

Filed on behalf of: DANAPAK FLEXIBLES A/S

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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.

PGR2023-00008
Patent 11,260,624

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

Exhibit No.	Description
2001	US Patent 11,504,954 assigned to Huhtamaki Flexible
2002	U.S. Patent Appl. No. 16425,067 Application File History (in-part)
2003	US Patent App. Pub. No. 20150225151A1 to Osborn et al.
2004	Redline Comparison Between Riis and Osborn
2005	US Patent 11,504,954 NFOA Response dated 11 March 2021
2006	US Patent 11,504,954 FOA Response dated 3 August 2022
2007	Huhtamaki Parent Website - Business Segments
2008	Huhtamaki Parent Website - Contact Us
2009	Huhtamaki Parent Website - Executive Team
2010	Huhtamaki Parent Annual Report 2021

PRELIMINARY RESPONSE

I. INTRODUCTION

Huhtamaki Flexible Packaging Germany GmbH & Co. KG ("Huhtamaki") filed a Petition requesting institution of post-grant review for U.S. Patent No. 11,260,624 ("624 Patent"), which issued from U.S. Application No. 16/835,108. U.S. Application No. 16/835,108 was filed on March 30, 2020 as a continuation of U.S. Application No. 15/780,999 ("Parent Application"), and the Parent Application was filed on June 1, 2018.

"Post-grant review shall not be instituted unless the Board decides that the information presented in the petition demonstrates that it is more likely than not that at least one of the claims challenged in the petition is unpatentable." 37 CFR § 42.208, *see also* 35 U.S.C. § 324. Also, a petition for PGR may be rejected when "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). Additionally, a petition for PGR "may be considered only if . . . the petition identifies all real parties in interest." 35 U.S.C. § 322(a)(2).

Institution of post-grant review should be denied because the Petition is both procedurally and substantively deficient. That is, institution of post-grant review should be denied outright under 35 U.S.C. § 325(d), because Huhtamaki submits the same prior art and substantially the same arguments previously presented to the Office and fails to show that the Office erred in a manner material to the

patentability of the challenged claims. Institution of post-grant review should also be denied outright under 35 U.S.C. § 322(a)(2), because Huhtamaki fails to properly identify the real parties-in-interest. Additionally, institution of post-grant review should be denied under 37 CFR § 42.208 because Huhtamaki fails to demonstrate, with respect to any ground of unpatentability asserted for any claim, that it is more likely than not that at least one of the challenged claims in the '624 Patent is unpatentable. Particularly, institution should be denied because all of the challenged claims are patentable (1) as one skilled in the art would understand, with reasonably certainty, the scope of what is claimed by the '624 Patent under 35 U.S.C. § 112, and (2) as the claims of the '624 Patent are not obvious under 35 U.S.C. § 103.

A. Institution should be denied under 37 CFR § 42.208 because one skilled in the art would understand what is claimed by the '624 Patent under 35 U.S.C. § 112.

With respect to the 35 U.S.C. § 112 allegations, Huhtamaki fails to show that one skilled in the art would not understand what is claimed by the '624 Patent when the claims are read in light of the specification of the '624 Patent.

1. One skilled in the art would understand, with reasonable certainty, the meaning of the term "aggressive chemical-resistant film."

Huhtamaki alleges that the claim term "aggressive chemical-resistant film" is indefinite under § 112(b). Independent claim 1 of the '624 Patent recites "a

method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine."

When reading the claims in light of the specification, one skilled in the art would understand, with reasonable certainty, that the term "aggressive chemical-resistant film" refers to:

- 1) films that allow less than 10% of the active pharmaceutical ingredient (API) in a packaged nicotine, fentanyl, rivastigmine, or lidocaine product to be absorbed into the film after 24 weeks; or
- 2) films that, when used to package a nicotine, fentanyl, rivastigmine, or lidocaine product, maintain an amount of the API in a respective product that is 90% to 110% of a corresponding amount of the API that remains when a Barex® film is used to package the nicotine, fentanyl, rivastigmine, or lidocaine product.

a. Put another way, one skilled in the art would understand that films that perform comparably with a Barex® film (10% worse or 10% better) with regard to the absorption of the API in a nicotine, fentanyl, rivastigmine, or lidocaine product are covered by the scope of the "aggressive chemical-resistant film" term.

It is important to note that these definitions are not mutually exclusive and that this limitation is satisfied when either (or both) of these definitions are

satisfied. As such, these definitions provide one skilled in the art two compatible, objective, and clear means for identifying whether a potentially infringing film is "an aggressive chemical-resistant film" as claimed in the '624 Patent. That is, one skilled in the art may determine that a potentially infringing film is "an aggressive chemical-resistant film" if it allows less than 10% of absorption, even if the film does not perform comparably with a Barex® film. Similarly, one skilled in the art may determine that a potentially infringing film is "an aggressive chemical-resistant film" if it performs comparably with a Barex® film, even if the film allows more than 10% of absorption. And one skilled in the art may determine potentially infringing film is "an aggressive chemical-resistant film" if it allows less than 10% absorption and performs comparably with a Barex® film.

This is akin to a hypothetical claim that recites a "stiffened tie rod" where the hypothetical specification provides that "a stiffened tie rod" is a tie rod made of "iron or steel." The mere fact that two alternative definitions are provided for a claim term does not render the term indefinite. In such a case, when read in light of the specification, one skilled in the art may determine that a potentially infringing tie rod is a "stiffened tie rod" if it is made of iron or steel.

2. One skilled in the art would understand, with reasonable certainty, the meaning of the term "loading."

Huhtamaki alleges that the claim term "loading" is indefinite under § 112(b). Independent claim 1 of the '624 Patent recites that "the tie layer comprises one or

more layers, [] 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."

When reading the claims in light of the specification, one skilled in the art would understand, with reasonable certainty, that the term "loading" refers to an amount of polymer in a layer of a film that is measured after manufacture of the film is completed. Further, in light of the units of measurement recited in the claims, one skilled in the art would understand, with reasonable certainty, that the amount of the polymer in the layer is expressed as a mass (in grams) of the polymer in the layer within a unit area (a square meter) — i.e., as a weight per unit area — and would understand how to determine a "loading" of a layer.

Indeed, Huhtamaki acknowledges the same, stating in the Petition that "[b]y knowing the thickness of the layer and the density of the polymer used, g/m² can be calculated" such that "'loading' as that term is used in the '624 Patent can be determined by (1) multiplying thickness in cm by density in g/cm³ and (2) converting g/cm² to g/m²." It is further noted that, in Huhtamaki's own patent (U.S. Patent No. 11,504,945 to Herb et al. ("Herb")), Huhtamaki uses similar terminology, claiming "a paper layer having . . . a weight per unit area of 35 to 45 g/m²." U.S. Patent No. 11,504,945, claim 18.

B. Institution should be denied under 35 U.S.C. § 325(d) because Huhtamaki submits the same prior art and substantially the same arguments previously presented to the Office and because Huhtamaki fails

to show that the Office erred in a manner material to the patentability of the challenged claims.

Huhtamaki submits the same prior art and substantially the same arguments previously presented to and raised by the Office during examination of the '624 Patent.

As noted *infra* § I.C, each of the § 103 allegations submitted by Huhtamaki relies heavily on WO Patent Publication No. 2015/123211 A1 to Riis et al. ("Riis"), a reference disclosed in an information disclosure statement explicitly considered by the Examiner during examination of the '624 Patent. In their plea to institute post-grant review, Huhtamaki incorrectly alleges that Riis was not evaluated during the examination of the '624 Patent and should not be considered the same prior art previously presented to the Office.

However, the record shows that the Examiner of the '624 Patent (Examiner T) was aware of and evaluated Riis at least because (1) Riis was disclosed in multiple information disclosure statements explicitly considered by Examiner T (one IDS submitted during examination of the '624 Patent and another IDS submitted during examination of a related copending application); Riis is named on the face of the '24 Patent; and (3) Examiner T was well acquainted with the Parent Application (examined by Examiner S) in which Riis was cited multiple times as the only reference in § 102 and § 103 rejections.

As a result, Huhtamaki relies on the same prior art previously presented to and considered by the Office.

Also, during examination of the '624 Patent, Examiner T explicitly cited U.S. Pub. No. 2005/0037162 to Adams ("Adams") and U.S. Pat. No. 6,120,860 to Bowen ("Bowen") in § 102 and § 103 rejections. As described herein, the disclosure of Riis is largely duplicative, and thus cumulative, of those of Adams and Bowen and shares common deficiencies as Adams and Bowen (alone or in combination). Accordingly, the record shows that, after evaluating Riis, Examiner T dismissed Riis as duplicative of Adams and Bowen.

The record further shows that, even if Examiner T had not evaluated Riis, Examiner T would have dismissed Riis as duplicative of Adams and Bowen in light of the common shortcomings of Riis, Adams, and Bowen. Indeed, this is what happened during prosecution of the Related Application when Examiner T explicitly considered US Pub. No. 2015/0225151 to Osborn et al. ("Osborn"), titled "ANTI-SCALPING TRANSDERMAL PATCH PACKAGING FILM." Osborn is the parent application to Riis; names two of the same inventors as Riis; similarly discloses the eight-layer film of the fifth example that is being relied on by the § 103 allegations in the Petition; and was also submitted in an information disclosure statement explicitly considered by the Examiner during examination of the '624 Patent.

Therefore, Huhtamaki submits substantially the same arguments raised and considered by Examiner T (and overcome) during examination of the '624 Patent.

As the prior art and arguments presented by Huhtamaki are the same or substantially the same as previously presented to the Office, the Petition should be rejected under 35 U.S.C. § 325(d) because Huhtamaki fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims at least because (1) the Office extensively evaluated the subject matter of Riis during examination of the '624 Patent; (2) Huhtamaki fails to sufficiently show how the Examiner erred in evaluating the prior art; and (3) Huhtamaki fails to assert any additional evidence and facts that warrant reconsideration of the prior art.

