

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

**DECLARATION OF RICHARD J. SPONTAK, PH.D.
IN SUPPORT OF PETITIONERS' OPPOSITION TO
PATENT OWNER'S MOTION TO AMEND**

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I, Richard J. Spontak, hereby declare and state as follows:

I. INTRODUCTION

1. I have previously authored and signed a declaration on November 30, 2022, which I understand was submitted as Exhibit 1003 to the Patent Trial and Appeal Board of the USPTO in case number PGR2023-00008. I may alternatively refer to that declaration as “Exhibit 1003,” “EX1003,” or “Original Declaration.” In this Second Declaration, I incorporate the facts and opinions set forth in my Original Declaration as it relates to the unpatentability of the challenged claims in view of the patent owner’s motion to amend the claims.

2. I have been retained as an expert witness on behalf of Huhtamaki Flexible Packaging Germany GmbH & Co. KG (“Huhtamaki”) for the above-captioned post-grant review (“PGR”). I am being compensated for my time in connection with this PGR through which Patterson Intellectual Property Law, P.C. has agreed to pay me for my services at a rate of \$500 per hour. My compensation is not contingent upon my opinion or testimony or the outcome of this PGR.

3. This Second Declaration incorporates my opinions and analysis as it relates to Patent Owner’s Motion to Amend the claims of U.S. Patent No. 11,260,624 (EX1001, the “’624 patent”), including how Patent Owner’s proposed substitute claims (1) add new matter not previously disclosed in the application specification, (2) are unpatentable as indefinite, pursuant to 35 U.S.C. § 112(b), and are

unpatentable as obvious, pursuant to 35 U.S.C. § 103, as understood by a person of skill in the art (“POSITA”) or, alternatively, a skilled artisan.

4. I understand that Patent Owner has filed a Motion to Amend the original claims of the ’624 patent and proposes to replace original claims 1-13 with substitute claims 14-21. I have been asked to provide my independent technical review, analysis, insights, and opinions regarding the substitute claims submitted by Patent Owner for the ’624 patent and the prior-art references that form the basis for the grounds of unpatentability in Petitioner’s Opposition (“the Opposition”).

5. In preparing this declaration, I have reviewed and am familiar with all the documents cited herein. I have reviewed and am familiar with the ’624 patent and its file history. I confirm that, to the best of my knowledge, the accompanying exhibits are true and accurate copies of what they purport to be, and that an ordinarily skilled artisan in the field would reasonably rely on them to formulate opinions such as those set forth in this declaration.

6. The matters and opinions stated herein are true and correct to the best of my understanding. The facts set forth in this declaration are personally known to me and I have firsthand knowledge thereof. If called upon to do so, I could and would competently testify to these matters under oath.

II. QUALIFICATIONS AND RELEVANT EXPERIENCE

7. My experience, qualifications, and CV are set forth in my Original

Declaration and are not reproduced here.

8. In forming the opinions expressed in this Second Declaration, I have considered and relied upon my approximately thirty-nine years' experience in polymer science, my education, and my knowledge in the relevant (and related) art. In addition, I have reviewed and relied upon additional materials in preparation of this declaration, as described below. In formulating my opinions, I have also considered the viewpoint of a POSITA before the time of the invention, which I have been told to assume for this case is December 29, 2015.

III. MATERIALS CONSIDERED

9. In my study of this matter, I have received various materials from counsel for Huhtamaki (these are listed on the following page, along with their Exhibit Nos.), and I have likewise searched for and examined relevant background material as I would with any project.

10. I have reviewed and relied upon the materials cited herein, as well as those listed in the table below, in preparation of this declaration. Citations to these materials that appear in this report are meant to be exemplary but not exhaustive. Although some references listed may not be directly cited in this declaration, they still informed my consideration of the knowledge of a POSITA and my opinions depending thereon.

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

1020	Declaration of Samuel A. Raque
1021	U.S. Patent Appl. Pub. No. 2009/0208685 to Rivers <i>et al.</i>
1022	Topas COC 8007F-400 Safety Data Sheet (2015)
1023	Topas COC 8007F-400 Safety Data Sheet (2017)
1024	Dr. Detlev Schulz Declaration
1025	WO 2012/037180 to Bonekamp <i>et al.</i>
1026	Reproduction of Fig. 2 – U.S. Patent No. 11,260,624 to Christensen <i>et al</i>
1027	Diagram #1 of 4-layer multilayer film
1028	Diagram #2 of 4-layer multilayer film
1029	PGR2022-00001 – EX1003 – Declaration of Stephen McCarthy PhD
1030	U.S. Patent No. 10,889,093 to Wang
1031	U.S. Patent No. 6,903,161 to Morris
1032	Deposition of Dr. Stephen McCarthy
1033	U.S. Patent App. Pub. No. 2017/0348246 to Tohara <i>et al.</i>
1034	U.S. Patent App. Pub. No. 2008/0286512 to Holzmuller <i>et al.</i>
1035	WO 2009/105205 to Rivers <i>et al.</i>
1036	The Science and Technology of Flexible Packaging - Morris

11. I relied on counsel for my legal understandings, particularly with respect to patent law. While I do not possess detailed knowledge of or practical background in

patent law, my opinions provided herein relate my expertise regarding polymer science and polymer engineering to the patentability of the '624 patent.

12. This Second Declaration represents my findings based on information available as of the date of this declaration. Additional information may become available that could further support or modify the conclusions that I have reached to date. I reserve the right to analyze newly discovered information and provide an updated report. Furthermore, I reserve the right to consider and comment on any additional expert statement and testimony provided in this matter. Any changes or necessary amplification of these conclusions will be addressed in supplemental reports or testimony, which I reserve the right to provide.

IV. APPLICABLE LEGAL STANDARDS

13. I have been told the following legal principles apply to an analysis of patentability. While I have endeavored to list the applicable legal standards here in this section, other portions of my Declaration may also be relevant, and may also contain my understanding of the legal standards as I applied them to the challenged claims, prior art, and other materials considered.

14. I understand that I must evaluate the patentability of each claim separately. Even if an independent claim is unpatentable, this does not mean that the dependent claims that ensue from it are automatically unpatentable. Rather, I must separately consider the unpatentability of each claim. That is, I understand that I must evaluate

the issue of patentability on a claim-by-claim basis.

A. Standard for Motions to Amend under 35 U.S.C. § 326

15. I understand that in a post-grant review, a Patent Owner may file a motion to amend the claims. I understand that the motion to amend must demonstrate: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the original disclosure sets forth written description support for each proposed claim. 35 U.S.C. § 326(d)(1)(B), (d)(3); 37 C.F.R. §42.221.

16. Regarding the requirement that the amendment must not enlarge the scope of the claims or introduce new subject matter, I understand that any claimed subject matter that lacks written description support in the original disclosure constitutes “new matter.” I understand written description support can be found in the text of the specification and also from the figures.

17. I understand that proposed amendments in a motion to amend are reflected through the use of underlining for additions and strikethroughs or double bracketing for deletions.

B. Standard for Indefiniteness under 35 U.S.C. § 112(b)

18. I have been told that, in a PGR proceeding, a patent claim may be deemed unpatentable if it is shown by a preponderance of evidence that the claim is indefinite

if the claim, read in light of the specification delineating the patent (and the prosecution history), fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

19. I understand that claim definiteness is measured from the viewpoint of a POSITA at the time the application was filed.

20. I understand that it is not sufficient that one can ascribe some meaning to a patent's claims, but reasonable efforts must result in a definition that provides sufficient specificity and clarity to inform skilled artisans of the bounds of the claim.

21. I understand that claims that are impossible are indefinite.

C. Standard for Obviousness under 35 U.S.C. § 103

22. I have also been told that, in a PGR proceeding, a patent claim may be deemed unpatentable if it is shown by a preponderance of evidence that the claim is rendered obvious by one or more prior art patents or publications under 35 U.S.C. § 103.

23. I understand that documents and materials such as printed publications or patents that qualify as prior art can be used to invalidate a patent claim as anticipated or as obvious.

24. I understand that terms of the claims are given their ordinary and customary meaning in light of the specification and prosecution history—that is, the meaning that the term would have to a POSITA in question at the time of the application's filing date.

25. I understand that, once the claims of a patent have been properly construed, the second step in determining obviousness of a patent claim requires a comparison of the properly construed claim language to the prior art on a limitation-by-limitation basis.

26. I understand that a patent may not be obtained “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

i. ***Graham* factors**

27. I further understand that an obviousness determination requires consideration of four factual inquiries. First, one must consider the scope and content of the prior art. Second, one must determine the differences between the prior art and the claims at issue. Third, one must resolve the level of ordinary skill in the pertinent art at the time of invention. Fourth, one must consider any objective evidence of non-obviousness.

28. With respect to determining the proper scope of prior art to examine, I understand that, for a prior art reference to be properly used in an obviousness ground under 35 U.S.C. § 103, the prior art reference must be analogous art to the claimed invention. I have been told that a reference is analogous art to the claimed invention only if: (1) the reference is from the same field of endeavor as the claimed

invention; or (2) the reference is reasonably pertinent to the particular problem solved by the inventor.

29. I understand that factors relevant to determining the proper field of endeavor include the inventor's explanations of the subject matter (including the patent specification), as well as the claimed invention's structure and function. And I further understand that to be reasonably pertinent to the particular problem solved by the inventor, a prior art reference must logically commend itself to the inventor's attention in considering his or her problem.

30. I have been told that an analogous reference may be modified or combined with other analogous references or with the POSITA's own knowledge if the person would have found the modification or combination obvious. I have also been told that a POSITA is presumed to know all the relevant, analogous prior art, and the obviousness analysis may take into account the inferences and creative steps that a POSITA would employ.

31. In determining whether a prior art reference could have been combined with another prior art reference or other information known to a POSITA, I have been told that the following principles may be considered:

- a. A combination of familiar elements according to known methods is likely to be obvious if it yields predictable results;
- b. The simple substitution of one known element for another is likely to

be obvious if it yields predictable results;

c. The use of a known technique to improve similar devices, products, or methods in the same way is likely to be obvious if it yields predictable results;

d. The application of a known technique to a prior art reference that is ready for improvement is likely obvious if it yields predictable results;

e. Any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed;

f. A POSITA often will be able to fit the teachings of multiple, but related, references together like a puzzle; and

g. The proper analysis of obviousness requires a determination of whether a POSITA would have a “reasonable expectation of success”—not “absolute predictability” of success—in achieving the claimed invention by combining prior art references.

