

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG,
Petitioner

v.

ADAPA FLEXIBLES DENMARK SLAGELSE A/S
f/k/a DANAPAK FLEXIBLES A/S,
Patent Owner

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

**PETITIONER’S OPPOSITION TO PATENT OWNER’S
REVISED MOTION TO AMEND**

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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	Adams, U.S. Pat. App. Pub. 2005/0037162
1007	Bowen et al., U.S. Patent No. 6,120,860
1008	Tatarka et al., U.S. Patent No. 9,452,593
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
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I. INTRODUCTION

Petitioner Huhtamaki Flexible Packaging Germany GmbH & Co. KG (“Huhtamaki”) opposes Patent Owner’s Revised Motion to Amend (Paper 31, herein “RMTA”). Patent Owner fails to capitalize on its second attempt to amend its claims and instead proposes incremental amendments that cannot patentably distinguish the claims from the prior art. The RMTA should be denied because substitute claims 14–24 remain obvious over the prior art previously asserted, as well as the references cited herein. A summary of Petitioner’s grounds for opposition is provided below:

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

II. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE OVER THE PRIOR ART

A. Substitute Claims 14, 15, and 20–24 Are Unpatentable as Obvious Over the Combination of Riis and Wypych

1. Substitute Claim 14

Patent Owner’s new revised amendments to substitute claim 14 require the coextrusion layer to include a tie layer having a first layer and a second layer. RMTA, 17-18. The combination of Riis and Wypych renders amended substitute claim 14 obvious for at least the reasons set forth below, further in view of Petitioner’s Opposition to the Motion to Amend for claim 14, and further in view of

the Petition and Petitioner's Reply regarding original claim 1. Pet. 31–45, 53–64; Pet. Reply, 4–16, Opp. MTA, 8–11. The limitations for amended substitute claim 14 not addressed specifically below have been previously argued by Petitioner and are rendered obvious by Riis in view of Wypych. See Opp. MTA, 8–11 (addressing “a base layer consisting of aluminum”); see also Prelim. Guidance, 9–10 (finding “a base layer consisting of aluminum” to be met by Riis at the preliminary stage).

a) Riis discloses a “coextrusion layer consisting of [a] tie layer [comprising a first layer and a second layer] and [a] contact layer.”

Riis discloses an exemplary film having a tie layer made with two individual layers, the first being EAA and the second being LDPE. See Pet. 40 (citing EX1004, ¶174; EX1003, ¶¶149, 154). Riis further utilizes a three-layer coextrusion with EAA and LDPE combined with COC as a “sealant film,” which is adhered to an aluminum barrier layer of a base film to form a multilayer film or laminate. See Pet. 31–45, 53–64 (citing EX1004, ¶¶159–62, 173–74). As addressed in Petitioner's Reply, a POSITA would understand the LDPE layer of Riis to meet the claimed tie layer for providing sufficient adhesion to promote adherence of adjacent layers in a multilayer film. Pet. Reply, 4–16; EX1004, ¶¶69, 71, 74. Accordingly, Riis provides a sealant film as the claimed coextrusion layer, with EAA as a first layer of the tie layer and LDPE as a second layer of the tie layer, and COC being the contact layer.

2. Substitute Claim 15

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

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

3. Substitute Claim 20

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

4. Substitute Claim 21

Substitute claim 21 amends original claim 10 to recite “wherein at least one of the ~~one or more layers~~ first layer of the tie layer and the second layer of the tie layer comprises an acrylic acid layer or a polyethylene layer.” RMTA, 29. For the same reasons above regarding Substitute Claim 14 and as set forth in the Petition

regarding original claim 10, the combination of Riis and Wypych render substitute claim 21 obvious. *See supra* § II.A.1.a; Pet. 50, 70 (citing EX1003, ¶¶197–98, 255–56; EX1004, ¶174). Additionally, the exemplary film of Riis further utilizes a three-layer coextrusion with EAA and LDPE as the first and second layer of the tie layer, combined with COC as the contact layer, thereby producing a “sealant film,” which is adhered to an aluminum barrier layer of a base film to form a multilayer film or laminate. *See* Pet. 31–45, 53–64 (citing EX1004, ¶¶159–62, 173–74). Thus, Riis discloses that at least one of the first layer and second layer of the tie layer comprises an acrylic acid layer (e.g., EAA) or a polyethylene layer (e.g., LDPE).