C. Institution should be denied under 37 CFR § 42.208 because the claims of the '624 Patent are not obvious under 35 U.S.C. § 103.

With respect to the two 35 U.S.C. § 103 allegations, Huhtamaki fails to show that the submitted references render at least one of the challenged claims obvious.

Each of the § 103 allegations submitted by Huhtamaki rely heavily on Riis, a reference that was disclosed to the Office in an information disclosure statement and is listed on the face of the '624 Patent.

In the first § 103 allegation, Huhtamaki alleges that the disclosure of Riis and the knowledge of one skilled in the art renders claims 1 through 13 obvious

after conceding that Riis does not disclose the loading ranges and relative melting points of the component tie layer and contact layer. Petition, pp. 30, 31, lns. 17–2.

In the second § 103 allegation, Huhtamaki alleges that the disclosure of Riis combined with the disclosures of the non-patent literature "Handbook of Polymers" by Wypych ("Wypych") and U.S. Patent No. 9,452,593 to Tatarka et al.

("Tatarka") renders claims 1 through 13 obvious. Huhtamaki alleges that Wypych and Tatarka provide material properties for the film disclosed in Riis but do not materially alter the arguments made in the first § 103 allegation. *See* Petition, p. 80, lns. 7–11 (stating "the rationale to combine the disclosure of Riis with the material properties provided by Wypych and Tatarka is simply to provide relevant and applicable material properties one of ordinary skill in the art would look to").

However, Riis — alone, or in combination with Wypych and/or Tatarka — fails to render obvious the claims of the '624 Patent because Riis, Wypych, Tatarka, or any combination thereof, fails to teach or suggest features of the issued claims, including but not limited to: (1) an "aggressive chemical-resistant film [that] consists of: the base layer comprising the aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC" and (2) a "tie layer [that] comprises one or more layers . . . 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. *See infra* § III.C and § III.D. It is further noted that Huhtamaki's own interpretations of Riis'

parent application Osborn (made during prosecution of a separate application) supports the foregoing, with Huhtamaki explicitly identifying that the corresponding film disclosed in the corresponding fifth example of Osborn includes separate base and sealant film. *See infra* § III.C.1.a).

D. Institution should be denied under 35 U.S.C. § 322(a)(2) because Huhtamaki fails to identify all of the real parties-in-interest.

Huhtamaki Flexible Packaging Germany Gmbh & Co. KG (referred to herein as Huhtamaki) is the only named real party-in-interest ("RPI"). See Petition § II(A). However, Huhtamaki should also have identified its parent corporation, Huhtamäki Oyj ("Huhtamaki Parent") as well as the related corporation Huhtamaki, Inc. ("Huhtamaki NA") as RPIs to comply with the statutory requirements for a PGR. 35 U.S.C. § 322(a)(2) (a petition for PGR "may be considered *only if* . . . the petition identifies all real parties in interest." (emphasis added)).

Particularly, Huhtamaki should have identified Huhtamaki Parent at least because (1) Huhtamaki is a wholly-owned subsidiary of Huhtamaki Parent; (2) the consolidated financial statements of Huhtamaki Parent list the revenue generated by all subsidiaries where over 50% of the subsidiary's voting rights are controlled directly or indirectly by the parent company, or the parent company is otherwise in control of the company; and (3) because it is difficult for both insiders and

outsiders to determine precisely where Huhtamaki ends and Huhtamaki Parent begins.

Also, Huhtamaki should have identified Huhtamaki NA at least because (1) Huhtamaki NA is a wholly-owned subsidiary of Huhtamaki Parent; (2) Huhtamaki NA is directed to the U.S. segment of Huhtamaki Parent's business; and (3) the outcome of this matter will affect the ability of Huhtamaki NA to sell products covered by the '624 Patent in the United States market.

II. OVERVIEW OF THE '624 PATENT

A. The '624 Patent — Summary

The '624 Patent is related to a film that exhibits "resistance toward highly aggressive substances . . . [and has] [i]nert properties for ensuring that chemical compounds do not migrate from the exterior environment . . . through the laminate getting into contact with a sealed substance." '624 Patent, col. 1, lns. 48–55. As described in the '624 Patent, a "film" describes "a product comprising [either] a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or a base layer laminated with a tie layer and a contact layer." *Id.*, col. 11, lns. 64–67. And "laminate" describes "the film to which a further layer [(e.g., an outer layer)] is laminated." *Id.*, col. 12, lns. 6–8.

More specifically, the '624 Patent discloses an aggressive chemical resistant film that includes a water and/or oxygen resistant base layer, a tie layer, and a contact layer, where the tie layer and contact layer are coextrusion coated to the

base layer. *Id.*, col. 2, lns. 45–51. The '624 Patent discloses that "[i]t has surprisingly been found that when coextruding the tie layer and the contact layer . . . the respective layers can be thinner while maintaining the overall mechanical and chemical robustness of the final film and laminates . . . made with the film. *Id.* col. 2, lns. 63–67.

The '624 Patent provides that "the contact layer comprises a polymer selected from the group consisting of a cyclic olefin polymer (COC), a polyamide (PA), or an ethylene vinyl alcohol (EVOH)." *Id.* col. 5, lns. 14–17. The '624 Patent further provides that "COC has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates . . . from a visual point of view . . . [and] it is very surprising that the inventors . . . have succeeded in providing a coextrusion layer comprising COC as a contact layer for sealing aggressive substances." *Id.*, col. 6, lns. 1–13. Specifically, the '624 Patent provides that the "inventors have found that an improved processing of COC is obtained when COC is coextruded with a tie layer having a glass transition temperature higher than or equal to that of a COC polymer. *Id.*, col. 6, lns. 13–17. "In an embodiment of the disclosure, the tie layer has a melting point that differs from COC with 30° C, or less." *Id.*, col. 6, lns. 19, 20.

The '624 Patent further provides that "[a]s an effect of having been able to process a chemical resistant laminate with a coextrusion layer laminated to a base

layer, thin laminates may be obtained." *Id.*, col. 6, lns. 27–30. "Consequently, in one embodiment[,] the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m² and/or the contact layer has a loading in the range of 4 to 20 g/m²[,] and the loading of the laminate is not more than 40 g/m²." *Id.*, col. 6, lns. 32–37. As described in the '624 Patent, "loading" described "the amount of polymer left[] in the layer when the film has dried." *Id.* col. 6, lns. 38, 39.

B. The '624 Patent — Independent Claims

The '624 Patent includes the following independent claims:

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

comprising the aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC,

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

13. A method for providing a laminate, wherein the laminate comprises an aggressive chemical-resistant film, said method comprising:

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

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

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

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

C. The '624 Patent — Prosecution History

As previously noted, the '624 Patent issued from U.S. Application No. 16/835,108, which was filed on March 30, 2020, as a continuation of the Parent Application (U.S. App. No. 15/780,999), which was filed on June 1, 2018.

The Parent Application was examined by Examiner S. The '624 Patent was initially examined by Examiner S (who issued a Restriction Requirement) before being transferred to Examiner T (who issued the Office Actions and Notice of Allowance). During examination, Examiner T issued two non-final Office Actions and one final Office Action. In the first non-final Office Action (issued on February 9, 2021), the claims were rejected under § 102 or § 103 over Adams and over § 103 over Bowen in view of Adams. EX1002, pp. 201–205. In the first non-final Office Action, Examiner T conceded that "Adams is silent regarding the loading and melting point of the layers." EX1002, pp. 202, ln. 7. Examiner T also conceded that "Bowen[,] in view of Adams[,] is silent regarding the loading and melting point of the layers." EX1002, pp. 204, ln. 22.

Also, in the first non-final Office Action, the claims were provisionally rejected on the grounds of nonstatutory double patenting over then-copending U.S. Application No. 16/425,067 (the "Related Application") and the then-copending

Parent Application. EX1002, pp. 207, 208. Accordingly, during examination of the '624 Patent, Examiner T was not only aware of, but acquainted with the claims of, both the Parent Application and the Related Application (which was also examined by Examiner T).

On January 12, 2022, the claims were allowed in the Notice of Allowance. In the Notice of Allowance, Examiner T acknowledged that 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, [] wherein the contact layer consists of only COC." EX1001, p. 21. Examiner T further acknowledged that Adams fails "to teach an aggressive chemical-resistant film which is resistant to a chemical selected from nicotine, fentanyl, rivastigmine or lidocaine." EX1001, p. 21. And Examiner T acknowledged that Adams failed "to teach [a loading in the loading range of] 7–20 g/m². EX1001, p. 21.

Additionally, in the Notice of Allowance, Examiner T acknowledged that Bowen "fails to teach making a film consisting only of a base layer comprising aluminum[] and a coextrusion layer consisting only of the tie layer and the contact layer, [] wherein the contact layer consists of only COC." EX1001, p. 22. Examiner T further acknowledged that Bowen fails "to teach [an] aggressive chemical film selected explicitly from nicotine, fentanyl, rivastigmine or lidocaine." EX1001, p. 22.

III. INSTITUTION OF POST-GRANT REVIEW SHOULD BE DENIED

"Post-grant review shall not be instituted unless the Board decides that the information presented in the petition demonstrates that it is more likely than not that at least one of the claims challenged in the petition is unpatentable." 37 CFR § 42.208. When deciding whether to institute a post grant review 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." 35 U.S.C. § 325(d).

Huhtamaki asserts in the Petition that the claims of the '624 Patent are unpatentable as (1) indefinite under 35 U.S.C. § 112(b), (2) obvious over Riis, and (3) obvious over Riis, Wypych, and Tatarka.