32. I understand that whether a prior-art reference renders a claim unpatentable as obvious is determined from the perspective of a POSITA. I have also been told that, while there is no requirement for the prior art to contain an express suggestion to combine known elements to achieve the claimed invention, a suggestion to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as filtered through the knowledge of one skilled in the art. In addition, I have been told the inferences and creative steps a POSITA would employ

are also relevant to the determination of obviousness.

33. I also understand that when a work is available in one field, design alternatives and other market forces can prompt application-specific variations, either in the same field or in another. I have also been told that if a POSITA can implement a predictable variation and would see the benefit of doing so, that variation is likely to be obvious. I have been told that in many fields, there might be little discussion of obvious combinations, and in these fields market demand—not scientific literature—may drive design trends. I have been told that, when there is a design need or market pressure and there are a finite number of predictable solutions, a POSITA has good reason to pursue those known options.

34. I also understand that when comparing claimed ranges with disclosures of ranges in the prior art, a specific range disclosed in the prior art which is within a claimed range anticipates the claimed range. I also understand that prior art which teaches a range overlapping or touching the claimed range anticipates the claimed range if the prior art discloses the claimed range with sufficient specificity. I further understand that ranges in the prior art which encompass a somewhat narrower range or which overlap with a claim range establish a *prima facie* case of obviousness of the claimed range.

35. I have been told there is no rigid rule prescribing that a reference or combination of references must contain a “teaching, suggestion, or motivation” to

combine references. But I also have been told that the “teaching, suggestion, or motivation” test can be a useful guide in establishing a rationale for combining elements of the prior art. I have been told this test poses the question as to whether there is an express or implied teaching, suggestion, or motivation to combine prior art elements in a way that realizes the claimed invention, and that it seeks to counter impermissible hindsight analysis.

36. I understand that the relevant time for considering whether a claim would have been obvious to a POSITA is the time of the invention, which I have been told to assume for this case is December 29, 2015.

V. SUMMARY OF THE AMENDED CLAIMS OF THE '624 PATENT

37. In my Original Declaration, I provided a technical overview section relating to the Original Claims of the '624 Patent. I am further providing a supplemental section relating to features added to the Substitute Claims of the '624 Patent in Patent Owner's Motion to Amend (“MTA”).

A. “the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine”

38. The preamble of proposed Substitute Claim 14 now recites “wherein the aggressive chemical resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, [[or]] and lidocaine.” MTA, 26. A similar limitation is recited at the end of the body of Substitute Claim 21 as “[[wherein]] the aggressive

chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, [[or]] and lidocaine.” MTA, 29.

39. For support in the written description, I understand Patent Owner identifies disclosures from the ’108 Application and the ’962 Application, with the disclosure from the priority ’962 Application providing that “[i]n an embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl, and lidocaine.” MTA, 5, 12 (citing ’108 App., ¶50; ’962 App. 2:34-35).¹

B. “the base layer consisting of the aluminum”

40. The proposed Substitute Claims 14, 15, 19, and 21 now recite a base layer that does not comprise, but consists of, aluminum. I understand that the phrase “consists of” excludes any element, step, or ingredient not specified in the claim.

41. For support in the written description, I understand Patent Owner identifies disclosures from the ’108 Application and the ’962 Application, with the disclosure from the priority ’962 Application providing that “[t]he 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.” MTA, 5 (citing ’108 App., ¶23;

¹ I understand that Patent Owner refers to U.S. Application No. 16/835,108 (the “’108 App”) and EP Application No. 15202962.5 (the “’962 App”) in support of its Motion to Amend. The ’108 App is provided at EX1002, pp. 310-345 and the ’962 App is provided as EX2012. To align with Patent Owner’s citation to these disclosures, I similarly cite to disclosures in the ’108 App and the ’962 App.

'962 App. 9:9-10).

C. Laminating the first outer layer to the base layer after the aggressive chemical-resistant film is formed

42. I understand that Substitute Claim 15 additionally recites “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.” MTA, 27.

43. For support in the written description, I understand Patent Owner identifies disclosures from the '108 Application and the '962 Application, with the disclosures providing that “[t]he first outer layer [] and the base layer side [] may be laminated together before, during, or after the coextrusion layer [] is applied/coated to the base layer.” MTA, 8-9 (citing '108 App., ¶123; '962 App. 15:6-12).

D. Loading of a first layer and second layer of the tie layer

44. I understand Substitute Claims 16, 17, and 21 all recite loading ranges of a first layer and a second layer, individually, of the tie layer. MTA, 27, 29. In particular, Substitute Claim 16 recites a range of the first layer from “7 to [[20]] 18 g/m²” and a loading of the second layer within the same range. Substitute Claims 17 and 21 both recite a first tie layer with “a loading in the range of 7 to [[20]] 14 g/m²” and a second layer having a loading in the same range.

45. For support in the written description, I understand Patent Owner identifies disclosures from the '108 Application and the '962 Application. For the new loading

ranges of 7 to 18 g/m², I understand Patent Owner identifies the following disclosures as supporting the new loading ranges of individual tie layers:

- [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, ¶43; '962 App, 8:12–15.
- 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, ¶147; '962 App, 19:1–6.

MTA, 7-8.

46. I understand that Patent Owner relies upon the exact same written description without further analysis to support Substitute Claims 17 and 21, reciting loading of the first and second tie layers individually in the range of 7-14 g/m². MTA, 9, 11.

E. Aggressive Chemical-Resistant Films

47. In my Original Declaration, I provided a discussion regarding the technology background of aggressive chemical-resistant films relating to the Original Claims of the '624 Patent. I further provided an overview of the different definitions the '624 Patent discloses for an “aggressive chemical-resistant film.” See EX1003, ¶¶96-112.

48. I understand that Substitute Claims 18 and 20 now recite specific requirements, or limitations, that the films must meet to qualify as an aggressive

chemical-resistant film. MTA, 13, 28-29. For instance, Substitute Claim 18 now recites “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.” And substitute claim 20 recites “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®.”

49. For support of Substitute Claim 18 in the written description, I understand Patent Owner identifies the following disclosure from the '108 Application and the '962 Application: “[I]n the context of the present disclosure aggressive chemical-resistant film means that no more than 1% of the original amount of API [active pharmaceutical ingredient] 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.” MTA, 9-10 (citing '108 App, ¶33; '962 App, 6:26-29).

50. For support of Substitute Claim 20 in the written description, I understand Patent Owner identifies the following disclosure from the '108 Application and the '962 Application: “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 from the patch.” MTA, 10-11 (citing ’108 App, ¶158-59, Fig. 5; ’962 App, 20:16-26).

VI. LEVEL OF ORDINARY SKILL IN THE ART

51. Huhtamaki has requested that I provide my understanding of what would be the qualifications of a POSITA with respect to the ’624 patent. I understand from Huhtamaki’s counsel that a POSITA is a hypothetical person who is presumed to have known the relevant art at the time of the invention. I further understand that factors to be considered in determining the level of ordinary skill in the art may include: (1) the types of problems encountered in the art, (2) the prior art solutions to those problems, (3) the rapidity with which innovations are made, (4) the sophistication of the technology, and (5) the educational level of active workers in the field.

52. In my Original Declaration, I opined that a POSITA with respect to the subject matter of the ’624 patent at the time of its invention can fairly be described as someone with at least a bachelor’s degree (or equivalent) in Chemical Engineering, Polymer Science and Engineering, Materials Science and Engineering, or the like,

and 2–3 years of experience in laminate or film manufacture or similar packaging manufacture. Less hands-on experience may be necessary with additional education and vice versa.

53. I understand that Patent Owner presents a different level of skill in the art, which is someone with “a relevant technical degree in Chemical Engineering, Polymer Science, Materials Science, or the like, and two (2) to three (3) years of experience in manufacturing flexible films using coextrusion processing techniques.”

54. In my professional opinion, both proposed definitions of a POSITA are not substantially different and overlap significantly. It is further my opinion that the difference in the levels of skill do not change the analysis below in determining the unpatentability of the proposed substitute claims.

VII. CLAIM CONSTRUCTION

55. My understanding of the principles of claim construction and my methodology for determining the meaning of claimed limitations are provided in my Original Declaration.

56. I further understand that in the context of a motion to amend, a substitute claim cannot present “new matter.” I understand that “new matter” refers to subject matter that does not have written description support in the originally filed application. In my Original Declaration, I provided my understanding of written description

support. EX1003 ¶¶18-21.

57. In my opinion, other than the terms discussed in my Original Declaration as indefinite (“aggressive chemical-resistant film” and “loading”), the ’624 Patent does not use any other unusual claim terms. Nor do any claim terms aside from “aggressive chemical-resistant film” and “loading” appear to be used outside their plain and ordinary meaning, as understood by a POSITA and in view of the ’624 Patent specification and the prosecution history and other patent content.

VIII. SUMMARY OF THE APPLIED REFERENCES

A. Riis (EX. 1004)

58. My summary of Riis is provided in my Original Declaration and not reproduced here.

B. Wypych (EX. 1005)

59. My summary of Wypych is provided in my Original Declaration and not reproduced here.

C. Tohara (EX. 1033)

60. Tohara is entitled “Packaging Body for Patch and Method of Packing Patch,” and provides for packaging formed of a multilayer laminate that includes a cyclic polyolefin film (“referred to as the COC [cyclic olefin copolymer] in some cases”) and contains lidocaine or rivastigmine. EX1033, ¶1, Abstract, Title. Tohara relates to a packaging body for a transdermal patch product; the packaging body can

suppress migration of drug content from the patch over time by utilizing a layer of cyclic polyolefin (COC). EX1033, ¶1. Tohara specifically identifies transdermal patch products containing lidocaine (a local anesthetic) or rivastigmine (an antimentia drug) as benefiting from a packaging body incorporating a COC film. EX1033, ¶1.

