

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG,
Petitioner

v.

ADAPA FLEXIBLES DENMARK SLAGELSE A/S,
Patent Owner

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

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

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I. INTRODUCTION

Petitioner Huhtamaki Flexible Packaging Germany GmbH & Co. KG (“Huhtamaki”) opposes the contingent motion to amend (Paper 22) filed by Patent Owner adapa flexibles Denmark Slagelse A/S (“Patent Owner”). Petitioner submits that proposed substitute claims 16, 17, and 21 violate 35 U.S.C. § 326(d) and 37 U.S.C. § 42.221 by introducing new matter. Further, proposed substitute claims 16-17 and 20-21 are indefinite. Lastly, all proposed substitute claims, 14-21, are obvious over the prior art, including Riis, Wypych, Tohara, Holzmuller, and Rivers. Patent Owner’s motion to amend should be denied, and a summary of Petitioner’s grounds for opposition is provided below:

Ground	Statutory Basis	Prior Art References	Challenged Substitute Claims
1	35 U.S.C. § 316(d)		16, 17, 21
2	35 U.S.C. § 112(b)		16, 17, 20, 21
3	35 U.S.C. § 103	Riis and Wypych	14, 15, 19, 20
4	35 U.S.C. § 103	Riis, Wypych, and Tohara	14
5	35 U.S.C. § 103	Riis, Wypych, Tohara, and Holzmuller	16, 17, 21
6	35 U.S.C. § 103	Riis, Wypych, Tohara, and Rivers	18

Petitioner further notes that Patent Owner’s Motion to Amend (at 1) misstates controlling legal precedent regarding the Board’s ability to *sua sponte* question the patentability of proposed substitute claims in view of the prior art of record. See *Hunting Titan, Inc. v. DynaEnergetics Europe GmbH*, Case IPR2018-00600, Paper 67, at 10 (PTAB July 6, 2020) (citing *Nike*, 955 F.3d 45, 51 (Fed. Cir. 2020)). While

Petitioner provides prior art and accompanying arguments supporting obviousness of the proposed substitute claims, the Board may, *sua sponte*, question the patentability of the proposed substitute claims.

II. NEWLY CITED PRIOR ART REFERENCES

The '624 Patent claims a priority date of December 29, 2015, from EP Application No. 15202962.5.

A. Tohara (EX1033)

Tohara qualifies as prior art under 35 U.S.C. § 102(a)(2) as a pending patent application that was filed before the effective filing date of the claimed invention, and no exceptions apply. Tohara published as US 2017/0348246 and claims the benefit of PCT/JP2015-082476, having a PCT filing date of November 18, 2015, pre-dating the '624 Patent filing date.

B. Holzmuller (EX1034)

Holzmuller qualifies as prior art under 35 U.S.C. § 102(a)(1) as a printed publication available to the public before the effective filing date of the claimed invention and no exceptions apply. Holzmuller published on November 20, 2008, before the effective filing date of the '624 Patent.

C. Rivers (EX1035)

Rivers qualifies as prior art under 35 U.S.C. § 102(a)(1) as a printed publication available to the public before the effective filing date of the claimed

invention and no exceptions apply. Rivers published on August 27, 2009, before the effective filing date of the '624 Patent.

III. SUBSTITUTE CLAIMS 16-17 AND 21 VIOLATE THE GOVERNING RULES FOR MOTIONS TO AMEND

Patent Owner's proposed substitute claims fail to meet the requirements of 35 U.S.C. § 326(d) and 37 C.F.R. § 42.221. In particular, a motion to amend must not introduce new subject matter and must set forth written description support for each claim. *See* 35 U.S.C. § 326(d)(1)(B), (d)(3); 37 C.F.R. §42.221; *Lectrosonics, Inc. v. Zaxcom*, IPR2018-01129, Paper 15 (precedential). Patent Owner has failed to carry its burden of persuasion to show that substitute claims 16, 17 and 21 do not introduce new matter and further fails to set forth written description support for substitute claims 16, 17, 20, and 21. *See* 85 FR 82923, 82927 (Dec. 21, 2020) (providing Patent Owner's burden).