Institution should be denied because (1) the claims of the '624 Patent provide objective boundaries for one skilled in the art to determine the scope of the claims and, thus, are not indefinite under § 112(b); (2) Huhtamaki relies on the same prior art and substantially the same arguments that have already been presented to and considered by the Office; and (3) the claims of the '624 Patent are not rendered obvious by any combination of Riis, Wypych, or Tatarka and, thus, are not obvious under § 103.

A. Institution should be denied under 37 CFR § 42.208 because one skilled in the art would understand what is claimed by the '624 Patent under 35 U.S.C. § 112.

In the first alleged ground of unpatentability, Huhtamaki alleges that the claims are indefinite under 35 U.S.C. § 112(b).

35 U.S.C. § 112(b) requires that a patent application specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). A decision on whether a claim is indefinite under § 112(b) "requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." MPEP § 2173.02 (emphasis added) (citing *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1350, 94 USPQ2d 1241, 1245 (Fed. Cir. 2010); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986)).

A patent is definite if it is "precise enough to afford clear notice of what is claimed . . . [and appraises] 'the public of what is still open to them'." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. at 2129 (2014) (quoting *Markman v. Westview Instruments, Inc.*, 116 S. Ct. 1384 (1996)). Thus, patents including claims that, "when read in light of the specification and the prosecution history, [] provide objective boundaries for those of skill in the art" are definite. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d at 1371 (Fed. Cir. 2014).

"Claim language employing terms of degree [have] long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing* at 1370. Also, "[a] patent's written description . . . can set forth more than one definition of a claim term." *Checkpoint Sys. v. Hangzhou Century Co.*, 2014 U.S. Dist. LEXIS 140466, 23 (N.D. Ohio 2014) (citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d at 1310 (Fed. Cir. 1999)). Indeed "just because a term has multiple definitions does not, by itself, mean that the term is indefinite" *Nanoco Techs., Ltd. v. Samsung Elecs. Co.*, 2021 U.S. Dist. LEXIS 89223 at 25 (E.D. Tex. 2021). "Indefiniteness does not require absolute certainty, but only reasonable certainty around the boundaries of the term." *Id.*

Thus, a claim is not indefinite under § 112(b) if the claim provides objective boundaries for those of skill in the art to understand, with reasonable certainty, what is still open to them.

1. One skilled in the art would understand, with reasonable certainty, the meaning of the term "aggressive chemical resistant film."

Huhtamaki alleges that claims 1 through 13 of the '624 Patent are indefinite for allegedly failing to inform one skilled in the art as to the scope of "aggressive chemical-resistant film" with reasonable certainty. Petition, p. 24 (citing to the non-precedential case, *Saso Golf, Inc. v. Nike, Inc.*, 843 Fed.Appx. at 296 (Fed. Cir. 2021), which cites to another non-precedential case, *Ball Metal Beverage*

Container Corp. v. Crown Packaging Tech., Inc., No. 2020-1212, 838 Fed.Appx. at 542 (Fed. Cir. 2020).

As a threshold matter, it is telling that Huhtamaki cites to two non-precedential cases to support this allegation rather than to the precedential Federal Circuit cases to which these non-precedential cases cite.

Independent claim 1 of the '624 Patent recites "a method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine." Independent claim 13 of the '624 Patent recites similar language.

a) The '624 Patent provides one skilled in the art objective boundaries for understanding the scope of the term "aggressive chemical-resistant film."

The '624 Patent provides that a "contact layer [of the film] must be chemically resistant to [an] aggressive substance and excipient . . . [and] must show an extreme low absorption of the aggressive substance migrating through the film or laminate." '624 Patent, col. 4, lns. 63–67. As a method for determining the degree of absorption of a packaged aggressive substance into a film or laminate, the '624 Patent provides that "the absorption is calculated as the weight of [the active pharmaceutical ingredient (API) absorbed] in[to] [the] packaging relative to the initial weight of the API in the commercial product" — i.e., the absorption exhibited by a film can be determined by dividing the weight of the API that has

migrated into the film or laminate by the initial weight of the API in the commercial product. *Id.* col. 5, lns. 5–7.

The '624 Patent provides that the acceptable "degree of absorption for a given substance is typically dictated by the manufacturer but often the accepted values lie in the range of 0 to 1% (w/w)." *Id.* col. 5, lns. 1–3. The '624 Patent also acknowledges that "[f]or some products up to 10% (w/w) is acceptable." *Id.* col. 5, lns. 3–5. It is noted that the w/w terminology represents (the weight of the API in the film or laminate)/(the initial weight of the API in the commercial product).

The '624 Patent further provides that, in the context of the present disclosure, "an aggressive chemical resistant film means [a film that allows] no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) [to] migrate[] into the packaging material after 24 weeks. *Id.* col. 5, lns. 8–12. Though the '624 Patent does note that, "[t]ypically, the degree of uptake is complete after 12 weeks or less." *Id.* col. 5, lns. 12, 13.

Thus, as disclosed in the '624 Patent, one skilled in the art would understand that an "aggressive chemical-resistant film . . . [that] is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," describes films that, after 24 weeks, allow a degree of absorption that is less than 10%, though often being less than 1%.

The '624 Patent also provides that 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.*, col. 7, lns. 21–25. This definition of an "aggressive chemical resistant film" is consistent with the prior definition, similarly allowing for less than 10% absorption, and would not change one skilled in the art's understanding of this term.

The '624 Patent additionally provides that the term "aggressive chemical resistant film" means "a film[,] which when in contact with an aggressive substance[,] does not allow more than 1.5% w/w of nominal content to migrate to the packaging material." *Id.* col. 12, lns. 16–19. Again, this definition of an "aggressive chemical resistant film" is consistent with the prior definitions, similarly allowing for less than 10% absorption, and would not change one skilled in the art's understanding of this term.

Additionally, the '624 Patent provides that the term "aggressive chemical resistant film" means "a film[,] which when in contact with an aggressive substance[,] . . . [results in] 90–110% of the aggressive chemical substance remain[ing] in the product when compared to Barex® as index 100." *Id.* col. 12, lns. 16–22. Earlier in the description, the '624 Patent provides that, "[in] a

particular embodiment of the disclosure, wherein the composition is provided as a patch, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40° C[] is a maximum $\pm 10\%$ in comparison to a Barex® patch as index 100." *Id.*, col. 7, lns. 5–9.

Thus, from the above portions of the '624 Patent, one skilled in the art would understand that an "aggressive chemical-resistant film . . . [that] is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," describes films that maintain an amount of a respective API that is 90% to 110% of a corresponding amount of the API that remains when a Barex® film is used to package the nicotine, fentanyl, rivastigmine, or lidocaine product. That is, one skilled in the art would understand that an "aggressive chemical-resistant film . . . [that] is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," describes films that perform comparably with films having a Barex® contact layer.

Accordingly, the '624 Patent provides one skilled in the art objective boundaries for understanding the scope of the term "aggressive chemical-resistant film."

b) Huhtamaki's argument as well as Huhtamaki's expert's opinion regarding the indefiniteness of the "aggressive chemical-resistant term" is flawed.

Huhtamaki alleges that there are three different definitions of the term "aggressive chemical-resistant film" in the '624 Patent that each recite a different amount of permissible migration of the aggressive chemical into the packaging. Petition, p. 25.

With respect to the first definition, Huhtamaki argues that the '624 Patent provides that an aggressive chemical resistant film means a film that allows no more than 1% of the original amount of packaged API (or sometimes no more than 10%) of the original amount of packaged API to migrate into the packaging material after 24 weeks. *Id.*, p. 25 (citing '624 Patent, col. 5, lns. 8–13). However, the Petition leaves out the immediately preceding text of the '624 Patent, which provides that the acceptable "degree of absorption for a given substance is typically dictated by the manufacturer but often the accepted values lie in the range of 0 to 1% (w/w)." *Id.* col. 5, lns. 1–3. Though the '624 Patent acknowledges that "[f]or some products up to 10% (w/w) is acceptable." *Id.* col. 5, lns. 3–5. As noted *supra* § III.A.1.a), when read in its full context, it is clear that the '624 Patent provides that an aggressive chemical resistant film is a film that allows less than 10% absorption into a package after 24 weeks (while noting that the acceptable

absorption of the aggressive chemical resistant film may be lower depending on the product and manufacturer).

With respect to the second definition, Huhtamaki alleges that the cited portion of the '624 Patent provides that an aggressive chemical resistant film means a film that does not allow more than 10%, such as 5% w/w/ or 1.5% w/w) of the aggressive chemical to migrate into the packaging material. *Id.*, p. 25 (citing '624 Patent, col. 7, lns. 21–25).

And with respect to the third definition, Huhtamaki alleges that the cited portion of the '624 Patent provides that an aggressive chemical resistant film means a film that does not allow more than 1.5% w/w of the content to migrate to the packaging material. *Id.*, p. 25 (citing '624 Patent, col. 12, lns. 16–22). Huhtamaki also notes that the third definition provides an alternative test methodology using Barex® as a comparator. *Id.*, p. 26.

With respect to the first methodology that defines an aggressive chemical resistant film as a film that limits absorption to an acceptable level, Huhtamaki goes on to allege that the different definitions provide different methods for determining an "aggressive chemical resistant film" that are internally inconsistent. *Id.* To that end, an unclearly derived and conclusory table that merely restates Huhtamaki's allegation is provided in the Expert's Declaration. EX1003, pp. 50, 51. In the Expert's Declaration, the Expert states that under the least restrictive

definition of allowed absorption (no more than 10%), some lower degrees of absorption would be allowed but not others. *Id.* However, this does not follow as each lower degree of absorption stated in the '624 Patent (e.g., 1%, 1.5%, and 5%) would be allowed under the least restrictive definition.