5. Substitute Claim 22

The RMTA amends original claim 11 to recite the chemical is provided in a first patch and add a definition for an aggressive chemical-resistant film based upon allowing a set percentage of chemical migration in comparison to a film comprising polyacrylonitrile. RMTA, 29. Substitute claim 22 is substantially the same as substitute claim 20 from the original MTA, except that Patent Owner replaces the trademark Barex® with polyacrylonitrile. *Compare* RMTA, 29 *with* MTA, 28–29.

As the Petition established, the combination of Riis and Wypych provides first and second layers of the tie layer comprising an acrylic acid layer and a polyethylene layer. Pet. 50, 70 (citing EX1003, ¶¶197–99, 255–57; EX1004, ¶174). For substantially the same reasons set forth in the original Opposition regarding then

substitute claim 20, the combination of Riis and Wypych render the additional limitations of substitute claim 22 obvious. Opp. Mot. 23–24. The Board agreed. Prelim. Guidance, 13–14.

First, Riis discloses that the package formed by its inventive film can be used to contain, for example, a transdermal drug delivery patch. EX1004, ¶92. Second, Riis discloses a range of 0–15% of chemical migration as compared to a similar Barex® product contacting layer, which provides the claimed migration of 90–110% when compared to films with a polyacrylonitrile contact layer. EX1004, ¶¶129, 132; EX1038, ¶¶75–76. Although Riis discloses its film’s resistance to migration in comparison to Barex®, Riis also recognizes that Barex® films comprise polyacrylonitrile—thus disclosing its aggressive chemical-resistant film as compared to films comprising polyacrylonitrile contact layers. *See* EX1004, ¶4; *see also* Prelim. Guidance, 13 n.7 (concluding Barex® as a polyacrylonitrile renders the films of the ’624 Patent and Riis the same).

Because Riis discloses a range of 0–15% of chemical migration as compared to a similar Barex® (*e.g.*, polyacrylonitrile) product contacting layer, Riis provides the claimed migration of 90–110% when compared to films comprising polyacrylonitrile. EX1038, ¶¶75–76; *ClearValue Inc. v. Pearl River Polymers Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012). Accordingly, substitute claim 22 is rendered obvious by the combination of Riis and Wypych.

6. Substitute Claim 23

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

7. Substitute Claim 24

Substitute Claim 24 is similar to substitute claim 14, the difference being the claim is directed to a laminate instead of a film, and the portion of the preamble referring to “the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine” is now in the body of the claim. For the same reasons discussed above for substitute claim 14, which are incorporated herein, the combination of Riis and Wypych renders substitute claim 24 obvious. *See supra* § II.A.1. The combination also renders substitute claim 24 obvious for the reasons set forth in the Petition and Petitioner’s Reply regarding original claim 13. *See* Pet. 51–53, 71 (citing EX1003, ¶¶201–10, 259–62; EX1004, ¶¶161–68, 173–74); Pet. Reply, 4–16. The RMTA fails to argue the patentability of substitute claim 24 over original claim 13 or over substitute claim 14 and fails to specifically address the patentability of substitute claim 24. *See generally* Revised MTA.

Per 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.” EX1001, 11:64–12:8. Riis’s Ex. 5 is an eight-layer laminate with 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, ¶¶161–68, 173–74. The Al foil/EAA/LDPE/COC layers constitute the claimed “film,” and with the outer layers included, Riis teaches the claimed “laminate.” EX1003, ¶¶204–05.

B. Substitute Claims 16–18 Are Unpatentable as Obvious Over Riis in View of Wypych, and Further in View of Holzmuller

1. Substitute Claim 16

Substitute claim 16 recites (1) loading ranges for the entirety of the tie layer falling between 7 and 20 g/m² as well as (2) each of the first layer and second layer of the tie layer falling within a range of 1–14 g/m². RMTA, 27. Although Riis discloses an exemplary loading range of 0.17 mil for the EAA layer as the first layer (a loading range of 3.94 g/m² to 4.15 g/m² (see Pet. 41–42)) and therefore falls within the claimed 1–14 g/m² range, the exemplary loading of the 0.65 mil LDPE layer as the second layer (a loading range of 15.11 g/m² to 15.34 g/m² (see Pet. 41–42)) falls just outside of the claimed 14 g/m² upper bound of the loading range of the second layer. See RMTA, 19. However, a POSITA would have found it obvious to modify Riis’s films with Holzmuller to optimize the interacting thicknesses of the layers of

the tie layer to prevent undesirable lamination, provide both mechanical and chemical stability, have a high tear resistance, and a high level of diffusion resistance which can be achieved through routine experimentation. EX1038, ¶¶87–88.

