

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 MOTION TO AMEND

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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
2011	Corrected PHV Affidavit (Timothy P. Getzoff)
2012	EP Application No. 15202962.5 – '624 Priority Application
2013	Curriculum Vitae - Dr. Stephen McCarthy
2014	Declaration of Dr. Stephen McCarthy
2015	Deposition Transcript - Dr. Richard Spontak

MOTION TO AMEND

I. INTRODUCTION

Patent Owner moves under 35 U.S.C. 326(d) to amend U.S. Patent No. 11,260,624 ("624 Patent").

Specifically, Patent Owner moves to amend the '624 Patent to (1) cancel claims 2 and 3 prior to the decision being rendered for this trial and (2) contingently include substitute claims for issued claims 1, 6–10, and 13, subject to the outcome of this trial.

This Motion and the substitute claims meet all of the requirements of 35 U.S.C. 326(d) and 37 CFR 42.24, 42.221. Thus, Patent Owner respectfully requests that the Board grant this Motion, thereby canceling claims 2 and 3 prior to rendering its decision; and, in the event the Board finds any of claims 1, 6–10, and 13 unpatentable, issuing the corresponding substitute claims presented herein.

Moreover, though Patent Owner does not bear the burden of either persuasion or production regarding the patentability of the proposed substitute claims, and though the Board may not *sua sponte* question the patentability of the proposed substitute claims (*see In re Aqua Products, Inc.*, 872 F.3d 1290, 1296 (Fed. Cir. 2017)), this Motion and the supporting declaration of Dr. McCarthy demonstrate that the proposed substitute claims are patentable over the asserted references at issue in this proceeding.

II. MOTION TO AMEND PILOT PROGRAM

Patent Owner requests that this Motion be subject to the MTA Pilot Program (84 F.R. 9497). Patent Owner requests preliminary guidance from the Board on this Motion and whether to file a revised motion to amend. Patent Owner reserves its right to file a revised motion to amend subject to the Board's preliminary guidance.

III. LEGAL STANDARD

A patent owner may file one motion to amend a patent by canceling any challenged patent claim and, for each challenged claim, proposing a reasonable number of substitute claims; 35 U.S.C. 326(d)(1), but only after conferring with the Board. 37 CFR 42.221(a).

A motion to amend may be 25 pages in length, not including a table of contents, table of authorities, mandatory notices, certificate of service or word count, or appendix of exhibits or claim listing. 37 CFR 42.24(a)(1)(vi). A motion to amend must submit a reasonable number of substitute claims — the presumption is that only one substitute claim would be needed to replace each challenged claim. 35 U.S.C. 326(d)(1)(B); 37 CFR 42.221(a)(3). Additionally, a motion to amend must include a claim listing (e.g., in an appendix to the motion) that shows the changes clearly. 37 CFR 42.221(b). Moreover, a motion to amend must set forth the support in the original disclosure of the patent for each claim that is added or

amended as well as support in an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought. 37 CFR 42.221(b)(1), (b)(2).

A properly proposed substitute claim (1) does not introduce new subject matter, (2) does not enlarge the scope of the claims, and (3) is responsive to a ground of unpatentability in the proceeding. *American Nat'l v. Sleep Number Corp.*, 52 F.4th at 1380 (Fed. Cir 2022); *see also* 35 U.S.C. 326(d)(3); 37 CFR 42.221(a)(2). To be responsive to a ground of unpatentability, a proposed substitute claim need only have a minimal relevancy to the proceeding. *Aqua Prods. v. Matal*, 872 F.3d at 1317 (Fed Cir. 2017). If a proposed substitute claim satisfies the foregoing criteria, the patent owner may make additional amendments to a substitute claim (including those that do not respond to a ground of unpatentability) without running afoul of the relevant statutes. *Id.*