The '624 Patent's original disclosure in U.S. Application No. 16/835,108 ("the '108 App") (EX1002, 309-45) and EP Application No. 15202962.5 ("the '962 App") (EX2012) fail to disclose the newly claimed limitations.¹ Such lack of written description support qualifies Patent Owner's substitute claims as "new matter" not allowed in motions to amend. *TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001). Claimed loading ranges of

¹ To be consistent with the MTA, this Opposition similarly cites to "the '108 App" and "the '962 App" as they are provided by Exhibits 1002 and 2012.

substitute claims 16, 17, and 21 are not supported by the specification. Patent Owner's recitation of new loading ranges of individual tie layers is not supported by the '108 or the '962 Applications. Claims 16, 17, and 21 require two tie layers, a first layer and a second layer, each of the layers having a claimed loading range of 7-18 g/m² (Claim 16) or 7-14 g/m² (Claims 17, 21). MTA, 27, 29. However, all supporting disclosures identified by Patent Owner refer to the loading "of the tie layers" collectively and plural, not of a single tie layer. *See e.g.*, '108 App, ¶43; '962 App, 8:12-15, '108 App, ¶147; '962 App, 19:1-6; *see also* EX1037, ¶70.

Further, the narrower claimed ranges (7-18 g/m² and 7-14 g/m²) are new matter not in the originally disclosed ranges (7-20 g/m² and 4-18 g/m²). The '624 Patent includes only two disclosures of the loading of the tie layers, 7-20 g/m² and 4-18 g/m², the latter range being disclosed in specific reference to example laminates 1-5 provided in Table 3. EX1001, 6:33-37, 16:17-67; *see also* EX1037, ¶¶71-73. This scant disclosure does not support (1) claiming loading ranges of multiple individual tie layers or (2) claiming a range with an upward bound of 14 g/m² as such upper bound is not disclosed nor enabled by the '624 Patent. *Indivior UK Limited v. Dr. Reddy's Laboratories S.A.*, 18 F.4th 1323, 1328-30 (Fed. Cir. 2021) (precedential) (holding that although limitations need not be set forth in *haec numera*, "a skilled artisan must be able to reasonably discern a disclosure of that range"); *In re Ruschig*, 379 F.2d 990, 994-95 (CCPA 1967) (where the broad

disclosures of a genus fails to provide “blaze marks” toward the claimed species, there is no written description support); *NeuroDerm Ltd. v. AbbVie Inc.*, PGR2022-00040, Paper 77, at 21 (PTAB Oct. 31, 2023) (citing *Indivior*) (denying motion to amend where “the claimed range is not disclosed in the application, [thus] Patent Owner had to do more than present [the Board] with a list of paragraphs in the application”).

Patent Owner’s substitute claims 16, 17, and 21 now recite ranges that read literally on embodiments outside of the originally disclosed ranges and thus cannot be adequately supported by the written description. *In re Wertheim*, 541 F.2d 257 (CCPA 1976). For instance, Patent Owner’s max loading of 18 g/m² in Claim 16 can only be supported by the specific laminates disclosed in Table 3, the sole disclosure showing such a loading range. *See* EX1001, 16:65-66. However, Table 3’s only example that could potentially fall within the scope of the claimed invention—Laminate 5—now falls outside the scope of substitute claims 16-17 and 21 as such claims require more than one tie layer yet Laminate 5 comprises a single tie layer. *See* EX1032, 47:11-21 (confirming the terpolymer tie layer of Laminate 5 is only one layer); *see also* EX1001, 16:55-60; EX1002, 336, EX2012, 21-22. Additionally, the 14 g/m² upper bound subgenus of claims 17 and 21 is not disclosed at all by the ’624 Patent and is not supported by genus ranges of 7-18 or 7-20 g/m². Accordingly, the amended loading ranges cannot be supported by the loading ranges described in

exemplary embodiments in Table 3. *Indivior*, 18 F.4th at 1329 (“For written description support of a claimed range, more clarity is required.”).

Patent Owner’s new limitations pluck out specific polymer components and layer thicknesses to create the newly claimed ranges. Such backward justification constitutes a mere “cobbling together [of] numbers after the fact.” *Indivior*, 18 F.4th at 1329-30. Accordingly, Patent Owner’s substitute claims 16-17 and 21 should not be allowed over introducing new matter.