61. Tohara recognizes a variety of prior art measures aimed to suppress the decomposition of drugs contained in patch products over time but notes the deficiencies of each related to the ability to store both lidocaine and rivastigmine patch products over a long period of time while preserving temporal stability of the packaged patch product (i.e., preventing oxidation, volatilization, and absorption of the chemical in the patch product). EX1033, ¶¶2-14, 30. To solve this problem, Tohara teaches the use of a laminate that is fabricated in at least three layers, including a COC layer. EX1033, ¶¶30, 36, 85. Tohara attributes the beneficial storage properties of the inventive laminate to the COC layer. EX1033, ¶30, 85.

D. Holzmuller (EX. 1034)

62. Holzmuller is entitled “Multilayered Laminate for Tubes Having an Embedded Aluminum Layer, a Process for the Production Thereof and a Tube Produced Therefrom.” EX1034, Title. Holzmuller relates to multilayered laminates that contain embedded aluminum barrier layers surrounded by protective layers, which are joined to the aluminum barrier layer by one or more intermediate layers.

EX1034, ¶2, Abstract.

63. Holzmuller recognizes that prior art multilayered laminates suffered from a lack of protection of the aluminum barrier layer, poor haptic/mechanical properties, and risk of delamination mostly due to the varying levels of thickness associated with each layer of the laminate. EX1034, ¶¶3-7. While thicker laminate layers provide a longer diffusion path for penetrating volatile chemicals and the damage prone aluminum barrier layer, such added thickness drives up cost and results in poor haptic/mechanical properties of the laminate. EX1034, ¶¶3-7.

64. Holzmuller teaches that exterior protective layers and various intermediate layers can be utilized to protect the internal aluminum barrier layer while simultaneously balancing the overall thickness. EX1034, ¶¶8-11, 16-17. To prevent undesirable delamination, Holzmuller teaches the use of multilayer adhesive and bonding intermediate layers of varying potential thicknesses. EX1034, ¶18-19. Holzmuller teaches that use of such intermediate adhesive and bonding layers yields a synergistic effect according to the combined materials, yielding “an additive effect” of the “intermediate layer material which, on the one hand, has both high mechanical stability and high chemical stability,” and also provides “a high degree of stretchability combined at the same time with high tear resistance, a high level of resistance to diffusion and the possibility of achieving good drive [and] good haptic properties.” EX1034, ¶20. Holzmuller further teaches that the various intermediate

layers may be formed through joint extrusion, tandem extrusion, and coextrusion processes to form a multi-ply composite. EX1034, ¶¶24-26.

E. Rivers (EX. 1035)

65. Rivers is entitled “Packaging Film,” and is directed to films employing cyclic olefin copolymers (COCs) to exhibit decreased scalping of packaged products. EX1035, 1:5-11, Abstract. Rivers recognizes that packaged products often leach or scalp some of the product into the surrounding packaging and that current compensation methods of adding additional product to account for such scalping is costly and inefficient. EX1035, 1:14-21. Rivers further recognizes that the packaging for such products often require special formats in order to preserve the packaged product, including scalp-resistant internal layers. EX1035, 1:20-28. However, these scalp-resistant polymers are sometimes difficult to incorporate into multilayer films useful for flexible packaging, have high melting temperatures that make them ineffectual in sealant layers, and are chemically incompatible with low-cost polyethylene polymers. EX1035, 1:23-31.

66. Rivers teaches packaging films that utilize COC within the sealant layer of the film to minimize scalping of the packaged product, in some cases not more than 1% of the packaged product. EX1035, 2:6-3:12, 4:12-5:2. Rivers ultimately teaches that it is the use of cyclic olefin copolymers in a packaging film that leads to minimal scalping of packaged contents. EX1035, 13:16-25.

IX. PATENTABILITY OF THE CHALLENGED CLAIMS OVER THE APPLIED REFERENCES

67. I understand Patent Owner's proposed Substitute Claims 14-21 are provided such that if any of original 1, 6-10, and 13 are found unpatentable, the Board may substitute the corresponding claim, pending the substitute claim is patentable over the prior art. Patent Owner makes substantive amendments to the independent claims and various dependent claims that are addressed further below. For all claims and limitations not substantively amended in the substitute claims, I refer generally to the opinions and facts presented in my Original Declaration. *See generally* EX1003, ¶¶120-262.

A. Substitute Claims 16, 17, and 21 Violate the Rules for Motions to Amend

68. As discussed above, I understand the applicable standards for a motion to amend require that the motion to amend must not seek to introduce new subject matter and must show support for each amendment in both the original disclosure and in the parent application of which the benefit of priority date is sought. *See* 37 C.F.R. § 42.221; *see also supra* § IV.A.

i. The loading ranges of 7-18 g/m² (Claim 16) and 7-14 g/m² (Claims 17, 21) are not supported by the original disclosure.

69. I understand Substitute Claims 16, 17, and 21 amend original claims 6, 7, and 13, respectively, and recite new loading ranges of the first and second layers of the

tie layer individually. MTA, 13, 14, 27, 29. Patent Owner relies upon the exact same written description to support all of the newly claimed ranges in Substitute Claims 16, 17, and 21, with such written description reproduced below for reference:

- [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, ¶43; '962 App, 8:12–15.
- 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, ¶147; '962 App, 19:1–6.

MTA, 7-8; *see also supra*, § V.D.

70. It is my opinion that the disclosures Patent Owner cites in support of Substitute Claims 16, 17, and 21 all refer to a loading of the tie layer as a whole and not as loading of individual layers of the tie layer. For instance, the disclosures identified by Patent Owner refer to (1) “the tie layer,” (2) “the plurality of tie layers constituting the tie layer,” and (3) “the tie layers.” First, reference to “the tie layer” is in the singular and references only a single-layer tie layer or the tie layer as a whole. Second, reference to “the plurality of tie layers constituting the tie layer” is in reference to the plurality, as a collective, and is not in reference to a single layer that may be included in the plurality. Third, reference to the “tie layers” in the

plurality does not delineate the layers that may account for the tie layers and again refers only to the tie layers as they exist together.

71. Further, the loading ranges of 7-14 g/m² and 7-18 g/m² are disclosed nowhere within the '624 Patent or its supporting disclosures. The '624 Patent includes only two loading ranges, 7-20 g/m² and 4-18 g/m², the latter range being disclosed only in specific reference to example laminates 1-5 provided in Table 3 of the '624 Patent. EX1001, 6:33-37, 16:17-67. Regarding the new range of 7-14 g/m², nothing in the '624 Patent indicates the maximum value of 14 g/m² was ever considered, either as a maximum in a range or as a specific loading within the range of 7-20 g/m². *See generally*, EX1001; EX1002, 310-345; EX2012.

72. The only portion of the '624 Patent that identifies a maximum loading of 18 g/m² is in reference to the exemplary laminates provided in Table 3. EX1001, 16:30-67. However, none of the laminates provided in Table 3 appear to fall within the scope of the claims: all claims require a COC contact layer, and Substitute Claims 16, 17, and 21 all require at least two layers, a first layer and a second layer. Laminate 5 is the only exemplary laminate to include a COC contact layer. However, upon review of the Deposition Transcript of Patent Owner's expert Dr. McCarthy, I understand that Laminate 5 contains only a single layer tie layer. *See* EX1032, 44:10-48:2 (testimony indicates that Laminate 5 has only a single layer tie layer and does not contain a tie layer with either a plurality of layers, two layers, or otherwise

comprise more than one layer). Neither Laminate 5 nor any other laminate provided by Table 3 thus fall within the scope of Substitute Claims 16, 17, and 21. It is my opinion that a POSITA would not understand a first layer loading of 18 g/m² and a second layer loading of 18 g/m² to be adequately supported by the disclosures of the '624 Patent.

73. The upper bound for loading of 14 g/m² of Substitute Claims 17 and 21 is not disclosed in the '624 Patent as the patent only discloses ranges of 7-18 or 7-20 g/m² for loading. It is my opinion that a POSITA would not interpret the ranges of 7-18 g/m² and 7-20 g/m² of the patent to support 14 g/m² as an upper bound for loading without some disclosure in the '624 Patent.

B. Substitute Claims 16, 17, 20, and 21 are Indefinite.

i. The loading ranges of 7-18 g/m² and 7-14 g/m² render Substitute Claims 16, 17, and 21 indefinite.

74. It is my opinion that a POSITA would not be able to determine the scope of Substitute Claims 16, 17, and 21 with reasonable certainty for all of the same reasons as discussed above regarding lack of adequate written description support and introduction of new matter. *See supra*, § IX.A.

ii. Substitute Claim 20 is indefinite for defining a particular material according to a trademark.

75. I understand that Substitute Claim 20 amends original claim 11 and adds the limitations that (1) the chemical is provided in a patch, and (2) defines the film as an

aggressive chemical-resistant film according to a comparison to Barex®. *See supra*, § V.E (citing MTA, 13, 28-29).

76. I understand that use of a trademark in a patent claim renders the claim indefinite under 35 U.S.C. § 112(b) where the trademark is used to identify or describe a particular material or product rather than identify the source of the goods. It is my opinion that Barex® is used in Substitute Claim 20 to indicate a particular material with specific properties rather than to indicate the source of any goods. Substitute Claim 20 requires comparison of the inventive film to “a second film comprising a contact layer that comprises Barex®.” Thus, Barex® is used to define a particular material residing within the contact layer of a second comparison film. Moreover, Substitute Claim 20 defines the film as an aggressive chemical-resistant film based upon this trademark.

77. Further, the '624 Patent does not provide any well-known or identifiable features covered by the trademark Barex® that would inform a POSITA of an accepted standard associated with Barex® at the time of the claimed invention. *See generally* EX1001. The only elaboration regarding Barex® discussed by the '624 Patent is the identification of a film of polyacrylonitrile [polyacrylonitrile] (PAN), which is known to possess extreme chemical resistance and barrier properties. EX1001, 1:58-2:9. However, the '624 Patent simply identifies Barex® as an exemplary resin of PAN-based films but otherwise fails to provide known standards

associated with films sold under the Barex® trademark. *See generally* EX1001. The transport properties responsible for minimizing packaged product scalping depend sensitively on the free volume of the polymer, and the free volume (the unoccupied volume between polymer chains) can vary from grade to grade and even batch to batch. It is therefore my opinion that this lack of guidance from the '624 Patent and the claiming of Barex® as a model, rather than commercial, material would fail to inform a POSITA, with reasonable certainty, of the scope of an aggressive chemical film of Substitute Claim 20.