IV. THIS MOTION AND THE SUBSTITUTE CLAIMS MEET ALL THE REQUIREMENTS OF 35 U.S.C. 326(D) AND 37 CFR 42.24, 42.221

This Motion and the substitute claims meet all of the requirements of 35 U.S.C. 326(d) and 37 CFR 42.24, 42.221. Namely, Patent Owner has conferred with the Board regarding this Motion to Amend. This Motion is of appropriate length; proposes only one substitute claim for each conditionally canceled claim; clearly shows changes for each conditional substitute claim in the claim listing attached as an appendix to this Motion; and sets forth support for each substitute

claim in the original disclosure of the patent and the earlier-filed disclosure for which benefit of the filing date is sought. None of the contingent substitute claims introduce new subject matter or seek to enlarge the scope of the claims. And each contingent substitute claim is responsive to a ground of unpatentability involved in this proceeding.

A. Patent Owner has conferred with the Board regarding this Motion.

On August 28, 2023, the Board considered Patent Owner's obligations to confer with the Board under 37 CFR 42.221(a) to be satisfied by Patent Owner's email (sent on August 25, 2023) requesting a conference with the Board.

B. This Motion submits a reasonable number of substitute claims and clearly shows the changes sought for each conditionally canceled claim.

As shown in the attached claims appendix, for each challenged claim for which substitution is sought, only one substitute claim is proposed. Also, the changes sought for each substitute claims are clearly shown relative to corresponding existing claims using amendment markings.

C. This Motion sets forth support for each substitute claim in the original disclosure of the patent and an earlier-filed disclosure for which benefit of the filing date is sought.

U.S. Patent No. 11,260,624 ("624 Patent") issued from U.S. Application No. 16/835,108 ("108 App"), which was filed on March 30, 2020, as a continuation of U.S. Application No. 15/780,999 ("Parent Application"). The Parent Application was filed on June 1, 2018, as a 371 of Int'l Application No. PCT/EP2016/082876

("Int'l Application"). The Int'l Application was filed on December 29, 2016, and claimed benefit to EP Application No. 15202962.5 ("962 App"), which was filed on December 29, 2015.

The '108 App is reproduced on page 309 of EX1002 (page 134 of EX1002, Part 3). The '926 App is reproduced in EX2012. Support for each substitute claim is shown in the following table.

Claim Limitation	Support in the '108 App (EX1002) and the '962 App (EX2012).
[14A] A method for providing an aggressive chemical-resistant film, wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine, said method comprising:	"In a first aspect this [the "needs" described in the preceding paragraph] is solved by a method for providing, e.g., an aggressive chemical-resistant film." '108 App ¶ [0010]; '962 App, p. 2, lns. 34, 35. "In an embodiment of the disclosure, the film is used to wrap a composition comprising a chemical selected from nicotine, fentanyl, lodicine [sic], and rivastigmine." '108 App ¶ [0050]. "In an embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl, and lidocaine." '962 App, p. 2, lns. 34, 35.
[14B] providing a base layer, wherein the base layer consists of aluminum and is resistant to one or more of water or oxygen;	The disclosure contemplates "a method for providing the packaging [of] the chemical substance, said method comprising the steps of: a) providing a base layer." '108 App ¶ [0066]; '962 App, p. 10, lns. 23–27. The disclosure provides that the "base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil." '108 App ¶ [0023]; '962 App, p. 9, lns. 9, 10.

	"The coextrusion layer may be coated to the aluminium layer by a coextrusion system." '108 App ¶ [0117]; '962 App, p. 14, lns. 12, 13. "To further improve the mechanical wear resistance of the film a first outer layer may be laminated to the base layer side of the film." "Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the disclosure, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer." '108 App ¶ [0123]; '962 App, p. 15, lns. 6–12.
[14C] coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	The disclosure contemplates "a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . b) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer." '108 App ¶ [0066]; '962 App, p. 10, lns. 28, 29. "In one preferred embodiment, the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer (COC), a polyamide (PA), or[] an ethylene vinyl alcohol." '108 App ¶ [0034]; '962 App, p. 6, lns. 30, 31.
[14D] coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer consisting of the aluminum; and	The disclosure contemplates "a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . c) coating the coextrusion layer to the base layer." '108 App ¶ [0066]; '962 App, p. 10, lns. 30. The disclosure provides that the "base layer, which is water and/or oxygen resistant, is