IV. SUBSTITUTE CLAIMS 16, 17, 20, AND 21 ARE INDEFINITE

Patent Owner’s motion to amend should be denied because the proposed substitute claims do not comply with 35 U.S.C. § 112(b). A claim is indefinite where the claim, read in light of the specification and prosecution history, fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

A. Reciting ranges of individual tie layers

Claims 16-17 and 21 are indefinite for all the reasons discussed above regarding the failure of the ’624 Patent’s original disclosures to adequately support the new and more narrow ranges proposed in the substitute claims. *See supra* § III.A; *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (an adequate description of a genus may not support claims to a subgenus or species within the

genus).

B. Use of the trademark Barex® lacks specific meaning and renders substitute claim 20 vague.

Proposed substitute claim 20 is indefinite under Section 112(b), because a POSITA would not be able to ascertain the metes and bounds of a method of providing a film defined by comparison to a product trademark. It is well established that using a trademark in a patent claim renders the claim indefinite under 35 U.S.C. § 112(b). This is because trademarks are used to identify the source of goods, not the goods themselves. *See Ex Parte Locke*, Appeal No. 2008-5853, at *17 (B.P.A.I. Feb. 10, 2009). Patent Owner improperly claims identification or description of a particular element by using the trademark Barex® as the identifier. *Ex parte Simpson*, 218 USPQ 1020 (B.P.A.I. 1982); *Eli Lilly & Co. v. Apotex, Inc.*, 837 F. App'x. 780, 784-85, (Fed. Cir. 2020) (“Trade names are not anchored to a single specific meaning and thus can introduce potential vagueness into patent claims.”).

There is nothing in the record of the '624 Patent to indicate with clarity the materials that fall under the claim limitation covered by Barex®. Further, the '624 Patent does not disclose any well-known or identifiable features of Barex® that would inform a skilled artisan of an accepted standard at the time of the claimed invention. *See generally* EX1001. This problem is further compounded by the fact that Barex® is no longer commercially available. EX1016; EX1017; EX1032, 105:7-16, 151:15-152:8. Accordingly, substitute claim 20 should not be allowed as

indefinite.

V. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE OVER THE PRIOR ART

A. Substitute Claim 14 is Unpatentable as Obvious Over Riis in View of Wypych, and Further in View of Tohara.

In addition to the reasons discussed below, the combination of Riis and Wypych renders substitute claim 14 obvious for at least the reasons set forth in the Petition regarding original claim 1. *See* Pet. 31-45, 53-64. Patent Owner alleges that the prior art of record fails to disclose “the base layer consisting of the aluminum” and “the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine,” as recited in substitute independent claim 14. MTA, 19-21.

1. Riis discloses a base layer consisting of aluminum.

Patent Owner’s argument that Riis solely teaches coextruding a sealant film of EAA, LDPE, and COC to the aluminum foil base layer of a five-layer film is an overly narrow reading of the prior art and does not consider the full disclosure of Riis. *See* MTA, 19; *see also Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804 (Fed. Cir. 1989) (a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments.). Patent Owner’s interpretation of Riis is limited to Example 5, asserting that the “base film” of Example 5 does not disclose a “base layer”

consisting of aluminum. MTA, 19-20. Patent Owner's interpretation is flawed in view of the entirety of Riis' disclosure.

Riis teaches "a flexible, multilayer packaging film suitable for packaging an article . . . such as transdermal drug delivery patches" that includes multiple layers, including a barrier layer that is preferably an oxygen and moisture barrier. EX1004, ¶¶12, 58-63. Riis' barrier layer is preferably both a gas and moisture barrier layer and may be in contact/sandwiched between two tie layers and/or two surface layers. EX1004, ¶59. Riis further teaches that the barrier layer may be made of "any suitable material," including aluminum foil. EX1004, ¶¶57-59, 62-63, 85-87, 157, 174. Like the '624 Patent, Riis teaches that aluminum foil is an excellent gas (oxygen) and moisture (water) barrier. *Compare* EX1001, 4:6-10, *with* EX1004, ¶86-87. A skilled artisan would have appreciated that the "base layer" of the '624 Patent and the "barrier layer" of Riis, while having different terminology, represent the same layers in a multilayer film, i.e., an oxygen and moisture barrier layer. EX1037, ¶¶80-81. Because Riis discloses aluminum foil as a suitable barrier material and teaches embodiments with the barrier layer being aluminum foil, Riis provides a base layer consisting of aluminum. *See e.g.*, EX1004, ¶174.

