

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG,
Petitioner

v.

DANAPAK FLEXIBLES A/S,
Patent Owner

Case No. PGR2023-00008
U.S. Patent No. 11,260,624 B2

**PETITION FOR POST-GRANT REVIEW
OF U.S. PATENT NO. 11,260,624 B2**

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Exhibit No.	Description
1001	U.S. Patent No. 11,260,624 to Christensen <i>et al.</i>
1002	U.S. Patent No. 11,260,624 Prosecution History
1003	Declaration of Richard J. Spontak, Ph.D.
1004	WIPO International Pub. No. 2015/123211 A1 to Riis <i>et al.</i>
1005	Wypych, G. (2012), Handbook of Polymers, ChemTec Publishing
1006	U.S. Pat. App. Pub. No. 2005/0037162 A1 to Adams
1007	U.S. Patent No. 6,120,860 to Bowen <i>et al.</i>
1008	U.S. Patent No. 9,452,593 to Tatarka <i>et al.</i>
1009	U.S. Patent Appl. No. 15/780,999 Application File History
1010	Curriculum Vitae of Richard J. Spontak, Ph.D.
1011	Dow NUCREL™ 3990 Product Data Sheet
1012	Dow LDPE 4012 Product Data Sheet
1013	U.S. Patent No. 8,003,179 to Merial <i>et al.</i>
1014	U.S. Patent Appl. Pub. No. 2006/0198973 to Jester
1015	U.S. Patent Appl. Pub. No. 2018/0354702 to Liu <i>et al.</i>
1016	Plastics News: Topas and MSM Make Progress on Barex Replacements
1017	Topas Advanced Polymers: TOPAS COC is Commercial Alternative to Barex
1018	Declaration of Julie Glascock
1019	Topas Cyclic Olefin Copolymers - March 2006 Brochure
1020	Declaration of Samuel A. Raque

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Exhibit No.	Description
1021	U.S. Patent Appl. Pub. No. 2009/0208685 to Rivers <i>et al.</i>
1022	Topas COC 8007F-400 Safety Data Sheet (2015)
1023	Topas COC 8007F-400 Safety Data Sheet (2017)

I. INTRODUCTION

Petitioner Huhtamaki Flexible Packaging Germany GmbH & Co. KG (“Petitioner”) requests post-grant review (“PGR”) of claims 1-13 of U.S. Pat. No. 11,260,624 (the “’624 patent”) that issued on March 1, 2022, and is assigned on its face to Danapak Flexibles A/S (“Patent Owner”). The ’624 patent is directed to packaging containing highly aggressive pharmaceutical ingredients that have the potential to leak through inferior packaging films. These aggressive pharmaceutical ingredients, such as nicotine, fentanyl, lidocaine, and rivastigmine, can be highly volatile and, if not properly packaged for storage and transport, can be problematic for consumer safety and retaining product quality. The films and laminates claimed in the ’624 patent have multiple polymer layers that provide the necessary material properties for the pharmaceutical packaging, including a cyclic olefin copolymer (COC) product-contacting layer that resists migration of aggressive chemicals from the drug product into the packaging.

The films claimed in the ’624 patent were well known in the art prior to December 29, 2015¹, the effective filing date of the ’624 patent. In 2014, the manufacturer of the leading aggressive chemical resistant polymer—a polyacrylonitrile (PAN) polymer product called Barex®—announced that it was

¹ A Cert. of Correction was entered on 6/28/2022 correcting the priority date from 12/29/2016 to 12/29/2015.

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discontinuing Barex® production. To fill this market opportunity, Topas, another manufacturer, announced that its COC polymers provided equivalent, if not improved properties, for pharmaceutical film packaging applications. Indeed, prior to the filing of the '624 patent, Bemis Company, a global manufacturer of flexible packaging products, filed its own patent application disclosing the same film structure, composed of the same materials—including a COC contact layer—as claimed in the '624 patent. That application, WO 2015/123211 to Riis (“Riis”), which published on August 20, 2015, identifies COCs as having useful material properties, including advantageous “anti-scalping” properties, i.e., resistance to migration of chemicals from the pharmaceutical product into the film. It also explicitly teaches product-contacting layers consisting of the same Topas COC polymers that the '624 patent disclosed for use in “all aspects” of the claimed invention. EX1001, 15:12-19. Thus, the '624 patent was wrong that “COC has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates.” EX1001, 6:1-8. In fact, Riis taught not only the coextrusion coating of COC to produce aggressive chemical resistant heat sealable laminates but also taught film structures virtually identical to those claimed in the '624 patent.

This Petition demonstrates that it is more likely than not that at least one of the challenged claims is unpatentable, and a trial for post-grant review must

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therefore be instituted. Here, the Examiner failed to identify the closest prior art—Riis—and allowed claims that are unpatentable over that art. Evidence in this Petition establishes that claims 1-13 are unpatentable under 35 U.S.C. § 103 and § 112. Petitioner respectfully requests that claims 1-13 be determined unpatentable and canceled.

II. MANDATORY NOTICES

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this Petition.

A. Real Parties-in-Interest

Huhtamaki Flexible Packaging Germany GmbH & Co. KG is the real party-in-interest for Petitioner.

B. Related Matters

Petitioner is not aware of any related matter under 37 C.F.R. § 42.8(b)(2).

C. Lead and Back-Up Counsel and Service Information

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner provides the following designation of counsel:

Lead Counsel	Back-Up Counsel
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D. Service Information

Service on Petitioner may be made by mail or hand delivery to: Patterson Intellectual Property Law, P.C., 1600 Division St., STE 500, Nashville, TN 37203. The fax numbers for lead and backup counsel are provided above. Petitioner also consents to electronic service by email at litigation@iplawgroup.com.

III. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.204, Petitioner certifies that the '624 patent is available for post-grant review and that Petitioner is not barred or estopped from requesting a post-grant review challenging the '624 patent claims on the grounds identified in this Petition. The '624 patent was granted on March 1, 2022 and the

present Petition is being filed on or before the date that is nine months after the date of the grant of the patent, or December 1, 2022. *See* Ex1001, code (45).

IV. STATEMENT OF GROUNDS OF UNPATENTABILITY

Ground	Statutory Basis	Prior Art References	Challenged Claims
1	35 U.S.C. § 112(b)		1-13
2	35 U.S.C. § 103	Riis ²	1-13
3	35 U.S.C. § 103	Riis, Wypych, ³ and Tatarka ⁴	1-13

V. TECHNOLOGY BACKGROUND

The '624 patent is directed to a method for providing a multilayer film and a laminate suitable for packaging aggressive chemical substances. The '624 patent's background discussion identifies Barex® as a known polymer meeting the requirements of being chemically resistant toward highly aggressive substances and possessing inert properties to prevent migration. EX1001, 1:58-62. The '624 patent recognizes the wide use of Barex® in drug and food applications due to its increased barrier properties compared to other polymers, and further for its chemical resistance toward several functional groups, including nicotine. EX1001, 1:58-2:2. Finally, the '624 patent states that since Barex® is heat stable it can be welded at increased temperatures such that the material can form flexible packaging. EX1001, 2:2-4.

² Riis et al. (WIPO Int'l Publication No. 2015/123211 A1), published August 20, 2015 ("Riis").

³ Wypych, G. (2012), *Handbook of Polymers*, ChemTec Publishing ("Wypych").

⁴ Tatarka et al., U.S. Patent No. 9,452,593, published October 20, 2011 ("Tatarka").

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In 2014, however, Barex®’s manufacturer announced that it would end production, prompting film packaging manufacturers to look for suitable replacements. EX1003, ¶¶[52]-[54]. In 2015, TOPAS Advanced Polymers announced that its COC products deliver effective chemical resistance and low adsorption rates and are suitable for “common thermoplastic processing methods including mono and multi-layer film, sheet, and extrusion coating, along with injection and extrusion blow molding.” EX1003, ¶[55]. Indeed, Topas touted its COC as “a key component in a broad range of global Barex® replacement products from leading healthcare packaging companies including Bemis Healthcare Packaging, Oshkosh, Wis., Rollprint Packaging Products, Addison, Ill., Tekni-Films Division of Tekni-Plex, Inc., Wayne, Pa, and other suppliers.” Ex1003, ¶[56]. This is consistent with Bemis’s filing of U.S. Patent App. No. 14/178,005 on February 11, 2014, to which WO 2015/123211 claims priority, which teaches multilayer films that include a COC product contacting layer. Ex1003, ¶[57].

VI. OVERVIEW OF THE ’624 PATENT

The ’624 patent, entitled “Method for Providing an Extreme Chemical Resistant Film, a Film and Laminate Obtainable Therefrom,” is directed to a method for providing a multilayer film and a laminate suitable for packaging aggressive chemical substances. EX1001, codes (54), (57), 2:44-62. The claims generally require providing “an aggressive chemical-resistant film” by coating a coextruded

tie layer and contact layer to a base layer comprising aluminum. The claims further require that the contact layer—the layer that contacts the aggressive chemical—consist of a cycloolefin copolymer (COC) and that the tie layer have a particular loading range. Claim 1 is exemplary:

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.

A. Claimed Invention

The '624 patent's background section explains that “[i]n the pharmaceutical industry substances, including highly aggressive substances such as nicotine, fentanyl, rivastigmine, and lidocaine, are packed as tablets in inhalers, patches etc. resulting in special requirements for the packing, laminate, or film for sealing these

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substances in order to ensure that no adverse degradation takes place.” EX1001, 1:31-36. This packaging typically requires (1) resistance towards highly aggressive substances, (2) inert properties for ensuring that chemical compounds do not migrate into the packaging and contact a sealed substance, and (3) child proofing. EX1001, 1:48-57. The ’624 patent discusses at least two materials known to provide these requirements: (1) a polyacetylonitrile-based film known as Barex® and (2) a polymeric-based film comprising dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers laminated to an aluminum base layer. EX1001, 1:58-2:20.

The ’624 patent purportedly provides a new “cost efficient” packaging solution for aggressive chemicals that has certain advantages. EX1001, 2:34-43. For example, the ’624 patent alleges that:

It has surprisingly been found that when coextruding the tie layer and the contact layer according to the disclosure, the respective layers can be thinner while maintaining the overall mechanical and chemical robustness of the final film and laminates and wrappings made with the film. The co-extrusion also results in a better adherence of the various layers resulting in a homogenous film in which the layers do not separate.

EX1001, 2:63-3:3. However, it does not purport to have invented any new coextrusion process. See EX1001, 13:11-14 (“The coextrusion layer may be coated to the aluminum layer by a coextrusion system generally known in the art to provide the coextrusion layer coated on the first side of the aluminum layer.”) The ’624

patent further asserts that the COC of the claimed contact layer “has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates,” but that COC processing is improved when COC is coextruded with a tie layer that has a melting point different from that of COC. EX1001, 6:1-24, Claims 2 and 3.

Figure 2 depicts a three-layer aggressive chemical-resistant film of the claims (annotations added), wherein tie layer 3 and contact layer 4 have been coextruded onto base layer 2. *Id.*, 13:34-41.

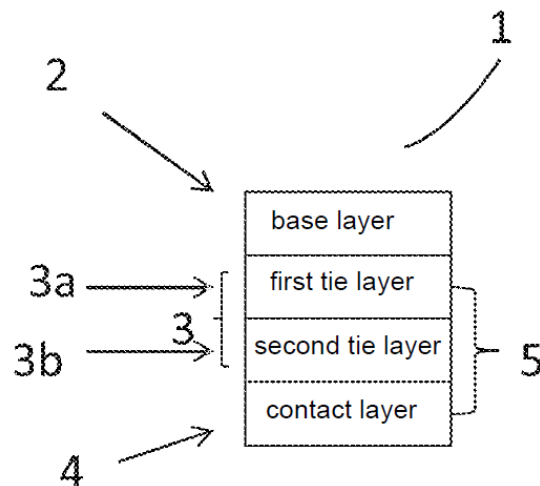


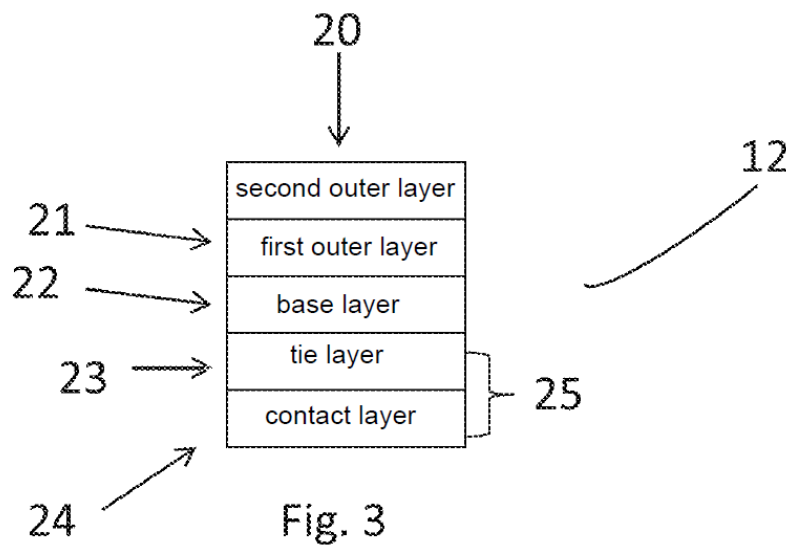
Fig. 2

(’624 patent, Fig. 2 (annotated))

The ’624 patent acknowledges that “[t]he preferred material for a laminate is aluminium due to its good oxygen and water barrier properties.” EX1001, 2:15-20. Accordingly, and consistent with claim 1, base layer 2 “comprises aluminum and is resistant to one or more of water or oxygen.” EX1001, claim 1; *see also, id.*, 13:11-

14. Also consistent with claim 1, “the tie layer comprises one or more layers [3a, 3b].” *Id.*, claim 1. The specification explains that “[t]hese layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b.” *Id.*, 13:42-46. Again, consistent with claim 1, the specification teaches that the contact layer comprises COC. *See id.*, claim 1, 5:14-17, 9:28-32, 9:60-64, 10:13-16, 10:35-38.

Figure 3 depicts a claimed laminate consistent with claim 13.



(’624 patent, Fig. 3 (annotated))

The laminate includes a three-layer film like that of claim 1, where layer 24 is the contact layer, layer 23 is the tie layer, and layer 22 is the base layer.⁵ *Id.*, 13:51-14:13 (noting that layer 25 is the coextrusion layer). The film’s base layer 22 is laminated

⁵ The specification explains that “[t]he base layer, 2, and the coextrusion layer, 5, define the film according to all aspects of the disclosure.” EX1001, 13:3-5.

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to first outer layer 21 (e.g., “a mechanically wear resistant layer”). *Id.* First outer layer is laminated to second outer layer 20 (e.g., “a paper layer”). *Id.* These exterior layers—first outer layer 21 and second outer layer 20—may make the material “difficult for children to open,” allow for printing, and “improve the stiffness of the packaging.” *Id.*

All’624 patent claims further require that “the tie layer, or the one or more layers of the tie layer, has a loading the range of 7 to 20 g/m².” EX1001, Claims 1 and 13. Dependent claims include further loading range limitations. EX1001, Claims 4-7. According to the specification, “loading means the amount of polymer left, in the layer when the film has dried.” EX1001, 6:38-39. The specification does not explain how to determine loading or identify any standard test for determining loading.

B. Prosecution History

The ’624 patent issued from U.S. Patent Application No. 16/835,018 (the “’018 application”), which was filed on March 30, 2020. EX1001, codes (21), (22). The ’624 patent was originally filed with claims 1-20 but was subject to a restriction requirement. See EX1002, 339-41. Applicant elected original claims 1-12 directed to the method of manufacture of the film without traverse. *Id.*, 231-36.