Holzmuller teaches the advantages of utilizing various thicknesses for intermediate bonding layers of multilayered constructions to achieve laminates with improved barrier properties as well as optimized properties. EX1034, ¶¶19, 20, 23. Holzmuller further recognizes that the tie layer materials disclosed by Riis, EAA and LDPE, are suitable polymeric materials that allow for advantages in laminates with multilayered intermedial layers, including improved barrier properties as well as optimized mechanical and chemical properties. *Id.*, ¶¶18, 23.

Holzmuller also teaches that bonding layers formed from polyolefins like polyethylene may be in an allowable thickness range of 5–140 μm (0.197–5.512 mils), a preferred range of 8–95 μm (0.315–3.740 mils), and an especially preferred range of 10–50 μm (0.394–1.968 mils). EX1034, ¶19; EX1038, ¶90. Regarding the thickness of bonding layers (such as a first bonding layer) formed from EAA, Holzmuller teaches thickness from 5–140 μm (0.197–5.512 mils), preferred thicknesses of 8–95 μm (0.315–3.740 mils), and especially preferred thicknesses of 10–50 μm (0.394–1.968 mils). EX1034, ¶19; EX1038, ¶94. Using the same conversion the Board and Patent Owner have credited to Dr. Spontak, Holzmuller teaches loading ranges of LDPE from 4.6–130.1 g/m^2 , preferably from 7.3–88.3

g/m², and especially preferably from 9.2–46.4 g/m². EX1038, ¶¶91-93. For an EAA layer, Holzmuller teaches loading ranges from 4.6–134.4 g/m², preferred from 7.4–91.2 g/m², and especially preferred from 9.2–48.0 g/m². *Id.*, ¶¶94-97.

Holzmuller thus teaches allowable ranges that overlap with the newly claimed loading range of 1–14 g/m²; the combination of Holzmuller with Riis and Wypych accordingly renders substitute claim 16 obvious. *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) (prima facie obviousness where prior art range encompasses claimed range); *In re Wertheim*, 541 F.2d 257 (CCPA 1976) (prima facie obviousness where claimed ranges overlap prior art ranges). A POSITA would recognize that Holzmuller discloses “additive effect[s]” by modifying thicknesses of intermediate bonding layers to achieve desirable properties of films, including barrier layer protection, sufficient adhesion for lamination, and desired mechanical and chemical properties. EX1034, ¶¶3–4, 7, 20; EX1038, ¶99.

a) Motivation to Combine Riis and Wypych with Holzmuller

Riis provides an aggressive chemical resistant film formed by coextrusion coating a three-layer sealant film of EAA/LDPE/COC onto an aluminum foil barrier layer. Although Riis provides dimensions with its exemplary film, Riis also discloses a wide range of possible thicknesses that can be used for layers of its inventive films, including intermediate layers having tie layers. *See e.g.*, EX1004, ¶91 (providing the “entire multilayer film[] or any single layer . . . can have any suitable thicknesses,

including 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 mils, or any increment of 0.1 to 0.01 mil therebetween”). However, Riis does not specifically disclose the loading ranges of substitute claims 16–18.

Holzmuller teaches the need to balance materials and thicknesses of intermediate bonding layers used in multilayered laminates of the packing industry to prevent delamination, block internal barrier layers from packaged substances, optimize haptic properties like stiffness, provide chemical and mechanical stability, have high tear resistance, and keep costs low. EX1034, ¶¶3–4, 7, 20. Holzmuller emphasizes that multilayered intermediate bonding layers in such films can produce additive effects. *Id.*, ¶¶19, 20, 23. As taught by Riis, Holzmuller similarly recognizes polymers like EAA and “polyolefins, especially polyethylene (PE)” provide suitable bonding layers for laminates. *Id.*, ¶18. Accordingly, Holzmuller would have motivated a POSITA to tailor and optimize the thicknesses, and thus the loadings, of the intermediate bonding layers as applied to Riis’s LDPE and EAA tie layers to achieve desired properties of the multilayered intermediate tie layers disclosed in Holzmuller. EX1038, ¶¶98-101. This would impart the associated beneficial characteristics upon the resultant film or laminate, including high mechanical and chemical stability, a high degree of stretchability with high tear resistance, a high level of resistance to diffusion, the possibility of achieving good drive, and good haptic properties. *Id.* The optimized ranges taught by Holzmuller show that a