Riis discloses coating a sealant film (EAA, LDPE, COC) onto the surface of the aluminum foil barrier (base) layer. EX1004, ¶¶135, 157, 174. In particular, Riis discloses "the sealant film was a three-layer coextrusion of EAA, LDPE, and

Ethylene-norbornene [cyclic olefin] copolymer (COC) which was extrusion coated *onto the aluminum foil surface* of the multilayer base film.” EX1004, ¶174. Patent Owner’s substitute claim 14 limitation requiring “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,” is met by Riis. Regardless of any additional layers that may be coated on the opposite side of the foil, the claim limitation requires only that the coextrusion layer (sealant film) is coated directly to aluminum, which is exactly what Riis teaches.

Patent Owner’s substitute claim 14 limitation including “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,” is also met by Riis. Although several examples of Riis include abuse-resistant outer layers and intermediate adhesive layers binding the outer layers to the barrier layer, a skilled artisan would recognize that Riis does not require such outer protective and intermediate layers to provide its inventive anti-scalping film. See EX1004, ¶¶66-67 (disclosing films “*may include an outer layer*”) (emphasis added), ¶¶70-72 (disclosing that tie layers are added to promote adherence of the exterior protective layer, the intermediate barrier layer, and the interior contact layer); EX1037, ¶¶87-89; *see also* DI, 34 (citing Pet. 37, 39;

EX1003, ¶146) (The Board recognizing that “the oxygen barrier layer, or aluminum foil base layer, together with the three-layer sealant film, would form an ‘aggressive chemical-resistant film.’”). Riis discloses the optional nature of such layers in reference to its exemplary film depicted in Figure 1. EX1004, ¶135. Further, Riis teaches various methods and steps for creating multilayer films are not to be construed as having any specific ordering of the steps. *Id.*, ¶48. “Any recited single or multiple feature or aspect in any one claim can be combined or permuted with any other recited feature or aspect any other claim or claims.” *Id.* A skilled artisan, appreciating Riis for its entire disclosure, would understand that the sealant film (EAA, LDPE, COC) could be coextruded onto the aluminum foil barrier (base) layer, excluding any exterior protective layers and intermediate layers, to form the foil, EAA, LDPE, COC film of the claimed invention. EX1037, ¶¶87-89. Thus, the amended aspects of claim 14 with respect to a base layer consisting of aluminum foil are rendered obvious.

2. Riis discloses an “aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine.”

As an initial point, Patent Owner’s amendment to the preamble does not change the scope of the claim, because Patent Owner never asserts the preamble is limiting or construes the claims to that effect. *See e.g.*, EX1032, 172:9-11. Moreover, the preamble merely expresses a purpose or intended use of the apparatus provided by the claimed method rather than any distinct limitation of the inventive method.

See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002) (explaining that an inventor may not obtain a patent on a process having the same steps as a prior art process, in which the new process merely identifies a new, advantageous property of the prior art process). The preamble of substitute claim 14 is thus not limiting.

Further, Patent Owner's mere change of the disjunctive "or" to the conjunctive "and" does not limit or alter the apparent Markush grouping that requires chemical resistance to only "a chemical" selected from the recited chemicals. A chemical "selected from" a list of exemplary chemicals is claimed in the Markush form where the group of exemplary chemicals is recited with a conjunctive "and." *See Merck & Co. v. Mylan Pharms., Inc.*, 190 F.3d 1335, 1339 (Fed. Cir. 1999); *see also Metcalfe v. Hampel*, 532 F.2d 1360, 1362 (C.C.P.A. 1976) (finding "'selected from spirit soluble azo dyes and finely divided pigmenting material,' sets forth a type of Markush group") (emphasis added); *Pharmacia & Upjohn Co. v. Ranbaxy Pharms., Inc.*, 85 F. App'x 205, 209 (Fed. Cir. 2003) (finding a listing of alternatives linked with the conjunctive "and" was in Markush form); *see also Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1357 n.2 (Fed. Cir. 2016) ("No precise linguistic formula is required to create a Markush claim."). Here, the chemicals identified are presented as alternative elements that can be selected as part of the claimed invention. *Abbott Lab'ys v. Baxter Pharm. Prod., Inc.*,

334 F.3d 1274, 1281 (Fed. Cir. 2003) (“If a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim.”). Accordingly, Riis renders this aspect of the substitute claims obvious as Riis teaches chemical resistance to chemicals including nicotine, fentanyl, and lidocaine. Pet. 17-18, 31 (citing EX1004, ¶¶ 5, 11).