	selected from the group consisting of a metal foil, preferably aluminum foil." '108 App ¶ [0023]; '962 App, p. 9, lns. 9, 10. "The coextrusion layer may be coated to the aluminium layer by a coextrusion system." '108 App ¶ [0117]; '962 App, p. 14, lns. 12, 13. "To further improve the mechanical wear resistance of the film a first outer layer may be laminated to the base layer side of the film." "Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the disclosure, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer." '108 App ¶ [0123]; '962 App, p. 15, lns. 6–12.
[14E] 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 consisting of the aluminum, and the coextrusion layer consisting of the tie layer and the contact layer consisting of the COC,	The disclosure contemplates "a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . d) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide a chemical resistant film comprising the tie layer and the contact layer formed as an coextrusion layer coated to the base layer." '108 App ¶ [0066]; '962 App, p. 10, lns. 31–34.
[14F] wherein: the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m ²	"In one embodiment the tie layer is made of 1, 2, 3, 4, or 5 layers." "All the layers are coextruded with the contact layer for a simplified processing." '108 App ¶¶ [0028], [0029]; '962 App, p. 6, lns. 3–9. "[I]n one embodiment, the tie layer or plurality of tie 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." '108 App ¶ [0043]; '962 App, p. 8, lns. 12–15. "In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b. '108 App ¶ [0121] & FIG. 3; '962 App, p. 14, ln. 34 – p. 15, ln. 2. "For the co-extrusion layers, the loading of the tie layers was between 4–18 g/m² and the loading of the contact layer was 8–12g/m²." '108 App ¶ [0147]; '962 App, p. 19, lns. 1–6.
[15A] The method according to claim 19, wherein:	See <i>supra</i> claim element 14A.
[15B] at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer, and	"The tie layer may be made of a material selected from but not limited to a copolymer made of a material selected from a copolymer of ethylene and acrylic acid." '108 App ¶ [0135]; '962 App, p. 17, lns. 6–8. "In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b. '108 App ¶ [0121] & FIG. 3; '962 App, p. 14, ln. 34 – p. 15, ln. 2.
[15C] the method further comprises laminating, after the aggressive chemical-resistant film is formed by coating the coextrusion layer to the base layer consisting of the aluminum, a first outer layer to the base layer of the aggressive chemical-resistant film.	See <i>supra</i> claim element 14D and 14E. "To further improve the mechanical wear resistance of the film a first outer layer may be laminated to the base layer side of the film." "Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the disclosure, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21

	and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer." '108 App ¶ [0123]; '962 App, p. 15, lns. 6–12.
[16A] The method according to claim 14,	See <i>supra</i> claim element 14A.
[16B] wherein a loading of a first layer of the tie layer is in the range of 7 to 18 g/m ² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m ²	See <i>supra</i> claim element 14F.
[17A] The method according to claim 14,	See <i>supra</i> claim element 14A.
[17B] wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of a first layer of the plurality of layers is in the range of 7 to 14 g/m ² and a loading of a second layer of the plurality of layers is in the range of 7 to 14 g/m ² .	See <i>supra</i> claim element 14F.
[18A] The method according to claim 14, wherein:	See <i>supra</i> claim element 14A.
[18B] the one or more layers of the tie layer consists of two layers, and	See <i>supra</i> claim element 14F.
[18C] wherein the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing less than 10% of the chemical to migrate into the aggressive chemical-resistant film.	"Hence, in the context of the present disclosure aggressive chemical-resistant film means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks. Typically, the degree of uptake is complete after 12