POSITA would tailor such ranges to achieve the desired results. *Id.*, ¶¶98–100. A POSITA would thus be motivated to optimize Riis’s intermediate tie layers to achieve desired additive effects and would have had a reasonable expectation of success in doing so due to the similarity in structure, function, and polymeric materials considered by both Riis and Holzmuller. *Id.*, ¶¶98–103.

Regarding the RMTA’s assertion that “Riis teaches away from using multi-layer tie layers,” Riis merely expresses a general preference for a single multifunctional tie layer, but does not “criticize, discredit or otherwise discourage” use of multi-layer tie layers. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004); *see also* Pet. Reply, 14–15 (addressing this same argument). The RMTA implicitly acknowledges such in its citation to Riis. *See* RMTA, 13–14 (citing EX1004, ¶71). Accordingly, the RMTA’s assertion that Riis teaches away from multi-layer tie layers fails to appreciate all the prior art reference teaches to a skilled artisan. *See Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804 (Fed. Cir. 1989) (a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments.).

Regarding substitute claim 16, a POSITA would *not* be discouraged from decreasing the thickness of Riis’s exemplary 0.65 mil LDPE layer during routine experimentation. RMTA, 20 (citing EX2015, 83:9–22); EX1038, ¶101. Riis specifically provides that such LDPE layers, even denoted as bulk layers, can range

from 0.1–7 mils. EX1004, ¶65; EX2015, 82:24–83:6 (confirming the 0.1–7 mil thickness range for a bulk layer is *not* “relative to the overall thickness of the film”) (emphasis added). Second, Dr. Spontak testified that to contribute to the structural properties of the film, then “you *might* want [a bulk layer] to be *slightly* thicker.” EX2015, 83:9–22 (emphasis added). Dr. Spontak specifically rebuts Patent Owner’s characterization by clarifying that if such an LDPE is “to be used in concert with another adhesive like EAA, then you probably want it to be on the thinner side.” *Id.*

b) Reasonable Expectation of Success

A POSITA would recognize that Holzmuller’s multilayered laminates are structurally, functionally, and polymerically similar to the films disclosed by Riis. First, Holzmuller—like Riis—relates to multilayer films exposed to chemicals that may leach through the film laminate. EX1034, ¶¶2–3; EX1004, ¶¶3–5, 91–92. Patent Owner’s assertion that Holzmuller’s film slows, but does not stop, diffusion of packaged substances does not render Holzmuller and Riis “functionally different films.” *See* RMTA, 14. Instead, Holzmuller explicitly discloses that its films have “improved barrier properties” and “a high level of resistance to diffusion.” EX1034, ¶¶8, 20. Patent Owner’s expert emphasizes Holzmuller’s teachings with respect to the “oriented coextruded protective layer” to highlight a functional difference between the prior art references. *See e.g.*, EX2016, ¶¶75, 138. The specific degree to which Riis’s and Holzmuller’s films resist diffusion of packaged substances

amounts to a distinction without a difference. The films of Riis and Holzmuller are structurally, functionally, and polymerically similar such that a skilled artisan would look to Holzmuller for its disclosure of the intermediate bonding layers and have a reasonable expectation of success in implementing different layer thicknesses. EX1038, ¶¶100–03.

Both Holzmuller and Riis contain central aluminum foil layers that are between intermediate adhesive or bonding layers formed of EAA and polyethylene (LDPE) and exterior layers aimed to protect against external environments and chemicals. EX1034, ¶¶8, 10; EX1004, ¶59. Thus, Riis and Holzmuller teach similar structure and polymer materials for similar purposes. EX1038, ¶102.