In view of the preamble’s Markush grouping, Riis discloses this chemical resistance. Patent Owner’s proposed amendment does not require the claimed method to provide a film resistant to all the recited chemicals. Instead, proposed claim 14 recites that the aggressive chemical-resistant film “is resistant to *a chemical selected from* nicotine, fentanyl, rivastigmine, *[[or]] and* lidocaine.” MTA, 26, 29 (emphasis added). Riis discloses a method for providing films that resist migration of chemicals and identifies nicotine, fentanyl, and lidocaine as exemplary pharmaceutical active ingredients, even providing experimental evidence demonstrating resistance to nicotine and lidocaine. EX1004, ¶¶5, 11, Table 2, 190-192; EX1003, ¶121. Thus, Riis teaches this limitation in view of the Markush grouping of substitute claim 14.

Even if Patent Owner’s preamble requires the claimed aggressive chemical-resistant film to be resistant to *all* chemicals selected from nicotine, fentanyl, rivastigmine, and lidocaine, such claimed method is unpatentable as obvious over

the combination of Riis, Wypych, and Tohara. Although Riis does not specifically disclose its aggressive chemical-resistant film to be resistant to rivastigmine, Tohara teaches methods and products related to packaging for drug patch products, including the use of a COC contact layer as resistant to rivastigmine. EX1033, Abstract, ¶¶89, 94-96; *see also* EX1004, ¶114 (disclosing that Riis's film is resistant to "any suitable pharmaceutical active agent"). Tohara teaches packaging formed of a laminate with three or more layers, including a cyclic polyolefin film, and a lidocaine or rivastigmine containing patch housed in the film. EX1033, ¶1. Because lidocaine and rivastigmine are known to be susceptible to oxidation, volatilization, and adsorption over time, Tohara proposes adopting a multi-layer laminate including a cyclic polyolefin ("COC"). EX1033, ¶¶11-14, 27-30, 87-89, 102. Tohara also teaches the usefulness of COC films in such a context. *See* EX1033, ¶¶93-96.

A POSITA would have been motivated to modify the method of Riis and Wypych to be chemically resistant to rivastigmine as taught by Tohara to prevent oxidation and decomposition of packaged patch products, like those including lidocaine and rivastigmine. EX1033, ¶¶12, 29-30, 85, 87-89; EX1037, ¶¶95-97. A POSITA would further have had a reasonable expectation of success in modifying the method of Riis and Wypych with Tohara's resistance to rivastigmine, because Tohara provides the suitability of using a COC contact layer, like those

commercially available from Topas, to package such products.² Compare EX1033, ¶¶87-89, 94-95, 102 (disclosing COCs commercially available from Topas), with EX1004, ¶¶52, 54, 97 (recommending commercially available COCs from Topas); EX1037, ¶99. Accordingly, the combination of Riis, Wypych, and Tohara renders substitute claim 14 obvious.

B. Substitute Claim 15 is Unpatentable as Obvious Over Riis in View of Wypych

Patent Owner seeks to limit the claimed method to laminating a first outer layer to the base layer only after the aggressive chemical-resistant film is formed. MTA, 8, 27. However, Riis renders this limitation obvious. Riis teaches exemplary methods of forming a film, such as coextrusion coating a sealant film (the claimed coextrusion layer) to the aluminum foil surface (barrier/base layer) of a base film that includes outer protective layers. EX1004, ¶¶160-174. Riis further provides that such methods and descriptions as set forth do not require the recited steps to be performed in that order, and, as such, possible alternatives are not expressly precluded. *Id.*, ¶48.

² To the extent Patent Owner argues that a POSITA would not have had a reasonable expectation of success modifying the combination of Riis and Wypych with Tohara's resistance to rivastigmine, the proposed substitute claims are invalid for lack of enablement. The '624 patent only discloses experimental results indicating resistance to rivastigmine and lidocaine. Thus, to the extent Patent Owner argues against a reasonable expectation of success in modifying Riis, the same would apply to modifying the disclosure of the '624 patent.

