

Substitute Claims 16, 17, & 18 – Obvious in view of Riis, Wypych, and Holzmuller

Riis (EX1004)

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Published:
with international search report (Art. 21(3))

(54) Title: ANTI-SCALPING PHARMACEUTICAL PACKAGING FILM

(57) Abstract: A film for packaging a product that has a pharmaceutical active agent includes a product-contacting sealing layer. The product contacting layer includes at least 90 wt. % of an ethylene norbornene copolymer having a glass transition temperature in a range from 50°C to 110°C. The pharmaceutical active agent comprises a Hansen Solubility Parameter for the product-contacting sealing layer of 0.5 or greater.

WO 2015/123211 A1

Wypych (EX1005)

Handbook
OF
POLYMERS

George Wypych

ChemTec PUBLISHING

Holzmuller (EX1034)

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Holzmuller et al.

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(54) MULTILAYERED LAMINATE FOR TUBES HAVING AN EMBEDDED ALUMINUM LAYER, A PROCESS FOR THE PRODUCTION THEREOF AND A TUBE PRODUCED THEREFROM

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B32B 15/08 (2006.01)
B29C 65/18 (2006.01)
U.S. CL. 428/35.9; 428/457; 428/461; 428/458; 428/339; 204/171.27

(57) ABSTRACT
The invention relates to a multilayered laminate for tubes having an embedded aluminum layer, the aluminum layer being surrounded on each side by an oriented co-extruded protective layer which is in each case joined to the aluminum layer by means of an intermediate layer material. The invention relates also to the production of such a laminate and to a tube produced from such a laminate.

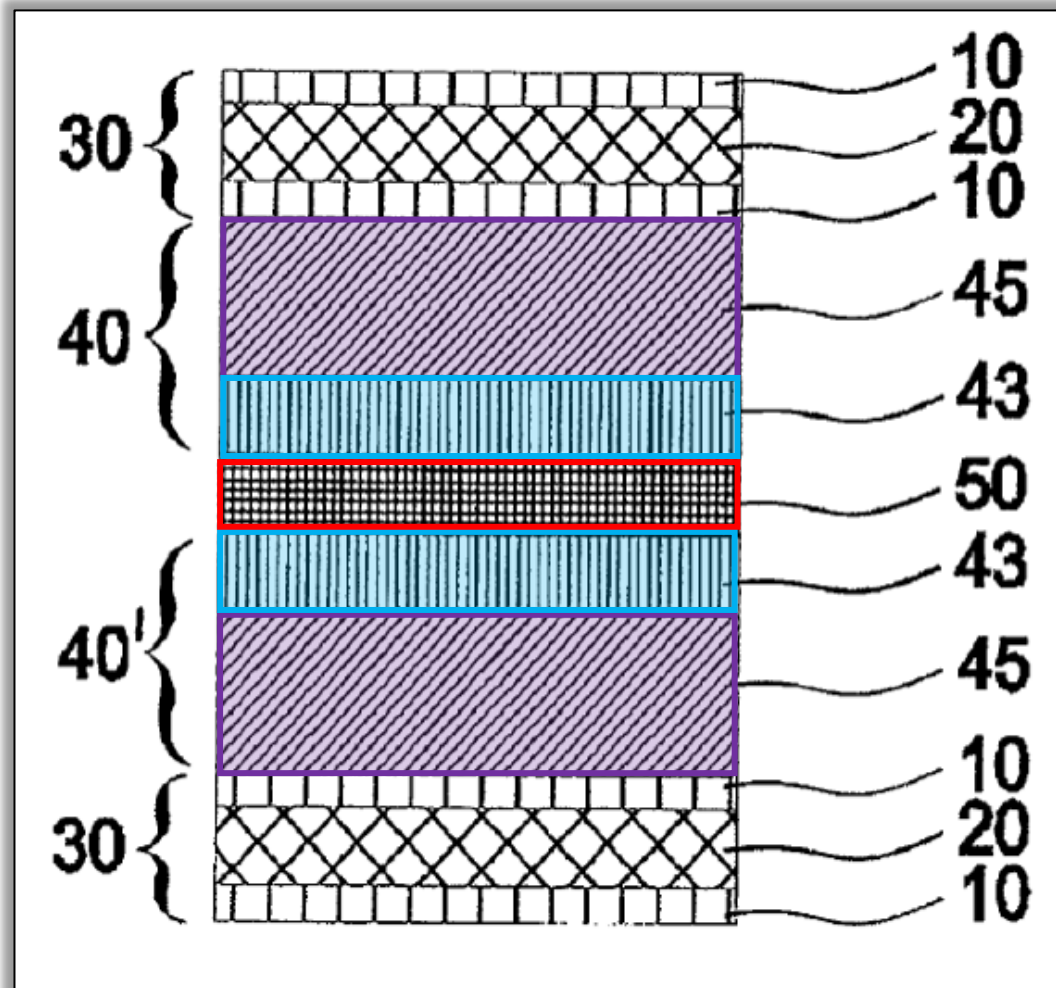
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Huhtamaki EX1034
U.S. Patent No. 11,260,624