Patent Owner's arguments that Holzmuller is incompatible because it requires lower temperature processing techniques fails to address the asserted combination of prior art. RMATA, 12–14. A POSITA would appreciate that Holzmuller teaches relative interacting thicknesses for intermediate bonding layers (i.e., tie layers) that result in synergistic effects for the overall film. EX1038, ¶103. Further, Holzmuller teaches that the interacting polymer materials in the multi-layer intermediate layer can be coated onto the aluminum foil barrier layer. EX1034, ¶24. Although Holzmuller does not disclose the use of COC as a contact layer, a POSITA would appreciate that Riis already discloses the ability to coextrude EAA and LDPE with COC in a sealant film coextruded coated onto an aluminum foil surface layer.

EX1038, ¶103. Indeed, Riis provides an exemplary film with that structure. As such, a POSITA would not rely upon incorporating an oriented coextruded protective layer into Riis's already aggressive-chemical resistant film. *Id.*

c) Holzmuller is presumed to be enabling prior art and may be properly combined with the teachings of Riis and Wypych to render obvious the claimed tie layer loading ranges.

The structure, materials, functionality, and associated methods of manufacture are all enabled and explicitly disclosed by the combination of Riis and Wypych. Holzmuller is relied upon to show known ranges of thickness of polymers that can be predictably applied to multilayer intermediate bonding layers comprising polyethylene and EAA. Holzmuller also discloses starting points and guideposts for ranges of thicknesses to apply to intermediate bonding layers. Holzmuller thus enables a POSITA to start with the broader range of disclosed thicknesses and routinely experiment with thicknesses of intermediate bonding layers in the preferred and especially preferred thickness ranges to practice the claimed invention. EX1038, ¶¶104–07.

It is well established that prior art patents and printed publications are presumed to be enabling, and a party challenging enablement of the prior art must present evidence that the practice of the invention would have required undue experimentation. *Apple Inc. v. Corephotonics, Ltd.*, 861 F. App'x 443, 449 (Fed. Cir. 2021). Patent Owner fails to carry its burden by generally asserting a high *quantity*

of possible combinations. RMTA, 14–16. Notably absent from Patent Owner’s assertions of undue experimentation is an analysis of the *Wands* factors.

Mere quantity of experimentation, the only asserted fact in the RMTA, is not enough so long as there’s a reasonable amount of guidance to direct experimentation. *In re Wands*, 858 F.2d at 737 (Fed. Cir. 1988). Holzmuller provides options for a variety of materials and layer thicknesses, including clear guideposts for allowable, preferred, and especially preferred ranges of thicknesses. EX1038, ¶¶107–08. A POSITA would thus recognize that providing such multilayer laminates requires experimentation with materials, thicknesses, and other parameters of extrusion, which would have been routine. *Id.* On this alone, Holzmuller is enabled for the claim elements that are being relied upon in the obviousness combination with Riis and Wypych.

Additionally, Holzmuller is relied upon as a teaching reference in an obviousness combination with Riis and Wypych, and thus need not be self-enabling. *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) (“[A] non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103.”); *Beckman Instruments Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) Because the combination of Riis and Wypych already enables and teaches the film’s structure, function, materials, and even exemplary constructions with dimensions, Holzmuller need not enable every aspect

of the claimed invention. *Raytheon Tech. Corp. v. General Electric Co.*, 993 F.3d 1374, 1381 (Fed. Cir. 2021) (citing *Commc 'ns Corp. v. Finisar Corp.*, 571 F. Supp. 2d 1137, 1145 (N.D. Cal. 2008), *aff'd sub nom. Comcast Cable Commc 'ns, LLC v. Finisar Corp.*, 319 F. App'x 916 (Fed. Cir. 2009)) (“such a reference may be used to supply claim element enabled by other prior art or evidence of record.”). Patent Owner’s assertions about the “high number of material/thickness combinations” ignores what Holzmuller discloses in combination with the teachings of Riis and Wypych. Again, Patent Owner fails to appreciate the entirety of the prior art. Riis and Wypych specifically provide the materials of the film, and the specific materials for the tie layer and contact layer (i.e., EAA/LDPE/COC). Patent Owner’s argument of Holzmuller disclosing 756 possible material combinations does not take into account the disclosure by Riis and Wypych already providing the materials of the film. Indeed, during the second deposition of Patent Owner’s expert, Dr. McCarthy admitted that he only considered Holzmuller in his enablement analysis and did not look to the other prior art (Riis or Wypych) in the obviousness combination. EX1039, 18:3–17, 22:2–23:17.