Accordingly, contrary to the behavior of one skilled in the art, Huhtamaki cherry-picks and reads each definition of "aggressive chemical resistant film" that is provided in the '624 Patent in isolation. Based on its selective reading, Huhtamaki unsurprisingly confuses the possible absorption values for the aggressive chemical resistant film named in the '624 Patent (e.g., no more than 10%) with multiple methods for identifying an aggressive chemical resistant film under the first methodology.

That is, with respect to the first methodology, the '624 Patent provides a single method for determining whether a film is an aggressive chemical resistant film — measuring an absorption of the film by comparing an amount of API that is absorbed into the packaging relative to the original amount of API in a packaged nicotine, fentanyl, rivastigmine, or lidocaine product. After measuring the absorption of the film, it would be clear to one skilled in the art to determine whether the absorption of the film fell within the absorption range provided in the '624 Patent (up to 10% absorption) to identify whether the film is an aggressive chemical resistant film.

With respect to the second methodology that defines an aggressive chemical resistant film as a film that performs comparably with Barex® when the composition is provided as a patch, as noted *supra* § III.A, a patent's written description can set forth more than one definition and just because a term has multiple definitions does not, by itself, mean that the term is indefinite. As also noted *supra* § III.A.1.a), the first and second methodologies are internally consistent and provide one skilled in the art objective and consistent methodologies for determining whether a film is an "aggressive chemical resistant film."

Huhtamaki further alleges that the patented claims are indefinite because variations in testing parameters will result in materially different outcomes for the claim's scope. Petition, p. 26. However, apart from this conclusory allegation, Huhtamaki fails to provide support for the assertion that the different testing parameters would result in materially different outcomes when determining whether a film is an "aggressive chemical resistant film." Instead, without stating any legal authority, Huhtamaki appears to allege that the patented claims are indefinite for not naming every testing parameter for determining whether a film is an aggressive chemical resistant film. *See Id.*

Huhtamaki goes on to state that the testing parameters that are provided within the '624 Patent are internally inconsistent. *Id.* For instance, Huhtamaki states that the '624 Patent discloses an example where a patch is tested for 2, 4, 8,

and 12 weeks and another example where a patch is tested for 7 days, none of which use the 24 weeks provided in the first definition. *Id.* However, in a pattern for this Petition, Huhtamaki ignores that the '624 Patent explicitly states that, "[t]ypically, the degree of uptake is complete after 12 weeks or less." *Id.* col. 5, lns. 12, 13. And Huhtamaki again focuses on cherry-picked sections of the '624 Patent, turning a blind eye to the holistic definition of the term "aggressive chemical resistant film" that one skilled in the art would obtain by studying the specification as a whole.

Accordingly, Huhtamaki's position that the term "aggressive chemical resistant film" is indefinite under § 112(b) is flawed at least for cherry-picking portions of the '624 description, ignoring the relationship between the cherry-picked portion as well as context surrounding the cherry-picked portions, and providing only conclusory assertions in support of its position.

2. One skilled in the art would understand, with reasonable certainty, the meaning of the term "loading."

Huhtamaki alleges that independent claims 1 and 13 as well as dependent claims 5 through 7 of the '624 Patent are indefinite for allegedly failing to inform one skilled in the art how "loading" is determined. Petition, p. 29.

Independent claim 1 of the '624 Patent recites that "the tie layer comprises one or more layers, [] 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." Independent claim 13 of the '624 Patent recites similar language.

The '624 Patent provides that "loading means the amount of polymer left[] in the layer when the film has dried." '624 Patent, col. 6, lns. 38, 39. The '624 Patent further provides that "in one embodiment[,] the tie layer or plurality of layers constituting the tie layer has a loading in the range of 7 to 20 g/m². *Id.*, col. 6, lns. 33–35. Accordingly, the '624 Patent provides that the loading of a layer is determined based on an areal density of a polymer in the layer, where the weight of the polymer is measured in grams and the unit area is a square meter. That is, in the '624 Patent, the loading of a layer refers to a weight of a polymer in the layer that is measured in a square meter section of the layer.

Accordingly, one skilled in the art would understand that "loading" refers to an areal density of a layer. And one skilled in the art would understand how to determine the areal density of a polymer in a layer — e.g., based on a density of the polymer resin used to create the layer, based on measuring a weight of the polymer in the layer within a square meter, etc. Indeed, Huhtamaki acknowledges the same. That is, when addressing the "loading" language for the purposes of the § 103 rejection, Huhtamaki notes that "[b]y knowing the thickness of the layer and the density of the polymer used, g/m² can be calculated" such that "'loading' as that term is used in the '624 Patent can be determined by (1) multiplying thickness in

cm by density in g/cm³ and (2) converting g/cm² to g/m²." Petition, p. 41.

Accordingly, Huhtamaki describes without issue a method for determining the loading in a layer and for determining whether the loading in the layer satisfies the claimed loading range. As further support for the assertion that one skilled in the art would understand that "loading" refers to areal density of a layer and how to determine "loading," It is further noted that, in Huhtamaki's own patent (U.S. Patent No. 11,504,945 to Herb et al. ("Herb")), Huhtamaki uses similar terminology, claiming "a paper layer having . . . a weight per unit area of 35 to 45 g/m²." EX2001, *see e.g.*, claim 18.

3. One skilled in the art would understand, with reasonable certainty, the meaning of the term "melting point."

Dependent claims 2 and 3 of the '624 Patent recite a "melting point of the tie layer" and a "melting point of COC."

Huhtamaki states that "[t]o 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 one skilled in the art would not have understood which of the many other temperature properties of polymers is equivalent to 'melting point'." Petition, p. 30.

Accordingly, Huhtamaki acknowledges that that this term is not indefinite but instead speculates that the term would be indefinite if Patent Owner asserts that this term means something different than "melting point."

Thus, Huhtamaki has failed to allege that this term is indefinite, and this allegation should not be deemed an asserted ground of invalidity.

B. Institution should be denied under 35 U.S.C. § 325(d) because Huhtamaki submits the same prior art and substantially the same arguments previously presented to the Office and because Huhtamaki fails to show that the Office erred in a manner material to the patentability of the challenged claims.

Huhtamaki alleges that the prior art and arguments submitted in the Petition are not the same prior art and arguments previously presented to the Office during examination of the '624 Patent.

"A petition may be denied because 'the same or substantially the same prior art or arguments previously were presented to the Office'." *Vovomart (HK) Enterprises Co. v. Office Kick, Inc.*, Case PGR2022-00048, slip op. at 6 (PTAB Jan. 12, 2023) (Paper 14) (citing 35 U.S.C. § 325(d)).

"When applying Section 325(d), [the PTAB] utilizes a two-part framework." *Id.* "First, [the PTAB] determines 'whether the same or substantially the same art previously was presented to the Office or whether the same arguments previously were presented to the Office'." *Id.* (emphasis added) (citing *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020)). In *Vovomart*, the PTAB determined that the submitted prior art was the same or substantially the same art previously presented to the Office as three of the references were cited on the face of the patent and the other references

were substantially duplicative of the references cited on the face of the patent. *Id.* at 11.

"Second, 'if either condition of [the] framework is satisfied' [the PTAB] consider[s] 'whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims'." *Id.* (emphasis added) (citing *Advanced Bionics*). "In the second part of [the] framework, [the PTAB] consider[s] (i) the extent to which the asserted art was evaluated during examination . . . (ii) whether Petitioner has pointed out sufficiently how the Examiner erred in evaluating the asserted prior art; and (iii) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art. *Id.* at 12. "[I]f 'petitioner fails to make a showing of material error,' generally discretion will be exercised to deny institution of review." *Id.*

The prior art submitted in the Petition is the same as the prior art presented to and evaluated by the Office during examination of the '624 Patent at least because (1) Examiner T explicitly considered an IDS citing Riis as part of the examination of the '624 Patent; (2) Riis is named on the face of the '624 Patent; and (3) Examiner T was well acquainted with the Parent Application (which explicitly cited Riis in multiple prior art rejections).

Also, the arguments submitted in the Petition are substantially the same as the arguments raised and considered by Examiner T (and overcome) during

examination of the '624 Patent. As described herein, the disclosure of Riis is largely duplicative, and therefore cumulative, of the disclosures of the references explicitly cited by Examiner T during examination of the '624 Patent — U.S. Pub. No. 2005/0037162 to Adams ("Adams") and U.S. Pat. No. 6,120,860 to Bowen ("Bowen"). As further support for the assertion that the arguments submitted in the Petition are substantially the same as those evaluated and dismissed by the Office, it is noted that Examiner T explicitly considered and dismissed Osborn (the parent application to Riis) as rendering the claims obvious during the examination of the Related Application.

As the prior art and arguments presented by Huhtamaki are the same or substantially the same as previously presented to the Office, the Petition should be rejected under 35 U.S.C. § 325(d) because Huhtamaki fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims at least because (1) the Office extensively evaluated the subject matter of Riis during examination of the '624 Patent; (2) Huhtamaki fails to sufficiently show how the Examiner erred in evaluating the prior art; and (3) Huhtamaki fails to assert any additional evidence and facts that warrant reconsideration of the prior art.

Therefore, Huhtamaki submits and relies upon substantially the same arguments raised by Examiner T during examination of the '624 Patent, and the Petition may be denied on this basis alone.

1. The record shows that Riis is the same prior art previously presented to the Office during examination of the '624 Patent.

The § 103 allegations submitted by Huhtamaki primarily rely on Riis as allegedly rendering the claims of the '624 Patent obvious, a reference that was disclosed to the Office in an information disclosure statement and that is listed on the face of the '624 Patent.