1/9

Holzmuller – Structurally, Functionally, and Polymerically Similar to Riis



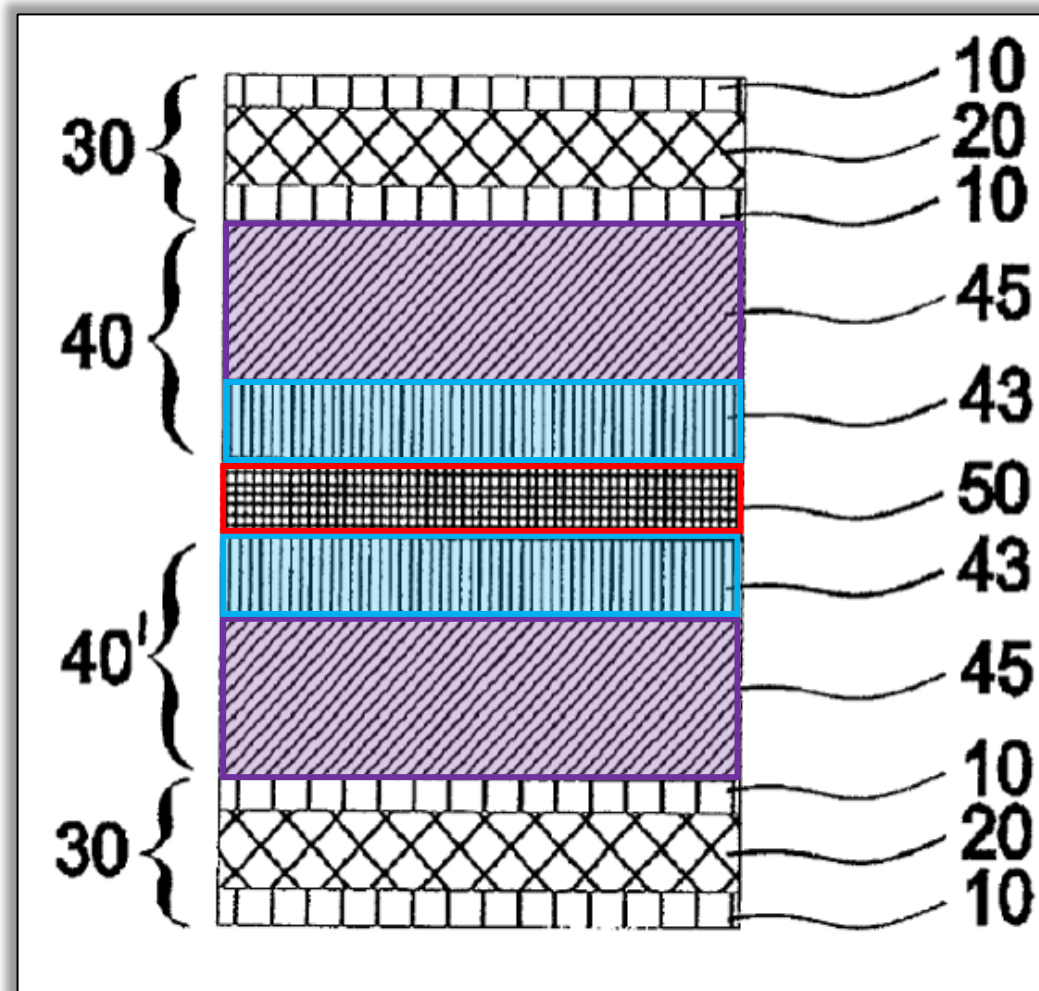
[0008] The problem underlying the invention is to provide a multilayered laminate having an embedded aluminum layer and the production thereof and packagings produced therefrom, which provides improved barrier properties combined at the same time with thinner layer thicknesses of the individual laminate layers, which exhibits advantageous producibility and individually improved printability and which furthermore offers improved haptic properties as well as improved environmental compatibility.