A POSITA would have found laminating an outer layer and associated adhesive layers to the base layer of the aggressive chemical-resistant film after the aggressive chemical-resistant film is formed obvious as a matter of design choice among a limited sequence of steps to forming such a film. *See In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (use of claimed feature solving no stated problem and presenting no unexpected result is an obvious matter of design choice); EX1037, ¶¶104-109. A POSITA would have been motivated to laminate an outer protective and accompanying adhesive layer to the sealant film of Riis, since Riis does not attribute any particularity to the order disclosed in regard to Example 5 and further provides only a finite number of solutions in ordering the inventive films of Riis: laminating the outer protective layers (1) *after* the inner sealant films, (2) *before* the sealant film, or (3) *simultaneous* therewith. EX1037, ¶¶107-109.

C. Substitute Claim 16 is Unpatentable as Obvious Over Riis in View of Wypych, Tohara, and Holzmuller

In addition to the reasons set forth above why substitute claim 16 introduces new matter and is not adequately supported by the written description, the claim is nonetheless unpatentable as obvious over the combination of Riis, Wypych, Tohara, and Holzmuller. Riis discloses a 0.65 mil LDPE layer of its tie layer as falling within the range of 7-18 g/m². *See* MTA, 23 (Patent Owner acknowledging as much); *see also* Pet. 40-43, 59-60. Although Riis's 0.17 EAA layer falls outside of the newly claimed loading range, a POSITA would have found it obvious to modify and

optimize the interacting thicknesses of the layers of the tie layer to promote adhesion of layers and to prevent undesirable lamination through routine experimentation. EX1004, ¶20; EX1037, ¶¶115-117, 126-127.

Holzmuller teaches the need to balance various properties of laminates used for packaging, including the need to prevent delamination, block internal barrier layers from packaged substances, optimize haptic properties like stiffness, and to keep costs low. EX1034, ¶¶3-4, 7, 20. Holzmuller recognizes that polymers like EAA and “polyolefins, especially polyethylene (PE)” provide suitable bonding layers for use in such laminates. EX1034, ¶18. Holzmuller further teaches various ranges of thicknesses for such bonding layers to achieve laminates with improved barrier properties as well as optimized mechanical and chemical properties. EX1034, ¶¶19, 23.

For example, bonding layers formed from polyolefins like polyethylene may be in an allowable range of 5-140 μm (0.197-5.512 mils), a preferred range of 8-95 μm (0.315-3.740 mils), and an especially preferred range of 10-50 μm (0.394-1.968 mils). EX1034, ¶19; EX1037, ¶118. Regarding the thickness of bonding layers (such as a first bonding layer) formed from EAA, Holzmuller teaches thickness from 5-140 μm (0.197-5.512 mils), preferred thicknesses of 8-95 μm (0.315-3.740 mils), and especially preferred thicknesses of 10-50 μm (0.394-1.968 mils). EX1034, ¶19; EX1037, ¶122. Applying the same conversion that both the Board and Patent Owner

have credited to Dr. Spontak, Holzmuller teaches loading ranges of LDPE from 4.6-130.1 g/m², preferably from 7.3-88.3 g/m², and especially preferably from 9.2-46.4 g/m². EX1037, ¶¶119-121. For an EAA layer, Holzmuller teaches loading ranges from 4.6-134.4 g/m², preferred ranges of 7.4-91.2 g/m², and especially preferred ranges of 9.2-48.0 g/m². EX1037, ¶¶123-125.

Holzmuller thus teaches ranges that encompass the newly claimed ranges and further teaches preferred and especially preferred ranges that overlap with the newly claimed range of 7-18 g/m²; the combination of Holzmuller with Riis and Wypych accordingly renders substitute claim 16 obvious. *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) (“[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness.”); *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists.). Holzmuller recognizes that modifying thicknesses of intermediate bonding layers achieves desirable properties of films, including barrier layer protection, sufficient adhesion for lamination, and desired mechanical and chemical properties. EX1034, ¶¶3-4, 7, 20. The optimized ranges taught by Holzmuller show that a POSITA would tailor such ranges to achieve the desired results. EX1037, ¶¶136-138, 147-149. A POSITA would thus be motivated to optimize Riis’s intermediate tie layers to achieve desired additive effects and

would have had a reasonable expectation of success in doing so due to the similarity in structure, function, and polymeric materials considered by both Riis and Holzmuller. EX1037, ¶¶115-117, 126-127.