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The Examiner rejected claims 1-12 under 35 U.S.C. § 102(a)(1) as anticipated by or, alternatively, as obvious over Adams⁶, or, alternatively, as obvious over the combination of Adams and Bowen⁷. *Id.*, 201-05. Adams is directed to a paperboard laminate for food packaging applications, such as juices, punches, milk, and other beverages. EX1006, ¶[0011]. Bowen is directed to multilayer film structures for packaging of organic liquids and solvents, such as products containing amines, xylenes, toluene, etc. EX1007, 1:10-15. Applicant amended the claims several times in response to repeated rejections in view of Adams and Bowen and filed a terminal disclaimer.

In response, Applicant amended claim 1—the sole independent claim—to recite “coextruding a tie layer and a contact layer, **wherein the contact layer consists of a cycloolefin copolymer (COC)** to provide a coextrusion layer” and to recite “coating the coextrusion layer **directly** to the base layer.” EX1002, 195 (bold and underlining in original). Applicant argued that, because Adams’ food contact layer contained filler, it “is not the same as ‘wherein the contact layer ***consists of a cycloolefin copolymer.***’” *Id.*, 190 (bold and italics in original). Applicant further argued that “applying a food contact layer ***containing filler*** to the tie layer is not the

⁶ Adams (US Pat. App. Pub. 2005/0037162 A1) published Feb. 17, 2005 (“Adams”). EX1006.

⁷ Bowen et al. (US Pat. 6,120,860), issued Sept. 19, 2000 (“Bowen”). EX1007.

same as ‘coating the coextrusion layer ***directly to*** the base layer.’ *Id.*, 190-91 (bold and italics in original). Applicant further argued that Bowen failed to cure those same deficiencies. *Id.*, 191-92.

The Examiner did not find Applicant’s arguments persuasive and again rejected claims 1-12 in view of Adams and Bowen for the same reasons. *Id.*, 167-68 (copying and pasting the previous rejections). The Examiner reasoned:

Regarding the amendment that the contact layer consists of COC, ADAMS discloses that the contact layer may or may not have a filler (abstract); discloses one or more olefin contact layer [i.e., COC layers] overlaying the functional barrier layer, wherein at least one of which incorporates fillers ([0011]); and further discloses that economic and converting configuration considerations dictate whether one, some or all layers between the functional barrier and food product have filler added ([0025]) [wherein the COC layers not having fillers read on the claimed layers consisting of COC]. Alternatively, and in addition, it would have been obvious to one of ordinary skill in the art to have used COC layers without fillers since ADAMS discloses to choose to either use or not use filler and that the choice of using fillers or not using fillers depends on economic and converting configuration considerations.

Id.

As part of a request for continued examination, Applicant amended claim 1 to recite “coating the coextrusion layer **consisting of the tie layer and the COC of the**

contact layer directly to the base layer.” *Id.*, 97 (bold and underlining in original). Applicant argued that Adams’ teaching of “coextruding the tie layer 19, a food contact layer 21, **and** additional layer or layers of filler 20 is not the same as a ‘coextrusion layer **consisting of** the tie layer and the COC of the contact layer.” *Id.*, 102-03 (bold and italics in original). Applicant further argued that “applying additional layer(s) **containing filler** to the tie layer is not the same as ‘coating the coextrusion layer **consisting of the tie layer and the COC of the contact layer directly to** the base layer.” *Id.*, 103-05 (bold and italics in original). Applicant additionally argued that “[t]he Office Action concedes, and Applicant agrees, that Adams is silent regarding the loading range values of the layers” and that “Adams teaches away from such loading range values.”⁸ *Id.* Applicant further argued that Bowen failed to cure those same deficiencies.⁹ *Id.*, 105-08. Applicant also argued

⁸ Applicant argued Adams loading was equivalent to a value outside of the claimed range. EX1002, 138. However, Applicant’s unit conversion is incorrect, and Examiner mistakenly allowed the claims as persuaded by incorrect attorney argument. *Infra* § XI.C.

⁹ Notably, Applicant claimed that, because “Bowen describes that ‘polymer tie layers can be as thin as about 0.15 mil,’” “Bowen describes a thickness of the tie layer to be about 3 g/m².” EX1002, 107. Thus, according to Applicant, “Bowen teaches away from such [claimed] loading range values.” *Id.* That argument materially misrepresents Bowen’s disclosure, which states that “individual layers of multilayer structures or layer elements may be thinner than about 1.5 mils, e.g., about 0.25 to about 1 mil and polymer tie layers can be as thin as about 0.15 mil).” EX1007, 6:41-62. Assuming Applicant’s calculation was correct, Bowen’s disclosure teaches layers ranging from 3 g/m²-30 g/m² (i.e., 0.15 mil-1.5 mils).

that a POSITA would not have combined Adams, which is directed to “food/juices” with Bowen, which is directed to “aggressive solvents.” *Id.*, 107.

The Examiner did not find Applicant’s arguments persuasive and again rejected claims 1-12 in view of Adams and Bowen. EX1002, 62-67. As to loading ranges, the Examiner noted that “it is not inventive to discover the optimum or workable ranges by routine experimentation” and that “merely selecting proportions and ranges is not patentable absent a showing of criticality.” *Id.*, 63, 66-67. Regarding the melting points of the dependent claims, the Examiner noted that Adams disclosed layers meeting the claim limitations and that “[w]here the claimed and prior art products are identical or substantially identical in structure or composition, ... a prima facie case of either anticipation or obviousness has been established.” *Id.*, 64, 67. The Examiner also reasoned that, because Adams discloses few contact and tie layers to choose from, the selection would have been obvious and that it would have been obvious to replace Bowen’s olefin copolymer with Adam’s COC. *Id.*, 64-66.

In response, Applicant amended the claims to recite that the film is “**an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine**” and that “the base layer **comprises aluminum**.” *Id.*, 42. Applicant also added claim 21 (which issued as claim 13). *Id.*, 44-45. Applicant argued that Adams failed to teach an aggressive

chemical-resistant film. *Id.*, 47. Applicant again argued that Adams and Bowen failed to teach that the “film ***consists: of the base layer*** comprising aluminum, ***and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC***” because both taught structures including more layers. *Id.*, 48, 50-51. Applicant did not address that the open-ended claim language—“base layer *comprising* the aluminum”—at least allows for additional components to the layer. Applicant also argued that “the loading value of the tie layer is critical” based on unexpected results disclosed in the application, but none of the cited paragraphs of the application discuss loading ranges, let alone their criticality to the invention. *Id.*, 49, 51.

The Examiner then allowed the claims. *Id.*, 19. In their Reasons for Allowance, the Examiner noted the following:

- Adams and Bowen “fail[] to teach making a film consisting only of a base layer comprising aluminum, and a coextrusion layer consisting only of a tie layer and a contact layer, and wherein the contact layer consists of only COC.”
- Adams and Bowen “fail[] to teach an aggressive chemical-resistant film which is resistant to a chemical selected from nicotine, fentanyl, rivastigmine or lidocaine.”
- “ADAMS...fail[s] to teach 7-20 g/m².”

Id., 21-22.

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art of the '624 patent at the time of the alleged invention would have had a relevant technical degree in Chemical Engineering, Polymer Science, Materials Science, or the like, and 2-3 years of experience in laminate or film manufacture or similar packaging manufacture and that less experience may be necessary with additional education and vice versa. EX1003, ¶¶[66]-[72].

VIII. OVERVIEW OF THE PRIOR ART

A. Riis (EX1004)

Riis qualifies as prior art under at least 35 U.S.C. § 102(a)(1) as a printed publication available to the public before the effective filing date of the claimed invention and no exception applies. Riis published on August 20, 2015, before December 29, 2015, the earliest effective filing date of the '624 patent. EX1004, codes (12), (43); EX1001, codes (22), (43). Riis also qualifies as prior art under at least 35 U.S.C. § 102(a)(2) as a published patent application with an effective filing date of February 11, 2014 and no exception applies. EX1001, code (30).

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-Scalping Pharmaceutical Packaging Film,” is directed to packaging films for pharmaceuticals such as fentanyl, nicotine, and lidocaine that resist migration of

drug components to the package structure (referred to in the art as “scalping”). EX1004, ¶¶[0003], [0005], [0011]; EX1003, ¶¶[78]-[79]. Like the ’624 patent, Riis teaches a chemical-resistant film created by coating a coextruded tie layer and contact layer to a base layer comprising aluminum. EX1004, ¶¶[00157]-[00158], [00174]; EX1003, ¶[80]. And like the ’624 patent, Riis teaches that the contact layer (a “product-contacting sealing layer”) includes a COC (“an ethylene norbornene copolymer”). EX1003, ¶[83].

Figure 1 of Riis depicts a six-layer laminate virtually identical to the laminate depicted in Figure 3 of the ’624 patent. EX1003, ¶[81].

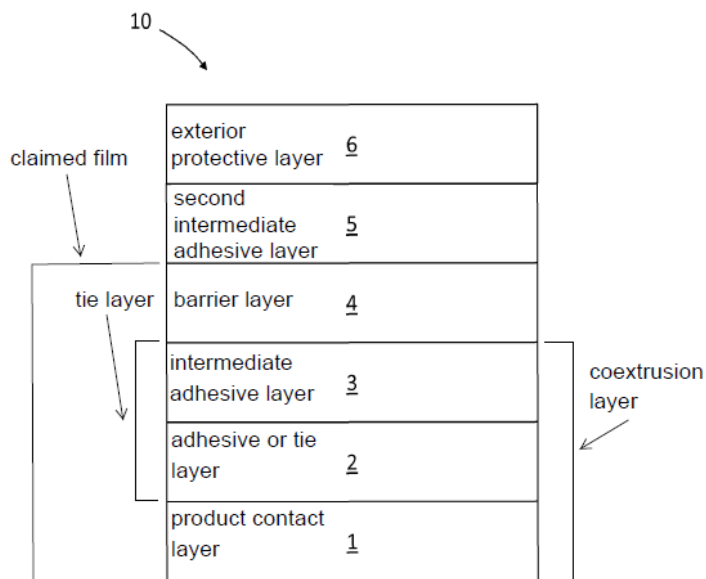


FIG. 1

(EX1004, Fig. 1 (annotated))

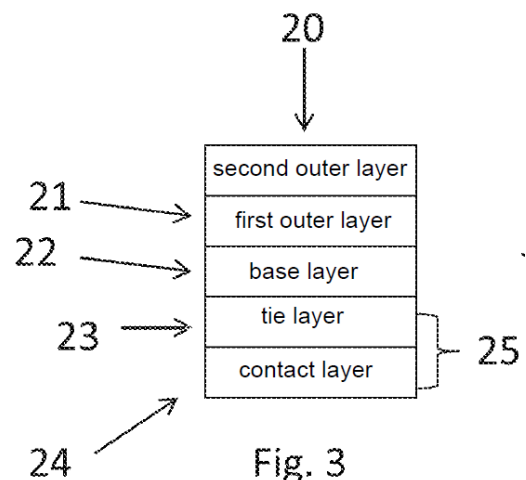


Fig. 3

(’624 patent, Fig. 3 (annotated))

Product contacting layer 1, which comprises COC, is adhered to polyolefin bulk layer 2. EX1004, ¶[00135]; EX1003, ¶[82]. Polyolefin bulk layer 2 is adhered to first intermediate adhesive layer 3. EX1004, ¶[00135]; EX1003, ¶[82]. Riis teaches that polyolefin bulk layer 2 “can serve as an adhesive or tie layer” and that the terms “adhesive layer” and “tie layer” are synonymous. EX1004, ¶¶[0020], [00135]; EX1003, ¶[82]. Thus, according to Riis’s terminology, polyolefin bulk layer 2 and first intermediate adhesive layer 3 form a multi-layer tie layer. EX1003, ¶¶[82], [84]. First intermediate adhesive layer 3 is adhered to oxygen barrier layer 4, which “may comprise aluminum foil.” EX1004, ¶¶[0062], [00135]; EX1003, ¶[85]. Oxygen barrier layer 4 is adhered to second intermediate adhesive layer 5, which in turn adhered to exterior protective layer 6. EX1004, ¶[00135].

In addition to Fig. 1, Riis discloses Example 5, which specifies the particular materials used to create an eight-layer laminate that comprises a “sealant film.” In Example 5, the “sealant film” consists of a product contact layer, a multi-layer tie layer, and a base layer. EX1004, ¶[00174]. Specifically, the “sealant film” consists of “a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface.” *Id.* Riis further teaches a laminate comprising the film (the three-layer coextrusion “sealant film” and the aluminum foil base layer), wherein the aluminum foil base layer is adhered to exterior layers—OPET, primer, LDPE, and EAA—to provide the eight-layer

laminate. *Id.*, ¶¶[00162]-[00174]; EX1003, ¶¶[88]-[89]. A depiction of Riis's Example 5 in the context of the structure of Riis's Figure 1 appears below.

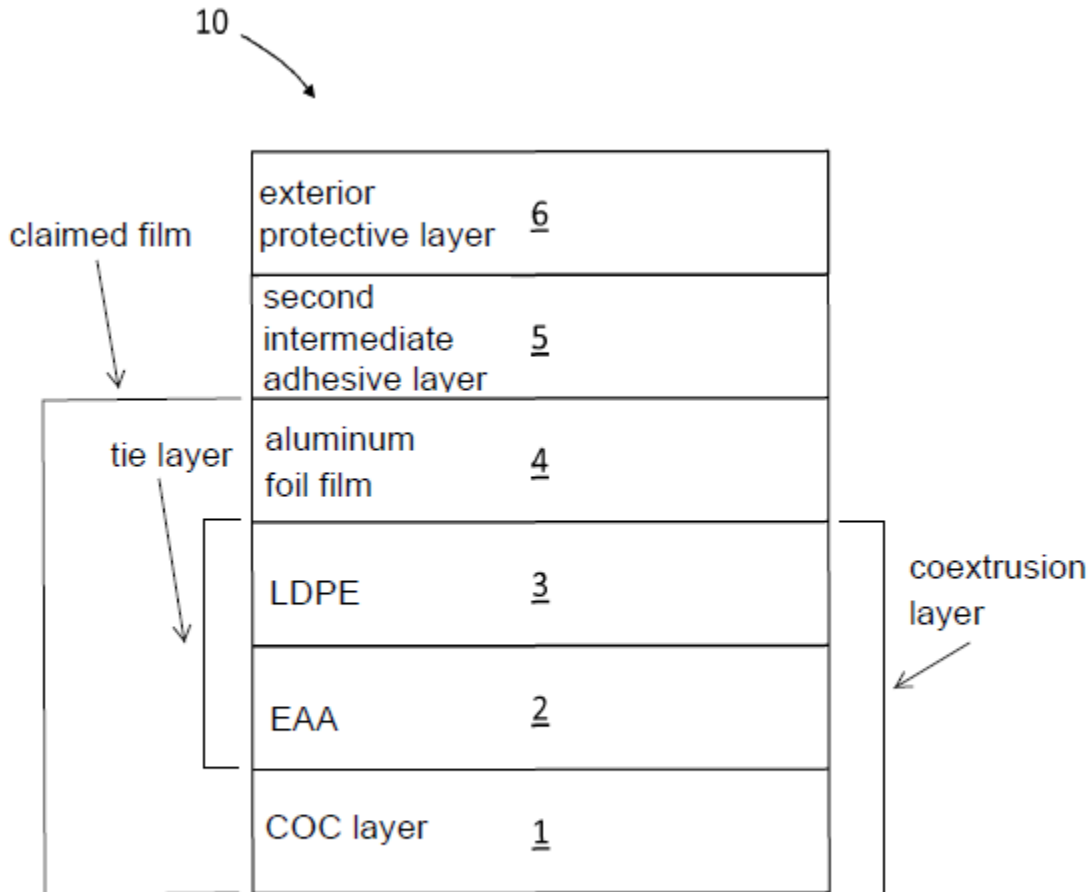


FIG. 1

(EX. 1004, Fig. 1 (annotated))

EX1003, ¶[89]. Thus, like claim 1 of the '624 patent, Riis teaches a coextruded tie layer (LDPE and EAA) and contact layer (consisting of COC) coated onto a base layer comprising aluminum.