Huhtamaki alleges that Riis was not evaluated during the examination of the '624 Patent and should not be considered the same prior art previously presented to the Office. Petition, p. 73. Specifically, Huhtamaki alleges that Adams and Bowen were the only prior art evaluated by Examiner T during examination of the '624 Patent simply because Examiner T rejected the pending claims over the same references throughout the examination of the '624 Patent. *Id.*, p. 75.

As a threshold matter, the use of the same references throughout examination does not support the assertion that the examiner only considered those references. Indeed, such a conclusion would render current disclosure practices largely performative.

With respect to the allegation that Examiner T failed to evaluate Riis, Patent Owner leads with a brief summary of the examination of the Parent Application. The Parent Application was examined by Examiner S. During examination of the Parent Application, Examiner S explicitly cited Riis. First, in the first non-final rejection dated April 26, 2021, in a short (one paragraph) § 102 rejection of claims

13 and 14 and a short (one-paragraph) § 103 rejection of claim 15. EX1009, pp. 126, 127. And again, in the second non-final rejection dated September 7, 2021, in a short (two-page) § 102 rejection of claims 16, 18, 19, 29, and 31 and a short (two-page) § 103 rejection of claims 17, 20, and 30. EX1009, pp. 77–80.

The '624 Patent was initially examined by Examiner S (who issued a Restriction Requirement on November 18, 2020). After the Restriction Requirement was issued, the '624 Patent was transferred to Examiner T, who performed the subsequent examination for the '624 Patent. On June 1, 2020, Riis was disclosed in the information disclosure statement submitted by the Applicant. EX1002, pp. 293–301 (*see* Cite No. 044 in the IDS). On February 1, 2021, the information disclosure statement was signed by Examiner T as being considered. EX1002, 214–220.

On February 9, 2021, Examiner T issued the first Office Action for the '624 Patent, where the first Office Action included a provisional nonstatutory double patenting rejection over the claims filed in the then-pending Parent Application and a provisional nonstatutory double patenting rejection over the claims filed in U.S. Patent Application No. 16/425,067 ("Related Application"). EX1002, pp.198–209. Examiner T also presided over the examination of the Related Application.

In the Related Application, Riis was additionally disclosed to Examiner T in an information disclosure statement submitted for the Related Application on

November 15, 2019 (EX2002, pp. 295–302; Cite. No. 52 in the IDS) — this information disclosure statement was signed by Examiner T as being considered on May 25, 2021. *See* EX2002, pp. 210–217 — about a month after Examiner S issued the first non-final rejection for the Parent Application. On June 1, 2021, Examiner T issued the first non-final rejection for the Related Application (*see* EX2002, pp. 189–201) that similarly included a provisional nonstatutory double patenting rejection over the claims filed in the then-pending Parent Application and the then-pending '624 Patent.

In the final Office Action issued for the '624 Patent by Examiner T on May 24, 2021 (EX1002, pp. 163–175) — nearly a month after the first non-final rejection issued in the Parent Application — Examiner T maintained the provisional nonstatutory double patenting rejection over the then-pending Parent Application and Related Application. Accordingly, Examiner T remained aware of, and continued to monitor the status of, the Parent Application and the Related Application throughout examination of the '624 Patent.

Accordingly, not only did Examiner T consider Riis disclosed in multiple information disclosure statements, but Examiner T was also aware of and acquainted with the then-pending Parent Application and the then-pending Related Application throughout examination of the '624 Patent.

The record therefore shows that Examiner T, having explicitly considered multiple information disclosure statements that identified Riis and monitored the status of the copending Parent Application and the copending Related Application, was aware of and evaluated Riis.

Therefore, by primarily relying on Riis for the § 103 allegations, Huhtamaki submits the same prior art previously presented to the Office.

As noted *infra* § III.C, Wypych and Tatarka are combined with Riis merely to provide material properties for the film disclosed in Riis but do not otherwise alter the § 103 analysis (a fact acknowledged by Huhtamaki itself at page 80 of the Petition). *See* Petition, 80, lns. 7–11 (stating "the rationale to combine the disclosure of Riis with the material properties provided by Wypych and Tatarka is simply to provide relevant and applicable material properties one of ordinary skill in the art would look to"). Therefore, despite the addition of Wypych and Tatarka, Huhtamaki submits the same prior art previously presented to the Office.

2. The record shows that the arguments raised in the Petition regarding Riis are substantially the same as the arguments evaluated by the Office (and overcome) during examination of the '624 Patent.

The record shows that Examiner T, being aware of Riis, determined that, with regard to teaching or suggesting the issued claims of the '624 Patent, the deficiencies of Riis were commensurate with the deficiencies of Adams and Bowen.

During examination of the '624 Patent, Examiner T acknowledged that Adams and Bowen both failed to disclose the loading of the tie layer, instead alleging that the inherent structure and/or experimental modification of Adams and Bowen would render the loading obvious (*see* EX1003, pp. 202, 204,205; EX1002, pp. 166, 167, 169; EX1002, pp. 63, 66, 67).

In the reasons for allowing the independent claims given in the Notice of Allowance dated January 12, 2022, Examiner T determined that Adams fails to disclose an aggressive chemical resistant film which is resistant to a chemical selected from nicotine, fentanyl, rivastigmine or lidocaine, and further failed to disclose a tie layer loading within the range of 7–20 g/m². EX1002, pp. 21–23. Examiner T further determined that Bowen fails to disclose a film consisting only of (1) a base layer comprising aluminum and (2) a coextrusion layer consisting only of a tie layer and a contact layer, the contact layer consisting of COC. *Id.* Examiner T further determined that Bowen fails to disclose an aggressive chemical resistant film which is resistant to a chemical selected from nicotine, fentanyl, rivastigmine or lidocaine. In the reasons for allowance, Examiner T was silent with regard to whether Bowen disclosed the loading but, in the non-final Office Action dated September 30, 2021, acknowledged that Bowen failed to express the loading of the tie layers. *see* EX1002, pp. 66, 67.

In the first non-final action issued for the Parent Application, Examiner S (similar to Examiner T) acknowledged that Riis is silent regarding the "loading of the tie layer" feature of the '624 Patent, instead alleging that experimental modification of Riis would render the loading obvious. *See* EX1009, p. 127. Further Examiner S analysis was silent with regard to additional distinguishing features in the claims of the '624 Patent, including an "aggressive chemical-resistant film [that] 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 this feature was excluded from the claims of the Parent Application.

Accordingly, the record shows that, once the disclosures of Adams and Bowen were overcome, Examiner T's additional search and consideration found (like Examiner S) that the disclosure of Riis was duplicative of and shared common deficiencies as Adams and Bowen. Thus, Examiner T found that Riis was cumulative and similarly failed to disclose the issued claims of the '624 Patent.

Moreover, the record shows that, even if Examiner T had failed to evaluate Riis during examination of the '624 Patent, the cumulative nature of Riis, Adams, and Bowen would have caused Examiner T to arrive at the same result. Indeed, this is what happened during prosecution of the Related Application when Examiner T explicitly considered Osborn (EX2002, Notice of Allowance, pp. 66, 67), titled "ANTI-SCALPING TRANSDERMAL PATCH PACKAGING FILM." Osborn the

parent application to Riis, names two of the same inventors as Riis; similarly discloses the eight-layer film of the fifth example that is being relied on by the § 103 allegations in the Petition (EX2003 (*see e.g.*, ¶ [00173]); and was also submitted in the information disclosure statement explicitly considered by the Examiner on February 1, 2021 during examination of the '624 Patent. EX1002, pp. 293–301 (*see* Cite No. 003 in the IDS). To further show the similarities between Osborn and Riis, a redline comparison of Riis and Osborn generated by running a Word® comparison is provided. EX2004.

Therefore, in light of the similar interpretations of these references by both examiners and the duplicative nature of the disclosure of Riis and the disclosures of Adams and Bowen, Huhtamaki submits substantially the same arguments raised by the Office (and overcome) during examination of the '624 Patent. That is, the arguments asserted by Huhtamaki using Riis mirror the arguments already raised by the Examiner using Adams and Bowen, where these arguments were overcome during examination. In other words, had the Examiner explicitly asserted Riis instead of Adams and Bowen, the substance of the rejections articulated by the Examiner would have remained the same, and the rejections would have been similarly overcome.

3. Huhtamaki fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims.

Huhtamaki's primary arguments alleging that the Office erred in a manner material to the patentability is that the Examiner failed to fully appreciate the teachings of Riis and that Riis renders obvious the claims of the '624 Patent for allegedly disclosing the "loading" range features claimed in the '624 Patent. Petition, pp. 71, 72, and 80–83.

The Petition incorrectly asserts that the Office "wholly ignored the Riis reference." However, as noted herein, Examiner T explicitly considered an IDS citing Riis as part of the examination of the '624 Patent; Riis is named on the face of the '624 Patent; Examiner T was well acquainted with the Parent Application (which explicitly cited Riis in multiple prior art rejections); and Examiner T explicitly considered and dismissed Osborn (the parent application to Riis) as rendering the claims obvious during the examination of the Related Application. Accordingly, the record shows that Riis (and a reference substantially the same as Riis) was evaluated by Examiner T during examination of the '624 Patent.

Moreover, the Petition fails to sufficiently show how the Examiner erred in evaluating Riis. The Petition asserts that the Examiner failed in evaluating Riis only because Riis teaches the "loading" range feature claimed in the '624 Patent. However, as noted herein, the "loading" range feature is not the only feature of the claims that Riis fails to disclose. Indeed, among other features, Riis fails to

disclose 1) an "aggressive chemical-resistant film [that] consists of: the base layer comprising the aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC" and (2) a "tie layer [that] comprises one or more layers . . . 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. See also *infra* § III.C. Nor was the "loading" range feature the only feature cited by Examiner T as leading to the allowance of the '624 Patent.