Moreover, Patent Owner has neither shown evidence nor alleged that the newly claimed range in substitute claim 16 is critical. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”); *see also* EX1032, 180:14-186:19 (discussing EX1029, ¶68) (failing to find discussion of criticality in his declaration and acknowledging his past sworn testimony to the Board that “absent any criticality, specific dimensions or dimensional ranges are obvious as a matter of design choice, especially when these ranges were known in the art, as is the case with the claimed thickness range.”). Thus, a POSITA would have been motivated to alter the specific dimensional ranges of the tie layer loading ranges as a matter of design choice, as these ranges were known in the art. EX1037, ¶¶128-130. Accordingly, substitute claim 16 is unpatentable as obvious over the combination of Riis, Wypych, Tohara, and Holzmuller.

D. Substitute Claim 17 is Unpatentable as Obvious Over Riis in View of Wypych, Tohara, and Holzmuller

Proposed substitute claim 17 is substantially the same as substitute claim 16, differing mainly in the loading range of the first and second tie layers. As discussed

for substitute claim 16 above, and incorporated herein, Riis in view of Wypych, Tohara, and Holzmuller render substitute claim 17 obvious. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985) (finding that a *prima facie* case of obviousness exists where the claimed ranges or amounts do not overlap with the prior art but are merely close without meaningful difference). For at least the reasons stated above with respect to substitute claim 16, Holzmuller teaches modifying the thicknesses and loading of the intermediate bonding (PE) and adhesive (EAA) layers such that a POSITA would have been motivated to tailor the thickness of each layer to provide sufficient mechanical and chemical stability. See *supra* § V.C. Because Holzmuller teaches loading ranges that encompass the newly claimed ranges, and further because Holzmuller teaches preferred and especially preferred ranges which overlap the newly claimed ranges, a POSITA would have found it obvious to modify Riis's LDPE and EAA layers to fall within the loading range of 7-14 g/m². EX1037, ¶¶136-138, 141-142, 145-149; *see also In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005) (finding a *prima facie* case of obviousness where the claimed ranges are entirely encompassed by prior art ranges which is even more compelling than in cases of mere overlap).

E. Substitute Claim 18 is Unpatentable as Obvious Over Riis in View of Wypych, Tohara, and Rivers

Riis discloses COC for use in the product contact layer of its inventive film. *See* Pet. 34 (citing EX1004, ¶¶52-53, 55, 133-35). Although Riis discloses that COC

contact layers are suitable for drug packaging and exhibit suitable RED/Hansen Solubility Parameters (HSPs) to prevent migration of “any suitable pharmaceutical active agent,” Riis does not specifically disclose percentages of API migration. *See* EX1004, ¶¶8-9. However, Rivers teaches that packaging films using COCs as product contact layers allow for as little as 1% scalping of a packaged product. EX1035, 4:13-5:2 (describing generally the film employing COC to prevent scalping), 9:31-10:3 (providing scalping as the result of transport into or absorption by the film of the packaged product), 25:1-31. In particular, Rivers teaches that COC’s provide minimal scalping of packaged products, providing ranges from 1% to 90% of the compounds. EX1035, 8:32-9:12, 9:31-10:3 (defining scalping).

A POSITA would have been motivated to look to Rivers to evidence and verify the anti-scalping properties of COCs recognized by Riis. EX1037, ¶¶153-154; *see also* EX1004, ¶¶8-9; EX1035, 13:16-25, 18:25-19:2. Patent Owner’s expert, Dr. McCarthy, confirms that verifying such a property would be important to a POSITA, thus confirming a POSITA would look to the prior art for specific COC properties and parameters. EX1032, 166:10-170:17 (insisting a POSITA would want to verify the nature of a film as an aggressive chemical-resistant film). A POSITA would have had a reasonable expectation of success in looking to Rivers to verify such anti-scalping properties since both Riis and Rivers are similarly directed to multilayer films used to package volatile products susceptible to degradation and adsorption.

EX1037, ¶¶152-155; EX1004, ¶55; EX1035, 25:1-31, 26:16-27:5. Accordingly, substitute claim 18 is rendered obvious by the combination of Riis, Wypych, and Rivers.

Further, Patent Owner's proposed amendment does not limit any manipulative step of the claimed method and merely seeks to capture inherent properties of the materials provided by the prior art (*i.e.*, an intended result of previous process steps). *Bristol-Myers*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (statements of purpose and intended result not resulting in a manipulative difference in the steps of a claim are generally not limiting); *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003) (simply expressing the intended result of a process step is given little patentable weight). Thus, the recitation of specific aggressive chemical-resistant film percentages does not impart patentable weight and fails to differentiate substitute claim 18 from the prior art.