B. Wypych (EX1005)

Wypych is prior art under 35 U.S.C. § 102(a)(1) as a printed publication available to the public before the effective filing date of the claimed invention and no exception applies. Wypych is a Handbook of Polymers that bears a copyright marking of “© ChemTec Publishing, 2012” and bears a statement that it was “[p]ublished by ChemTec Publishing.” EX1005, 3; *see also FLIR Systems, Inc. v. Lead Surveys, Inc.*, IPR2014-00411, Paper 9 at 18-19 (PTAB Sept. 5, 2014) (finding the presence of a Copyright notice *prima facie* establishes a prior art date). Further, the Declaration of Julie Glascock (EX1018), the Director of Acquisitions and E-resources at Vanderbilt University’s Jean & Alexander Heard Libraries, corroborates the Wypych qualifies as a prior art printed publication. Wypych is an authentic publication that was publicly accessible to interested persons exercising reasonable diligence. *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008).

Wypych includes information on all major polymeric materials used by the plastics industry and other branches of the chemical industry, including the material properties of COC, EAA, and LDPE. EX1005, 4-12, 20-25; EX1003, ¶¶[90]-[91].

C. Tatarka (EX1008)

U.S. Patent No. 9,452,593 (“Tatarka”) is prior art under 35 U.S.C. § 102(a)(1) as a printed patent available to the public before the effective filing date of the

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claimed invention and no exception applies. Tatarka is U.S. Patent that was published October 20, 2011, and issued September 27, 2016, the publication date being more than one year prior to the '624 patent's earliest effective filing date of December 29, 2016. EX1008, codes (45), (65); EX1001, codes (45), (65). Tatarka also qualifies as prior art under at least 35 U.S.C. § 102(a)(2) as a published patent application with an effective filing date of at least as early as April 7, 2011, and no exception applies. EX1008, code (22).

Tatarka discloses cyclic olefin copolymers (COC) that are durable and can be used in coextrusion processes with other polymers in “flexible packaging applications.” EX1008, 3:45-60. Tatarka teaches various COCs, including ethylene norbornene copolymer, and their physical properties, including melting points. *Id.* at 4:43-47, 6:66-7:15. Tatarka also discloses that “[m]ultilayer, all-olefin packaging films can likewise be produced using the inventive compositions combined with layers of other polyolefins.” *Id.* at 17:40-42. Tatarka identifies suitable polyolefins including polyethylenes. *Id.* at 17:42-50.

IX. CLAIM CONSTRUCTION

Claim terms in PGRs “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action.” 37 C.F.R. § 42.200(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Petitioner does not believe any specific constructions are required at this time. In this Petition,

all terms of the '624 patent claims have been given their ordinary and customary meaning as understood by one of ordinary skill in the art in light of the specification and the prosecution history pertaining to the patent, in accordance with § 42.200(b).

X. GROUNDS OF UNPATENTABILITY

A. Ground I: Claims 1-13 Are Unpatentable Under 35 U.S.C. § 112(b) As Indefinite

Claims 1-13 are unpatentable as indefinite for failing to particularly point out and distinctly claim the invention. Section 112(b) “require[s] that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 572 U.S. at 910. Under *Nautilus*, “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Id.* at 901.

Here, the limitations reciting “aggressive chemical-resistant film,” and/or “loading” ranges render the claims indefinite. EX1003, ¶¶[96], [113]-115]. The '624 patent lacks a definite scope of “aggressive chemical-resistant film” and fails to inform a POSITA how to test whether a film product meets the claimed chemical resistant film. *Id.*, ¶¶[96]-[97]. Similarly, the '624 patent gives one brief definition of the term “loading,” a term lacking an ordinary and customary meaning in the art,

and fails to provide any particular method or standard by which to measure loading.

Id., ¶¶[114]-[115].

- 1. The '624 patent fails to inform a POSITA as to the scope of “aggressive chemical-resistant film” with reasonable certainty because it fails to provide any method by which to determine whether a film is an “aggressive chemical-resistant film”**

Claims 1-13 are indefinite because the '624 patent fails to inform a POSITA as to the scope of “aggressive chemical-resistant film” with reasonable certainty. EX1003, ¶¶[96]-[97]. All the '624 patent claims recite “an aggressive chemical-resistant film” and include the clause, “wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine.” See EX1001, Claims 1 and 13. The Examiner allowed the claims because the prior art references before them “fail[ed] to teach an aggressive chemical-resistant film which is resistant to a chemical selected from nicotine, fentanyl, rivastigmine or lidocaine.” EX1002, 21-22. As the Federal Circuit recently explained, “our precedents indicate that ‘a claim may be invalid as indefinite when (1) different known methods exist for calculating a claimed parameter, (2) nothing in the record suggests using one method in particular, and (3) application of the different methods result in materially different outcomes for the claim’s scope.’” *Saso Golf, Inc. v. Nike, Inc.*, 843 Fed.Appx. 291, 296 (2021) (citing *Ball Metal Beverage Container Corp. v. Crown Packaging Tech., Inc.*, No. 2020-1212, 838 Fed.Appx. 538, 542 (Fed. Cir. Dec. 31, 2020)). All three elements are met here for “aggressive chemical-resistant film.”

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As to (1), the '624 patent identifies three different methods for determining if a film is an aggressive chemical-resistant film. In particular, the specification provides three inconsistent definitions of “aggressive chemical-resistant film” that specify different standards for determining whether a film is an aggressive chemical-resistant film.

[Definition 1] In the context of the present disclosure aggressive chemical resistant film means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks.

Id., 5:8-13.

[Definition 2] The term “aggressive chemical resistant film” means a film which when in contact with an aggressive substance does not allow more than 10%, such as 5% w/w or 1.5% w/w based on the nominal content of the aggressive chemical to migrate to the packaging material.

Id., 7:21-25.

[Definition 3] [T]he term “aggressive chemical resistant film” means a film which when in contact with an aggressive substance does not allow more than 1.5% w/w of nominal content to migrate to the packaging material or that 90-110% w/w of the aggressive chemical substance remains in the product when compared to Barex® as index 100.

Id., 12:16-22; EX1003, ¶¶[101]-[105]. The inconsistencies in the standards set out by these definitions are plain on their face. *First*, each definition recites a different amount of permissible migration of the aggressive chemical into the packaging. Definition 1 recites “no more than 1%”; Definition 2 recites no “more than 10%”; and Definition 3 recites no “more than 1.5%.” *Second*, the definitions themselves

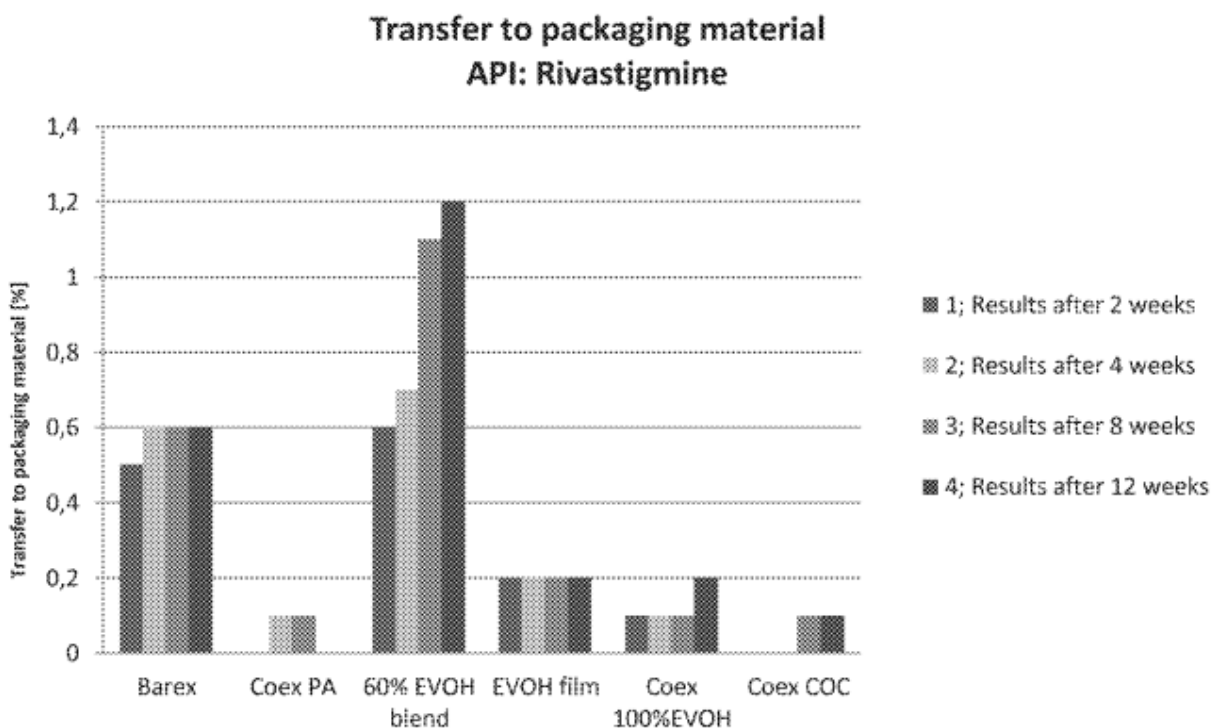
are internally inconsistent. Definition 1 recites “no more than 1% . . . (or sometimes no more than 10%)”; Definition 2 recites no “more than 10%, such as 5% w/w or 1.5% w/w”; and Definition 3 recites an alternative test methodology using a proprietary product, Barex®, as a comparator. EX1003, ¶¶[101]-[105].

As to (2), nothing in the record suggests which method should be used. Nothing suggests which limitation applies—1%, 1.5%, 5%, or 10%. The specification, through its failed attempt at lexicography, accords equal weight to each methodology. EX1003, ¶[106].

As to (3), application of the different methods results in materially different outcomes for the claim’s scope. For example, based on Figure 4, laminate 2 (60% EVOH blend) would not be an “aggressive chemical resistant-film” under Definition 1 because more than 1% of the rivastigmine has migrated to the packaging after only eight weeks. However, laminate 2 would be an “aggressive chemical resistant-film” under any of the limits of Definitions 2 (<10%, <5%, or <1.5%) or at least a portion of Definition 3 with respect to “w/w of nominal content” (<1.5%). EX1003, ¶[107].

The standards set out in the three alternative definitions render the claims indefinite for yet another reason related to (3)—variations in testing parameters will result in materially different outcomes for the claim’s scope. The ’624 patent fails to provide specific parameters for carrying out the test methodologies suggested by the definitions. At the very least, a POSITA would need to know (1) what form of

nicotine, fentanyl, rivastigmine, or lidocaine should be placed in the test laminate (e.g., patch, sublingual strip, powder, liquid applied to paper, etc.); (2) how much nicotine, fentanyl, rivastigmine, or lidocaine should be placed in the test laminate; (3) and for how long, at what temperature, and at what humidity the test samples should be stored before determining the amount of aggressive chemical that has migrated into the packaging. EX1003, ¶¶[108]-[112]. The specification of the '624 patent either fails to provide these parameters or provides inconsistent parameters. EX1003, ¶¶[102]-[112]. In example 1, the '624 patent discloses testing of a patch containing 9.5 mg rivastigmine stored at 40°C for intervals of 2, 4, 8, and 12 weeks. In example 2, the '624 patent discloses testing of a patch containing 40 mg of lidocaine at 40°C for seven days. Thus, none of these tests utilize the time interval of Definition 1. EX1003, ¶¶[110]-[112]. The data for the 60% EVOH blend in Figure 4 of the '624 patent demonstrates the criticality of the storage interval. *Id.*



The 40°C storage temperatures of the '624 patent's examples also differ significantly from 100°C storage temperatures of Riis's detailed methodologies, indicating that there is no accepted standard for determining when a film is "aggressive chemical resistant." See EX1004, ¶¶[00141], [00144], [00148]. And, in contrast to the methodologies described in Riis, *id.*, none of these tests indicate the relative humidity at which the samples were stored. Variations in these critical testing parameters will result in material different outcomes for the claims' scope. EX1003, ¶¶[106]-[107].

Because the chemical resistance testing method is "critical to discerning whether [a product] has been produced by the claimed process," the lack of such an

identified testing method renders the claim indefinite. *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1340 (Fed. Cir. 2003)).

2. The loading range limitations are indefinite because the '624 patent fails to inform a POSITA how “loading” is determined.

The independent claims (1 and 13) and dependent claims 5-7 recite limitations including the “loading” of the tie layer, or portions thereof, falling within a range of “7 to 20 g/m².” EX1001, 18:30-32, 41-49. The Examiner allowed the claims because the prior art references before them “fail[ed] to teach 7-20 g/m².” EX1002 at 21-22. Additionally, claim 4 recites a limitation for the “loading” range of the contact layer, specifically, “the contact layer [having] a loading in the range of 4 to 20 g/m².” EX1001, 18:39-40. These limitations render all challenged claims indefinite because they fail to inform a POSITA how to determine if the loading range limitations are met.

“Loading” is not a term that has an ordinary and customary meaning in the art, and the specification does not inform a skilled artisan how to determine “loading.” EX1003, ¶[114]. The '624 patent provides a single-sentence explanation of “loading”: “[i]n terms of the disclosure loading means the amount of polymer left, in the layer when the film has dried.” EX1001, 6:38-39. The '624 patent fails to identify any test methodology or parameters (e.g., timing, temperature, humidity) to determine loading. EX1003, ¶[115]. Nor does it explain how to determine when “the film has dried.” EX1003, ¶[115]-[117]. Consequently, a skilled artisan could not

determine whether a particular aggressive chemical-resistant film or laminate would meet the loading range limitations. EX1003, ¶[118]; *Nautilus*, 572 U.S. at 909 (“[A] patent must be precise enough to afford clear notice of what is claimed, thereby ‘appris[ing] the public of what is still open to them.’”).

3. To the extent Patent Owner argues that the construction of “melting point” differs from the ordinary and customary meaning, “melting point” is indefinite.

Dependent claims 2 and 3 recite “wherein [a / the] melting point of the tie layer differs from a melting point of COC by [30°C / 5-15°C] or less.” EX1001, 18:33-38. Tatarka explicitly recites a “melting point” for COCs. To the extent Patent Owner, in an effort to avoid Tatarka’s disclosure, argues that Tatarka’s “melting point” means something different than the “melting point” recited in the claims, claims 2 and 3 are indefinite because a POSITA would not have understood which of the many other temperature properties of polymers is equivalent to “melting point.” EX1003, ¶[119].

B. Ground II: Riis Renders Claims 1-13 Obvious

Claims 1-13 are unpatentable as obvious over Riis. Like the ’624 patent, Riis discloses a method of providing an aggressive chemical-resistant film, where the film consists of a base layer comprising aluminum, a coextrusion layer consisting of a tie layer and a contact layer where the contact layer consists of a cyclic olefin copolymer (COC). Riis’s Example 5 discloses the entirety of the claimed invention

except for specific materials properties, such as loading ranges and the relative melting points of the component tie layer and contact layer. A POSITA would, however, have found it obvious to construct Example 5 using the components identified by Riis, which would have had the claimed materials properties.