Additionally, the Petition does not provide additional evidence and facts that warrant reconsideration of the prior art. That is, the Petition merely provides conjecture (in the face of contrary evidence) that Examiner T was unaware of Riis. Also, the additional references (Tatarka and Wypych) asserted in the Petition do not present additional evidence that warrant reconsideration as Wypych and Tatarka provide material properties for the film disclosed in Riis but do not materially alter the arguments made in the first § 103 allegation. See Petition, p. 80, lns. 7–11.

Therefore, Huhtamaki fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims.

C. Institution should be denied under 37 CFR § 42.208 because Riis fails to render the claims of the '624 Patent obvious under 35 U.S.C. § 103.

In the second alleged ground of unpatentability, Huhtamaki alleges that Riis renders claims 1 through 13 of the '624 Patent obvious under 35 U.S.C. § 103.

Petition, p. 30.

However, Riis fails to teach or suggest the features recited in claims 1 through 13 of the '624 Patent.

1. Riis fails to render obvious independent claim 1.

Huhtamaki concedes that Riis fails to teach specific material properties of the claimed film, such as loading ranges and relative melting points for the tie and contact layers; Petition, pp. 30, 31, Huhtamaki instead alleging that it would have been obvious based on the disclosure of Riis (particularly with reference to example 5 of Riis) and commercially available polymers. Petition, p. 40.

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

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

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

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

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

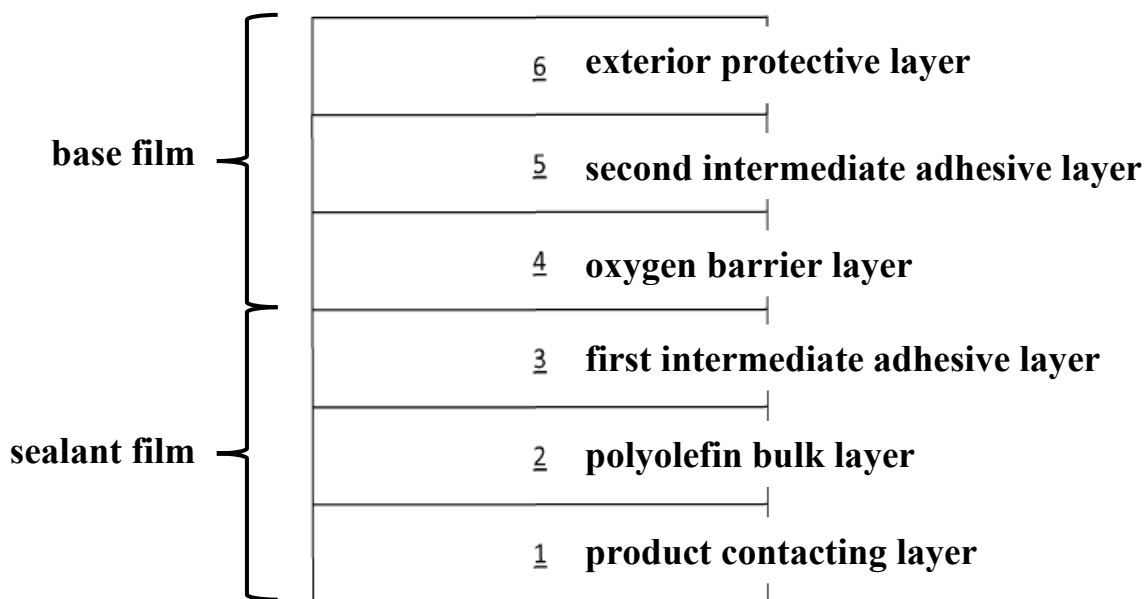
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m².

a) Summary of Riis

Riis is related to a film for packaging a product that has a pharmaceutical active agent and that includes a product-contacting sealing later including at least 90 wt. % of an ethylene norbornene copolymer (COC). EX1004, Abstract. The pharmaceutical active agent is selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine. EX1004 ¶ [0011].

FIG. 1 of Riis depicts a six-layer film 10 that includes a product contacting layer 1, a polyolefin bulk layer 2, a first intermediate adhesive layer 3, an oxygen barrier layer 4, a second intermediate adhesive layer 5, and an exterior protective layer 6. *Id.*, FIG. 1 (reproduced below). In Riis, "the product contacting layer 1 . . . comprises an ethylene norbornene copolymer." *Id.* ¶ [00135]. Also, as described in Riis, "a bulk layer [is] provided to provide additional functionality such as stiffness or heat sealability or to improve machinability, cost, flexibility, barrier properties,

etc." *Id.* ¶ [0065]. In some embodiments of Riis, the "polyolefin bulk layer can serve as an adhesive or tie layer." *Id.* ¶ [00135].



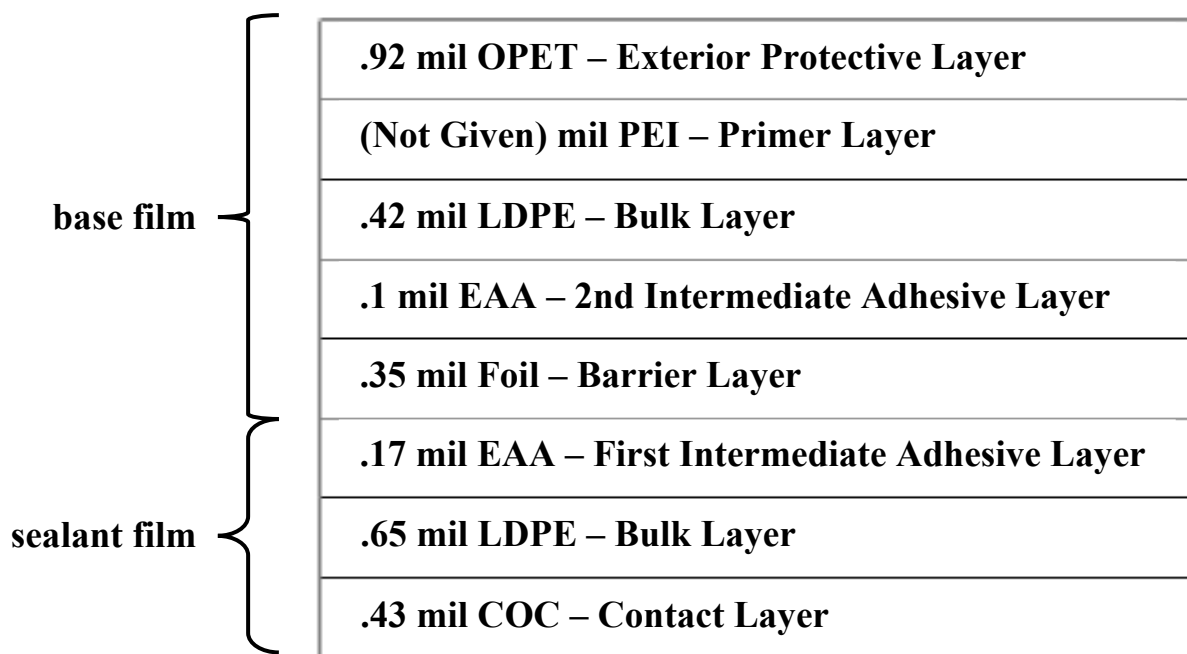
EX1004, FIG. 1 (annotated)

In the example film of the invention (the fifth example) of Riis, a film structure includes a base film made of .92 mil OPET/ primer/ .42 mil LDPE/ .1 mil EAA/ .35 mil foil. *Id.* ¶ [0174]. The film structure also includes a sealant film having a three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene copolymer (COC) that was extrusion coated on the aluminum foil surface of the multilayer base film. *Id.* Together the base film and sealant film result in an eight-layer film having the following structure .92 mil OPET/ primer/ .42 mil LDPE/ .1 mil EAA/ .35 mil foil/ .17 mil EAA/ .65 mil LDPE/ .43 mil COC. *Id.* ¶ [0174].

So, Riis describes an eight-layer film that is composed of a base film that includes an oxygen barrier layer (the .35 mil foil layer) and a sealant film that

includes a product contacting layer (the .43 mil COC layer), a polyolefin bulk layer (the .65 mil LDPE layer), and a first intermediate adhesive layer (the .17 mil EAA layer), where the product contacting layer, the polyolefin bulk layer, and the first intermediate adhesive layer of the sealant film are coextrusion coated to the foil layer of the base film. Huhtamaki acknowledges the delineation between the base film and the sealant film in its own characterization of Riis' parent application Osborn (made during prosecution of a separate application), providing that the film described in the fifth example of Osborn uses the same base film disclosed in the first and second examples of Osborn but a different sealant film. EX2005, p. 8.

The eight-layer film of Riis can be depicted and characterized as shown:



Response, Figure 1

Further, Riis describes (1) providing the base film including the oxygen barrier layer; (2) providing the sealant film including the product contacting layer, the polyolefin bulk layer, and the first intermediate layer; and (3) coextrusion coating, by way of a three-layer coextrusion, the product contacting layer, the polyolefin bulk layer, and the first intermediate layer of the sealant film onto the foil layer of the base film to obtain the eight-layer film.

b) Riis fails to teach or suggest that an "aggressive chemical-resistant film [that] 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 independent claim 1.

But, neither the sealant film, the base film, nor the resulting eight-layer film, as described in Riis, teaches or suggests an "aggressive chemical-resistant film [that] ***consists*** of[] [a] base layer comprising [] aluminum[] and [] a coextrusion layer consisting of[] a tie layer[] and [a] contact layer consisting of COC," as recited in independent claim 1 (emphasis added).