F. Substitute Claim 19 is Unpatentable as Obvious Over Riis in View of Wypych

As discussed above for substitute claim 14, and incorporated herein, Riis in view of Wypych render substitute claim 19 obvious because the prior art discloses coextruding the coextrusion layer directly to the base layer consisting of aluminum. As discussed above with respect to substitute claim 14, Riis discloses coextruding a sealant film (EAA, LDPE, COC) onto the surface of the aluminum foil barrier (base) layer. EX1004, ¶¶ 135, 157, 174.

G. Substitute Claim 20 is Unpatentable as Obvious Over Riis in View of Wypych

In addition to the reasons set forth above (*supra*, § IV.B) regarding indefiniteness, substitute claim 20 is also unpatentable as obvious over Riis in view of Wypych, because the prior art discloses Patent Owner's newly added limitations. Patent Owner recites "the chemical is provided in a first patch" ("the chemical" being "a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine") and also includes a limitation requiring the aggressive chemical-resistant film to be "based at least in part on allowing 90% to 110% of the claimed 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 path allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises Barex®." MTA, 28-29.

Riis discloses both newly added limitations to substitute claim 20. First, Riis discloses that the package formed by its inventive film can be used to contain, for example, a transdermal drug delivery patch. EX1004, ¶¶2, 4, 55, 91-92, 114, 122, 137, 160, 174. Second, Riis further discloses an aggressive chemical-resistant film that allows 90-110% migration of the chemical when compared with Barex®. *Id.*, ¶¶178-181.

For instance, Riis discloses that a product contacting layer of the inventive film is considered effective for purposes of an aggressive chemical-resistant film by

the following:

[A]n amount of the active agent that migrates into the product contacting layer of the film (the test film) is not more than 15% greater than migrates into a substantially similar film having a Barex® product contacting layer (the reference film) when a product containing the pharmaceutical active agent is positioned relative to the test and reference films such that the pharmaceutical active agent is in direct contact with the product contacting layers of the test and reference films.

Id., ¶129. Because Riis discloses a range of 0-15% of chemical migration as compared to a similar Barex® product contacting layer, Riis provides the claimed migration of 90-110% when compared to Barex® as an index 100. *ClearValue Inc. v. Pearl River Polymers Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012) (finding no allegation of criticality or any evidence demonstrating any difference across the range); *see also In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003). Riis teaches preferred embodiments that allow “no more than 10% more than the amount of the pharmaceutical active agent that migrates into film having Barex® as a sealing layer” and further teaches embodiments having no more than 1% migration. EX1004, ¶132. Such preferred embodiments of Riis similarly render substitute claim 20’s range unpatentable. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682 (CCPA 1962)) Accordingly, substitute claim 20 is obvious over Riis.

H. Substitute Claim 21 is Unpatentable as Obvious Over Riis in View of Wypych, Tohara, and Holzmuller

For the same reasons discussed above for substitute claims 14 and 17, which are incorporated herein, the prior art of Riis, Wypych, Tohara, and Holzmuller render this claim obvious. *See supra* §§ V.A.1-2, V.D.

Although substitute claim 21 recites chemical-specific resistance in the body of the claim instead of the preamble, the same interpretation applies. Originally presented as a “wherein” clause, the last limitation of substitute claim 21 does not positively recite a manipulative step or otherwise give meaning and purpose to the manipulative steps. Instead, this limitation simply expresses the intended results of the previously recited process steps, to provide a film that is resistant to a certain chemical and does not limit the claimed method.

VI. CONCLUSION

Petitioner respectfully requests the Board to find that substitute claims 16-17 and 21 introduce new matter, substitute claims 16-17, 20-21 are indefinite, substitute claims 14, 19-20 are rendered obvious by Riis and Wypych, substitute claim 14 is obvious over Riis, Wypych, and Tohara, substitute claims 16-17, 21 are obvious over Riis, Wypych, Tohara, and Holzmuller, and substitute claim 18 is obvious over Riis, Wypych, Tohara, and Rivers.

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Respectfully submitted,

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e) and 42.105(a))

The undersigned hereby certifies that, on December 5, 2023, true and correct copies of the foregoing **PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO AMEND** and all associated exhibits were served in their entirety on Patent Owner via email as follows:

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