EX1034 (Holzmuller), ¶0008

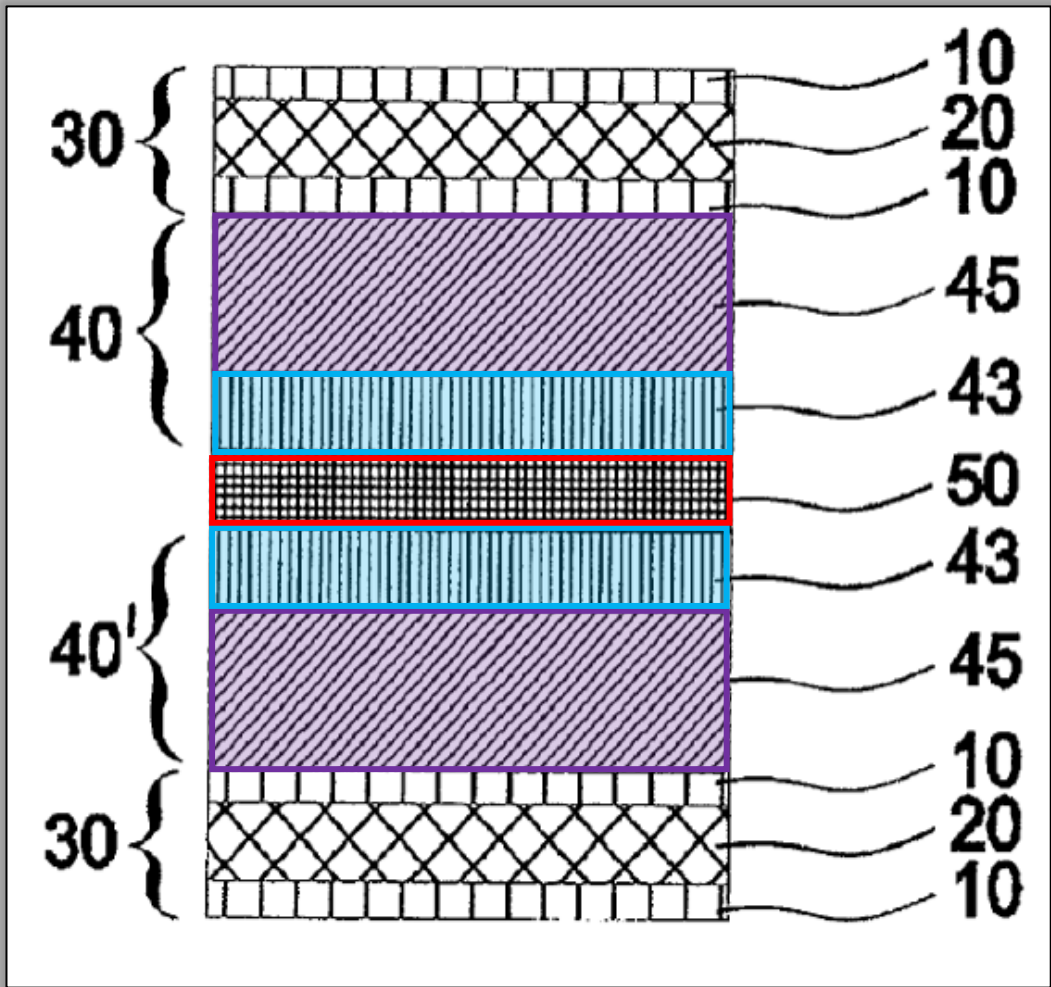
MTA Prior Art - Holzmuller

Holzmuller

- Multilayer Film
- (50) – Aluminum Barrier Layer
- (40) & (40') – *Intermediate Layers*
 - (43) – First Bonding Layer
 - (45) – Second Bonding Layer
- (30) – *Coextruded Protective Layer*
 - (10) – Cover Layer
 - (20) – Oriented Polymer



Holzmuller – Structurally, Functionally, and Polymerically Similar to Riis



[0026] Furthermore, the layers forming the intermediate layer material are co-extruded and/or extruded immediately one after the other to form the laminate.

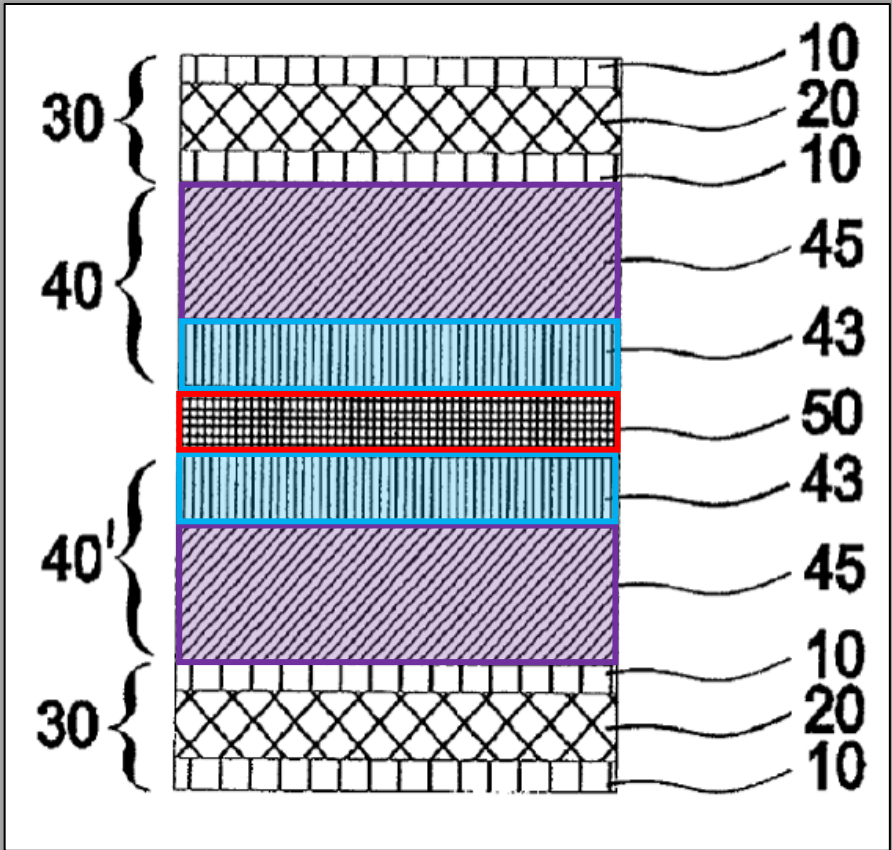
EX1034 (Holzmuller), ¶10026

[0036] FIG. 2 differs from FIG. 1 to the extent that the two intermediate layer materials A and I do not consist only of a first bonding layer 43, but both the intermediate layer material A 40 and the intermediate layer material I 40' are made of a first bonding layer 43 and a second bonding layer 45, the