C. The Combination of Riis, Wypych, and Tohara Renders Substitute Claim 14 Obvious.

78. I understand that Substitute Claim 14 proposes two main substantive amendments: (1) amending the preamble to recite “wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, [[or]] and lidocaine”; and (2) replacing the claim language “the base layer comprises aluminum” with narrower language of “the base layer consists of aluminum.” *See* MTA, 12-13, 26.

79. It is my opinion that the combination of Riis, Wypych, and Tohara disclose and render obvious the added limitations of Substitute Claim 14, and therefore render obvious the claim as a whole in combination with the disclosures of Riis and Wypych as discussed in my Original Declaration for Original Claim 1. *See* EX1003, ¶¶121-165, 212. Claim limitations not explicitly discussed herein are disclosed by

the prior art as discussed in my Original Declaration.

i. Riis discloses a base layer consisting of aluminum.

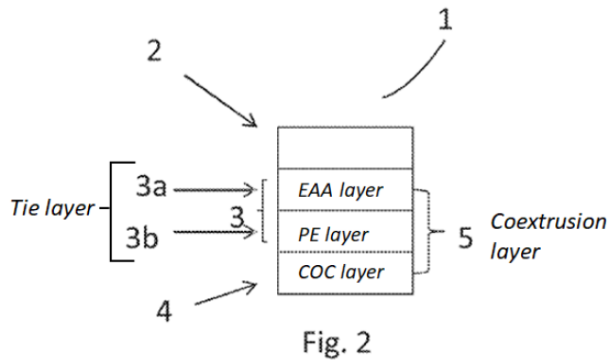
80. As explained in my Original Declaration, it is my opinion that Riis discloses a film with a base layer, otherwise known as a barrier layer, that includes aluminum foil, which provides resistance to both water and oxygen. EX1003, ¶¶124-125, 213.

81. Although Riis identifies the aluminum foil layer as a “barrier layer,” a POSITA would understand such a barrier layer to be equivalent to the “base layer” described by the ’624 Patent as being “water and/or oxygen resistant.” *Compare* EX1004, ¶¶58-64, *with* EX1001, 4:6-10; *see also* EX1035, 6:17-22, 19:3-20:32 (providing exemplary terminology of such an aluminum layer capable of oxygen and water blocking as a barrier layer).

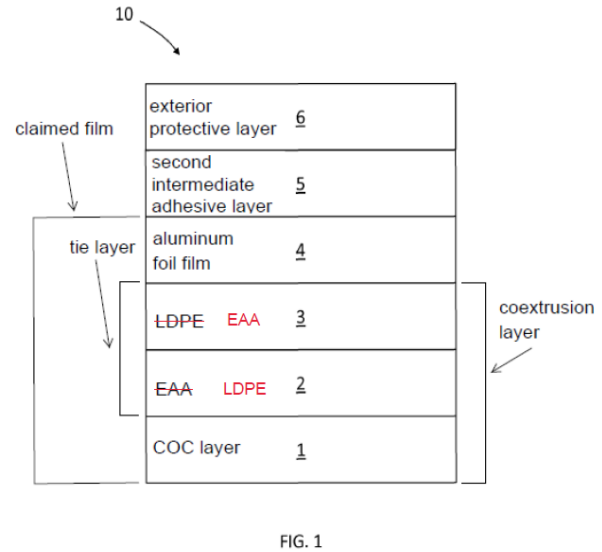
82. As discussed above, I understand that this amendment to Substitute Claim 14 excludes any element, step, or ingredient not specific in the claim. *See supra* §V.B.

83. It is my opinion that Riis discloses and renders obvious a base layer consisting of aluminum. For instance, I provided the below annotated figures in my Original Declaration showing the correspondence between the aluminum foil barrier layer of Riis to the claimed base layer, with Riis’s barrier layer positioned between tie layers (Ref. Nos. 2, 3, 5) and exterior layers (Ref. Nos. 1, 6). EX1003, ¶131.²

² I clarified in my Deposition, taken on August 31, 2023, that “the EAA and LDPE layers [in annotated Figure 1] have been inadvertently switched.” EX2015, 105:20-



('624 patent, Fig. 2 (annotated))



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

84. The configuration of the aluminum foil barrier layer (layer no. 4) in Riis's annotated Figure 1 above further supports the understanding that such a layer provides the claimed base layer consisting of aluminum. For example, Riis discloses that the barrier layer may be sandwiched between tie layer and surface layers, precisely how the aluminum foil layer in annotated Figure 1 is disposed. EX1004, ¶59; *see also* EX1004, ¶135 (describing the layered structure depicted in Figure 1). Thus, a POSITA would understand that barrier layer to consist of aluminum foil, with other layers surrounding the aluminum foil barrier layer.

85. Riis also discloses that the “barrier layer can comprise any suitable material.”

¶62. Riis provides that a “[s]uitable moisture barrier layer[] includes aluminum foil”

25. Annotated Figure 1 of Riis as reproduced here corrects that error as shown in red and in strikethroughs deleting the previous labeling.

and that “[a]n oxygen barrier layer . . . may comprise aluminum foil.” EX1004, ¶¶62-63, 86-87. Because Riis also discloses that the “barrier layer preferably functions both as a gas barrier layer[] and as a moisture barrier layer,” a POSITA would understand that aluminum foil is a preferred barrier layer providing both moisture barrier and gas barrier functionality. EX1004, ¶58. Thus, it is my opinion that the barrier layer disclosed by Riis is formed from aluminum foil and meets the limitation of Substitute Claim 14 reciting the base layer “consists of” aluminum.

86. As discussed above in reference to annotated Figure 1 of Riis, Riis discloses the aluminum foil barrier layer as sandwiched between adhesive layers and/or surface layers. See EX1004, ¶¶59, 135. According to Figure 1 of Riis (annotated above), the laminate includes exterior protective layers and intermediate adhesive layers, a barrier (“base”) layer consisting of aluminum, and a coextrusion layer consisting of EAA, LDPE, and COC, thereby disclosing the method of providing the claimed film of Substitute Claim 14. This makes sense as a POSITA would understand that outer protective layers prevent damage to the aluminum foil barrier layer, which in turn would compromise that layer’s ability to function as a barrier layer. It is my opinion that while Riis discloses a larger laminate having additional external protective layers, the method claims of Substitute Claim 14 are met because the claimed film structure is a subcomponent of the laminate of Riis, and includes each layer as claimed.

87. Riis also recognizes that the structure depicted in annotated Figure 1 above may be provided without an exterior protective layer (6) and a second intermediate adhesive layer (5). Riis discloses that its films “*may* include an outer layer.” EX1004, ¶¶66-67 (emphasis added). Riis similarly discloses that the intermediate adhesive or tie layers are present for the purpose of adhering the exterior protective layer to the intermediate barrier layer and for adhering the intermediate barrier layer to the interior product contact layer. EX1004, ¶70-71 (“In addition to the exterior layer, the interior layer, and intermediate layer such as a barrier layer, a multilayer packaging film can further comprise one or more adhesive layers, also known in the art as ‘tie layers,’ which can be selected to promote the adherence of adjacent layers to one another in a multilayer film and prevent undesirable delamination.”). Accordingly, a POSITA would understand that if the exterior protective layer is not included, as allowed by Riis, the adhesive tie layer disposed between the aluminum barrier layer and the non-included exterior protective layer would also be omitted, since its purpose is to promote adherence between the exterior protective layer and the aluminum foil barrier layer.

88. Because a POSITA would understand that Riis discloses the optional nature of the exterior protective layer and associated adhesive layer, a POSITA would also understand how to manufacture such a film. As discussed in my Original Declaration, Riis provides that its films may be manufactured by conventional

processes and methods, including coextrusion, extrusion coating, and lamination. *See* EX1003, ¶¶87-89 (citing EX1004, ¶¶82, 156-158). Riis also discloses that, unless an order is explicitly limited in an example, the disclosed methods of manufacture are not limited to any specific order or aspect and that features from one film/process may be combined or permuted with any other order, aspect, or feature from another film/process. Riis, ¶48. With all of these disclosure in mind, a POSITA would understand how to manufacture the film depicted in annotated Figure 1 without the exterior protective layer and the second intermediate adhesive layer disposed between the exterior protective layer and the barrier layer. One such method would be to coextrude the three-layer coextrusion of EAA, LDPE, and COC onto only the aluminum foil barrier layer similar to the process of manufacture disclosed with respect to Example 5. *See* EX1004, ¶¶173-174.

89. It is therefore my opinion that a POSITA would understand that Riis discloses leaving off the exterior protective layer and second intermediate adhesive layer from the film depicted in annotated Figure 1 above, leaving only a film consisting of a barrier layer consisting of aluminum foil and a three-layer coextrusion of LDPE and EAA tie layers and a COC contact layer. With respect to the production of consumer product package, it must be recognized, however, that exclusion of the exterior protective layer would expose the aluminum barrier layer to environmental factors that could damage the barrier layer and thus compromise its vital barrier

performance in the package product.

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

90. I understand that a preamble may be limiting where the preamble limits the method or process claimed. I understand that statements in the preamble that recite the purpose or intended use of the claimed invention must be evaluated to determine whether or not the recited purpose or intended use results in a manipulative difference between the claimed invention and the prior art.

91. It is my opinion that a POSITA would understand the statements in the preamble of Substitute Claim 14 recite an intended use or purpose of the claimed method—to be resistant to certain chemicals—and do not result in a manipulative step that is necessary for understanding the claimed method recited in the body of Substitute Claim 14.

92. I further understand that a claim that recites a listing of alternatives may in some instances be characterized as a “Markush” grouping. It is my further understanding that, in patent law, a Markush Group limits the claim term to a list of specified alternatives that are selected because they belong to a recognized physical or chemical class or they each possess at least one property in common, which is the reason the alternatives are grouped together in the claims. It is further my understanding that if a patent owner wishes to allow the list of alternatives to be

combined, language such as “and mixtures thereof” or “and combinations thereof” would be typically included. Without such language, it is my understanding that the claim term is “closed” and cannot include mixtures of one specified alternative with another.