Patent Owner’s reliance on *Raytheon* is misplaced. In *Raytheon*, the Federal Circuit found that *standalone* § 103 references must enable the relied-upon portions of its own disclosure. 993 F.3d at 1381 (Fed. Cir. 2021). That is not the case here. Petitioner relies on the combination of Riis, Wypych, and Holzmuller to render the

substitute claims obvious. The prior art of Riis and Wypych in combination with the disclosure of Holzmuller enables a skilled artisan to make the claimed invention. Patent Owner instead seeks “to shift the emphasis from obviousness in light of the prior art, taken as a whole, to the sufficiency of each prior art teaching separately considered,” something the Federal Circuit has cautioned against. *Id.* (citing *Minn. Mining & Mfg. Co. v. Blume*, 684 F.2d 1166, 1173 n.10 (6th Cir. 1982)).

d) The Revised MTA provides insufficient evidence that the tie layer loading ranges of the '624 Patent are critical.

In IPR proceedings,

“where there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence” of teaching away, unexpected results or criticality, or other pertinent objective indicia indicating that the overlapping range would not have been obvious in light of that prior art.

E.I. DuPont de Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1008 (Fed. Cir. 2018) (quoting *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013)). Patent Owner’s conclusory assertion that “[e]vidence of criticality of the claimed ranges can be found throughout the ’624 Patent” fails to meet its burden of production to show unexpected results over the entire claimed range. *In re Patel*, 566 F. App’x 1005, 1011–12 (Fed. Cir. 2014) (citing *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003); *In re Geisler*, 116 F.3d 1465, 1469–70 (Fed. Cir. 1997)).

Any evidence of criticality identified by Patent Owner is limited to generic

statement of alleged inventive concepts. For instance, Patent Owner argues the '624 Patent discloses generally that "[i]t 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." See RMTA, 17 (citing EX1001, 2:63–67). At best, this disclosure alleges a general point of novelty that both the tie layers and contact layer can be thinner. This "evidence" presents no data, comparative results or otherwise, to tie the specific claimed ranges to any special characteristic or critical operability of the claimed invention. *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) (citing *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972)) (mere conclusory statements in the specification and affidavits are entitled to little weight and are not sufficient to show unexpected properties for the claimed compositions). Dr. McCarthy's declaration goes no further. See EX2016, ¶148 (relying on the same specification statements and presenting no objective evidence of unexpected results or criticality of the loading range). Patent Owner's asserted unexpected results identifies no comparison to the closest prior art or a nexus to the claimed invention and thus cannot carry its burden. "When an applicant seeks to overcome a prima facie case of obviousness by showing improved performance in a range that is within or overlaps with a range disclosed in the prior art, the applicant must 'show that the [claimed] range is critical, generally

by showing that the claimed range achieves unexpected results relative to the prior art range.”” *In re Geisler*, 116 F.3d 1465, 147071 (Fed. Cir. 1997) (quoting *In re Woodruff*, 919 F.2d. 1575, 1578 (Fed. Cir. 1990)). Patent Owner has failed to demonstrate how the claimed range achieves such unexpected results over the prior art. Indeed, during the second deposition of Dr. McCarthy, when asked what the unexpected result was of the claimed range, Dr. McCarthy stated that such conclusions were not provided in his Second Declaration. EX1039, 36:3–37:1.

Even considering Patent Owner’s cited evidence of unexpected results, the prior art and other evidence of record shows not only that the general conditions of the claimed loading ranges are met, but also identifies optimum or workable ranges in the prior art. See EX1004, ¶¶91 (providing the “entire multilayer film[] or any single layer . . . can have any suitable thicknesses, including 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 mils, or any increment of 0.1 to 0.01 mil therebetween”), 174 (providing an exemplary film with dimensional thicknesses); EX1034, ¶19 (providing general ranges, preferred ranges, and especially preferred ranges, all of which overlap the claimed ranges); EX1038, ¶¶89, 93, 97, 106–07; see also *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (“optimum or workable ranges by routine experimentation are not inventive”). Accordingly, this Opposition meets the applicable standards to render substitute claim 16 obvious over the combination of Riis, Wypych, and Holzmuller.

2. Substitute Claim 17

Substitute claim 17 recites a relationship of parts among the base layer, first tie layer, second tie layer, and contact layer, and further recites the loading of the first layer of the tie layer is from 5–19 g/m² and the loading of the second layer of the tie layer is from 1–14 g/m². RMTA, 27. Patent Owner’s amendments to adjust the loading ranges of the tie layers do not render such ranges nonobvious of the overlapping ranges taught by Holzmuller in combination with Riis and Wypych.