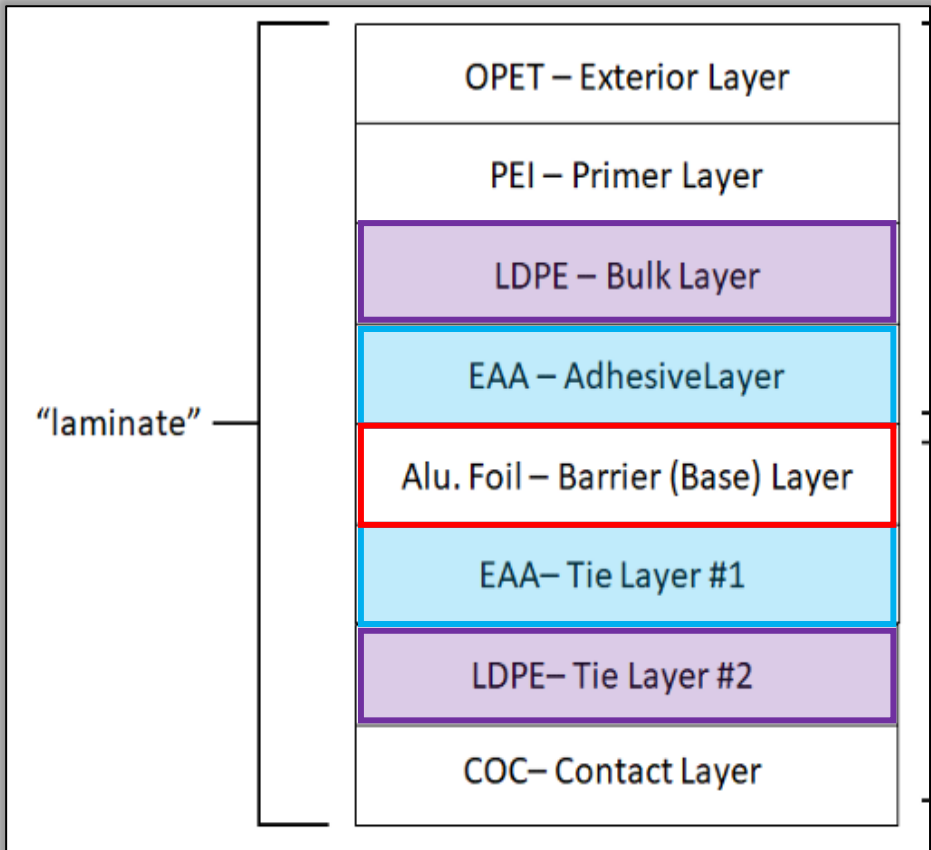
EX1034 (Holzmuller), ¶10036

Holzmuller – Structurally, Functionally, and Polymerically Similar to Riis

Holzmuller (EX1034)



Riis (EX1004)



Holzmuller – Overlapping Loading Ranges

Layer	Material(s)
First bonding layer (43)	Maleic acid anhydride (MSA), ethylene methacrylate (EMA), ethyleneacrylic acid copolymers (EAA), ionomers, terpolymers (ethyleneacrylic acid-maleic acid ester anhydrides), ethylene vinyl acetates (EVA), modified olefins, mixtures of the afore-mentioned materials
Second bonding layer (45)	Maleic acid anhydride (MSA), ethylene methacrylate (EMA), ethyleneacrylic acid copolymers (EAA), ionomers, terpolymers (ethyleneacrylic acid-maleic acid ester anhydrides), ethylene vinyl acetates (EVA), polyolefins, especially polyethylene (PE), polypropylene (PP), modified olefins, mixtures of the afore-mentioned materials

EX1034 (Holzmuller), ¶0018

Layer	Layer thickness	Layer thickness preferably	Especially preferred layer thickness
First bonding layer (43)	5 µm-140 µm	8 µm-95 µm	10 µm-50 µm
Second bonding layer (45)	5 µm-140 µm	8 µm-95 µm	10 µm-50 µm

EX1034 (Holzmuller), ¶0019

Holzmuller –Overlapping Loading Ranges

120. According to the methodology employed in my Original Declaration for determining loading, Holzmuller teaches loading ranges of Riis's LDPE from 4.6-130.1 g/m², preferably from 7.3-88.3 g/m², and especially preferably from 9.2-46.4 g/m² (keeping to one decimal place for consistency). I note that a POSITA would

EX1037 (Spontak 2nd Dec.), ¶120

124. According to the methodology employed in my Original Declaration for determining loading, Holzmuller teaches loading ranges of Riis's EAA of an allowable range of 4.6-134.4 g/m², preferred ranges of 7.4-91.2 g/m², and especially preferred ranges of 9.2-48.0 g/m² (keeping to one decimal place for consistency).

EX1037 (Spontak 2nd Dec.), ¶124

Revised Motion to Amend – Substitute Claim 16

16. The method according to claim ~~[[1]]~~ 14, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m², and wherein a loading of the first layer of the tie layer is in the range of 1 to 14 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m².

Paper 31 (PO RMTA), 27

Riis (EX1004) + Wypych (EX1005)