	weeks or less." '108 App ¶¶ [0033]; '962 App, p. 6, lns. 26–29.
[19A] The method according to claim 14,	See <i>supra</i> claim element 14A.
[19B] wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating of the coextrusion layer directly to the base layer consisting of the aluminum.	See <i>supra</i> claim element 14D.
[20A] The method according to claim 14, wherein:	See <i>supra</i> claim element 14A.
[20B] the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer,	See <i>supra</i> claim element 15B.
[20C] the chemical is provided in a first patch, and	"In a particular embodiment . . . wherein the composition is provided as a patch, the amount of the aggressive chemical substance remaining . . . [is compared] to a Barex® patch as index 100. '108 App ¶ [0051]. "A lidocaine patch containing 40 mg lidocaine was wrapped in the pouch, packaged and stored at 40°C for seven days." '108 App ¶ [0157]; '962 App, p. 20, lns. 9–11.
[20D] the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing 90% to 110% of the chemical in the first patch to migrate into a first pouch formed by the aggressive chemical-resistant film relative to an amount of the chemical in a second patch allowed to migrate into a second pouch formed by a	"Stability of the API is important . . . [a] value of 90% - 110% of the original does after one week when stored at 40°C using Barex® as index 100 is considered acceptable." "As can be seen from figure 5, both inventive laminates have a lower value than the index 100 Barex® comparative product, however with at [sic] a value within the acceptable limits." "The lower value of the laminates according to the invention indicates that more lidocaine has disappeared

second film comprising a contact layer that comprises Barex®.	from the patch." '108 App ¶¶ [0158], [0159] & FIG. 5; '962 App, p. 20, lns. 16–26.
[21A] A method for providing a laminate, wherein the laminate comprises an aggressive chemical-resistant film, said method comprising:	See <i>supra</i> claim element 14A.
[21B] providing a base layer, wherein the base layer consists of aluminum and is resistant to one or more of water or oxygen;	See <i>supra</i> claim element 14B.
[21C] coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	See <i>supra</i> claim element 14C.
[21D] coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer consisting of the aluminum; and	See <i>supra</i> claim element 14D.
[21E] 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 the COC,	See <i>supra</i> claim element 14E.
[21F] wherein: the tie layer comprises a first tie layer having a loading in the range of 7 to 14 g/m ² and a second layer having a loading in the range of 7 to 14 g/m ² , and	See <i>supra</i> claim elements 14F and 17B.

[21G] [wherein] the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine.	See <i>supra</i> claim element 14A.
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Thus, support for each substitute claim can be found in the original disclosure of the patent and the earlier-filed disclosure for which benefit of the filing date is sought.

D. None of the contingent substitute claims introduce new subject matter.

As demonstrated *supra* IV.C, the proposed substitute claims are supported by the original non-provisional application from which the '624 Patent issued and by the Priority Application to which the '624 Patent claims benefit. Thus, the proposed substitute claims do not introduce new subject matter.

E. None of the contingent substitute claims enlarge the scope of the claims.

With reference to the attached claims appendix:

Substitute independent claim 14 clarifies antecedent basis of claim terms (including "the film"), adds narrowing features, and removes certain features relative to independent claim 1. That said, the removed features only involve replacing claim terms with narrower claim terms or addressing grammatical informalities. That is, this claim clarifies that "the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine," replaces the claim language "the base layer comprises aluminum" with

the narrower claim language "the base layer consists of aluminum," and removes a stray comma.

Substitute dependent claims 15 adds narrowing features and removes certain features relative to dependent claims 10. That said, the removed features only involve updating the dependencies.

Substitute dependent claim 16 clarifies antecedent basis of the claim term "A method," adds narrowing features, and removes certain features relative to dependent claim 6. That said, the removed features only involve updating the dependency or improving consistency with the narrowed scope of this claim. That is, this claim removes the indicated language in the claim term "a loading of ~~at least a portion of~~ the tie layer" to be consistent with a tie layer that includes "a first layer . . . and a second layer" each having a loading "in the range of 7 to 18 g/m²."