Riis fully discloses the ordering of layers as recited in substitute claim 17, with an EAA as the first layer of the tie layer and an LDPE as the second layer. EX1004, ¶174. Although the exemplary loading ranges of both the EAA tie layer and the LDPE tie layer disclosed in Riis fall just outside the ranges in substitute claim 17 (EAA: Riis’s 3.97–4.15 g/m² v. 5–19 g/m²; LDPE: Riis’s 15.11–15.34 g/m² v. 1–14 g/m²), a POSITA would have found it obvious to modify and optimize the interacting thicknesses of the layers of the tie layer to promote adhesion of layers and to prevent undesirable lamination through routine experimentation. EX1038, ¶118.

As discussed above, Holzmuller would have motivated a POSITA to tailor and optimize the thicknesses, and thus the loadings, of the intermediate bonding layers as applied to Riis’s LDPE and EAA tie layers to achieve desired synergistic properties of the multilayered intermediate tie layers. *See supra* § II.B.1.a. Regarding layer thicknesses, Holzmuller teaches loading ranges of Riis’s EAA of an

allowable range of 4.6–134.4 g/m², preferred ranges of 7.4–91.2 g/m², and especially preferred ranges of 9.2–48.0 g/m². EX1038, ¶¶94-97. These disclosed ranges for EAA overlap substitute claim 17's range of 5 to 19 g/m². Holzmuller also teaches loading ranges of Riis's LDPE from 4.6–130.1 g/m², preferably from 7.3–88.3 g/m², and especially preferably from 9.2–46.4 g/m². *Id.*, ¶¶119–22. Likewise, these disclosed ranges for LDPE overlap substitute claim 17's range of 1 to 14 g/m². For the reasons stated above regarding substitute claim 16 and for reasons stated below regarding substitute claim 18, substitute claim 17 is obvious over the combination of Riis, Wypych, and Holzmuller. *See supra* § II.B.1; *see infra* § II.B.3.

Holzmuller thus teaches allowable ranges that overlap with the newly claimed loading of the first layer of the tie layer from 5–19 g/m² and the loading of the second layer of the tie layer from 1–14 g/m²; the combination of Holzmuller with Riis and Wypych accordingly renders substitute claim 17 obvious. *In re Wertheim*, 541 F.2d 257 (CCPA 1976). Further, the optimized ranges taught by Holzmuller show that a POSITA would tailor such ranges to achieve the desired results. EX1038, ¶¶128-130. A POSITA would thus be motivated to optimize Riis's intermediate tie layers to achieve desired additive effects and would have had a reasonable expectation of success in doing so due to the similarity in structure, function, and polymeric materials considered by both Riis and Holzmuller. *See supra* § II.B(1)(a) and (b); EX1038, ¶¶98-100, 128-130.

3. Substitute Claim 18

Substitute claim 18 recites loading ranges for each of the first layer and second layer of the tie layer falling within a range of 7–20 g/m². Patent Owner's amendments to incrementally adjust the loading ranges of the tie layers do not render such ranges nonobvious of the overlapping ranges taught by Holzmuller.

Riis's loading range of the 0.65 mil LDPE (15.11 g/m²-15.34 g/m²) layer falls within the claimed 7–20 g/m² range. Riis' disclosure in Example 5 of 0.17 mil EAA layer (at 3.97–4.15 g/m²) does not fall within or overlap the claimed loading range of 7-20 g/m². Although the exemplary loading ranges of Riis's EAA tie layer falls outside of the claimed range in substitute claim 18, a POSITA would have found it obvious to modify and optimize the interacting thicknesses of the layers of the tie layer to promote adhesion of layers and to prevent undesirable lamination through routine experimentation. EX1038, ¶138.