That is, the sealant film of Riis includes an adhesive layer, a bulk layer, and a contact layer, thereby lacking "the base layer" comprising aluminum in the "aggressive chemical-resistant film" recited in independent claim 1 and including a bulk layer omitted from the "aggressive chemical-resistant film" recited in independent claim 1.

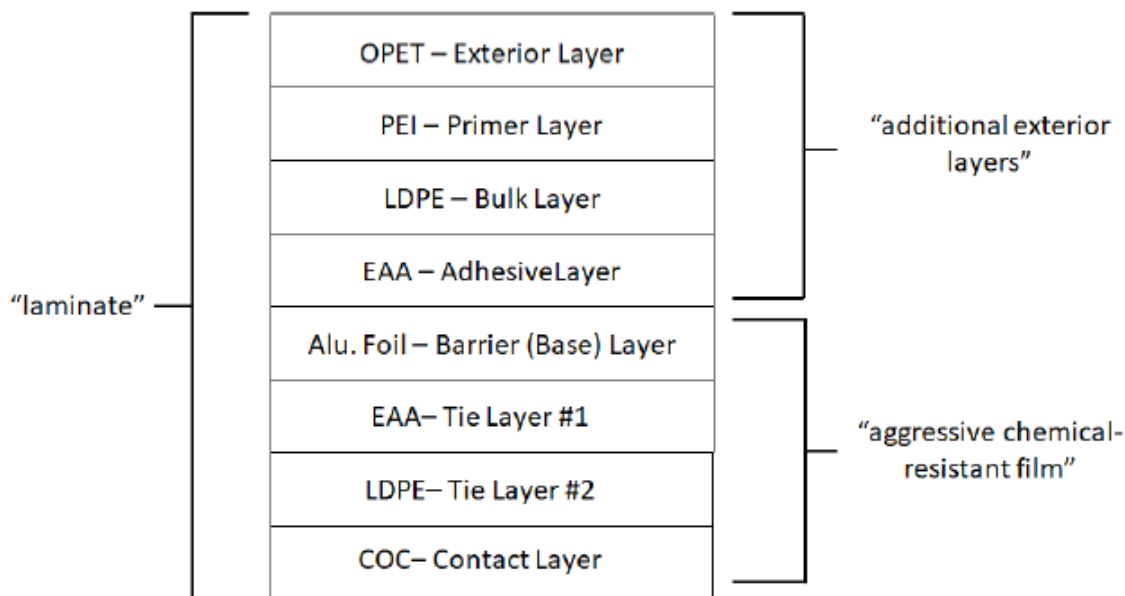
The base film of Riis includes an exterior protective layer, a primer layer, a bulk layer, an adhesive layer, and a barrier layer, thereby lacking "the contact

layer" in the "aggressive chemical-resistant film" recited in independent claim 1 and including a primer layer and a bulk layer omitted from the "aggressive chemical-resistant film" recited in independent claim 1.

And the resulting eight-layer film of Riis includes an exterior protective layer, a primer layer, a second bulk layer, a second adhesive layer, a barrier layer, a first adhesive layer, a first bulk layer, and a contact layer, thereby including an exterior protective layer, a primer layer, two bulk layers, and an additional adhesive layer omitted from the "aggressive chemical-resistant film" recited in independent claim 1.

Accordingly, neither the sealant film, the base film, nor the resulting eight-layer film of Riis teaches or suggests an "aggressive chemical-resistant film [that] *consists* of[] [a] base layer comprising[] aluminum[] and [] a coextrusion layer consisting of[] a tie layer[] and [a] contact layer consisting of COC," as recited in independent claim 1 (emphasis added).

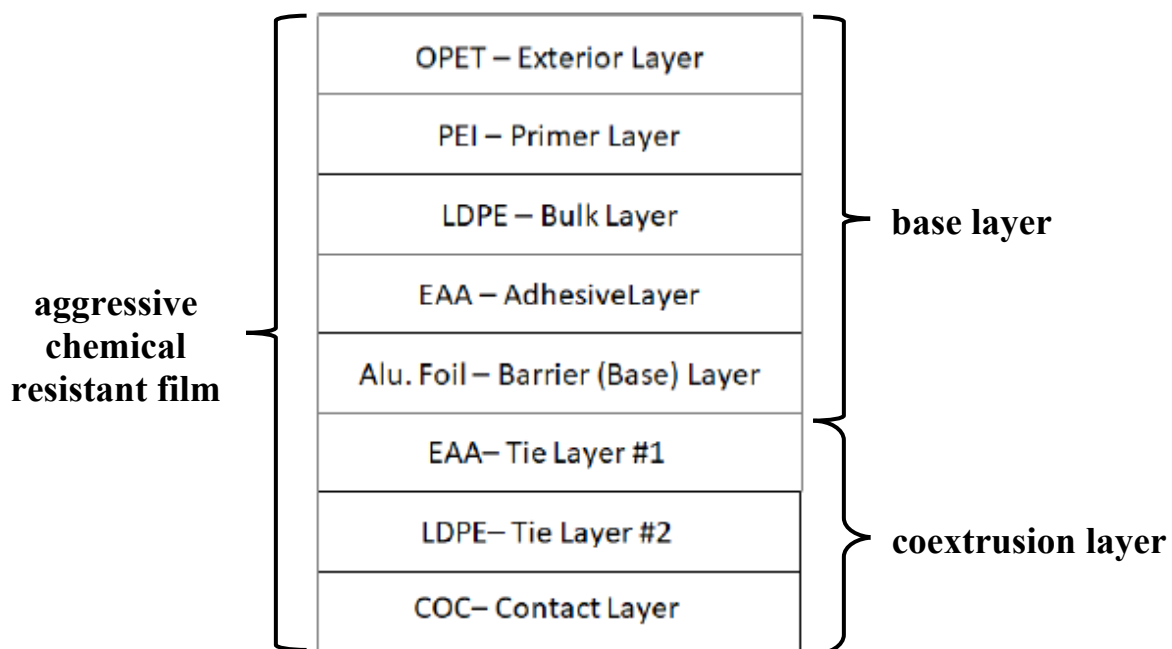
Huhtamaki depicts and characterizes, as applied to the issued claims of the '624 Patent, the eight-layer film of Riis as follows:



Petition, p. 38

Thus, Huhtamaki alleges that the foil layer of the base film of Riis and the tie layer, bulk layer, and contact layers of Riis compose the aggressive chemical resistant film of a laminate, and the other layers compose the exterior layers of the laminate. However, as noted and depicted in Figure 1 of the Response *supra* § III.C.1.a), the base film of Riis is composed of the "additional exterior layers" and the foil layer, while the sealant film of Riis is composed of the EAA, LDPE, and COC layers. Since the foil layer is a component of a different film than the EAA, LDPE, and COC layers, the foil, EAA, LDPE, and COC layers cannot make up the "aggressive chemical resistant film" of independent claim 1.

In the alternative, the Petition states that "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." Petition, p. 39. Under this interpretation, the Petition's depiction of the eight-layer film, as applied to the issued claims of the '624 Patent, of Riis would be characterized as follows:



See Petition, p. 39

This second interpretation of the eight-layer film of Riis is inconsistent with the disclosure of Riis which explicitly states that the OPET, PEI, LDPE, EAA, and foil layers are included in a base film and that the EAA, LDPE, and COC layers are included in a sealant film.

Accordingly, for the purposes of this Petition, Huhtamaki has adopted two conflicting interpretations of Riis: One interpretation where the foil layer of the base film and the EAA, LDPE, and COC layers of the sealant film compose the "aggressive chemical resistant film;" and another interpretation where all of the layers of the eight-layer film compose the "aggressive chemical resistant film." These conflicting interpretations expose the weakness in Huhtamaki's position as even Huhtamaki is unable to decide how the film of Riis corresponds to the claims in the '624 Patent. Moreover, in a related matter, Huhtamaki has adopted yet another interpretation of this subject matter through its interpretation of Riis' parent application Osborn. Huhtamaki's inability to characterize the film of Riis consistently suggests that Huhtamaki will interpret Riis in whatever manner suits Huhtamaki's current interests.

c) Riis fails to teach or suggest that "the tie layer comprises one or more layers . . . 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," as recited in independent claim 1.

As noted and depicted in Figure 1 of the Response *supra* § III.C.1.a), in Riis, the sealant film includes a .17 EAA adhesive (or tie) layer, a .65 mil LDPE bulk layer, and a .43 mil COC contact layer. Huhtamaki provides that EAA has a density within the range of .92–.96 g/cm³. Petition, pp. 41, 42. Accordingly, by Huhtamaki's calculations, Riis discloses a tie layer with a loading of 3.97–4.15 g/m². *Id.*, p. 42.

But a tie layer having a loading of 3.97–4.15 g/m², as described in Riis, fails to teach or suggest a "tie layer . . . [that] has a loading in the range of 7 to 20 g/m²," as recited in independent claim 1.

2. Riis fails to render obvious independent claim 13.

13. *A method for providing a laminate, wherein the laminate comprises an aggressive chemical-resistant film, said method comprising:*

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

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

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

wherein the tie layer comprises one or more layers, and wherein the 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) Riis fails to teach or suggest "a laminate . . . [that] comprises an aggressive chemical-resistant film . . . [that] 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 independent claim 13.

As noted *supra* § III.C.1.b), neither the sealant film, the base film, nor the resulting eight-layer film, as described in Riis, teaches or suggests an "aggressive chemical-resistant film [that] ***consists*** of[] [a] base layer comprising [] aluminum[] and [] a coextrusion layer consisting of []a tie layer[] and [a] contact layer consisting of COC," as recited in independent claim 1 (emphasis added).