EAA	3.97 – 4.15 g/m ²
LDPE	15.11 – 15.34 g/m ²
Total	19.08 – 19.49 g/m ²

Paper 1 (Petition), 40-43

combination
with →

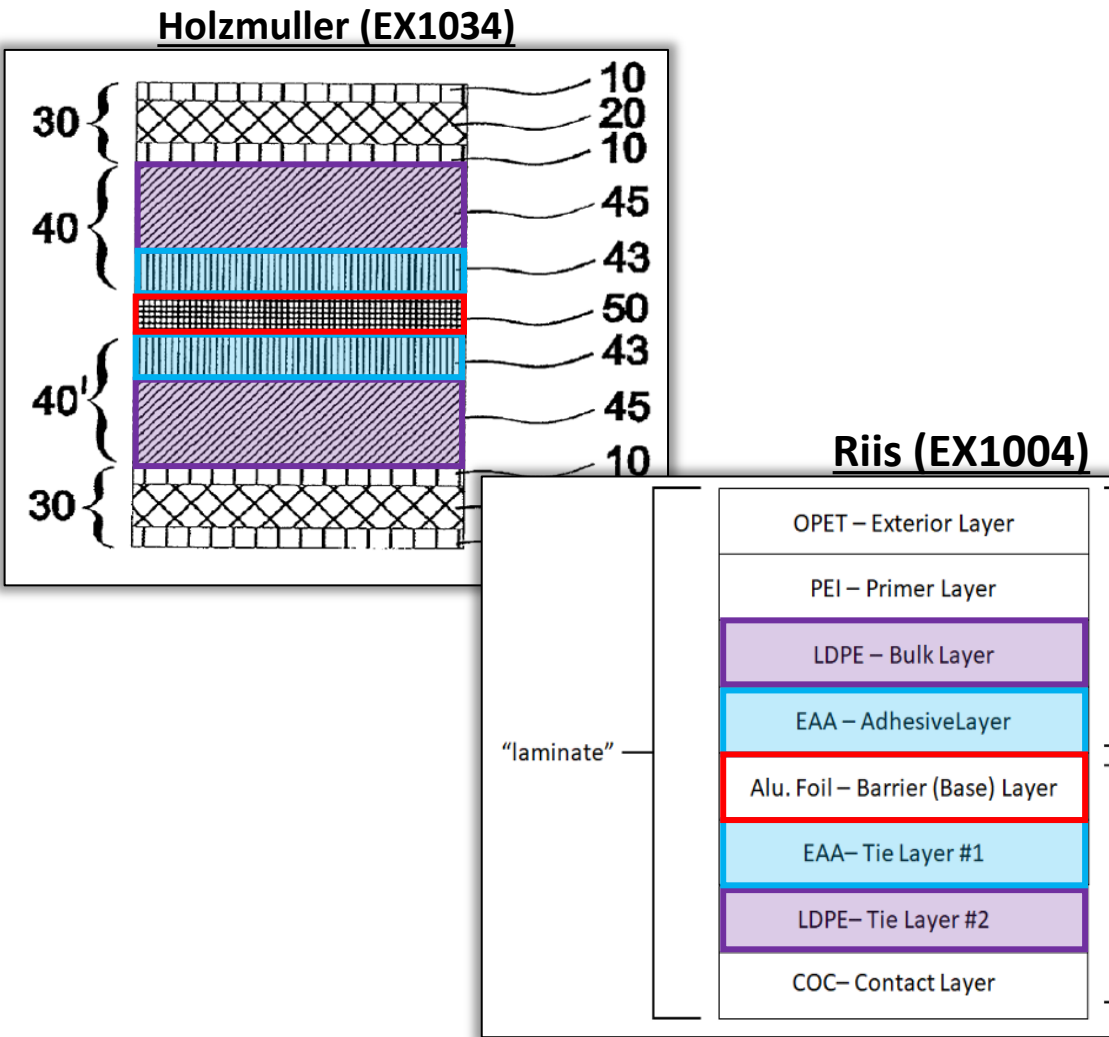
Holzmuller (EX1034)

EAA (<i>esp. preferred</i>)	9.2 – 48.0 g/m ²
LDPE (<i>esp. preferred</i>)	9.2 – 46.4 g/m ²
Total	18.4 – 94.4 g/m ²

Paper 36 (Petitione’s Opp. to RMTA), 7-9

Revised Motion to Amend – Substitute Claim 17

17. [[A]] The method according to claim [[1]] 14, wherein a loading of at least a portion of the entirety of the tie layer is in the range of 7 to 20 g/m², wherein the first layer of the tie layer is adjacent to the base layer, wherein the second layer of the tie layer is adjacent to the first layer and the contact layer, and wherein a loading of the first layer of the tie layer is in the range of 5 to 19 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m².



Revised Motion to Amend – Substitute Claim 17

17. [[A]] The method according to claim [[1]] 14, wherein a loading of at least a portion of the entirety of the tie layer is in the range of 7 to 20 g/m², wherein the first layer of the tie layer is adjacent to the base layer, wherein the second layer of the tie layer is adjacent to the first layer and the contact layer, and wherein a loading of the first layer of the tie layer is in the range of 5 to 19 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m².

Riis (EX1004) + Wypych (EX1005)

EAA	3.97 – 4.15 g/m ²
LDPE	15.11 – 15.34 g/m ²
Total	19.08 – 19.49 g/m ²

Paper 1 (Petition), 40-43

combination
with →

Holzmuller (EX1034)

EAA (<i>esp. preferred</i>)	9.2 – 48.0 g/m ²
LDPE (<i>esp. preferred</i>)	9.2 – 46.4 g/m ²
Total	18.4 – 94.4 g/m ²

Paper 36 (Petitione’s Opp. to RMTA), 7-9

Revised Motion to Amend – Substitute Claim 18

18. The method according to claim [[1]] 14, wherein ~~the one or more layers of the tie layer~~ comprises a plurality of layers consisting of the first layer of the tie layer and the second layer of the tie layer, [[and]] wherein a loading of the ~~plurality of layers~~ first layer of the tie layer is in the range of 7 to 20 g/m² and a loading of the second layer of the tie layer is in the range of 7 to 20 g/m².