For all the same reasons, discussed above regarding substitute claims 16 and 17, Holzmuller would have motivated a POSITA to tailor and optimize the thicknesses, and thus the loadings, of the intermediate bonding layers as applied to Riis's LDPE and EAA tie layers to achieve desired synergistic properties of the multilayered intermediate tie layers. *See supra* § III.B.1–2. Holzmuller teaches loading ranges of Riis's EAA of an allowable range of 4.6–134.4 g/m², preferred ranges of 7.4–91.2 g/m², and especially preferred ranges of 9.2–48.0 g/m². EX1038,

¶¶94-97. Holzmuller's teachings of allowable ranges, including preferred and especially preferred ranges, overlap with the newly claimed loading ranges of 7–20 g/m² and therefore render substitute claim 18 obvious over the combination of Riis, Wypych, and Holzmuller. *In re Wertheim*, 541 F.2d 257 (CCPA 1976).

Further, the optimized ranges taught by Holzmuller show that a POSITA would tailor such ranges to achieve the desired results. EX1038, ¶¶137–39, 148–50. A POSITA would thus be motivated to optimize Riis's intermediate tie layers to achieve desired additive effects and would have had a reasonable expectation of success in doing so due to the similarity in structure, function, and polymeric materials considered by both Riis and Holzmuller. *Id.*, ¶¶137-39,149.

Contrary to Patent Owner's assertions, a POSITA would not be discouraged from increasing the thickness of the 0.17 mil EAA layer during routine experimentation. RMTA, 23 (citing EX1004, ¶71; EX2015, 75:10–20, 76:7–20, 79:24–81:7; EX2016, ¶156). Although Riis may express a general preference for a thin tie layer, such disclosures do not rise to the level of teaching away. Patent Owner relies upon disclosures that thick tie layers may be relatively inferior, but Riis does not discredit having a tie layer thicker than the exemplary 0.17 mil EAA layer disclosed. *See DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006) (“We will not read into a reference a teaching away from a process where no such language exists.”). With respect to

preferred or preferable language, Riis explicitly states that any use of preferred embodiments in the specification “does not imply that other embodiments are not useful” despite Patent Owner’s assertions to the contrary. EX1004, ¶45. As discussed above, Riis allows for a wide range of thicknesses for each individual layer and merely includes the 0.17 mil EAA layer as a working example film. *See supra* § II.B.1.d (citing EX1004, ¶¶91 (providing suitable thickness of individual layers can range from 1–10 mils), 174 (providing exemplary film thicknesses)).

C. Substitute Claim 19 is Unpatentable as Obvious Over the Combination of Riis, Wypych, and Rivers.

Although Riis does not specifically disclose percentages of API migration, substitute claim 19 is unpatentable as obvious over the combination of Riis, Wypych, and Rivers for the same reasons set forth in the original Opposition regarding then-substitute claim 18. *See* Mot. Opp. 20–22. The Board agreed. Prelim. Guidance, 17–18.

Riis discloses the use of COC in the product contact layer of its inventive film and further discloses that such COC contact layers are suitable to prevent migration of “any suitable pharmaceutical active agent.” EX1004, ¶¶8–9, 52–53, 55, 133–35. Rivers is similarly directed to multilayer films used to package volatile products susceptible to degradation and adsorption and which use COCs as product contact layers to allow for as little as 1% scalping of a packaged product. EX1035, 4:13–5:2, 82–9:12, 9:31–10:3, 25:1–31. A POSITA would have been motivated to look to

Rivers to evidence and verify the anti-scalping properties of COCs recognized by Riis. EX1038, ¶¶151–53; *see also* EX1004, ¶¶8–9; EX1035, 13:16–25, 18:25–19:2. A POSITA would have had a reasonable expectation of success in looking to Rivers to verify such anti-scalping properties as both Riis and Rivers are similarly directed to multilayer films used to package volatile products susceptible to degradation and adsorption. *See* Prelim. Guidance, 17–18 (citing EX1004, ¶¶6, 55; EX1035, 4:13–5:2, 25:1–31, 26:16–27:5; EX1037, ¶¶152–55). Accordingly, substitute claim 19 is rendered obvious by the combination of Riis, Wypych, and Rivers.

III. CONCLUSION

Accordingly, substitute claims 14, 15, and 20–24 are rendered obvious by Riis and Wypych, substitute claims 16–18 are rendered obvious by Riis, Wypych, and Holzmuller, and substitute claim 19 is rendered obvious by Riis, Wypych, and Rivers.

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Respectfully submitted,

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that the foregoing **PETITIONER'S
OPPOSITION TO PATENT OWNER'S REVISED MOTION TO AMEND**
was served in its entirety electronically via e-mail on March 5, 2024, on the
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