1. Independent claim 1

a) “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:”

Riis discloses a method for providing films that resist migration of chemicals, (anti-scalping films) used in the packaging of products containing a pharmaceutical active agent. EX1004, ¶¶[0002]-[0006], [0081]-[0089] (describing “Methods of Manufacture”); EX1003, ¶¶[121]-[123]. Riis identifies nicotine, fentanyl, and lidocaine as exemplary pharmaceutical active ingredients. EX1004, ¶¶[0005], [0011]; EX1003, ¶[121]. Thus, Riis teaches this limitation.

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

The '624 patent explains that “[t]he base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil.” EX1001, 4:6-8. Riis discloses “[s]uitable moisture barrier layers” and “oxygen barrier layer[s]” of a film may include “aluminum foil.” EX1004, ¶[0062]-[0063]. In particular, Riis’s Example 5 includes a base layer that comprises aluminum: “[i]n 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.” *Id.*, ¶[00174]; EX1003, ¶¶[124]-[125]. Thus, Riis teaches this limitation.

c) “coextruding a tie layer and a contact layer to provide a coextrusion layer,”

Riis discloses the use of a tie layer as a component of aggressive chemical-resistant films. EX1003, ¶[129]. Riis specifically teaches the use of tie layers which, in addition to other layers of the films, may be included as “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.” EX1004, ¶[0071]; EX1003, ¶[129]. Riis identifies a variety of appropriate thermoplastic materials suitable for forming the tie layer, including “LDPE” and “EAA”. EX1004, ¶¶[0069], [0074], EX1003, ¶[129].

Riis also discloses a “product contact layer” which comprises a cyclic olefin copolymer (COC), specifically identifying ethylene norbornene copolymer as the COC. EX1004, ¶¶[0052]-[0053], EX1003, ¶¶[126], [128]. In Example 5, Riis teaches the coextrusion of the tie layer and contact layer together: “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 based film.” EX1004, ¶[00174]. Figure 2 of the ’624 patent depicts an aggressive chemical-resistant film where “tie layer, 3, comprises two layers” where first layer

3a is EAA and second layer 3b is polyethylene (PE).”¹⁰ EX1001, Fig. 2 (annotated), 13:34-46, EX1003, ¶[131]. This is the same as the exemplary structures disclosed by the ’624 patent where the “contact layer” includes COC: “[s]pecific films according to the disclosure comprise but are not limited to base layer/tie-layer/contact-layer (the latter two coextruded) EAA/PE/COC” EX1001, 9:27-30, EX1003, ¶¶[129]-[131].

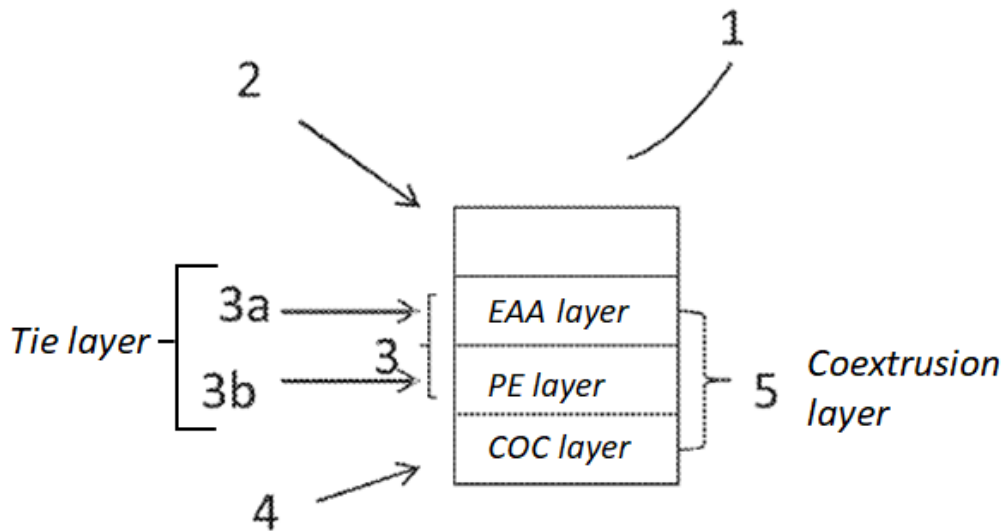


Fig. 2

(’624 patent, Fig. 2 (annotated))

EX1003, ¶[131]. Riis’s Example 5 is identically configured and a skilled artisan would understand that Riis’s EAA and LDPE are a “tie layer” as that term is used in

¹⁰ LDPE, used in Riis, is a type of polyethylene known as “low density polyethylene.” EX1004, ¶[0018]; *see also id.*, ¶[0027] (“Another broad grouping of polyethylene is ‘high pressure, low density polyethylene’ (LDPE).”).

claim 1 of the '624 patent. EX1003, ¶¶[128]-[131]. A skilled artisan would also understand the “product contact layer” including ethylene norbornene copolymer is the “contact layer,” and as stated in Example 5, each of the EAA, LDPE, and COC layers are coextruded onto the aluminum foil base layer. EX1003, ¶¶[129]-[130]. Thus, Riis teaches this limitation.

d) “wherein the contact layer consists of cycloolefin copolymer (COC);”

As detailed *supra* § X.B.1.c), Riis discloses a “product contact layer” which comprises a cyclic olefin copolymer (COC), specifically identifying ethylene norbornene copolymer as the COC. *Id.*, ¶[0052]-[0053]; EX1003, ¶[132]. Riis further teaches that “[t]he article contact layer comprises at least 90 wt.% of ethylene norbornene COC, most preferably at least 95 wt. %, and most preferably 100 wt. %.” *Id.*, ¶[0055]. Because the only polymer component of the contact layer of Riis’s Example 5 is COC, a POSITA would have understood that the contact layer of Example 5 consists of COC. EX1003, ¶¶[133]-[135]. Thus, Riis teaches this limitation.

e) “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”

As detailed *supra* § X.B.1.b), Riis teaches “a three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer based film.” *Id.*, ¶[00174]; EX1003, ¶[136]. Thus, Riis teaches this limitation.

f) “allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,”

The '624 patent explains that “[a]fter coating of the aluminum layer and subsequently cooling, the coextrusion layer is adhered to the side of the tie layer facing away from the aggressive chemical substance.” EX1001, 13:11-18; *see also id.*, 6:65-67 (“The adhering step iv) preferably occurs instantly for example by cooling the co-extrudate in cooling cylinders during the lamination process.”).

Regarding the coextrusion process, Riis teaches:

Typically the resins and any desired additives are mixed and introduced to an extruder where the resins are melt plastified by heating and then transferred to an extrusion (or coextrusion) die. Extruder and die temperatures will generally depend upon the particular resin or resin containing mixtures being processed and suitable temperature ranges for commercially available resins are generally known in the art, or are provided in technical bulletins made available by resin manufacturers.

EX1004, ¶[00158]; EX1003, ¶[138]. Riis teaches that the sealant film of Example 5 was created by coextrusion of EAA, LDPE, and COC. *Supra* § X.B.1.e). Wypych teaches that typical extrusion processing temperatures for these materials are 193-288°C for EAA, 199-232°C for LDPE, and 190-240°C for COC. EX1005 at 9, 12, 25; EX1003, ¶[140]. These processing temperatures are all well above room temperature (~20°C). *Id.* Thus, a POSITA would have found it obvious to cool the coextrusion of Riis’s Example 5 to cause it to adhere to form an aggressive chemical-resistant film. *Id.* 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. EX1003, ¶[140] (citing EX1008, 19:34-42); *In re Best*, 562 F.2d 1252, 1254-55 (C.C.P.A. 1977) (finding that although a prior art reference failed to disclose a specific “cooling” step, there was no indication that the cooling rate differed from a normal rate by removal of the heat source and thus, any sample of the prior art product “would necessarily be cooled to facilitate subsequent handling”). Thus, Riis teaches this limitation.

g) “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;”

According to the '624 patent, an aggressive chemical-resistant film is a component of a laminate, such that the laminate may also include outer layers adhered to the film. The specification expressly defines the terms “film” and “laminate”:

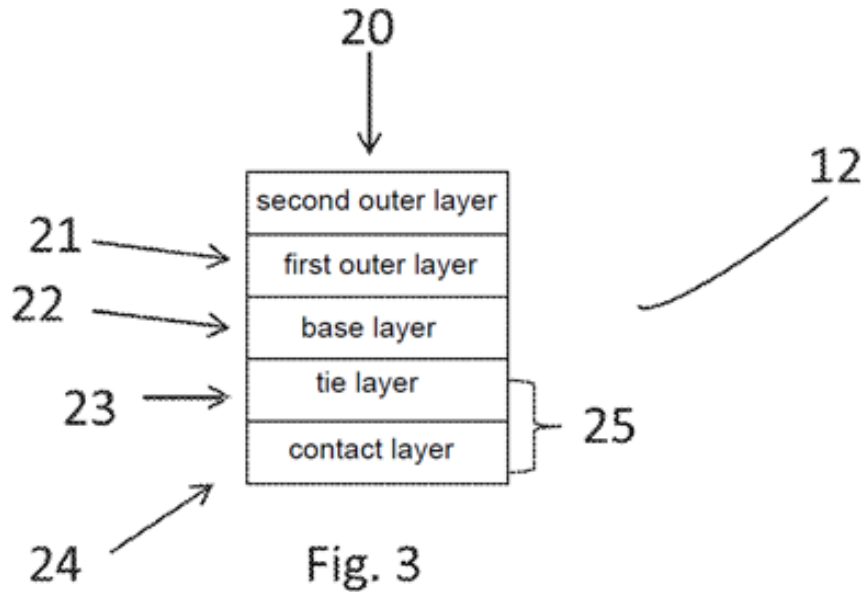
The term “film” according to the disclosure contemplates a product comprising a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or base layer laminated with a tie layer and a contact layer.

...

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

EX1001, 11:64-12:8; EX1003, ¶[141]. The specification also discloses embodiments wherein a laminate comprises a film (i.e., a contact layer, tie layer, and

base layer) and first and second outer layers, such as that depicted in Figure 3. EX1001, 7:54-8:23, 13:51-14:13, 16:17-67.

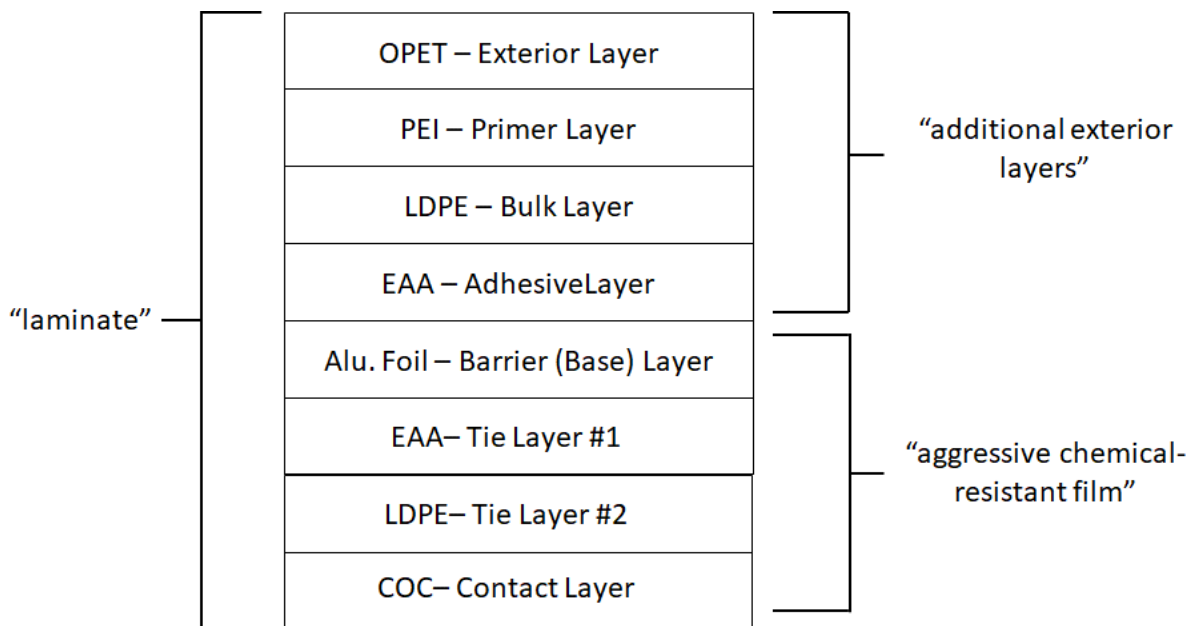


(‘624 patent, Fig. 3 (annotated))

EX1003, ¶¶[142]-[143]. Thus, a POSITA would understand that the term “film” is limited to the contact (24) layer, tie layer (23), and base layer (22) and that the term “laminate” includes the film plus any additional layers (21, 20). EX1003, ¶[143].

Riis’s Example 5 comprises a “sealant film” consisting of a product contact layer and a multi-layer tie layer coextruded to a base layer. EX1004, ¶[00174], EX1003, ¶[144]. Specifically, the “sealant film” consists of “a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface” of a “multilayer base layer.” *Id.* The “sealant film” of Riis’s Example 5 is part of an eight-layer laminate that, like

the embodiment of Figure 3 of the '624 patent, further includes exterior layers. *Id.* For example, Riis teaches a “multilayer base film” of OPET/PEI/LDPE/EVA/Al foil/. EX1004, ¶¶[00160]-[00162], [00174]; EX1003, ¶[145]. An illustration of the laminate of Example 5, including the aggressive chemical-resistant film, is depicted below.



See, EX1004, ¶¶[00160]-[00162], [00174]; EX1003, ¶[144].

A POSITA would have understood that the aluminum foil serves as a water and oxygen resistant “base layer,” as that term is used in the '624 patent. EX1003, ¶[146]. A POSITA also would have understood that PEI, LDPE, and EAA serve as intermediate or adhesive layers arranged on the side of the aluminum base layer opposite the tie layer and COC layer. EX1003, ¶[146]; EX1004, ¶¶[0068]-[0078],

[00163], [00174] (noting that “adhesive layers...may also be primers,” e.g., PEI, and that “[s]uitable intermediate layers may include” LDPE and EAA). And a POSITA would have understood that the OPET serves as an abuse-resistant outer layer. EX1003, ¶[146]; EX1004, ¶¶[0018] (defining “OPET” as “biaxially oriented polyester terephthalate”), [0066]-[0067] (describing “polyester terephthalate” as a “preferred exterior child resistant layer). Accordingly, in the context of the ’624 patent, Riis’s three-layer coextrusion “sealant film” along with the aluminum foil base layer forms an “aggressive chemical-resistant film.” EX1003, ¶[146]. Thus, Riis teaches this limitation.

However, even if the exterior and intermediate / adhesive layers are considered part of the “base layer,” Riis’s Example 5 still meets the limitation “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.” EX1001, Claims 1 and 13; EX1003, ¶[148]. The plain language of the claims requires only “the base layer *comprising the* aluminum,” *id.*; the composition of the base layer is therefore open-ended. Riis specifies that the three-layer coextrusion (contact layer / tie layer 1 / tie layer 2) of Example 5 “was extrusion coated onto the aluminum foil surface of the multilayer base film.” EX1004, ¶[00174]. That “multilayer base film”—OPET/PEI/LDPE/EAA/Al foil—comprises aluminum. *Id.*, ¶¶[00160]-[00174]. Thus, Riis teaches this limitation even

if the base layer is deemed to include the additional outer and intermediate / adhesive layers of Example 5. EX1003, ¶¶[147]-[148].

h) “wherein the tie layer comprises one or more layers, and”

As discussed 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].” EX1004, ¶ 174; EX1003, ¶[149]; *see also supra* § X.B.1.c. Thus, Riis teaches this limitation.

i) “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.”