Paper 31 (PO RMTA), 28

Riis (EX1004) + Wypych (EX1005)

EAA	3.97 – 4.15 g/m ²
LDPE	15.11 – 15.34 g/m ²
Total	19.08 – 19.49 g/m ²

Paper 1 (Petition), 40-43

combination
with →

Holzmuller (EX1034)

EAA (<i>esp. preferred</i>)	9.2 – 48.0 g/m ²
LDPE (<i>esp. preferred</i>)	9.2 – 46.4 g/m ²
Total	18.4 – 94.4 g/m ²

Paper 36 (Petitione’s Opp. to RMTA), 7-9

Riis— Optionality Around Riis's Thicknesses

Riis (EX1004)

embodiments being from about 2 to 3.5 mils. For example, entire multilayer films or any single layer of a multilayer film can have any suitable thicknesses, including 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 mils, or any increment of 0.1 or 0.01 mil therebetween. Although suitable films for packaging

polymeric resins falling in the "olefin" family classification. The bulk layer may be of any suitable thickness from 0.1 to 7 mils or may even be omitted for use in certain applications, but is preferably present to improve especially stiffness/flexibility properties and heat sealability.

[0045] The words "preferred" and "preferably" refer to embodiments of the disclosure that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the inventive technology.

EX1004, ¶¶45, 65, 90-91

Insufficient Evidence of Criticality of Claimed Loading Ranges

Patent Owner's Assertion

Nevertheless, if a particular claimed range produces a "new and unexpected result which is different in kind . . . such ranges are termed 'critical' ranges." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). Evidence of criticality of the claimed ranges can be found throughout the '624 Patent. See EX1001, 2:63–67; 6:1–13, 24–28; EX2014 ¶¶ 57–65, 68–70.

Paper 31 (RMTA), 17

The “Evidence”

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

EX1001, 2:63-67

The “Evidence”

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

EX1001, 6:1-13

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

EX1001, 6:24-28

Presumed Enablement of the Asserted Combination, Not Holzmuller Alone

Because the combination of Riis and Wypych already enables and teaches the film's structure, function, materials, and even exemplary constructions with dimensions, Holzmuller need not enable every aspect of the claimed invention. *Raytheon Tech. Corp. v. General Electric Co.*, 993 F.3d 1374, 1381 (Fed. Cir. 2021) (citing *Commc'ns Corp. v. Finisar Corp.*, 571 F. Supp. 2d 1137, 1145 (N.D. Cal. 2008), *aff'd sub nom. Comcast Cable Commc'ns, LLC v. Finisar Corp.*, 319 F. App'x 916 (Fed. Cir. 2009)) ("such a reference may be used to supply claim element enabled by other prior art or evidence of record.").

RMTA Opp., 15-16.

RAYTHEON TECHNOLOGIES CORP. v.
GENERAL ELECTRIC COMPANY

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The enabling disclosure concept [for a prior art reference] is a commonsense factor in making a determination of obviousness, for if neither any item of prior art, nor the background knowledge of one with ordinary skill in the art, would enable one to arrive at an invention, that invention would not be obvious. But to argue, as does [the patentee], that the sufficiency of each prior art teaching must be tested under the strict standard requiring an enabling disclosure is to shift the emphasis from obviousness in light of the prior art, taken as a whole, to the sufficiency of each prior art teaching separately considered.

Minn. Mining & Mfg. Co. v. Blume, 684 F.2d 1166, 1173 n.10 (6th Cir. 1982); see also *Beckman*, 892 F.2d at 1551 (citing *Minn. Mining* with approval).

Presumed Enablement of the Asserted Combination, Not Holzmuller Alone

McCarthy Deposition (EX1039)

11 Q. So in this section, you did an
12 analysis on whether Holzmuller enables a -- a
13 POSITA to make a modified film.

14 Is that correct?

15 A. Yeah. So it has a listing of
16 materials, and then it includes combinations of
17 those materials, you know, mixtures of those
18 materials.

1 Q. Right. So in your analysis that ^{Page 23}
2 you just sort of went through quickly right there,
3 you were basing that only on Holzmuller. Is that
4 your understanding?

5 A. That's what I was primarily
6 basing it on.

7 Q. Okay. Is there anything else you
8 were basing it on? You said "primarily"?

9 A. I'm not sure what -- I mean, my
.0 experience.

.1 Q. Okay. No other -- no other prior
.2 art? So -- so Holzmuller and your experience.

.3 But you weren't -- you weren't
.4 analyzing any other piece of prior art at this
.5 point -- is that correct -- in these three
.6 paragraphs?

.7 A. I don't believe so.

Huhtamaki's Representations to the USPTO Are Consistent

'624 Patent (EX1001)

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

EX1001, 4:35-37

McCarthy (EX1032)

13 So the purpose of the tie layer is to
14 provide sufficient adhesion between the base layer
15 and the coextrusion layer, correct?

16 A Yeah, I think the tie layer would give
17 sufficient adhesion between the base layer and the
18 contact layer.

EX1032, 99:14-100:18

Herb Declaration (EX2019)

10. It has been found and proven by laboratory testing that using metallocene C8 LLDPE as a layer connecting the COC-layer to the adhesive (EAA) layer surprisingly and tremendously promotes the delamination stability of the multilayer structure. Using regular LDPE allows to create a multilayer structure, but the COC-layer more or less easily delaminates or can be peeled off of the neighboring regular LDPE-layer. According to the

11. In addition, metallocene C8 LLDPE, as is recited in the claims, increases the ties (lamination forces) between the polyethylene layer and the COC-layer to such an extent that, with the same laboratory equipment that allows for a rather easy delamination of the COC-layer from the neighboring regular LDPE-layer, the COC-layer cannot be delaminated from the metallocene C8 LLDPE layer without destroying the multilayer structure as such.