93. The claim language in question recites chemical resistance to “a chemical,” that chemical “selected from” a listing of four alternative chemicals—nicotine, fentanyl, rivastigmine, and lidocaine. If these limitations of Substitute Claims 14 and 21 are limiting, they require chemical-specific resistance to only one chemical of the identified chemicals, as reflected by the claim’s recitation of the singular “a chemical.” Also, the claims do not require resistance to more than one of the identified chemicals, because Substitute Claims 14 and 21 do not include language after the listing of chemicals indicating the list of alternatives could be combined. Thus, a POSITA would understand the disclosure of a film resistant to a single specified chemical entity renders the film unpatentable with respect to all alternative chemical entities.

94. Since Substitute Claim 14 does not require an aggressive chemical-resistant film that is resistant to all of nicotine, fentanyl, rivastigmine, and lidocaine, it is my opinion that a POSITA would understand that Riis renders obvious this new limitation to Substitute Claim 14. To the extent the proposed substitute claim requires resistance to all specified chemicals, the combination of Riis and other prior

art, as provided below, renders the claim obvious.

iii. The combination of Riis, Wypych, and Tohara renders obvious an aggressive chemical-resistant film resistant to rivastigmine.

95. As explained in my Original Declaration, Riis discloses a method of providing an aggressive chemical-resistant film that is resistant to various chemicals, including nicotine, fentanyl, and lidocaine. EX1003, ¶¶121-123, 212 (citing EX1004, ¶¶2, 4-5, 11). Although Riis does not specifically identify rivastigmine as a pharmaceutical active agent chemical to be packaged by Riis's film in certain embodiments, Riis leaves open its film's resistance to all sorts of chemicals. See EX1004, ¶¶11, 114 (identifying pharmaceutical active agents in the context of "[i]n some embodiments"). For instance, Riis discloses that "pharmaceutical product[s] for packaging in [its inventive films] can include *any suitable pharmaceutical active agent*." EX1004, ¶114 (emphasis added). A POSITA would thus understand that Riis's film may be resistant to additional chemicals not specifically identified in Riis's disclosure.

96. As discussed above, Tohara teaches methods of providing films resistant to various chemicals contained in packaged patch products, including lidocaine and rivastigmine. See *supra* § VIII.C. Tohara, in particular, addresses preventing oxidation and decomposition of susceptible chemicals provided in patch products, including lidocaine as a local anesthetic and rivastigmine as an antimentia drug. EX1033, ¶¶11-12, 28-30.

97. Tohara teaches that films utilizing a COC film beneficially prevent oxidation, volatilization, and adsorption of chemicals in the packaged patch product. EX1033, ¶85, 93-95; *see also* EX1033, ¶89 (teaching that COC is an “essential constituent in the laminate constituting the packaging material to enclose the patch” for the purpose of “suppressing the adsorption of lidocaine or rivastigmine”). Tohara further teaches that Topas films are commercially available COC polymers that may be used for its films. EX1033, ¶102.

98. A POSITA would recognize that Riis discloses chemical resistance to any number of suitable pharmaceutical active agents, beyond those specifically listed in its disclosure, and would look to other teachings of films which employ a COC contact layer, such as Tohara, and which identify the need to prevent oxidation and decomposition of packaged pharmaceutical patch products. Accordingly, it is my opinion that a POSITA would have been motivated to extend the method of providing an aggressive chemical-resistant film of Riis (in conjunction with Wypych) to be additionally chemically resistant to rivastigmine as taught by Tohara to prevent oxidation, decomposition, and adsorption of susceptible packaged patch products—such as lidocaine and rivastigmine patches.

99. Further, it is my opinion that a POSITA would have had a reasonable expectation of success in modifying the method of providing a film of Riis (and Wypych) with Tohara’s resistance to rivastigmine, because Tohara provides the

suitability of using a COC product contact layer, specifically from Topas, to prevent the adsorption of such products. Both Tohara and Riis focus on the use of COCs, and specifically mention commercially available COCs from Topas, for use in product contact layers of multilayer films. *See* EX1004, ¶¶52, 54, 97 (recommending commercially available COCs from Topas due to their beneficial properties, including high transparency and gloss, excellent barrier properties, etc.); EX1033, ¶¶87-89, 94-95, 102 (disclosing COCs capable of suppressing adsorption of lidocaine or rivastigmine are commercially available from Topas). Both Riis and Tohara are directed to ultimately providing multilayer films for use in packaging such patch products containing chemicals susceptible to degradation over time. *See e.g.*, EX1033, ¶128-130 (providing a multilayer film for a packaging body); EX1004, ¶135 (same). Accordingly, a POSITA would reasonably expect that incorporating Tohara's teachings regarding resistance to rivastigmine into the method of fabricating a laminate of Riis (and Wypych) would be successful.

D. The Combination of Riis and Wypych Renders Substitute Claim 15 Obvious

100. I understand that Substitute Claim 15 proposes adding the following limitation to original claim 10: "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* MTA, 13, 27.

101. It is my opinion that the combination of Riis and Wypych disclose and render obvious the added limitations of Substitute Claim 15, and therefore render obvious the claim as a whole in combination with the disclosures of Riis and Wypych as discussed in my Original Declaration for original claim 10. *See* EX1003, ¶¶197-198, 255-256. Claim limitations not explicitly discussed herein are disclosed by the prior art as discussed in my Original Declaration.

102. As discussed regarding Substitute Claim 14 above, Riis discloses that the order of conventional processes of manufacture of its films may be altered and changed in a variety of ways unless specifically limited. *See supra* § IX.C.i. Riis discloses that unless an order is explicitly limited in an example, the disclosed methods of manufacture are not limited to any one order or aspect and that features from one film/process may be combined or permuted with any other order, aspect, or features from another film/process. EX1004, ¶48. As discussed in my Original Declaration, Riis provides that its films may be manufactured by conventional processes and methods, including coextrusion, extrusion coating, and lamination. *See* EX1003, ¶¶87-89 (citing EX1004, ¶¶82, 156-158).

103. Riis also discloses exemplary methods of manufacture, which include coextrusion coating a sealant film to the aluminum foil surface of a base film where the base film includes outer protective layers and adhesive tie layers adhering the

outer protective layers to the aluminum barrier layer. EX1004, ¶¶160-174. As discussed above, a POSITA would understand that Riis discloses coextrusion coating of the EAA, LDPE, COC sealant film (i.e., coextrusion layer) to the aluminum barrier layer without the exterior protective layers or adhesive layers disposed between the exterior protective layers and the aluminum foil barrier layer. *See supra* § IX.C.i.

104. It is my opinion that a POSITA would have been motivated to try a different order to the method of manufacture disclosed by Riis, since Riis suggests the possibility of reordering the steps of manufacture. A POSITA would have been motivated to try a finite number of predictable order of steps of manufacture, including laminating the outer protective layer and associated adhesive layer (1) after coextruding the sealant film (i.e., coextrusion layer)—the method specifically disclosed by Riis—(2) simultaneously with coextruding the sealant film, or (3) before coextruding the sealant film on the aluminum foil barrier layer.

105. It is my understanding that absent some new or unexpected result, a POSITA would have found it obvious to change the sequence of adding film layers to the film of Riis, and the preferred order of fabrication could be influenced by the thermal, flow or mechanical properties of the constituent polymers used in the final product.

106. Riis discloses one order of a method of forming the film, which includes coextrusion coating an EAA, LDPE, and COC sealant film onto the aluminum foil

barrier layer that already had exterior protective layers and associated adhesive layers laminated to it. EX1004, ¶174. However, Riis does not limit the order of manufacture to this one example or otherwise discourage a POSITA from trying a different order of steps. Riis also provides that any of the disclosed methods of forming its inventive film are not limited to any specific order. EX1004, ¶48. Thus, a POSITA would be motivated to try a different sequence of manufacturing the inventive films of Riis, including coextrusion coating the EAA, LDPE, and COC coextrusion layer to the aluminum foil barrier layer either before or simultaneous with the laminating of the exterior protective layers and associated adhesive layers.

107. Further, the '624 Patent does not attribute any new or unexpected results to the order of laminating the outer protective layers to the film and merely identifies three alternative permutations: “the first outer layer and the base layer side may be laminated together before, during, or after the coextrusion layer is applied/coated to the base layer.” EX1001, 13:51-60.

108. Thus, it is my opinion that a POSITA would be motivated to try different sequences of coextrusion coating the EAA, LDPE, and COC sealant film to the aluminum foil barrier layer, including before the exterior protective layers and associated adhesive layers laminated to the barrier layer.

109. As described above, a POSITA would have recognized the finite number of predictable order of steps of manufacture, including laminating the outer protective

layer and associated adhesive layer (1) after coextruding the sealant film (*i.e.*, coextrusion layer)—the method specifically disclosed by Riis—(2) simultaneously with coextruding the sealant film, or (3) before coextruding the sealant film on the aluminum foil barrier layer. While some of these orders may be preferable in terms of practical handling the package product, this limited number of possibilities coupled with Riis’s disclosures that the methods of manufacture are not limited in any one order or aspect would motivate a POSITA to try to coextrusion coat the EAA, LDPE, and COC sealant film to the aluminum foil barrier layer both before and simultaneous with the outer protective layers and associated adhesive layers as a matter of design choice. Because Riis leaves open the possibility of modifying the order of steps of described methods of manufacture, a POSITA would find a reasonable expectation of success in choosing a different order of extrusion coating and laminate as a matter of design. Accordingly, it is my opinion that a POSITA would find it obvious to laminate a first outer layer to the aluminum barrier layer after the three-layer EAA, LDPE, and COC sealant film has been coextrusion coated to the opposite side of the aluminum barrier layer.

E. The Combination of Riis, Wypych, Tohara, and Holzmuller Renders Substitute Claim 16 Obvious

110. I understand that Substitute Claim 16 proposes adding a loading of each of a first layer and a second layer of the tie layer to original claim 6 as follows: 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. MTA, 13, 27.

111. It is my opinion that the combination of Riis, Wypych, Tohara, and Holzmuller disclose and render obvious the added limitations of Substitute Claim 16, and therefore render obvious the claim as a whole in combination with the disclosures of Riis and Wypych as discussed in my Original Declaration for original claim 6. *See* EX1003, ¶¶150-159, 181-187, 226-234, 251. Claim limitations not explicitly discussed herein are disclosed by the prior art as discussed in my Original Declaration.