This limitation would have been obvious based on Riis’s teachings regarding Example 5 and preferred commercially available polymers. As discussed above, Riis’s Example 5 teaches a tie layer consisting of coextruded EAA and LDPE layers. EX1004, ¶[00174], EX1003, ¶[154]. Riis does not disclose a loading range but does disclose the thickness of the EAA layer—0.17 mil—and the LDPE layer—0.65 mil. *Id.* Riis further teaches that Dupont 3990-L (tradename Nuclrel) is an exemplary commercially available EAA polymer and that Dow 4012 is an exemplary commercially available LDPE polymer. EX1004, ¶¶[0093], [0095], EX1003, ¶[155]. As discussed *infra* § X.B.j, a POSITA would have found it obvious to use the polymers disclosed in Riis, as well as other commercially available resins, to create Example 5. EX1003, ¶¶[160]-[165].

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As discussed *supra* § X.A.2, the '624 patent does not teach a POSITA how to determine “loading.” By knowing the thickness of the layer and the density of the polymer used, g/m^2 can be calculated. EX1003, ¶¶[151]-[152]. Riis provides thickness in “mil” units, where 1 mil = 0.001 inch = 0.00254 cm.¹¹ Thus, “loading,” as that term is used in the '624 patent, can be determined by (1) multiplying thickness in cm by density in g/cm^3 and (2) converting g/cm^2 to g/m^2 . EX1003, ¶¶[151]-[153]. Here, a 0.17 mil layer of Dupont 3990-L (EAA), which has a density¹² of 0.94 g/cm^3 , would have had a “loading” of 4.06 g/m^2 . EX1003, ¶¶[154]-[157]. A 0.65 mil layer of Dow 4012 (LDPE), which has a density¹³ of 0.918 g/cm^3 , would have had a loading of 15.16 g/m^2 . EX1003, ¶¶[154]-[156], [158]. These are both consistent with sources of densities like Wypych, which provides that densities¹⁴ of EAA range from

¹¹ National Institute of Standards and Technology (NIST) Physical Measurement Laboratory, Special Publication 811, Appx B.8: Conversion Factors for Units List Alphabetically (2008) (<https://www.nist.gov/pml/special-publication-811/nist-guide-si-appendix-b-conversion-factors/nist-guide-si-appendix-b8>).

¹² Dow NUCREL™ 3990 Product Data Sheet (EX1011) provides the physical properties for Dupont 3990-L as the exemplary commercial resin of “EAA,” including Density determined by ASTM D792 and ISO 1183 test methods. EX1011.

¹³ Dow LDPE 4012 Product Data Sheet (EX1012) provides the physical properties for Dow 4012 as the exemplary commercial resin of “LDPE,” including Density determined by ASTM D792 test method. EX1012.

¹⁴ Wypych (EX1005) provides the physical properties for “EAA,” including “Density at 20°C.” EX1005, 10. Additionally, it is noted that Wypych identifies a list of “commercial polymers” which includes DuPont Nucrel, as similarly listed in Riis.

0.92-0.96 g/cm³, which with a 0.17 mil layer of EAA would have had a “loading” of 3.97 g/m²-4.15 g/m². EX1003, ¶¶[156]-[157]. Further consistent with Wypych, which provides that densities¹⁵ of LDPE range from 0.915-0.929 g/cm³, a 0.65 mil layer of LDPE would have had a “loading” of 15.11 g/m²-15.34 g/m². EX1003, ¶¶[156], [158].

Accordingly, use of the polymers taught by Riis at the thicknesses taught for Example 5 would have resulted in a chemical-resistant film with a tie layer having the claimed “loading” range. EX1003, ¶[160]. The ’624 patent does not specify how to determine “loading” of a tie layer comprising two polymer layers. However, a POSITA would have understood that “loading,” i.e., “the amount of polymer left, in the layer when the film has dried,” of a tie layer comprising two polymer layers is represented by the sum of the “loading” of the two layers. EX1003, ¶[186]. A tie layer consisting of a 0.17 mil layer of Dupont 3990-L (EAA) and a 0.65 mil layer of Dow 4012 (LDPE) would have had a “loading” of 19.22 g/m². *Id.* This is again consistent with Wypych, which teaches that a tie layer consisting of a 0.17 mil layer of EAA and a 0.65 mil layer of LDPE would have had a “loading” of 19.08 g/m²-

¹⁵ Wypych, like for EAA, discloses the physical properties of “LDPE,” including “Density at 20°C.” EX1005, 21. Additionally, it is noted that Wypych identifies a list of “commercial polymers” which includes DOW LDPE, as similarly listed in Riis.

19.49 g/m². *Id.* Thus, Example 5, as taught by Riis, using EAA and LDPE as the tie layer falls within the claimed range of “7 to 20 g/m².”

Because a POSITA would have found it obvious to use the exemplary polymers taught by Riis to create Riis’s Example 5, Riis teaches this limitation. See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (finding that a specific exemplary range in the prior art which is within a claimed range anticipates the range).

j) Motivation to Combine and Reasonable Expectation of Success

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.

Aluminum Base Layer: All of Riis’s examples, including Example 5, use aluminum foil as the base layer. EX1004, ¶¶[00159]-[00174]. Riis also discloses that aluminum foil advantageously serves as both an oxygen and moisture barrier, which is consistent with the teachings of the prior art that aluminum is known to provide an inexpensive barrier. EX1003, ¶[161] (citing EX1013, EX1015, EX1021). Accordingly, a POSITA would have been motivated to use aluminum foil as the base layer because (1) Riis taught success in doing so, (2) aluminum foil provides suitable

oxygen and moisture barrier properties with a single material, and (3) aluminum foil provides costs savings over other barrier materials. EX1003, ¶[161]. Indeed, the '624 patent's background discussion acknowledges that "[t]he preferred material for a laminate is aluminium due to its good oxygen and water barrier properties." EX1001, 2:15-20.

Coextruding an LDPE/EAA Tie Layer: All of Riis's examples, including Example 5, coextrude an LDPE layer and EAA layer onto an aluminum base layer. EX1004, ¶¶[00159]-[00174]. Example 5 of Riis further uses a coextrusion of LDPE and EAA as part of a sealant film to join the product contact layer to the aluminum foil base layer. EX1004, ¶[00174]. The use of an LDPE/EAA coextrusion layer is consistent with known tie layers in the art used to join layers to metal foil barrier layers. EX1003, ¶[162] (citing EX1013, EX1015). Accordingly, a POSITA would have been motivated to coextrude an LDPE layer and EAA layer onto an aluminum base layer because at least Riis, Merical, and Liu taught success in doing so. EX1003, ¶[162].

COC Contact Layer: In view of Riis's suggestion to use Topas COCs—and specifically Topas 8007F-400—for the product contacting layers of its films, a POSITA would have been motivated to do exactly that when creating Example 5. EX. 1004, ¶¶[0007], [0052], [0054], [0097], [00158]. Further, the state of the art discussed *supra* § V would have led a POSITA to look to Topas COCs as a suitable

product contact layer to be implemented in multi-layer films. A POSITA would have appreciated the March 2006 brochure, “Topas® Cyclic Olefin Copolymers,” incorporated by reference in Riis as presenting a finite number of identified and predictable solutions; thus, a POSITA would have found it obvious to try those COCs in the contact layer of Example 5. EX1003, ¶[163]. Even if a POSITA would be motivated to use other commercially available COCs, a POSITA would have been motivated to use commercially available COC polymers to ensure the ability to scale up production for commercial purposes. EX1003, ¶[163].

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]. The disclosure of Riis’s success in implementing a COC contact layer in a multi-layer film with an aluminum base layer and a coextrusion layer of a tie layer and contact layer is consistent with suitable film packaging for drugs known in the art to use COC for the product contact layer. EX1003, ¶[164].

Accordingly, a POSITA would have found claim 1 obvious over Riis.

2. Claim 2

a) “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.”

This limitation would have been obvious based on Riis’s teachings regarding Example 5 and exemplary polymers identified in Riis’s specification. As discussed above, Riis’s Example 5 teaches coextruding a tie layer consisting of EAA and LDPE layers with a contact layer consisting of COC. EX1004, ¶[00174]. Riis does not disclose the melting point of the tie layer or COC but does disclose exemplary polymers that are suitable for coextrusion onto a base film. *Id.*, ¶¶[0093]-[0097]. A POSITA would have found it obvious to use the exemplary polymers that Riis discloses to create Example 5, and thereby render the claimed invention obvious. EX1003, ¶¶[160]-[163], [166].

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” limitations, Wypych (EX1005) discloses various physical properties for polymers, including EAA and LDPE. Wypych discloses the melting point of EAA is 75°C-112°C (EX1005, 10), and the melting point of LDPE is 105°C-115°C (EX1005, 10). The melting point of ethylene norbornene copolymer (COC) is 60°C-125°C, as disclosed in Tatarka. EX1008, 4:43-47, 13:60-63 (disclosing a melting point of 84°C for E-140), 15:11-13 (teaching that preferred COC polymers have melting

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temperatures of less than 90°C and more than 60°C); EX1003, ¶[167]. Similarly, the 2006 brochure teaches that Topas COCs have a glass transition temperature “from about 80°C to 180°C.” EX1019, 8.

For the same reasons as discussed for claim 1 *supra* §§ X.B.1.i)-j), a POSITA would have found it obvious to use the polymers disclosed in Riis, as well as other commercially available resins, to create Example 5. EX1003 ¶¶[83], [138]-[139]. A POSITA would have had a reasonable expectation of success in using the EAA, LDPE, and COC taught by Riis in view of Riis's experimental data demonstrating the successful anti-scalping properties of the film of Example 5. EX1003, ¶¶[207]-[210].

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

And, as summarized in the table above, the melting points for each of EAA, LDPE, and COC all overlap. And even an alternative interpretation of the melting point of COC as a glass transition temperature overlaps with the melting point ranges of EAA and LDPE. Furthermore, the '624 patent fails to identify any reason that the selection of polymers to obtain the claimed difference in melting points is critical to the claimed invention. Accordingly, a POSITA would have found it obvious to produce the film of claim 1 wherein the melting point of the tie layer differs from the melting

point of COC by 30°C or less. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018).

3. Claim 3

b) “The method according to claim 1, wherein a melting point of the tie layer differs from the melting point of COC by a value in the range of 5-15°C.”

A POSITA would have found claim 3 obvious for the same reasons discussed for claims 1 and 2. EX1003, ¶[169].

4. Claim 4

a) “The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m².”

This limitation would have been obvious based on Riis’s teachings regarding Example 5 and exemplary COC polymers as disclosed in the specification. As discussed above, Riis’s Example 5 teaches a COC product contacting layer having a thickness of 0.43 mil. *Id.*, ¶[00174]. Riis further teaches the use of Topas COC polymers, such as 8007F-400, which have “a density (Δ) of 1.02 g/cm³.” *Id.*, ¶[0054]; EX1019, 7. Here, a 0.43mil layer of Topas 8007F-400, which has a density of 1.02 g/cm³, would have had a “loading” of 11.14 g/m². EX1003, ¶¶[171]-[172]. This is consistent with sources of density like Wypych, which provides that densities of commercially available COCs, including “Topas COC,” range from 1.00-1.08 g/cm³, which at a thickness of 0.43 mil would have had a “loading” of 10.92-11.80 g/m². EX1005, 7; EX1003, ¶[172].

For the same reasons discussed for claim 1 and because a POSITA would have found it obvious to use the disclosed COC polymers taught by Riis to create Riis's Example 5, a POSITA would have found claim 4 obvious. EX1003, ¶[173].

5. Claim 5

- a) “The method according to claim 1, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².”***

A POSITA would have found claim 5 obvious for the same reasons discussed above for claim 1. EX1003, ¶¶[174]-[180].

6. Claim 6

- a) “The method according to claim 1, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².”***

A POSITA would have found claim 6 obvious for the same reasons discussed above for claim 1. EX1003, ¶¶[181]-[187]. For example, the LDPE portion of the tie layer would have had a “loading” of 15.16 g/m² (or at least in the range of 15.11 g/m²-15.34 g/m²).

7. Claim 7

- a) “The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers is in the range of 7 to 20 g/m².”***

A POSITA would have found claim 7 obvious for the same reasons discussed above for claim 1. EX1003, ¶¶[188]-[193].

8. Claim 8

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

A POSITA would have found claim 8 obvious for the same reasons discussed above for claim 1. EX1003, ¶[194]. For example, the tie layer of Example 5 consists of two layers—EAA and LDPE. EX1004, ¶[00174].

9. Claim 9

- a) “The method according to claim 1, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.”*

A POSITA would have found claim 9 obvious for the same reasons discussed above for claim 1. EX1003, ¶¶[195]-[196].

10.Claim 10

- a) “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.”*

A POSITA would have found claim 10 obvious for the same reasons discussed above for claim 1. EX1003, ¶¶[197]-[198]. Riis’s Example 5 includes a tie layer formed from a layer of EAA, an acrylic acid, and a layer of LDPE, a polyethylene. EX1004, ¶[00174].

11.Claim 11

- a) “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.”*

A POSITA would have found claim 11 obvious for the same reasons discussed above for claims 1 and 10. EX1003, ¶[199].

12.Claim 12

a) “The method according to claim 11, wherein the acrylic acid layer comprises ethylene acrylic acid.”

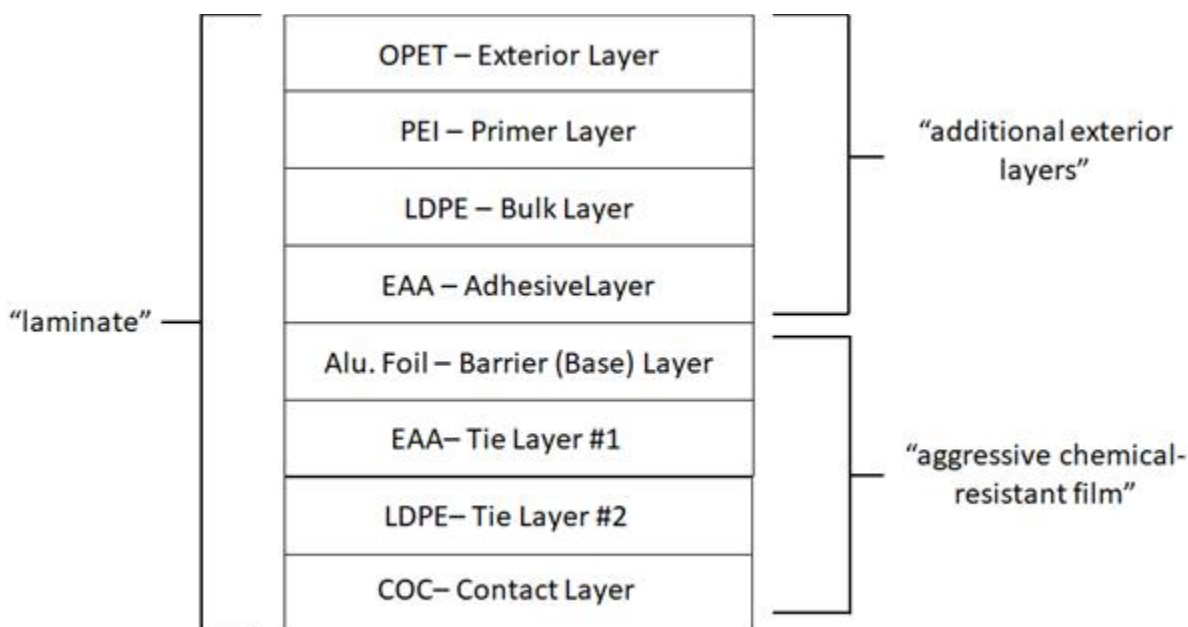
A POSITA would have found claim 12 obvious for the same reasons discussed above for claims 1, 10, and 11. EX1003, ¶[200].