Substitute dependent claim 17 adds narrowing features and removes certain features relative to dependent claim 7. That said, the removed features only involve updating the dependency or replacing claim terms with mor narrow claim terms. That is, this claim replaces the claim term "in the range of 7 to 20 g/m²" with the narrower claim term "in the range of 7 to 14 g/m²."

Substitute dependent claims 18, 19, and 20 add narrowing features and remove certain features relative to dependent claims 8, 9 and 11. That said, the removed features only involve updating the dependencies.

Substitute independent claim 21 adds narrowing features and removes certain features relative to independent claim 1. That said, the removed features only involve replacing claim terms with narrower claim terms, improving consistency with the added narrowing features (by their removal), or narrowing the scope of the claims (by their removal). That is, this claim replaces the claim language "comprising" with the narrower claim language "consisting of." Replaces the claim language "the tie layer comprises one or more layers" with the narrower claim language "the tie layer comprises a first layer . . . and a second layer." Replaces the claim language "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" with the narrower claim language, "a first layer having a loading . . . and a second layer [each] having a loading in the range of 7 to 18 g/m²." And clarifies that "the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine."

Thus, none of the contingent amendments enlarge the scope of the issued claims in the '624 Patent.

F. Each contingent amendment is responsive to a ground of unpatentability involved in this proceeding.

Huhtamaki Flexible Packaging Germany GmbH & Co. KG ("Petitioner") asserted in their petition requesting institution of post-grant review that claims 1 through 13 were unpatentable on the grounds of indefiniteness under 35 U.S.C.

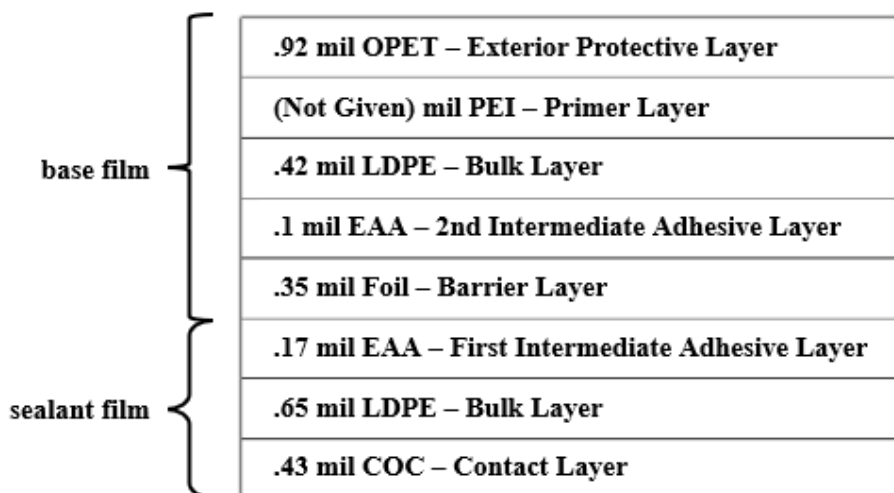
112 and that claims 1 through 13 were unpatentable on the grounds of obviousness under 35 U.S.C. 103 over a set of asserted references. The proposed substitute claims are responsive to one or more grounds of unpatentability at issue in this proceeding at least because the amendments enhance clarity of the claims, introduce features that add additional distinguishing features that are not rendered obvious by the asserted references, or both.

V. THE SUBSTITUTE CLAIMS ARE PATENTABLE OVER THE PRIOR ART

The proposed substitute claims are patentable over the asserted references at issue in this proceeding.

A. Summary of Riis, Wypych, and Tatarka

Riis is related to a film for packaging a product that has a pharmaceutical active agent selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine. EX1004, Abstract & ¶ [0011]. Riis (in example 5) discloses an eight-layer film, which can be depicted and characterized as shown:



Motion to Amend, Figure 1.