112. As discussed in my Original Declaration, a POSITA would be able to determine the loading of any layer of material by multiplying the thickness of the layer by the mass density to yield an area density. EX1003, ¶152. I utilize the same methodology to ascertain loading ranges in this Second Declaration.

113. As discussed in my Original Declaration, a first layer of the tie layer is the LDPE layer and a second layer of the tie layer is the EAA layer. EX1003, ¶¶194, 253. As also discussed in my Original Declaration, the 0.65 mil LDPE layer disclosed in the three-layer coextrusion sealant film of Example 5 of Riis has a loading range of 15.11-15.34 g/m², which falls within the newly claimed range of 7 to 18 g/m² as recited in Substitute Claim 16. EX1003, ¶¶150-159, 226-234. As

further discussed in my Original Declaration, Riis discloses that the polyolefin bulk layer, which may be a tie layer, “may be of any suitable thickness from 0.1 to 7 mils,” which provides a broad loading range beyond the approximate 15 g/m² disclosed by the combination of Riis and Wypych. EX1003, ¶233 (citing EX1004, ¶65). A POSITA would thus be motivated to alter the thickness of the LDPE layer to be of any suitable thickness disclosed by Riis. Accordingly, it is my opinion that the combination of Riis and Wypych provides an LDPE layer of the tie layer within the claimed loading range of 7 to 18 g/m².

114. As additionally discussed in my Original Declaration, the 0.17 mil EAA layer disclosed in the three-layer coextrusion sealant film of Example 5 of Riis has a loading range of 3.97-4.15 g/m², which falls outside the newly claimed range of 7 to 18 g/m² as recited in Substitute Claim 16. EX1003, ¶¶150-159, 226-234.

115. However, Holzmuller teaches multilayered laminates may have varying disclosed and preferred ranges of thicknesses of intermediate bonding layers to produce a synergistic effect of both high mechanical and chemical stability along with other added benefits. *See supra* § VIII.D. In particular, Holzmuller teaches that adequate protection of a sandwiched aluminum barrier layer can be obtained while also balancing haptic/mechanical properties and costs by utilizing more than one intermediate bonding layers of varying thicknesses to yield an “additive effect.” EX1034, ¶¶18-20. Additional benefits of this approach include “high tear resistance,

a high level of resistance to diffusion and the possibility of achieving good drive [and] good haptic properties.” EX1034, ¶20.

116. It is my opinion that a POSITA would appreciate Holzmuller’s teaching that varying the thicknesses of intermediate bonding layers would produce an additive effect, yielding multiple positive benefits for the end laminate or film, including “high mechanical stability and high chemical stability,” and also provides “a high degree of stretchability combined at the same time with high tear resistance, a high level of resistance to diffusion and the possibility of achieving good drive [and] good haptic properties.” EX1034, ¶20. Thus, a POSITA would be motivated to modify and optimize the interacting thicknesses of the layers that make up the tie layer to promote adhesion, prevent undesirable lamination, and otherwise produce an additive effect through routine experimentation.

117. As discussed above, Holzmuller teaches various thicknesses of intermediate bonding layers, including an allowable layer thickness, a preferred layer thickness, and an especially preferred layer thickness. EX1034, ¶¶19, 23. Thus, a POSITA would be motivated to start with the broad allowable ranges taught by Holzmuller and experiment within those ranges, including into the narrower preferred and especially preferred layer thickness ranges, to determine which thicknesses produce the desired additive effect.

118. Regarding intermediate bonding layers, Holzmuller teaches that such layers

may be formed from polyolefins, like polyethylene, and from EAA. EX1034, ¶19. Holzmuller teaches exemplary thicknesses of bonding layers formed from polyolefins like polyethylene to 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.

119. As discussed above, a POSITA would be able to determine the loading of any layer of material by multiplying the thickness of the layer by the mass density to yield an area density. EX1003, ¶152. For Holzmuller, a POSITA would understand to take the thickness of each polymer layer as disclosed in microns and convert it to centimeters, then multiply its thickness in centimeters by the mass density (typically expressed in grams per cubic centimeter), and finally convert to an area of square meters. Table 1 is provided below summarizing the dimensional analysis of allowable loading, preferred loading, and especially preferred loading of Riis's LDPE layer as taught by Holzmuller's polyethylene layers.

Layer	Thickness	LDPE Density	Square Meter Conversion
Allowable	5-140 μm = 0.0005-0.014 cm	$\frac{(0.915-0.929) \text{ g}}{1 \text{ cm}^3}$	$\frac{10,000 \text{ cm}^2}{1 \text{ m}^2}$
Preferred	8-95 μm = 0.0008-0.0095 cm		
Especially Preferred	10-50 μm = 0.001-0.005 cm		

Table 1

120. According to the methodology employed in my Original Declaration for

determining loading, Holzmuller teaches loading ranges of Riis's LDPE from 4.6-130.1 g/m², preferably from 7.3-88.3 g/m², and especially preferably from 9.2-46.4 g/m² (keeping to one decimal place for consistency). I note that a POSITA would understand LDPE to be a polyethylene. See *e.g.*, EX1004, ¶¶69, 74 (“The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example . . . polyolefins, and in particular members of the polyethylene family such as . . . LDPE.”).

121. Holzmuller thus teaches an allowable loading range of LDPE that encompasses the claimed range recited in Substitute Claim 16. Holzmuller's preferred and especially preferred ranges overlap with the new claimed range recited in Substitute Claim 16. Accordingly, it is my opinion that Holzmuller's LDPE layer loading ranges render obvious the claimed range of “a loading of a first layer of the tie layer is in the range of 7 to 18 g/m².”

122. Holzmuller further teaches exemplary thicknesses of bonding layers (such as a first bonding layer) formed from EAA to be in the same 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.

123. Table 2 is provided below summarizing the dimensional analysis of allowable loading, preferred loading, and especially preferred loading of Riis's EAA layer as taught by Holzmuller's EAA layers.

Layer	Thickness	EAA Density	Square Meter Conversion
Allowable	5-140 μm = 0.0005-0.014 cm	$\frac{(0.92-0.96) \text{ g}}{1 \text{ cm}^3}$	$\frac{10,000 \text{ cm}^2}{1 \text{ m}^2}$
Preferred	8-95 μm = 0.0008-0.0095 cm		
Especially Preferred	10-50 μm = 0.001-0.005 cm		

Table 2

124. According to the methodology employed in my Original Declaration for determining loading, Holzmuller teaches loading ranges of Riis's EAA of an allowable range of 4.6-134.4 g/m², preferred ranges of 7.4-91.2 g/m², and especially preferred ranges of 9.2-48.0 g/m² (keeping to one decimal place for consistency).

125. Holzmuller thus teaches an allowable loading range of EAA that encompasses the claimed range recited in Substitute Claim 16. Holzmuller's preferred and especially preferred ranges overlap substantially with the new claimed range recited in Substitute Claim 16. Accordingly, it is my opinion that Holzmuller's EAA layer loading ranges render obvious the claimed range of "a loading of a second layer of the tie layer is in the range of 7 to 18 g/m²."

126. As discussed above, Holzmuller's teachings of not only allowable ranges of bonding layer thicknesses, but also of preferred and especially preferred thickness ranges would have motivated a POSITA to tailor the thicknesses, and thus the loadings, of the intermediate bonding layers to achieve the desired additive effects. It is thus my opinion that a POSITA would optimize the ranges of intermediate

bonding layers taught by Holzmuller to the LDPE and EAA tie layers of the combination of Riis, Wypych, and Tohara to achieve desired synergistic properties of intermediate layers and thus impart the associated beneficial characteristics upon the resultant film or laminate, including high mechanical stability and high chemical stability, a high degree of stretchability combined at the same time with high tear resistance, a high level of resistance to diffusion, the possibility of achieving good drive, and good haptic/mechanical properties.

127. It is my opinion that a POSITA would have a reasonable expectation of success in modifying the individual tie layer thicknesses of the combination of Riis, Wypych, and Tohara with Holzmuller's teachings of varying thicknesses to employ among the intermediate bonding layers to achieve the additive effects benefitting the end resulting film or laminate. A POSITA would further have a reasonable expectation of success as Holzmuller similarly relates to multilayer films exposed to chemicals that may leach through the film laminate. EX1034, ¶¶2-3; EX1004, ¶¶3-4, 91-92. Both Holzmuller and Riis contain aluminum foil layers that may be sandwiched between intermediate adhesive or bonding layers formed of polyethylene and EAA and exterior layers aimed to protect against external environments and chemicals. EX1034, ¶¶8, 10; EX1004, ¶59. Due to the similarity in structure, function, and polymeric materials considered, a POSITA would have a reasonable expectation of success in implementing Holzmuller's teachings into the

method of providing a film with the combination of Riis, Wypych, and Tohara.

128. Based upon my review of Dr. McCarthy's previous opinions, I understand that in cases involving multilayer polymer films or sheets, prior art thicknesses within the claimed thickness ranges render the claim obvious as a matter of design choice. EX1029, ¶¶37-38, 68. In particular, I understand "that absent 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 [loading] range)." EX1029, ¶68. I understand that obviousness of the claimed range as a matter of design choice may exist where "the [challenged] patent discusses thickness ranges without tying the thickness to any functionality, much less a patentable feature." EX1029, ¶68.

129. Similar to the subject matter of McCarthy's prior testimony, the film of the '624 Patent comprises a multilayer polymeric structure with a barrier layer situated between exterior layers and tie layers between the barrier layer and other adjacent layers. *Compare* EX1030, claims 6-7, *with* EX1001, claim 1. Similarly, the level of skill in the art substantially overlaps and is virtually identical. EX1029, 13 (providing "a Bachelor of Science degree in Chemical Engineering, Material Science, or Mechanical Engineering (or equivalent), as well as at least 2-4 years of academic or industry experience with multilayer polymer material production or research"); POR, (providing "a relevant technical degree in Chemical Engineering,

Polymer Science, Materials Science, or the like, and two (2) to three (3) years of experience in manufacturing flexible films using coextrusion processing techniques”).

130. Accordingly, it is my opinion that absent any criticality, the specific dimensional ranges in Substitute Claim 16 are obvious as a matter of design choice, especially because such ranges were known in the prior art of Holzmuller.