13.Claim 13

Claim 13 differs from claim 1 in two respects. First, claim 13 recites “[a] method for providing a laminate, wherein the laminate comprises an aggressive chemical-resistant film” whereas claim 1 recites “[a] method for providing an aggressive chemical-resistant film.” Second, the clause “wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine” recited in the preamble of claim 1 has been moved to the body of claim 13.

Because neither difference alters the analysis, a POSITA would have found claim 13 obvious for the same reasons discussed above for claim 1. *See, e.g., supra* § X.B.1.g). According to the ’624 patent, the “film” is the “base layer laminated with a tie layer and a contact layer,” and the “laminate” is “the film to which a further layer is laminated.” *Id.*, 11:64-12:8. Riis’s Example 5 is an eight-layer laminate that, as depicted below, has the following layers (from exterior to product-contacting interior): OPET (abuse-resistant outer layer) / PEI (intermediate / primer layer) / LDPE (intermediate / adhesive layer) / EAA (intermediate / adhesive layer / Al foil (base layer) / EAA (first tie layer) / LDPE (second tie layer) / COC (contact layer).

EX1004, ¶¶[00161]-[00168], [00173]-[00174]. The Al foil / EAA / LDPE / COC layers constitute the claimed “film,” and, in combination with the remaining layers, make up the claimed “laminate.” EX1003, ¶¶[204]-[205].



a) Motivation to Combine and Reasonable Likelihood of Success

In view of Riis’s disclosures regarding Example 5, a skilled artisan would have been motivated to follow Riis’s disclosure to recreate the eight-layer laminate comprising an aggressive chemical-resistant film of Example 5 and would have had a reasonable expectation of doing so to arrive at the claimed invention.

For the reasons discussed with respect to claim 1 above, a POSITA would have found claim 13 obvious. Furthermore, a POSITA would have been motivated to follow Riis’s disclosure to recreate the laminate of Example 5 because chemically resistant films are implemented in a practical end-product packaging that includes a

film laminated to exterior layers. EX1003, ¶¶[208]-[209]. Riis discloses that “[s]ince [the film] is seen by the user/consumer...the exterior surface of the film preferably has desirable optical properties,” and also “preferably withstands contact with sharp object and provides abrasion resistance.” EX1004, ¶[0067]. Riis terms the outer layer an exterior abuse-resistant layer that is most often “the exterior layer of any package, bag, pouch or other container made from the inventive film.” *Id.* In addition to provide abuse resistance to external abrasive forces, the outer layers “may be tough to impart resistance to opening by children.” *Id.* Accordingly, a POSITA would have been motivated to form the example laminate of Riis’s Example 5 by incorporating the aggressive chemical resistant film into an end-user package, such as a pouch, by further adding an abuse resistant outer layer to the film to form a laminate packaging. EX1003, ¶¶[208]-[209]. And, in view of Riis’s teachings of how to produce the laminate of Example 5, as further reinforced by the relevant prior arts’ teachings of similar multilayer films laminated with outer abuse resistant layers, a POSITA would have had a reasonable expectation of success of arriving at the claimed invention. EX1003, ¶[210].

C. Ground III: The Combination of Riis, Wypych, and Tatarka Renders Claims 1-13 Obvious

Claims 1-13 are unpatentable as obvious over the combination of Riis, Wypych, and Tatarka. Riis discloses the entirety of the claimed invention except for specific materials properties, such as the loading ranges and relative melting points

of the component tie layer and contact layer. A POSITA would have found it obvious to look to references such as Wypych and Tatarka to select polymers exhibiting these missing materials properties. Both Wypych and Tatarka show that the materials properties of the types of polymers taught by Riis exhibit ranges overlapping with those of the challenged claims, thereby rendering them obvious.

1. Independent claim 1

b) “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:”

Riis teaches this limitation for same the reasons discussed *supra* § X.B.1.a).

EX1003, ¶[212].

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

Riis teaches this limitation for same the reasons discussed *supra* § X.B.1.b).

EX1003, ¶[213].

Riis teaches a multilayer base film that includes a barrier layer to serve as both a gas and moisture barrier layer. EX1004, ¶¶[0058]-[0059], [00159]-[00163]. Riis’s barrier layer “provide[s] an oxygen permeability sufficiently diminished to protect the packaged article from undesirable deterioration or oxidative processes.” *Id.*, ¶[0060]. Riis’s barrier layer also “provide[s] a moisture permeability sufficiently diminished to protect the packaged article from undesirable deterioration.” *Id.*, ¶[0061]. To accomplish the disclosed function of acting as both a gas and moisture

barrier layer, Riis provides that its barrier layer “can comprise any suitable material,” specifically identifying aluminum foil. *Id.*, ¶¶[0062]-[0063]. Furthermore, as discussed for claim 1, Riis’s Example 5 includes an aluminum foil base layer. *Supra* § X.B.1.b). And, the ’624 patent’s background discussion acknowledges that “[t]he preferred material for a laminate is aluminium due to its good oxygen and water barrier properties.” EX1001, 2:15-20.

Thus, Riis teaches this limitation.

d) “coextruding a tie layer and a contact layer to provide a coextrusion layer,”

Riis teaches this limitation for same the reasons discussed *supra* § X.B.1.c). EX1003, ¶¶[214]-[220].

Riis teaches a multilayer laminate that includes a tie layer and contact layer. Riis’s Figure 1 depicts a cross-section of a six-layer laminate, wherein the layers are (from interior contact layer to exterior): (1) product contacting layer, (2) polyolefin bulk layer, (3) intermediate adhesive layer, (4) oxygen barrier layer, (5) second intermediate adhesive layer, (6) exterior protective layers. EX1004, ¶[00135].

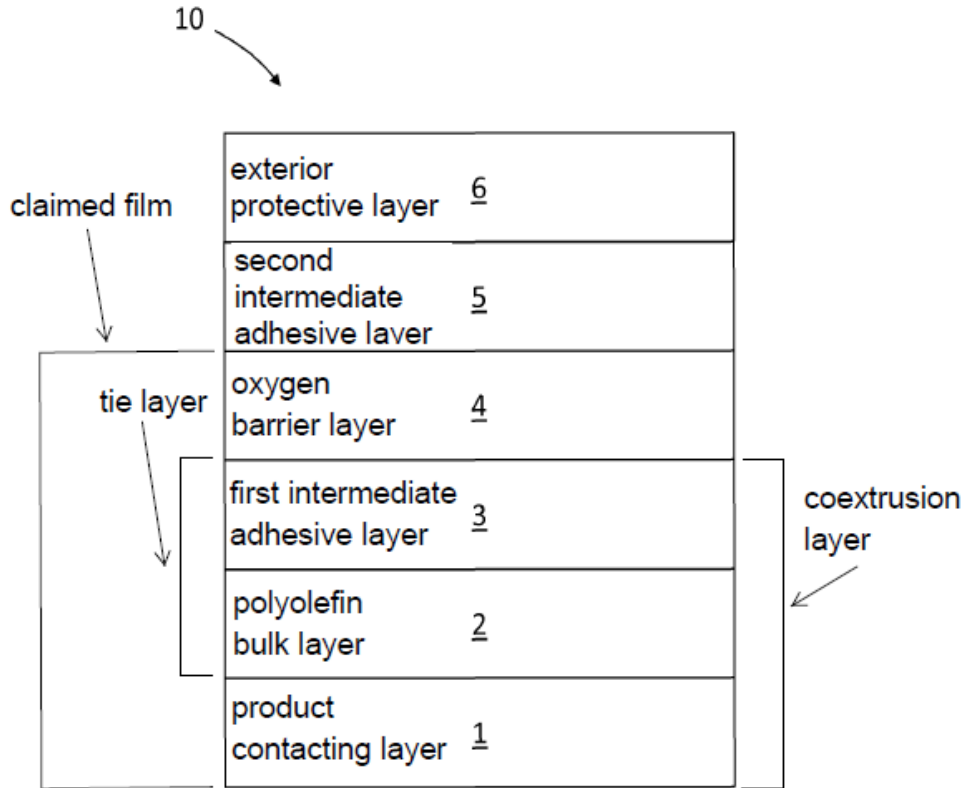


FIG. 1

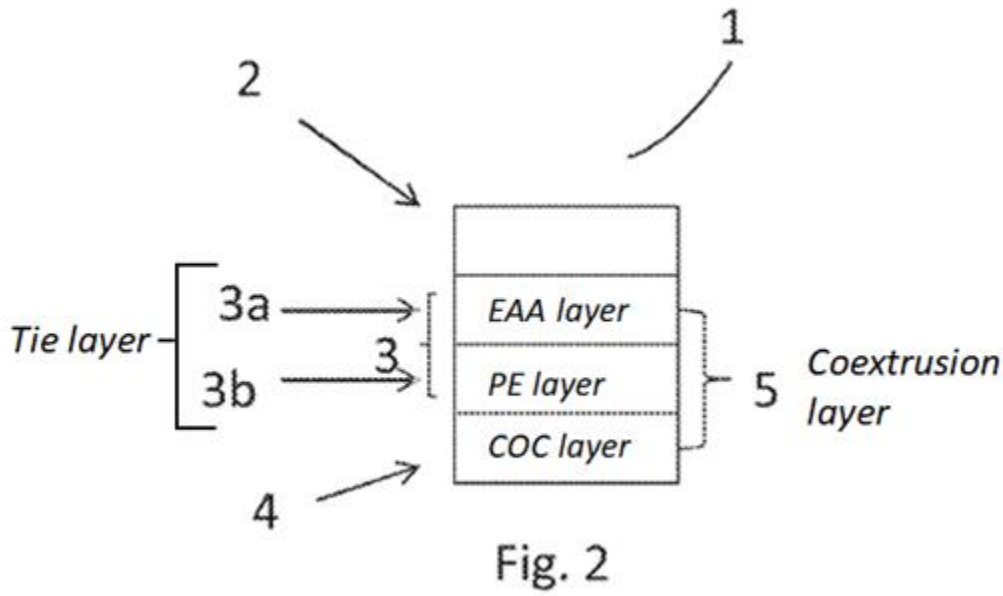
(EX1004, Fig. 1 (annotated))

As to (1), Riis teaches that “[t]he article contact layer comprises at least 90 wt.% of ethylene norbornene COC, more preferably at least 95 wt.%, and most preferably 100 wt.%.” *Id.*, ¶[0055]. As to (2), Riis teaches that “a polyolefin bulk layer can serve as an adhesive or tie layer” and that “[p]referred bulk layers comprise one or more polyolefins such as polyethylene.” *Id.*, ¶¶ [0065], [00135]. As to (3), Riis equates “tie layers” to “adhesive layers” and further explains that “[a]dhesives useful in the present invention include...acrylic and anhydride modified polymers,” such as EAA. *Id.*, ¶¶[0071], [0085], [0088]; EX1003, ¶[217]. As to (4), Riis teaches that

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“[a] barrier layer can comprise any suitable material” and specifies that both moisture and oxygen barrier layers may comprise aluminum foil.” EX1004, ¶[0062]. Riis also teaches that such multilayer films “may be formed by any suitable method including coextrusion, extrusion coating and lamination,” noting that “extruder and die temperatures...for commercially available resins are generally known in the art, or are provided in technical bulletins made available by resin manufacturers.” *Id.*, ¶¶[00157]-[00158]. Furthermore, as detailed *supra* § X.B.1.b)-c), Riis’s Example 5 was manufactured by “three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer based film.” *Id.*, ¶[00174].

The ’624 patent’s disclosure mirrors the pre-dating teachings of Riis. For example, Figure 2 of the ’624 patent depicts an aggressive chemical-resistant film where “tie layer, 3, comprises two layers” where first layer 3*a* is EAA and second layer 3*b* is polyethylene (PE). EX1001, 13:42-46.



(EX1001, Fig. 2 (annotated))

Thus, the '624 patent confirms that EAA and LDPE, as taught by Riis, are a “tie layer” when coextruded with a COC layer onto aluminum foil. EX1003, ¶[220]. This is consistent with Riis’s teaching that the “tie layers may be formed of any suitable thermoplastic materials... in particular members of the polyethylene family such as LLDPE, VLDPE, HOPE, LDPE, ethylene vinyl ester copolymer or ethylene alkyl acrylate copolymer.” EX1004, ¶[0074] (emphasis added). Thus, Riis teaches this limitation.

e) “wherein the contact layer consists of cycloolefin copolymer (COC);”

As detailed *supra* §§ X.B.1.c)-d) and X.C.1.c), Riis teaches this limitation.

f) “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”

As detailed *supra* §§ X.B.1.b) and e) and X.C.1.c), Riis teaches this limitation.

- g) “allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,”***

As detailed *supra* §§ X.B.1.f), Riis teaches this limitation.

- h) “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;”***

As detailed *supra* §§ X.B.1.g) and X.C.1.c), Riis teaches this limitation.

- i) “wherein the tie layer comprises one or more layers, and”***

As detailed *supra* §§ X.B.1.h) and X.C.1.c), Riis teaches this limitation.

- j) “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. ”***

This limitation would have been obvious over Riis in view of Wypych. Riis teaches a variety of polymers suitable for use as a tie layer and identifies LDPE and EAA as exemplary polymers. EX1003, ¶¶[229]-[230]; *see generally* EX1004, ¶¶[0070]-[0080]. A POSITA would also have understood that different commercial applications require optimization of various properties. EX1003, ¶[230]-[231]. In one example, Riis teaches that “[v]arious adhesive layers are formulated and positioned to provide a desired level of adhesive between specific layers of the film.” EX1004, ¶[0072]. In another example, Riis teaches that “[p]referred films may also provide a beneficial combination of one or more of all of the properties including low haze, high gloss, good machinability, good mechanical strength and good barrier properties including high barriers to oxygen and water permeability.” *Id.*, ¶[0080]. In yet another example, Riis teaches that it is desirable to “modify various properties

of the desired film such as heat sealability, interlayer adhesion, wrinkle resistance, puncture resistance, printability, toughness, gas and/or water barrier properties, abrasion resistance, printability, and optical properties such as gloss, haze, freedom from lines, streaks or gels.” *Id.*, ¶[00157]. Riis further teaches various tests that may be used to determine the suitability of particular polymers and layer structures as aggressive chemical-resistant films. *See, e.g., id.*, ¶¶[00175]-[00195]. By looking to inform selection of polymer processing parameters, a POSITA would have known to look to technical bulletins or other sources of knowledge. EX1004, ¶[00158]; EX1003, ¶¶[231]-[232]. Thus, a POSITA would have been motivated to look to reference material, such as Wypych to determine materials properties of exemplary polymers discussed in Riis and to identify other commercial purveyors of such polymers. EX1003, ¶¶[237]-[239]. Accordingly, a POSITA would have looked to publications that provide relevant material properties, including Wypych as a polymer handbook, detailing various polymers useful in coextrusion processing for packaging applications. EX1003, ¶¶[237]-[239]; *see also* EX1005, 1-2; EX1008, 3:55-60. A POSITA would have had reasonable expectation of success in looking to Wypych to identify useful polymers because Wypych’s teachings address polymer properties, processing parameters, and commercial sources of the same commercial polymers taught by Riis. EX1003, ¶¶[237]-[239]; *see also* EX1005, 7, 87, 21 (disclosing under Commercial Polymers that Topas COC, DuPont Nucrel, and DOW

LDPE are all suitable commercially available sources of polymers); *see also* EX1004, ¶¶[0054], [0093], [0095], [0097] (disclosing the use of polymers such as EAA, LDPE, and COC within the scope of being used for forming film packaging and further discloses exemplary commercial suppliers of each polymer, including Dupont, Dow, and Topas).