EX2019, ¶¶10-11

Tie Layer vs. Bulk Layer

'624 Patent (EX1001)

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

EX1001, 4:35-37

McCarthy Depo (EX1041)

14 Q. Okay. So in the modified laminate they
15 just simply replaced the LDPE layer with a metallocene
16 LLDPE layer, and I understand it has the same loading.
17 Is that correct?

18 A. That is correct.

19 Q. So is the metallocene LLDPE layer a tie
20 layer or a bulk layer?

21 A. A bulk layer.

EX1041, 26:14-21,

Herb Declaration (EX2019)

regular LDPE layer. The bond strength per length between the C8 metallocene LLDPE layer and the COC layer was so large that any attempt to delaminate the C8 metallocene LLDPE layer and the COC layer resulted in a destruction of the laminate by tearing without achieving a delamination of the C8 metallocene LLDPE layer and the COC layer. The

EX2019, ¶11

Revised Motion to Amend – Untimely Arguments & Evidence

F. Any new amendments, arguments, or evidence submitted with this Motion are responsive to issues raised in the Board's Preliminary Guidance on Patent Owner's Motion to Amend ("PG") and/or Petitioner's Opposition to Patent Owner's Motion to Amend ("Opposition").

The subject matter of the revised substitute claims submitted in this Motion includes similar subject matter as the revised substitute claims submitted in the initial MTA and, among other issues, is related to the per-layer loading ranges raised in the Opposition and the PG.

McCarthy (EX2016)

Adapa's

originally proposed substitute claim 14 also sought to make similar amendments (additionally replacing the broader “comprising” language with the narrower “consisting of” language relating to the claimed base layer), but did not seek to narrow the tie layer to two layers, as does the current revised proposed Substitute Claim 14.

Revised Motion to Amend – Untimely Arguments & Evidence

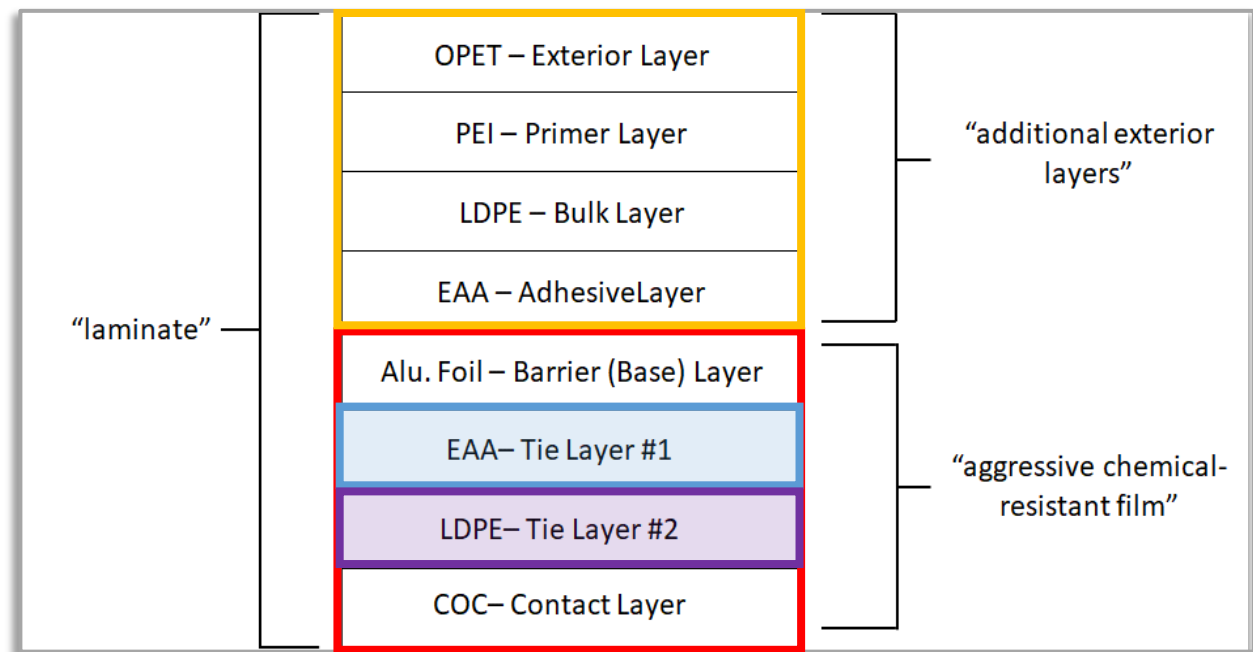
1. Riis fails to teach or suggest a "coextrusion layer consisting of [a] tie layer [comprising a first layer and a second layer] and [a] contact layer."

As established by Adapa in this proceeding, a POSITA would identify the .17 mil EAA layer as primarily serving a tying purpose (i.e., as a tie layer) and the .65 mil LDPE layer as primarily serving a bulking purpose (i.e., as a bulk layer, not a tie layer). *See* EX2016 ¶ 151. Moreover, a POSITA would not identify the .65 mil LDPE layer as a layer of a multi-layer tie layer that includes the .17 mil EAA layer and the .65 mil LDPE layer (which is four times thicker than the .17 mil EAA layer). *See id.*; EX2015, 83:16–22 (Dr. Spontak noting that “[i]f you want it to be used [as an adhesive] in concert with another adhesive like EAA, then you probably want it to be on the thinner side”).