F. The Combination of Riis, Wypych, Tohara, and Holzmuller Renders Substitute Claim 17 Obvious

131. I understand that similar to Substitute Claim 16, Substitute Claim 17 proposes adding a loading of each of a first layer and a second layer of the tie layer to original claim 7 as follows: 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. MTA, 13, 27.

132. It is my opinion that the combination of Riis, Wypych, Tohara, and Holzmuller disclose and render obvious the added limitations of Substitute Claim 17, and therefore render obvious the claim as a whole in combination with the disclosures of Riis and Wypych as discussed in my Original Declaration for Original Claim 7. *See* EX1003, ¶¶150-159, 188-193, 226-234, 252. Claim limitations not explicitly discussed herein are disclosed by the prior art as discussed in my Original

Declaration.

133. As discussed in my Original Declaration and above in this Second Declaration, a POSITA would be able to determine the loading of any layer of material by multiplying the thickness of the layer by the mass density to yield an area density. EX1003, ¶152; *see also supra* § IX.E. I utilize the same methodology to ascertain loading ranges in this Second Declaration.

134. As discussed in my Original Declaration, a first layer of the tie layer is the LDPE layer and a second layer of the tie layer is the EAA layer. EX1003, ¶¶194, 253. As also discussed in my Original Declaration, the 0.65 mil LDPE layer disclosed in the three-layer coextrusion sealant film of Example 5 of Riis has a loading range of 15.11-15.34 g/m², which falls outside of the newly claimed range of 7 to 14 g/m² as recited in Substitute Claim 17. EX1003, ¶¶150-159, 226-234. As further discussed in my Original Declaration, Riis discloses that the polyolefin bulk layer, which may be a tie layer, “may be of any suitable thickness from 0.1 to 7 mils,” which provides a broad loading range beyond the approximate 15 g/m² disclosed by the combination of Riis and Wypych. EX1003, ¶233 (citing EX1004, ¶65). A POSITA would thus be motivated to alter the thickness of the LDPE layer to be of any suitable thickness disclosed by Riis.

135. As additionally discussed in my Original Declaration, the 0.17 mil EAA layer disclosed in the three-layer coextrusion sealant film of Example 5 of Riis has a

loading range of 3.97-4.15 g/m², which falls outside the newly claimed range of 7 to 14 g/m² as recited in Substitute Claim 17. EX1003, ¶¶150-159, 226-234.

136. However, Holzmuller teaches multilayered laminates which have varying disclosed and preferred ranges of thicknesses of intermediate bonding layers in order to produce a synergistic effect of both high mechanical and chemical stability along with other added benefits. *See supra* §§ VIII.D, IX.E. In particular, Holzmuller teaches that adequate protection of a sandwiched aluminum barrier layer can be obtained while also balancing haptic properties and costs by utilizing more than one intermediate bonding layers of varying thicknesses to yield an “additive effect.” EX1034, ¶¶18-20. Additional benefits of this approach include “high tear resistance, a high level of resistance to diffusion and the possibility of achieving good drive [and] good haptic properties.” EX1034, ¶20.

137. It is my opinion that a POSITA would appreciate Holzmuller’s teaching that varying the thicknesses of intermediate bonding layers would produce an additive effect, yielding multiple positive benefits for the end laminate or film, including high mechanical stability and high chemical stability,” and also provides “a high degree of stretchability combined at the same time with high tear resistance, a high level of resistance to diffusion and the possibility of achieving good drive [and] good haptic properties.” EX1034, ¶20. Thus, a POSITA would be motivated to modify and optimize the interacting thicknesses of the layers that make up the tie layer to

promote adhesion, prevent undesirable lamination, and otherwise produce an additive effect through routine experimentation.

138. As discussed above, Holzmuller teaches various thicknesses of intermediate bonding layers, including an allowable layer thickness, a preferred layer thickness, and an especially preferred layer thickness. EX1034, ¶¶19, 23. Thus, a POSITA would be motivated to start with the broad allowable ranges taught by Holzmuller and experiment within those ranges, including into the narrower preferred and especially preferred layer thickness ranges, to determine which thicknesses produce the desired additive effect.

139. Regarding intermediate bonding layers, Holzmuller teaches that such layers may be formed from polyolefins, like polyethylene, and from EAA. EX1034, ¶19. Holzmuller teaches exemplary thicknesses of bonding layers formed from polyolefins like polyethylene to 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.

140. As discussed above, a POSITA would be able to determine the loading of any layer of material by multiplying the thickness of the layer by the mass density to yield an area density. EX1003, ¶152. For Holzmuller, a POSITA would understand to take the thickness of each polymer layer as disclosed in microns and convert it to centimeters, then multiply its thickness in centimeters by the mass density (typically

expressed in grams per cubic centimeter), and finally convert to an area of square meters. Table 1 is provided below summarizing the dimensional analysis of allowable loading, preferred loading, and especially preferred loading of Riis's LDPE layer as taught by Holzmuller's polyethylene layers.

Layer	Thickness	LDPE Density	Square Meter Conversion
Allowable	5-140 μm = 0.0005-0.014 cm	$\frac{(0.915-0.929) \text{ g}}{1 \text{ cm}^3}$	$\frac{10,000 \text{ cm}^2}{1 \text{ m}^2}$
Preferred	8-95 μm = 0.0008-0.0095 cm		
Especially Preferred	10-50 μm = 0.001-0.005 cm		

Table 1

141. According to the methodology employed in my Original Declaration for determining loading, Holzmuller teaches loading ranges of Riis's LDPE from 4.6-130.1 g/m², preferably from 7.3-88.3 g/m², and especially preferably from 9.2-46.4 g/m² (keeping to one decimal place for consistency). I note that a POSITA would understand LDPE to be a polyethylene. See *e.g.*, EX1004, ¶¶69, 74 ("The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic materials, for example . . . polyolefins, and in particular members of the polyethylene family such as . . . LDPE.").

142. Holzmuller thus teaches an allowable loading range of LDPE that encompasses the claimed range recited in Substitute Claim 17. Holzmuller's preferred and especially preferred ranges overlap with the new claimed range recited

in Substitute Claim 17. Accordingly, it is my opinion that Holzmuller's LDPE layer loading ranges render obvious the claimed range of "a loading of a first layer of the plurality of layers is in the range of 7 to 14 g/m²."

143. Holzmuller further teaches exemplary thicknesses of bonding layers (such as a first bonding layer) formed from EAA to be in the same 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.

144. Table 2 is provided below summarizing the dimensional analysis of allowable loading, preferred loading, and especially preferred loading of Riis's EAA layer as taught by Holzmuller's EAA layers.

Layer	Thickness	EAA Density	Square Meter Conversion
Allowable	5-140 μm = 0.0005-0.014 cm	$\frac{(0.92-0.96) \text{ g}}{1 \text{ cm}^3}$	$\frac{10,000 \text{ cm}^2}{1 \text{ m}^2}$
Preferred	8-95 μm = 0.0008-0.0095 cm		
Especially Preferred	10-50 μm = 0.001-0.005 cm		

Table 2

145. According to the methodology employed in my Original Declaration for determining loading, Holzmuller teaches loading ranges of Riis's EAA of an allowable range of 4.6-134.4 g/m², preferred ranges of 7.4-91.2 g/m², and especially preferred ranges of 9.2-48.0 g/m² (keeping to one decimal place for consistency).

146. Holzmuller thus teaches an allowable loading range of EAA that encompasses

the claimed range recited in Substitute Claim 17. Holzmuller's preferred and especially preferred ranges overlap substantially with the new claimed range recited in Substitute Claim 17. Accordingly, it is my opinion that Holzmuller's EAA layer loading ranges render obvious the claimed range of "a loading of a second layer of the plurality of layers is in the range of 7 to 14 g/m²."

147. As discussed above, Holzmuller's teachings of not only allowable ranges of bonding layer thicknesses, but also of preferred and especially preferred thickness ranges would have motivated a POSITA to tailor the thicknesses, and thus the loadings, of the intermediate bonding layers to achieve the desired additive effects. It is thus my opinion that a POSITA would optimize the ranges of intermediate bonding layers taught by Holzmuller to the LDPE and EAA tie layers of the combination of Riis, Wypych, and Tohara to achieve desired synergistic properties of intermediate layers and thus impart the associated beneficial characteristics upon the resultant film or laminate, including high mechanical stability and high chemical stability, a high degree of stretchability combined at the same time with high tear resistance, a high level of resistance to diffusion, the possibility of achieving good drive, and good haptic/mechanical properties.

148. It is my opinion that a POSITA would have a reasonable expectation of success in modifying the individual tie layer thicknesses of the combination of Riis, Wypych, and Tohara with Holzmuller's teachings of varying thicknesses to employ

among the intermediate bonding layers to achieve the additive effects benefitting the end resulting film or laminate. A POSITA would further have a reasonable expectation of success as Holzmuller similarly relates to multilayer films exposed to chemicals that may leach through the film laminate. EX1034, ¶¶2-3; EX1004, ¶¶3-4, 91-92. Both Holzmuller and Riis contain aluminum foil layers that may be sandwiched between intermediate adhesive or bonding layers formed of polyethylene and EAA and exterior layers aimed to protect against external environments and chemicals. EX1034, ¶¶8, 10; EX1004, ¶59. Due to the similarity in structure, function, and polymeric materials considered, a POSITA would have a reasonable expectation of success in implementing Holzmuller's teachings into the method of providing a film with the combination of Riis, Wypych, and Tohara.

149. Accordingly, it is my opinion that absent any criticality, the specific dimensional ranges in Substitute Claim 17 are obvious as a matter of design choice, especially because such ranges were known in the prior art of Holzmuller. *See supra* § IX.E (citing EX1029) (discussing obviousness of claimed thickness ranges as a matter of design choice).

**G. The Combination of Riis, Wypych, Tohara, and Rivers Renders
Substitute Claim 18 Obvious**

150. I understand that Substitute Claim 18 proposes adding the following limitation to original claim 8: "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.” *See* MTA, 13, 28.