In the example film of Riis, a film structure includes a base film made of a .92 mil OPET layer/ a primer layer / a .42 mil LDPE layer/ a .1 mil EAA layer/ and a .35 mil foil layer. *Id.* ¶ [0174]. The film structure also includes a sealant film having a three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene copolymer (COC) that is extrusion coated on the aluminum foil surface of the multilayer base film. *Id.* ¶¶ [0160], [0165], [0168], p0174]. Accordingly, the sealant film is made of a .17 mil EAA layer/ a .65 mil LDPE layer/ and a .43 mil COC layer. *Id.* ¶ [0174]. 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].

As conceded by Petitioner, 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. Petitioner instead alleges that these

characteristics would have been obvious based on commercially available polymers. Petition, p. 40. Based on these commercially available polymers, Petitioner calculates that the .17 mil EAA layer has a loading within the range of 3.97–4.15 g/m² and that the .65 mil LDPE layer has a loading within the range of 15.11–15.34 g/m². Petition, pp. 41, 42.

With regard to the process for forming the eight-layer film in example 5 of Riis, Riis describes (1) providing the base film including, among other layers, the .35 mil Al layer; (2) providing the sealant film including the .17 mil EAA layer, the .65 mil LDPE layer, and the .43 mil COC layer; and (3) coextrusion coating (by way of a three-layer coextrusion) the .17 mil EAA layer, the .65 mil LDPE layer, and the .43 mil COC layer of the sealant film onto *the .35 mil Al foil layer of the base film* to obtain the eight-layer film. EX1004 ¶¶ [00163]–[00174].

As noted above, Riis gives little thought to processing specific parameters, such as loading, melting points, and the order of formation of the film layers. And is silent with regard to optimizing these parameters for a contact layer that includes COC. Accordingly, Riis does not provide one skilled in the art with a motivation to vary the processing parameters or order of operations for forming the layers to obtain a preferred film. By contrast, the '624 Patent directly contemplates achieving an aggressive chemical-resistant film that maintains strong barrier properties while supporting robust, yet thin layers, as well as aesthetically pleasing

properties — especially when using a contact layer that includes COC (a material known for being unsuitable for coextrusion, including from a visual point of view). See '624 Patent, col. 2, lns. 63-37, col. 6, lns. 1-28; *see also* EX2014 ¶¶ 57-70.

As acknowledged in the Petition, Wypych and Tatarka are simply used to provide material properties for the film disclosed in Riis (Petition, p. 80) and do not materially alter the 103 analysis over Riis.

B. Riis fails to render obvious substitute independent claim 14 (substitute for existing independent claim 1).

Substitute independent claim 14 is reproduced below.

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

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

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

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

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

the base layer consisting of the aluminum, and

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

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

1. Riis fails to teach or suggest "coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer consisting of the aluminum," as recited in substitute independent claim 14.

As noted *supra* § V.A, Riis discloses a five-layer base film and a three-layer sealant film, where the materials (EAA, LDPE, and COC) of the sealant film are coextruded to the *aluminum foil surface of the five-layer base film* in a three-layer coextrusion. So, in Riis, the three-layer sealant film is coated to the aluminum foil surface of the five-layer base film. EX2014 ¶ 227.

Coating the three-layer sealant film to the aluminum layer of the five-layer base film, as described in Riis, does not teach or suggest "coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to [a] base layer ***consisting of*** the aluminum," as recited in substitute independent claim 14 (emphasis added).

2. Riis fails to teach or suggest "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 consisting of the aluminum, and the coextrusion layer consisting of the tie

layer and the contact layer consisting of the COC," as recited in substitute independent claim 14.

As noted *supra* § V.B.1, the materials of the sealant layer are coextruded to the *aluminum foil surface of the five-layer base film* in a three-layer coextrusion. So, in Riis, after the three-layer coextrusion, the three-layer coextrusion layer is allowed to adhere to the five-layer base film to form the eight-layer film. EX2014 ¶ 229.