As discussed *supra* § X.B.1.i), “loading” can be determined from polymer thickness and density. Riis teaches that “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.” EX1004, ¶[0091]. Riis teaches that the polyolefin bulk layer, which may be a tie layer, “may be of any suitable thickness from 0.1 to 7 mils.” *Id.*, ¶[0065]. Riis further teaches that Example 5 has an EAA layer of 0.17 mil and an LDPE layer 0.65 mil. *Id.*, ¶[00174]. Wypych teaches that EAA has a density range of 0.92 g/m²-0.96 g/cm³ and that LDPE has a density of 0.915 g/m²-0.929 g/cm³. Ex. 1005 at 10. Thus, based on the thicknesses of Riis’s Example 5, in view of Wypych, teaches “loading ranges” for the EAA layer of 3.97 g/m²-4.15 g/m² and for the LDPE layer of 15.11 g/m²-15.34 g/m². The sum of those ranges provides the “loading” range of the “tie layer”—19.08 g/m²-19.49 g/m²—which falls within the claimed range of 7 g/m² to 20 g/m². EX1003, ¶[233].

This limitation would have been obvious over Riis in view of Wypych because the loading ranges resulting from the use of exemplary polymers including EAA and

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LDPE at the thicknesses taught by Riis fall within the claimed loading ranges. Specifically, a POSITA would have been motivated to use polymers, such as EAA and LDPE taught by Riis. EX1003, ¶[234]. Wypych taught the density ranges for such commercially available polymers, as well as identifying the manufacturers of such polymers. *Id.* Using EAA and LDPE polymers having the density ranges taught by Wypych results in loading ranges that fall within those of claim 1. *Id.* Accordingly, the claimed loading range is presumed to be obvious. *See Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (finding that a specific exemplary range in the prior art which is within a claimed range anticipates the range); *cf. E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018) (“The point of our overlapping range cases is that, in the absence of evidence indicating that there is something special or critical about the claimed range, an overlap suffices to show that the claimed range was disclosed in—and therefore obvious in light of—the prior art.”).

k) Motivation to Combine and Reasonable Likelihood of Success

In view of Riis’s disclosures regarding exemplary polymers used in Example 5, a skilled artisan would have been motivated to look to Wypych to learn more about the properties and characteristics of exemplary polymers and to identify

suitable commercial sources to obtain polymers for a desired film attribute. EX1003, ¶[235].

Similarly, for at least the reasons discussed with respect to Ground II above, a POSITA would have been motivated to follow Riis's Example 5 to arrive at the claimed inventive film and would have had a reasonable expectation of success in doing so. EX1003, ¶[236].

As discussed above, Riis discloses several desirable properties and attributes of an aggressive chemical resistant film and identifies suitable polymers for forming the film. Riis also teaches that particular polymers used in the processing of forming the film can inform selection of processing parameters, such as by looking to manufacturer provided technical bulletins or other sources of knowledge for used polymers. Thus, a POSITA would have known that polymers disclosed by Riis have known properties and processing parameters and such polymers come from commercial suppliers. EX1003, ¶[237] (citing EX1004, ¶¶[0073], [00158]). A POSITA would have also recognized that Wypych, as a Handbook of Polymers, provides relevant polymer data for use in practical problem solving. EX1003, ¶[238] (citing EX1005).

In view of Riis's disclosure of polymers used to make the film of Example 5 and Wypych's teachings of relevant polymer properties, commercial sources, and processing parameters, a POSITA would have had a reasonable expectation of

success of arriving at the claimed invention. EX1003, ¶[240]. For example, Riis discloses the use of polymers such as EAA, LDPE, and COC within the scope of being used for forming film packaging and further discloses exemplary commercial suppliers of each polymer, including Dupont, Dow, and Topas. EX1003, ¶[240]; EX1004, ¶¶[0093], [0095], [0097]. Wypych similarly discloses “commercial polymers” for each polymer that aligns with the disclosure of Riis, including Dupont for EAA, Dow for LDPE, and Topas for COC. EX1005, 7 (listing Topas and Topas COC), 10 (listing DuPont Nucrel for EAA), 21 (listing Dow LDPE).

Accordingly, a POSITA would have found claim 1 obvious over Riis and Wypych.

2. Claim 2

a) “The method according to claim 1, wherein a melting point of the tie layer differs from a melting point of COC by 30° C or less.”

This limitation would have been obvious based on Riis in view of Wypych and Tatarka. As discussed above, Riis’s Example 5 teaches coextruding a tie layer consisting of EAA and LDPE layers with a contact layer consisting of COC. EX1004, ¶[00174]. Riis does not disclose the melting point of the tie layer or COC but does disclose exemplary polymers that are suitable for coextrusion onto a base film. *Id.*, ¶¶[0093]-[0097]. A POSITA would have been motivated to use the exemplary polymers that Riis discloses to create Example 5, and thereby render the claimed invention obvious. EX1003, ¶¶[235]-[236], [242].

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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” limitations, Wypych (EX1005) discloses various physical properties for polymers, including EAA and LDPE. Wypych discloses the melting point of EAA is 75°C-112°C (EX1005, 10), and the melting point of LDPE is 105°C-115°C (EX1005, 21). The melting point of ethylene norbornene copolymer (COC) is 60°C-125°C, as disclosed in Tatarka. EX1008, 4:43-47, 13:60-63 (disclosing a melting point of 84°C for E-140), 15:11-13 (teaching that preferred COC polymers have melting temperatures of less than 90°C and more than 60°C); EX1003, ¶[243]. Similarly, the 2006 brochure teaches that Topas COCs have a glass transition temperature “from about 80°C to 180°C.” EX1019, 8. As discussed in §§ X.C.1.i)-j) above, a POSITA would have been motivated to look to reference material, such as Wypych, and for similar reasons, Tatarka, to determine materials properties of exemplary polymers discussed in Riis and to identify other commercial purveyors of such polymers. EX1003, ¶¶[237]-[239]. For the same reasons, a POSITA would have had reasonable expectation of success in looking to both Wypych and Tatarka, since the teachings of both address polymer properties, processing parameters, and commercial sources of the same commercial polymers disclosed in Riis. *Supra* §§ X.C.1.i)-j); EX1003, ¶¶[237]-[239].

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As discussed *supra* §§ X.C.1.i)-j), a POSITA would have found it obvious to use the polymers disclosed in Riis, as well as other commercially available resins, to create Example 5. EX1003, ¶¶[83], [138]-[139]. A POSITA would have had a reasonable expectation of success in using commercially available polymers disclosed by Riis in view of Riis's experimental data demonstrating the successful anti-scalping properties of the film of Example 5. EX1003, ¶[236]-[240].

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

As summarized in the table above, the melting points for each of EAA, LDPE, and COC all overlap. And even an alternative interpretation of the melting point of COC as a glass transition temperature overlaps with the melting point ranges of EAA and LDPE. Furthermore, the '624 patent fails to identify any reason that the selection of polymers to obtain the claimed difference in melting points is critical to the claimed invention. Therefore, the melting point of the tie layer differs from the melting point of COC by 30°C or less when the disclosure of Riis, Example 5, is practiced by one of skill in the art. A POSITA would have been motivated to use polymers, such as the COCs taught by Riis to create the film disclosed in Example 5. Accordingly, for the reasons discussed for claim 1 and because the melting temperature ranges for the relevant polymer polymers overlap, a POSITA would

have found claim 2 obvious. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018).

3. Claim 3

a) “The method according to claim 2, wherein a melting point of the tie layer differs from the melting point of COC by 5 to 15 °C.”

A POSITA would have found claim 3 obvious for the same reasons discussed *supra* § X.C.2. for claim 2. EX1003, ¶[245].

4. Claim 4

b) “The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m².”

This limitation would have been obvious based on Riis’s teaching that COC should be used as the product contacting layer. EX1004, ¶[0052]. As discussed *supra* § X.B.1.i), loading can be determined from a known thickness and known polymer density. Riis teaches that “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.” EX1004, ¶[0091]. Riis further teaches that Example 5 has a COC layer of 0.43 mil. *Id.*, ¶[00174]. Wypych teaches that COCs have a density¹⁶ of 1.00-1.08 g/cm³. EX1005 at 7. This is consistent with Riis’s teaching that “[i]n some embodiments, the product contacting layers of the films described herein” have

¹⁶ Wypych identifies a list of “commercial polymers” which includes Topas COC, as listed in the ’624 patent, Riis, and Tatarka

“a density (Δ) of 1.02 g/cm³.” EX1004, ¶[0054]; EX1019, 7. Thus, Riis, in view of Wypych, teaches “loading” ranges for the contact layer of 10.92 g/m²-11.80 g/m². EX1003, ¶[247].

This limitation would have been obvious over Riis in view of Wypych because the loading ranges resulting from the use of exemplary COCs at the thicknesses taught by Riis fall within the claimed loading ranges. EX1003, ¶[248]. Specifically, a POSITA would have been motivated to use polymers, such as the COCs taught by Riis. EX1003, ¶[248]. Wypych taught the density ranges for such exemplary polymers, as well as identifying the manufacturers of such polymers. Using COC polymers having the density ranges taught by Wypych results in loading ranges that overlap with those of claim 4. Accordingly, the claimed loading range is obvious. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985); cf. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018).

Thus, a POSITA would have found claim 4 obvious.

5. Claim 5

c) “The method according to claim 1, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².”

A POSITA would have found claim 5 obvious for the same reasons discussed above for claim 1. EX1003, ¶[250].

6. Claim 6

- d) “The method according to claim 1, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².”***

A POSITA would have found claim 6 obvious for the same reasons discussed above for claim 1. EX1003, ¶[251]. For example, the LDPE portion of the tie layer would have had a “loading” range of 15.11 g/m²-15.34 g/m², which falls within the claimed “loading” range. See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

7. Claim 7

- e) “The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers is in the range of 7 to 20 g/m².”***

A POSITA would have found claim 7 obvious for the same reasons discussed above for claim 1. EX1003, ¶[252].

8. Claim 8

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

A POSITA would have found claim 8 obvious for the same reasons discussed above for claim 1. EX1003, ¶[253]. For example, the tie layer of Example 5 consists of two layers—one EAA layer and one LDPE layer. EX1004, ¶[00174].

9. Claim 9

g) “The method according to claim 1, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.”

A POSITA would have found claim 9 obvious for the same reasons discussed above for claim 1. EX1003, ¶[254].

10.Claim 10

h) “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.”

A POSITA would have found claim 10 obvious for the same reasons discussed above for claim 1. EX1003, ¶[255]-[256]. Riis’s Example 5 includes a tie layer formed from a layer of EAA, an acrylic acid, and a layer of LDPE, a polyethylene. EX1004, ¶[00174].

11.Claim 11

i) “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.”

A POSITA would have found claim 11 obvious for the same reasons discussed above for claims 1 and 10. EX1003, ¶[257].

12.Claim 12

j) “The method according to claim 11, wherein the acrylic acid layer comprises ethylene acrylic acid.”

A POSITA would have found claim 12 obvious for the same reasons discussed above for claims 1, 10, and 11. EX1003, ¶[258].

13.Claim 13

A POSITA would have found claim 13 obvious for the same reasons discussed above for claim 1. *See, e.g., supra* §§ X.B.13), X.C.1.g); EX1003, ¶¶[259]-[262].

XI. THE BOARD SHOULD NOT EXERCISE DISCRETION TO DENY INSTITUTION UNDER 35 U.S.C § 325(d)

The Board should decline to exercise discretion to deny institution under 35 U.S.C. § 325(d), because the Office erred in a manner material to the patentability of all claims of the '624 patent. Riis was cited by an examiner during examination of a patent application related to the '624 patent – the parent '999 application.¹⁷ However, the examiner of the '018 application, which led to the '624 patent, was a different examiner and failed to appreciate the teachings of Riis as they apply to the claims of the '624 patent. As shown above, Riis did more than teach multilayer films and provide lists of suitable polymers. Riis taught an example nearly identical to the '624 patent's preferred embodiments of Figures 2 and 3 and that met the “consisting of” limitation that the Examiner identified in their Reasons for Allowance. And a POSITA would have understood that, to the extent the “loading” range limitations that the Examiner identified in their Reasons for Allowance are definite, the

¹⁷ U.S. Patent Application No. 16/835,018 (the “'018 application”), which claims domestic benefit of U.S. Patent Application No. 15/780,999 (the “'999 application”), issued as the '624 patent. Ex. 1001, codes (21), (63); *see also* EX1002, 350–51 (providing Domestic Benefit/National Stage Information in Application Data Sheet as filed Mar. 30, 2020).

“loading” ranges of Riis’s Example 5 met those limitations. Accordingly, reasonable minds cannot disagree that it was material error by the Office to overlook the teachings of Riis.

A. Legal Framework of 35 U.S.C. § 325(d)

Institution of a post grant review is discretionary and is guided by 35 U.S.C. § 325(d), which states, in relevant part, that “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” In determining whether to exercise discretion to institute, the Board considers several non-exclusive factors, including:

- a) the similarities and material differences between the asserted art and the prior art involved during examination;
- b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art;
- e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art;
- f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, Case IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017) (“*Becton Dickinson*”) (precedential as to § III.C.5, first para.). The so-called *Becton Dickinson* factors outlined above are grouped for

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consideration according to *Advanced Bionics*, which groups factors (a), (b), and (d) as relating to whether prior art or arguments were previously presented to the Office; and groups factors (c), (e), and (f) as relating to whether the petitioner has demonstrated error by the Office. *Advanced Bionics, LLC v. Med-El Electromedizinische Geräte GMBH*, IPR2019-01469, Paper 6 at 10 (Feb. 13, 2020) (“*Advanced Bionics*”) (precedential). In accordance with these groupings, *Advanced Bionics* provides the following two-part framework to apply for § 325(d) analysis:

- 1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
- 2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Id. at 8.

B. Whether the Same or Substantially the Same Prior Art or Arguments Were Previously Presented to the Office

Although Riis was before the Office upon issuance of the ’624 patent, Riis was not evaluated during examination of the ’624 patent and should not be considered the same prior art previously presented to the Office. Unlike the paperboard food packaging and organic liquid packaging prior art evaluated during examination, Riis provides a film and laminate packaging aim at preventing migration through the film of the aggressive chemicals recited in the ’624 patent claims. A comparison of Riis to the previously presented art clearly shows Riis as

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the closest art of record. To the extent aspects of Riis were previously presented to another Examiner in the context of the parent to the '624 patent, the Examiner of the '624 patent clearly erred by failing to consider Riis. That failure amounts to a disregard of pertinent art that warrants reconsideration of the '624 patent.

a) The combination of Riis and Wypych was not considered by the examiner of the '624 patent, and the disclosure of Riis provides an aggressive chemical-resistant film with features not contemplated by Bowen or Adams as considered during examination.