As further noted *supra* § III.C.1.b), in the Petition, Huhtamaki sets forth two conflicting interpretations of Riis when alleging that Riis teaches or suggests this feature. The first interpretation of Riis provides that the eight-layer film in example 5 of Riis is a laminate, where the foil layer of the base film of Riis, and the tie layer, bulk layer, and contact layers of Riis compose the aggressive chemical resistant film of the laminate. Petition, p. 38. However, as noted and depicted in Figure 1 of the Response *supra* § III.C.1.a), the base film of Riis is composed of the "additional exterior layers" and the foil layer, while the sealant film of Riis is composed of the EAA, LDPE, and COC layers. Since the foil layer is a component of a different film than the EAA, LDPE, and COC layers, the foil, EAA, LDPE, and COC layers cannot make up the "aggressive chemical resistant film" of independent claim 1.

The second interpretation of Riis provides that the eight-layer film in example 5 of Riis is the aggressive chemical resistant film. Petition, p. 39. As previously noted, this second interpretation of the eight-layer film of Riis is inconsistent with the disclosure of Riis which explicitly states that the OPET, PEI, LDPE, EAA, and foil layers are included in a base film and that the EAA, LDPE, and COC layers are included in a sealant film. Moreover, under this interpretation, Riis fails to teach or suggest "*a laminate . . . [that] comprises an aggressive chemical-resistant film . . . [that] 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 independent claim 13 (emphasis added). That is, under this interpretation, the entire eight-layer film makes up the aggressive chemical resistant film, and thus, cannot also be used to teach or suggest "a laminate . . . that comprises [the] aggressive chemical resistant film," as recited in independent claim 13.

For the reasons provided herein, under either conflicting interpretation, Riis fails to teach or suggest the subject matter recited in independent claim 1 and independent claim 13. That said, Patent Owner submits that it is improper for Huhtamaki to assert conflicting interpretations of Riis in this Petition, and requests that Huhtamaki's § 103 allegations be limited to one of the conflicting interpretations.

It is further noted that, if the second conflicting interpretation is adopted for the purposes of this proceeding, the second interpretation cannot be used to teach or suggest both independent claim 1 and independent claim 13. That is, independent claim 1 recites an "aggressive chemical resistant film" while independent claim 13 recites a "laminate [that] comprises an aggressive chemical resistant film." Huhtamaki's second interpretation alleges that the full eight-layer film of Riis teaches or suggests the "aggressive chemical resistant film." Accordingly, under the second interpretation, the eight-layer film cannot also teach or suggest a "laminate [that] comprises an aggressive chemical resistant film," as recited in independent claim 13.

Thus, if the second conflicting interpretation is adopted for the purposes of this proceeding, post-grant review cannot be instituted on independent claim 13.

b) Riis fails to teach or suggest that "the tie layer comprises one or more layers . . . 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," as recited in independent claim 13.

As noted *supra* § III.C.1.c), the sealant film includes a .17 EAA adhesive (or tie) layer, a .65 mil LDPE bulk layer, and a .43 mil COC contact layer, a tie layer having a loading of 3.97–4.15 g/m², as described in Riis, fails to teach or suggest a "tie layer . . . [that] has a loading in the range of 7 to 20 g/m²," as recited in independent claim 13.

3. Riis fails to render obvious dependent claims 2 through 12.

Dependent claims 2 through 12 at least depend from independent claim 1, and Riis fails to render dependent claims obvious for at least their dependence on independent claim 1. Also, dependent claims 2 through 12 recite additional features that are not taught or suggested by Riis.

D. Institution should be denied under 37 CFR § 42.208 because Riis, Wypych, Tatarka, or any combination thereof, fails to render the claims of the '624 Patent obvious under 35 U.S.C. § 103.

In the third alleged ground of unpatentability, Huhtamaki alleges that the combination of Riis with Wypych, and Tatarka renders claims 1 through 13 of the '624 Patent obvious under 35 U.S.C. § 103. Petition, p. 53.

However, for at least the reasons stated *supra* § III.C, Riis fails to teach or suggest the features recited in claims 1 through 13 of the '624 Patent. As acknowledged in the Petition, Wypych and Tatarka are simply used to provide material properties for the film disclosed in Riis. Petition, p. 80. Because the addition of Wypych and Tatarka does not alter the § 103 analysis *supra* § III.C, it follows that Riis, Wypych, Tatarka, or any combination thereof, similarly fails to render obvious claims 1 through 13 of the '624 Patent.

E. Institution should be denied under 35 U.S.C. § 322(a)(2) because Huhtamaki fails to identify all of the real parties-in-interest.

Huhtamaki Flexible Packaging Germany GmbH & Co. KG (referred to herein as Huhtamaki) is the only named real party-in-interest ("RPI"). *See* Petition

§ II(A). However, for the reasons discussed below, Huhtamaki should also have identified its parent corporation, Huhtamäki Oyj ("Huhtamaki Parent") as well as the related U.S. corporation Huhtamaki, Inc. ("Huhtamaki NA") as RPIs to comply with the statutory requirements for a PGR. 35 U.S.C. § 322(a)(2) (a petition for PGR "may be considered *only if* . . . the petition identifies all real parties in interest." (emphasis added)).

There are a number of factors to consider when determining whether a non-party is an RPI. These factors include "without limitation, (1) "whether the non-party exercised or could have exercised control over the proceeding"; (2) the non-party's relationship with the petitioner; (3) whether the non-party funded the proceeding; (4) the non-party's relationship with the petition itself, including the nature and/or degree of involvement in the filing; and (5) the nature of the entity filing the petition." *Google LLC v. CYWEE Group LTD.*, Case IPR2018-01258, slip op. at 100, 101 (PTAB 2020) (Paper 86) (citing Patent Trial and Appeal Board Consolidated Trial Practice Guide 13 (Nov. 2019), available at <https://go.usa.gov/xpvPF>).

Where the unnamed party is a parent corporation, "the Board has found that the relationship . . . blurred the lines of corporate separation such that the parent could control conduct of the [post-issuance] review, thus making the parent an RPI." *Reflectix, Inc. v. Promethean Insulation Tech. LLC*, Case IPR2015-00042,

slip op. at 9 (PTAB Apr. 24, 2015) (Paper 18) (citations omitted). "When the intertwined nature of two corporations demonstrates that 'it is difficult for both insiders and outsiders to determine precisely where one ends and the other begins, there exists an actual measure of control or opportunity to control.'" *Id.* at 11 (citation omitted).

Huhtamaki, Huhtamaki Parent, and Huhtamaki, Inc. are inextricably intertwined. Huhtamaki Parent's website provides that Huhtamaki Parent's business is organized into three segments: Fiber and Food Service Europe-Asia-Oceania (EAO), North America, and Flexible Packaging. EX2007 (available at <https://www.huhtamaki.com/en/packaging-business-segments/>). Under the "Contact us" section of the packaging business segments page of Huhtamaki Parent's website, Huhtamaki Flexible Packaging Germany GmbH & Co. KG is listed as one of many companies under the "Flexible Packaging" segment of Huhtamaki Parent's business. EX2008 (available at <https://www.huhtamaki.com/en/flexible-packaging/>). Also, Huhtamaki, Inc. is listed under the "North America" segment of Huhtamaki Parent's business. *Id.*

Also, Huhtamaki Parent's website provides their executive team which consists of Marco Hilty (the President of the Flexible Packaging segment) and Ann O'Hara (the President of the North America segment). EX2009 (accessible at <https://www.huhtamaki.com/en/about/global-executive-team/>).

Moreover, Huhtamaki and Huhtamaki NA are wholly-owned subsidiaries of Huhtamaki Parent. EX2010, slide 113 (which lists Huhtamaki as a 100% owned subsidiary of Huhtamaki Parent). According to Huhtamaki Parent's annual report, "the consolidated financial statements [in the annual report] include [the consolidated financial statements of] the parent company Huhtamäki Oyj and all its subsidiaries where over 50% of the subsidiary's voting rights are controlled directly or indirectly by the parent company, or the parent company is otherwise in control of the company." *Id.*, slide 72.

Accordingly, it is clear that Huhtamaki Parent (having an executive in control of the flexible packaging segment and control of Huhtamaki's voting rights) is exercising or could exercise control over the proceeding. Also, due to the executive team of Huhtamaki Parent having control over the flexible packaging segment and the mixing of the financial statements of these entities, it is difficult for both insiders and outsiders to determine precisely where Huhtamaki ends and Huhtamaki Parent begins.

Additionally, there can be no doubt that Huhtamaki Parent has an interest in the outcome of this PGR. Huhtamaki Parent reports the income of its subsidiaries in the consolidated financial statements of its annual report. Accordingly, the outcome of this matter may impact Huhtamaki's ability to earn revenue selling

products covered by the '624 Patent, which may in turn impact Huhtamaki Parent's financial statements.

Also, Huhtamaki NA clearly has an interest in the outcome of this matter. Huhtamaki NA controls the business operations of Huhtamaki in the North American markets. Accordingly, the outcome of this matter may impact Huhtamaki NA's ability to sell products covered by the '624 Patent in the United States market.

Thus, for failing to identify Huhtamaki Parent and Huhtamaki NA, Huhtamaki's petition fails to comply with the statutory requirements for identifying the real parties-in-interest under 35 U.S.C. § 322(a)(2) and should be denied.

IV. CONCLUSION

Huhtamaki's petition is procedurally and substantively defective and fails to meet the minimum threshold for PGR institution. Accordingly, the petition should be denied in its entirety.

Respectfully submitted,

Dated: March 28, 2023

By: /Steven A. Avena/
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CERTIFICATE OF SERVICE

I, Steven A. Avena, hereby certify that a copy of the foregoing **PATENT OWNER'S PRELIMINARY RESPONSE** has been served on the attorneys of record of Petitioner Huhtamaki Flexible Packaging Germany GMBH & Co. KG via FedEx and electronically by email as of today, March 28, 2023, at the following addresses:

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