But allowing a three-layer coextrusion to adhere to a five-layer base film to form an eight-layer film, as described in Riis, fails to teach or suggest "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 consisting of the aluminum, and the coextrusion layer consisting of the tie layer and the contact layer consisting of the COC," as recited in substitute independent claim 14. That is, in Riis, after the three-layer coextrusion adheres to the five-layer base film, the result is an eight-layer film that includes a .92 mil OPET layer, a PEI layer, a .42 mil LDPE layer, a .1 mil EAA layer, a .35 mil Al foil base layer, and the coextrusion layer, which does not disclose an "aggressive chemical-resistant film [that] . . . consists of [a] base layer consisting of [] aluminum[] and [a] coextrusion layer," as recited in substitute independent claim 14.

3. Riis fails to teach or suggest that "the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine," as recited in substitute independent claim 14.

As noted *supra* § V.A, the film of Riis is used for packaging a product that has a pharmaceutical active agent selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine. EX1004, Abstract & ¶ [0011].

But Riis is silent with regard to the pharmaceutical active agent of rivastigmine. Thus, Riis fails to teach or suggest that "the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine," as recited in substitute independent claim 21.

C. Riis fails to render obvious substitute dependent claim 15 (substitute for existing dependent claim 10).

Substitute dependent claim 15 is reproduced below.

*15. The method according to claim 14, wherein:
at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer, and
the method further comprises laminating, after the aggressive chemical-resistant film is formed by coating the coextrusion layer to the base layer consisting of the aluminum, a first outer layer to the base layer of the aggressive chemical-resistant film.*

1. Riis fails to teach or suggest "laminating, after the aggressive chemical-resistant film is formed by coating the coextrusion layer to the

base layer consisting of the aluminum, a first outer layer to the base layer," as recited in substitute dependent claim 15.

Because Riis discloses coating the sealant film to the aluminum foil surface of the five-layer base film in a three-layer coextrusion (as noted *supra* § V.B.1), it follows that Riis does not teach or suggest "laminating, after the aggressive chemical-resistant film is formed, a first outer layer to the base layer," as recited in substitute dependent claim 15. That is, in Riis, the base film includes all of its outer layers prior to the three-layer coextrusion and, thus, does not contemplate laminating any outer layers to the base film after the three-layer coextrusion.

D. Riis fails to render obvious substitute dependent claim 16 (substitute for existing dependent claim 6).

Substitute dependent claim 16 is reproduced below.

16. The method according to claim 1, wherein a loading of a first layer of the tie layer is in the range of 7 to 18 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m².

1. Riis fails to teach or suggest that "a loading of a first layer of the tie layer is in the range of 7 to 18 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m²," as recited in substitute dependent claim 16.

As noted *supra* § V.A, Riis discloses 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. Petitioner alleges that the .17 mil EAA/ .65 mil LDPE/ .43 mil COC form a coextrusion layer, the EAA and LDPE layers allegedly being tie layers. *See* Petition, pp. 38, 39. In accordance with Petitioner's

calculations, the .17 mil EAA layer has a loading within the range of 3.97–4.15 g/m² and the .65 mil LDPE layer has a loading within the range of 15.11–15.34 g/m². Petition, pp. 41, 42.

Assuming *arguendo* that the EAA and LDPE layers are both tie layers, a .17 mil EAA layer having a loading of 3.97–4.15 g/m² and a .65 mil LDPE layer has a loading of 15.11–15.34 g/m², as described in Riis, does not teach or suggest that "a loading of a first layer of the tie layer is in the range of 7 to 18 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m²," as recited in substitute dependent claim 16. That is, only one of the alleged tie layers (the LDPE layer) of Riis has a loading that falls within the claimed range of 7 to 18 g/m².

As noted *supra* § V.A and acknowledged by Petitioner, Riis gives little thought to processing specific parameters, such as loading, melting points, and the order of formation of the film layers, while the '624 Patent directly contemplates achieving an aggressive chemical-resistant film that maintains strong barrier properties while supporting robust, yet thin layers, as well as aesthetically pleasing properties — especially when using a contact layer that includes COC.