Examiner considered only two prior art references throughout examination of the '624 patent, Adams and Bowen. See EX1001, code (56); *see generally* Ex. 1002. Patent Owner (then Applicant) filed two separate Information Disclosure Statements (IDSs) prior to any action on the merits of the '018 application. See EX1002, 246-52, 255-58. Prior to reviewing and considering the IDSs, a Requirement for Restriction was made by a first examiner (Examiner 1), the examiner of the parent application. *Id.* at 241-44. After Applicant elected, without traverse, claims directed to the process of making the film, a second, different examiner (Examiner 2) considered the IDS references and issued a Non-Final Office Action rejecting all pending claims in view of Adams alone, or in combination with Bowen. See *id.* at 235 (Applicant's election of claims directed to a method of making a film), 226 (Examiner 2 consideration of IDS containing foreign priority WIPO publication), 214-18 (IDS containing 57 references, one of which being Riis, signed as considered by Examiner 2), 201-05 (Non-Final Office Action rejecting all elected claims over

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Adams or the combination of Bowen and Adams). In the same Non-Final Office Action, Examiner issued two provisional double patenting rejections in view of copending application Nos. 16/425,067 and 16/780,999 (the parent application to the '018 application). *Id.* at 206-08. Despite several amendments to the claims and accompanying remarks attempting to distinguish the claimed invention from the prior art and copending applications, Examiner 2 continued to reject pending claims of the '018 application as unpatentable over Adams, or a combination of Bowen and Adams, until eventually allowing the claims to issue as the '624 patent. Thus, the prosecution history of the '624 patent demonstrates that Adams and Bowen were the only prior art evaluated by the Examiner during examination.

To the extent that Patent Owner asserts that Riis was involved with or evaluated during examination due to the inclusion of Riis within a signed IDS, such cursory consideration is not enough to warrant denial of a petition under § 325(d). *See, e.g., Digital Check Corp. d/b/a ST Imaging v. E-Imagedata Corp.*, IPR2017-00178, Paper 6 at 12-13 (PTAB Apr. 25, 2017) (acknowledging that a prior art reference was cited in an IDS, but granting institution because there was no indication that the claims were rejected based on those references or that the examiner substantively discussed those references during prosecution); *Fox Factory, Inc. v. SRAM, LLC*, IPR2016-01876, Paper 8 at 7-9 (PTAB Apr. 3, 2017) (denying institution under 325(d) for grounds based on prior art references that were

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substantively addressed during prosecution, but refusing to deny institution based on 325(d) for grounds based on a prior art reference that was simply cited in an IDS and not considered at any length); *Praxair Distribution, Inc. v. INO Therapeutics LLC*, IPR2015-00893, Paper 14 at 8 (PTAB Sept. 22, 2015) (granting institution even though the references were previously cited in an IDS because Patent Owner failed to identify with specificity where the references asserted in the Petition were considered during examination). The Board has consistently held that a reference that “was neither applied against the claims nor discussed by the Examiner” does not weigh in favor of exercising discretion to deny institution. *Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (PTAB Jan. 17, 2019); *see also Shenzhen Zhiyi Technology Co. Ltd., d/b/a iLife v. iRobot Corp.*, IPR2017-02137, Paper 9 at 9-10 (PTAB Apr. 2, 2018) (declining to exercise discretion under 35 U.S.C. § 325(d) when the reference was merely cited in a Notice of References Cited); *Hobbico, Inc. v. Traxxas, L.P.*, IPR2018-00010, Paper 8 at 19 (PTAB Apr. 18, 2018) (explaining that mere citation of a reference in an IDS and consideration without comment was insufficient to indicate the Examiner substantively considered the references).

Outside of Riis’s inclusion within a signed IDS, the Examiner failed to consider the relevance of Riis as it applied to the pending method claims. Although Riis was considered during examination of the parent ’999 application, Riis was not similarly considered during examination of the ’018 application which led to the

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'624 patent. *Solvay USA, Inc. v. WorldSource Enterprises, LLC*, IPR2019-00046, Paper 7 at 13 (PTAB Aug. 13, 2019) (“While we recognize that the parent and grandparent file histories were cited in an Information Disclosure Statement (“IDS”) during prosecution of the '108 patent[], Patent Owner provides no evidence that [the asserted prior art references] were relied on by the Examiner in a rejection during prosecution of the '108 patent.”). Further, Riis was not considered during examination of the '018 application in the same manner as it was considered during examination of the parent '999 application, because there were different examiners between the two applications. *Compare* Ex. 1002, 216 (showing Riis as one of 57 references submitted to Examiner in an IDS filed June 1, 2020 and considered by one Examiner), *with* EX1009, 77-80, 126-27 (evidencing a different Examiner's continued reliance on Riis throughout examination); *cf.* *Cultec, Inc. v. StormTech LLC*, IPR2017-00777, Paper 7 at 9-10 (PTAB May 24, 2017) (finding in part that because the Examiner of the challenged patent was also the Examiner of a related application in which the asserted reference was considered, the Examiner “was well-aware of the [asserted] reference and its specific disclosure.”) (designated informative).

Riis presents disclosures related to the '624 patent not contemplated by Adams or Bowen as considered during examination. Examiner of the '624 patent acknowledged that Adams is directed to a process of making a paperboard laminate

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for food packaging of orange juice or milk, not aggressive chemicals like nicotine, fentanyl, rivastigmine, or lidocaine. EX1002, 21. Similarly, examiner recognized Bowen as directed to a film for packages containing organics such as amines, xylenes, toluene, and epoxies. *Id.* at 22. Both examiner findings ultimately contributed to the stated Reasons for Allowance. *Supra* § VI.B. In contrast to Adams and Bowen, *Riis* directly provides for packaging of aggressive chemicals such as nicotine, fentanyl, lidocaine and rivastigmine. EX1004, ¶[0011]. *Riis* is further materially distinct from the disclosures of Adams and Bowen due to *Riis*'s disclosure of a film structure consisting of only necessary layers to provide a coextrusion layer, including a COC contact layer, and barrier layer, and the finished laminate product containing an outer protective layer adhered to the barrier layer comprising aluminum. *See supra* §§ X.B.1,13. As shown in the examiner's reasons for allowance, Adams includes additional fillers in layers and Bowen fails to provide a COC contact layer. EX1002, 21-22. For at least these reasons, *Riis* presents a disclosure more closely aligned with the claims of the '624 patent and is noncumulative over Adams and Bowen.

b) The Petition's reliance on Riis and Wypych as materially distinct references from that of Adams or Bowen presents nonoverlapping arguments to those considered during examination.

There is little to no overlap between Examiner arguments made during examination and the Petition, because the combination of prior art asserted in the

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Petition presents a new ground of unpatentability not addressed during examination. Examiner relied upon Adams and Bowen during examination to provide a general film structure and coextrusion process, but Examiner notably found that the references failed to explicitly disclose limitations reciting the loading value of the tie layer and melting points. *See* EX1002, 62-67 (Examiner generally relying upon design choice and routine optimization to achieve the claimed loading range and inherent material properties to achieve the claimed relative melting points). Examiner's rationale in finding the claim obvious over Adams and Bowen was based primarily on general arguments for unpatentability based on case law and anticipation of ranges; once this rationale was overcome, the Examiner failed to present any additional evidence of unpatentability based upon prior art. *See id.*; *see also id.* at 21-22, 25, 42, 46-52 (providing the Reasons for Allowance directly followed an Applicant amendment and interview presenting arguments to traverse Adams and Bowen). Examiner failed to cite to any disclosures in the reference in direct contrast to Adams and Bowen and as shown in the discussion of Riis and Wypych above, Riis discloses specific thicknesses and materials of the tie layer polymers and contact layer COC such that in combination with the materials properties disclosed by Wypych, the asserted combination provides all claimed limitations without resorting to exemplary obviousness rationales that do not rely on prior art references (e.g., routine optimization). *See supra* §§ X.B.1.i)-j), X.B.2-3.

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In addition to different scope of disclosure between the asserted prior art and the art considered during examination, Examiner's explanation as to how and why a person of ordinary skill in the art would combine the references is wholly different from that asserted in this Petition. During prosecution, Examiner found that one of ordinary skill in the art would have combined the teachings of Adams and Bowen because "linear polyolefins and cyclic olefin copolymers are interchangeably used as contact layers." EX1002, 66 (citing EX1006, ¶ 23). In this Petition, the rationale to combine the disclosure of Riis with the material properties provided by Wypych and Tatarka is simply to evidence relevant and applicable material properties one of ordinary skill in the art would look to for practical applications and research regarding a variety of polymers. *See generally supra* § X.C. Moreover, Riis provides an Example 5 that mirrors both the structure and materials of the film produced by the claimed method, thus providing a disclosure substantially closer to the claimed invention than the prior art of record.

C. Whether the Office Erred in a Manner Material to the Patentability of the Challenged Claims

The Office erred in a manner material to patentability by failing to consider Riis in a basis for rejection of the claimed method of providing a film. In particular, the Examiner of the '018 application which led to the '624 patent considered only the prior art that was identified in the ISR/WO of the ultimate priority application WO 2017/114922 A1 and wholly ignored the Riis reference considered in detail in

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the parent '999 application. See EX1002, 226 (Examiner considered IDS denoted priority WIPO application), 259-99 (evidencing submitted Foreign Reference filed June 1, 2020 and ISR listing Adams and Bowen as documents of particular relevance). By overlooking the specific teachings of Riis identified by a different Examiner in the parent '999 application, the Examiner erred in a manner material to the patentability of the issued claims of the '624 patent.

a) Riis was not substantively considered or applied to the claims of the '624 patent.

As previously indicated above, Riis was not substantively evaluated during examination of the '624 patent, only Adams and Bowen. As evidenced generally by the prosecution history of the '624 patent, all rejections in view of the prior art involved Adams, a combination of Bowen and Adams, or the copending '067 and '999 applications. Although Riis was relied upon during examination of the parent '999 application, there is no evidence establishing that Riis served as a basis for rejection during examination of the '624 patent.

To the extent that Patent Owner argues that consideration of Riis in the parent '999 application directly bears upon the patentability of the '624 patent, such argument ignores the critical limitation reciting cyclic olefin copolymer as the film contact layer. In particular, Applicant in the '999 application specifically amended independent claims to exclude cyclic olefin copolymer as the contact layer in order to traverse the applied Riis reference which ultimately led to allowance. See Ex.

1009, 61-70 (Amended Claims and Applicant Remarks filed Nov. 22, 2021 omitting cyclic olefin copolymer as the material of the contact layer), 14-15 (Examiner Reasons for Allowance in the Notice of Allowance mailed Apr. 8, 2022). Accordingly, discussion of the Riis reference in the parent '999 application cannot suffice as evidence of the same consideration in the '624 patent due to the clear difference in claim scope.

b) The examiner of the '624 patent failed to recognize the applicability of Riis as shown by a different examiner's application of a Riis in a related application

The Examiner erred in evaluating Riis as an applicable prior art reference by failing to consider Riis's application to substantially similar claims in the '999 application. Importantly, the examiner in the '018 application considered the lengthy IDS containing Riis before the same IDS material and submitted foreign references were considered in the parent '999 application or any action on the merits in the '999 application. Because the IDS containing reference to Riis and the accompanying copy of the Riis WIPO publication was submitted in the '999 application, even though not considered by the examiner of the '999 application at the time, the examiner in the '018 application failed to appreciate the Riis reference since no copy of the WIPO publication had been submitted in the '018 application.

Further, the examiner of the '624 patent failed to search all foreign publications listed on the IDS where Riis was submitted and instead chose to

individually search US Patent publications identified in the ISR. *Compare* Ex. 1002, 223 (Examiner search strategy and results search strings S1-S7 indicating individual references search as listed on the ISR), *with* 296-99 (ISR denoting specific disclosures of Bowen and Adams as relevant to the claimed invention). Accordingly, the examiner chose to merely assert two prior art references previously identified as relevant in an ISR and continue to assert only those two references throughout examination even though other prior art relevant to the '624 patent.

c) Examiner misapprehended and overlooked the teachings of Adams laminate structure as including the “consisting of” structure of the claimed film

Examiner's Reasons for Allowance include acknowledging Adams “fails to teach making a film consisting only of a base layer comprising aluminum, and a coextrusion layer consisting only of a tie layer and a contact layer, and wherein the contact layer consists of only COC,” because Adams “discloses a process of making a film that provides...an aluminum base layer, a COC-containing contact layer, an EAA-containing tie layer, and several more layers, and wherein one or more layers comprise a filler.” EX1002, 21. Applicant's argument that led to the reason for allowance addresses the embodiment of Figure 3 of Adams which includes additional layer or layers of filler. *Compare id.* at 49 (including Applicant argument that Adams Figure 3 and paragraph 31 require a laminate structure that includes an additional layer of filler with the tie layer and food contact layer, where the filler

layer is applied between the tie layer and contact layer), *with id.* at 21 (addressing Figure 3 and paragraph 31 of Adams as not disclosing the claimed layer). However, Examiner wholly ignored Adams's disclosure relating to Applicant's first argument.

Applicant's first argument addressing laminate structure of Figure 2 is as follows:

With reference to FIG. 2, Adams describes that "the laminate structure of FIG. 2 comprises an exterior coating 9 that is applied onto the paperboard substrate 10." [Adams], ¶ [0030]. However, a laminate structure including a substrate and exterior coating is not the same as a "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," as recited in amended independent claim 1 (emphasis added). Rather, Adams describes example laminate structures that include more than a base layer, a tie layer, and a contact layer. *Id.*, ¶ [0034].

Id. at 48. Applicant argues the additional layers, including a paperboard substrate and outer protective coating, all laminated to an outer side of the functional barrier layer fail to disclose the claimed film consisting of the base layer, tie layer, and contact layer.

Examiner overlooked or misconstrued Adams Figure 2 and paragraph 30 as disclosing a base layer comprising aluminum, among other additional outer protective layers, a layer with or without filler (a tie layer), and a COC food contact layer. Adams Figure 2 shows a laminate structure, much like that recited in independent claim 13, further including the claimed film. *See supra* §§ VI.B

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(discussing the open-ended claiming of base layer during examination), X.B.1.g (discussing the plain language of the claim allowing for exterior adhesive and protective layers laminated at the base layer).

d) Riis's disclosure as clearly applicable to the claims of the '624 patent, in combination with the relevant material property teachings of Wypych present additional evidence that warrant reconsideration

As shown in this Petition above, the Riis reference was mistakenly not considered during examination of the '624 patent. As discussed regarding whether the same or substantially the same prior art was previously presented to the Office, Riis provides clear disclosures related to the claims of the '624 patent that were missing from the Adams and Bowen references as applied during examination.

To the extent Patent Owner asserts that Riis was “evaluated” or “considered” during examination by mere citation in an IDS as part of the parent '999 application file history, this Petition sets forth sufficient facts that warrant reconsideration of the Riis reference in combination with Wypych as it applies to the '624 patent. *Solvay USA, Inc. v. WorldSource Enterprises, LLC*, IPR2019-00046, Paper 7 at 15 (PTAB Aug. 13, 2019).

XII. CONCLUSION

Petitioner respectfully requests post-grant review and cancellation of claims 1-13 of the '624 patent.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 37 C.F.R. § 42.24(b). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 18,462 words, excluding the parts of the Petition exempted by 37 C.F.R. § 42.24(a).

Dated: December 1, 2022

/s/ Ryan D. Levy
Ryan D. Levy
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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e) and 42.105(a))

The undersigned hereby certifies that, on December 1, 2022, true and correct copies of the foregoing **PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 11,260,624 B2**, the accompanying Power of Attorney, and all associated exhibits were served in their entirety on the following parties via in-person service and USPS Priority Mail Express:

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