Riis – Two-Layer Tie Layer

[00173] Example 5 (Of the Invention)

[00174] The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer10.42 mil



Spontak (EX1003)

8. Claim 8

i. *“The method according to claim 1, wherein the one or more layers of the tie layer consists of two layers.”*

194. As discussed in limitations [1.c] and [1.h] above, Riis discloses a tie layer further comprising layers of EAA and LDPE as two distinct layers of a “three-layer coextrusion...which was extrusion coated onto the [base layer].” Ex. 1004, ¶[00174]. Example 5 of Riis does not disclose any additional layers between the aluminum foil surface of the base film and the COC contact layer. Thus, the EAA and LDPE layers are the only two layers that make up the tie layer disclosed by Riis’s Example 5. Accordingly, the tie layer of Example 5 consists of two layers—one EAA layer and one LDPE layer. Ex. 1004, ¶[00174].

Herb Declaration (EX2019)

- Riis laminate is different from Herb laminate



20 So there are -- so there are some
21 differences between the laminate provided in the Herb
22 declaration versus what's provided in Riis or -- and/or
23 Osborn?

24 A. Yeah. Can you go back to Herb?

25 Q. Sure.

Page 15

1 A. Yeah, there appear to be some differences
2 up until the aluminum layer, and then on the interior
3 side, it appears to be the same; you know, the aluminum
4 ethylene acrylic acid copolymer LDPE and COC.

EX1041, 14:20 – 15:4

Herb Declaration (EX2019)

- Unknown “COC” polymer for Herb laminate

EX1004 (Riis)

The film structure in Example 5 is exemplary of a film according to the present invention. The base film for example 5 was produced in the same manner as for comparative example 2. In this example, the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight layer film having the structure: 0.92 mil OPET/primer/0.42 mil



EX1004, ¶0174

10 Q. Okay. And so for the COC layer, do you
11 know what type of COC that they -- that they used in the
12 Herb declaration?
13 A. I can -- I don't know exactly what they
14 used, but I would imagine it would be something to copy
15 the example 5 in Riis.

EX1041, 11:10-15

Herb Declaration (EX2019)

- McCarthy lacks any firsthand knowledge of loading ranges of the Herb laminate



21 What I'm asking is have you actually
22 seen or have firsthand knowledge of what the
23 loading ranges are of the laminate that was used
24 for laboratory testing?
25 A. I don't believe so.

EX1041, 18:51-25

Herb Declaration (EX2019)

- How to determine an LDPE layer as either a “bulk” layer or a “tie” layer – ***Measure adhesion***



11 Q. Okay. So if I just create the laminate
12 structure of paragraph 10 without any reference to Riis
13 or Osborn or the '624 patent -- I just simply create
14 that laminate -- can you tell me, is the LDPE layer a
15 tie layer or a bulk layer?

16 A. I would -- without any reference, I would
17 conclude it would be a bulk layer because of the
18 adhesive strength reported in paragraph 10.

19 Q. So -- so based on that, in order to
20 determine a bulk layer/tie layer, you need to understand
21 the adhesive strength? Is that your -- is that what
22 you're saying?

23 A. That would be one of the definitions of a
24 tie layer versus a bulk layer.

25 Q. Okay. What -- what quantity of adhesion

1 would be needed in order to go from a bulk layer to a
2 tie layer?

3 MR. GETZOFF: Objection. Outside the
4 scope.

5 A. I'm not sure.

6 BY MR. KILGORE:

7 Q. Okay. What if it was ten newtons per
8 15 millimeters? Would that be a tie layer?

9 A. Possibly.

10 MR. GETZOFF: Same objection.

11 BY MR. KILGORE:

12 Q. What about five newtons per
13 15 millimeters? Possibly a tie layer?

14 MR. GETZOFF: Objection. Outside the
15 scope.

16 A. It depends on the application. It's
17 possible.

EX1041, 23:11 – 24:17

Herb Declaration (EX2019)

- How to determine an LDPE layer as either a “bulk” layer or a “tie” layer – ***Application-dependent***



19 Q. So without knowing the strength per
20 length, would you be able to determine whether LDPE is a
21 tie layer or bulk layer?
22 MR. GETZOFF: Objection. Outside the
23 scope.
24 A. I would need to know the context, you
25 know, the application, etc.

EX1041, 24:19-25

Revised Motion to Amend - Substitute Claim 14

A. Proposed substitute claim 14 to replace claim 1, if claim 1 is found unpatentable.

14. A method for providing an aggressive chemical-resistant film, wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said method comprising:

providing a base layer, wherein the base layer ~~comprises~~ consists of aluminum and is resistant to one or more of water or oxygen;

coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);

coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer ~~comprising~~ consisting of the aluminum; and

allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of:

the base layer ~~comprising~~ consisting of the aluminum, and

the coextrusion layer consisting of the tie layer[[.]] and the

contact layer consisting of the COC, wherein:

the tie layer comprises ~~one or more layers~~ a first layer and a second layer, and wherein the tie layer, or each of the one or more layers first layer of the tie layer and the second layer of the tie layer, has a loading in the range of 7 to 20 g/m².

the tie layer comprises ~~one or more layers~~ a first layer and a second layer, and wherein the tie layer, or each of the one or more layers first layer of the tie layer and the second layer of the tie layer, has a loading in the range of 7 to 20 g/m².