E. Riis fails to render obvious substitute dependent claim 17 (substitute for existing dependent claim 7).

Substitute dependent claim 17 is reproduced below.

17. The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and

wherein a loading of a first layer of the plurality of layers is in the range of 7 to 14 g/m² and a loading of a second layer of the plurality of layers is in the range of 7 to 14 g/m².

1. Riis fails to teach or suggest that "a loading of a first layer of the plurality of layers is in the range of 7 to 14 g/m² and a loading of a second layer of the plurality of layers is in the range of 7 to 14 g/m²," as recited in substitute dependent claim 17.

As noted *supra* § V.D.1, in accordance with Petitioner's calculations, the .17 mil EAA layer has a loading in the range of 3.97–4.15 g/m² and the .65 mil LDPE layer has a loading in the range of 15.11–15.34 g/m². Petition, pp. 41, 42.

Again, assuming *arguendo* that the EAA and LDPE layers are both tie layers, the .17 mil EAA layer having a loading of 3.97–4.15 g/m² and the .65 mil LDPE layer having a loading of 15.11–15.34 g/m², as described in Riis, does not teach or suggest that "a loading of a first layer of the tie layer is in the range of 7 to 14 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 14 g/m²," as recited in substitute dependent claim 16. That is, neither of the alleged tie layers of Riis has a loading that falls within the claimed range of 7 to 14 g/m².

F. Riis fails to render obvious substitute independent claim 21 (substitute for existing independent claim 13).

Substitute independent claim 21 recites similar features to those discussed above. Thus, Riis fails to teach or suggest the features of substitute independent claim 21 for at least the foregoing reasons.

VI. CONCLUSION

As stated above Patent Owner requests that the Board grant this Motion to Amend requesting (1) cancellation of claims 2 and 3 before the Board's decision is rendered for this trial and (2) entry of only the provided substitute claims corresponding to issued claims that are found unpatentable.

Respectfully submitted on behalf of DANAPAK FLEXIBLES A/S on
September 12, 2023, by:

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VII. CLAIMS APPENDIX

The proposed amended claims are shown in marked-up form below.

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

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

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

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

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

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

the base layer ~~comprising~~ consisting of the aluminum, and
the coextrusion layer consisting of the tie layer[[,]] and the contact layer consisting of the COC, wherein:

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

B. Proposed substitute claim 15 to replace claim 10, if (a) claim 1 is found unpatentable and replaced with substitute claim 14 and (b) claim 10 is found unpatentable.

15. The method according to claim ~~[[1]]~~ 14, wherein:
at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer, and
the method further comprises laminating, after the aggressive chemical-resistant film is formed by coating the coextrusion layer to the base layer consisting of the aluminum, a first outer layer to the base layer of the aggressive chemical-resistant film.

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

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

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

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

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

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

F. Proposed substitute claim 19 to replace claim 9, if (a) claim 1 is found unpatentable and replaced with substitute claim 14 and (b) claim 9 is found unpatentable.

19. The method according to claim [[1]] 14, wherein coating the
coextrusion layer to the base layer comprises performing a coextrusion coating of
the coextrusion layer directly to the base layer consisting of the aluminum.

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

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

patch allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises Barex®.

H. Proposed substitute claim 21 to replace claim 13, if claim 13 is found unpatentable.

21. 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~~ consists of aluminum and is resistant to one or more of water or oxygen;

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

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

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

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

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

the tie layer comprises ~~one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a first tie layer having~~ a loading in the range of 7 to ~~[[20]]~~ 14 g/m² and a second layer having a loading in the range of 7 to 14 g/m², and

~~[[wherein]]~~ the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, ~~[[or]]~~ and lidocaine.

CERTIFICATE OF SERVICE

I, Steven A. Avena, hereby certify that a copy of the foregoing **PATENT OWNER'S MOTION TO AMEND** has been served on the attorneys of record of Petitioner Huhtamaki Flexible Packaging Germany GmbH & Co. KG electronically by email as of today, September 12, 2023, at the following electronic addresses:

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