151. It is my opinion that the combination of Riis, Wypych, Tohara, and Rivers disclose and render obvious the added limitations of Substitute Claim 18, and therefore render obvious the claim as a whole in combination with the disclosures of Riis and Wypych as discussed in my Original Declaration for original claim 8. *See* EX1003, ¶¶126-131, 149, 194, 214-220, 225, 253. Claim limitations not explicitly discussed herein are disclosed by the prior art as discussed in my Original Declaration.

152. As discussed in my Original Declaration, Riis discloses that its inventive film is an aggressive chemical-resistant film in that it possesses anti-scalping purposes, allowing only a limited amount of pharmaceutical chemical migration through the film. EX1002, ¶¶121-123, 212. Riis also discloses that such anti-scalping properties are the result of employing cyclic olefin (or cycloolefin) copolymers (COCs) in the product contact layers. EX1004, ¶¶6, (disclosing layers with at least 90% ethylene norbornene copolymer (COC) were found to resist migration of nicotine and fentanyl), 8-9 (disclosing use of HSP as a predictive parameter to determine anti-scalping properties). Although Riis discusses how such films utilizing COC contact layers result in anti-scalping properties to resist migration of pharmaceutical active agents through the film over time, the combination of Riis, Wypych, and Tohara

does not specify a certain allowable percentage of migration allowable over time as defined by Substitute Claim 18. However, Riis discloses that the determination of whether a product contact layer of a film results in an aggressive chemical-resistant film may be a subjective determination, which may depend on the amount that the active agent migrates into layers of other films and the like. EX1004, ¶128. A POSITA would thus be motivated to look elsewhere to determine various ways by which a film qualifies as an aggressive chemical resistant film.

153. As discussed above, Rivers similarly highlights use of films employing cyclic olefin copolymers to limit the scalping of packaged products. 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; *see also supra* § VIII.E. Rivers teaches packaging films that utilize COC within the sealant layer of the film in order to minimize scalping of the packaged product, in some cases not more than 1% of the packaged product. EX1035, 2:6-3:12, 4:12-5:2. Rivers ultimately teaches that it is the use of cyclic olefin copolymers in a packaging film which leads to the minimal scalping of packaged contents. EX1035, 13:16-25.

154. It is my opinion that a POSITA would have been motivated to verify and evidence whether the film of the combination of Riis, Wypych, and Tohara is an aggressive chemical resistant film according to various subjective determinations

contemplated by Riis by looking to the teachings of Rivers which express the degree of anti-scalping in absolute terms of allowable percentages of chemical migration.

155. It is further my opinion that a POSITA would have a reasonable expectation of success in verifying and evidencing the degree to which the film of Riis, Wypych, and Tatarka is an aggressive chemical-resistant film by looking to the determination taught by Rivers. Both Riis and Rivers are directed to multilayer films used to package volatile products susceptible to degradation and adsorption, with both Riis and Rivers teaching the use of COC contact layers as advantageous for such purposes. EX1004, ¶¶6, 55; EX1035, 4:13-5:2, 25:1-31, 26:16-27:5.

H. The Combination of Riis and Wypych Renders Substitute Claim 19 Obvious

156. I understand that Substitute Claim 19 proposes adding the following amendment to original claim 9: “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 MTA, 13, 28.

157. It is my opinion that the combination of Riis and Wypych disclose and render obvious the added limitations of Substitute Claim 19, and therefore render obvious the claim as a whole in combination with the disclosures of Riis and Wypych as discussed in my Original Declaration for original claim 9. See EX1003, ¶¶126-131, 195-196, 214-220, 254. Claim limitations not explicitly discussed herein are

disclosed by the prior art as discussed in my Original Declaration.

I. The Combination of Riis and Wypych Renders Substitute Claim 20 Obvious

158. I understand that similar to Substitute Claim 19, Substitute Claim 20 proposes adding the following limitations to original claim 11 which is directed to defining what film qualifies as an aggressive chemical-resistant film: “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®.” See MTA, 13, 28-29.

159. It is my opinion that the combination of Riis and Wypych disclose and render obvious the added limitations of Substitute Claim 20, and therefore render obvious the claim as a whole in combination with the disclosures of Riis and Wypych as discussed in my Original Declaration for original claim 11. See EX1003, ¶¶199, 257. Claim limitations not explicitly discussed herein are disclosed by the prior art as discussed in my Original Declaration.

160. It is my opinion that 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. Riis specifically discloses that “[t]ypical contents for various embodiments of the inventive container may include, for example, transdermal *patches*, thin strips of dissolvable material for oral administration, as well as articles for collecting or administering a physiologically active substance e.g. a microdiffusion cassette.” EX1004, ¶92.

161. It is also my opinion that Riis discloses an aggressive chemical-resistant film that allows 90-110% migration of the chemical when compared with Barex®. Riis discloses the following in determining whether a film is considered effective for purposes of an aggressive chemical resistant film:

For purposes of the present application, a product contacting layer of a film is considered to serve as an effective anti-scalping layer if an amount of the active agent 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.

EX1004, ¶129.

162. Riis also discloses that it is preferred that its inventive COC containing films will limit an amount of an active pharmaceutical agent that migrates into the film as being “no more than 10% more than the amount of the pharmaceutical active agent that migrates into [a] film having Barex® as a sealing layer.” EX1004, ¶132. Riis even discloses such percentages as low as no more than 1%. EX1004, ¶132.

163. A POSITA would understand that 10% difference range disclosed by Riis is

equivalent to a range of allowing 90-110% migration as compared to the original amount of chemical present in the contained patch product. Accordingly, it is my opinion that Riis discloses an aggressive chemical-resistant film is resistant to the chemical based on allowing 90-110% chemical migration as compared to Barex®, because Riis teaches the ranges based upon the same comparison allow no more than 10% of chemical migration. EX1004, ¶132.

J. The Combination of Riis, Wypych, Tohara, and Holzmuller Renders Substitute Claim 21 Obvious

164. I understand that Substitute Claim 21 proposes three main substantive amendments: (1) replacing the claim language “the base layer comprises aluminum” with narrower language of “the base layer consists of aluminum; (2) 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 (3) amending the final wherein clause to recite “[[wherein]] the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, ~~[[or]]~~ and lidocaine.” See MTA, 14, 29.

165. It is my opinion that the combination of Riis, Wypych, Tohara, and Holzmuller disclose and render obvious the added limitations of Substitute Claim 21, and therefore render obvious the claim as a whole in combination with the

disclosures of Riis and Wypych as discussed in my Original Declaration for Original Claim 13. See EX1003, ¶¶201-210, 259-262. Claim limitations not explicitly discussed herein are disclosed by the prior art as discussed in my Original Declaration.

i. Riis discloses a base layer consisting of aluminum

166. As discussed above and in my Original Declaration, a POSITA would understand that the exterior protective layer and corresponding intermediate adhesive layer adhering the outer protective layer to the aluminum foil barrier layer provides the outer layers laminated to the film formed from the aluminum foil barrier layer and three-layer EAA, LDPE, and COC coextrusion layer. EX1003, ¶¶201-205, 259; *see supra* § IX.C.i. Thus, Riis discloses forming a laminate structure, the outer layers being adhered to the exterior surface aluminum foil barrier layer.

167. As discussed above, it is my opinion that a POSITA would understand the resulting laminate structure to yield an aluminum foil barrier layer that consists of aluminum. *See supra* §§ IX.C.i, IX.D (discussing how laminating outer protective layers onto the film of Substitute Claim 14 still results in a film with a base layer consisting of aluminum foil).

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

168. As discussed above, the claimed film of Substitute Claim 14 does not require an aggressive chemical-resistant film that is resistant to all of nicotine, fentanyl,

rivastigmine, and lidocaine. *See supra* § IX.C.ii (discussing both the opinion that a similar limitation recited in Substitute Claim 14 does not result in a manipulative step and is structured as a Markush group requiring resistance to only one of the chemicals identified). Similarly, the last limitation of Substitute Claim 21, originally presented as a “wherein” clause, does not recite a manipulative step to be taken by the claimed method 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. Accordingly, it is my opinion that a POSITA would understand that the disclosure of Riis renders obvious this new limitation to Substitute Claim 14. In the event this is not the case, my analysis below addresses how additional prior art renders such chemical resistance obvious.

a) The combination of Riis, Wypych, and Tohara renders obvious an aggressive chemical-resistant film resistant to rivastigmine.

169. As explained in my Original Declaration, Riis discloses a method of providing an aggressive chemical-resistant film that is resistant to various chemicals, including nicotine, fentanyl, and lidocaine. EX1003, ¶¶121-123, 212 (citing EX1004, ¶¶2, 4-5, 11). Although Riis does not specifically identify rivastigmine as a pharmaceutical active agent chemical to be packaged by Riis’s film in certain embodiments, Riis leaves open its film’s resistance to all sorts of chemicals. *See* EX1004, ¶¶11, 114 (identifying pharmaceutical active agents in the context of “[i]n some

embodiments”). For instance, Riis discloses that “pharmaceutical product[s] for packaging in [its inventive films] can include *any suitable pharmaceutical active agent*.” EX1004, ¶114 (emphasis added). A POSITA would thus understand that Riis’s film may be resistant to additional chemicals not specifically identified in Riis’s disclosure.

170. As discussed above, Tohara teaches methods of providing films resistant to various chemicals contained in packaged patch products, including lidocaine and rivastigmine. *See supra* § VIII.C. Tohara particularly addresses preventing oxidation and decomposition of susceptible chemicals provided in patch products, including lidocaine as a local anesthetic and rivastigmine as an antimentia drug. EX1033, ¶¶11-12, 28-30.

171. Tohara teaches that films utilizing a COC film beneficially prevent oxidation, volatilization, and adsorption of chemicals in the packaged patch product. EX1033, ¶85, 93-95; *see also* EX1033, ¶89 (teaching that COC is an “essential constituent in the laminate constituting the packaging material to enclose the patch” for the purpose of “suppressing the adsorption of lidocaine or rivastigmine”). Tohara further teaches that Topas films are commercially available COC polymers that may be used for its films. EX1033, ¶102.

172. A POSITA would recognize that Riis discloses chemical resistance to any number of suitable pharmaceutical active agents, beyond those specifically listed in

its disclosure, and would look to other teachings of films which employ a COC contact layer, such as Tohara, and which identify the need to prevent oxidation and decomposition of packaged pharmaceutical patch products. Accordingly, it is my opinion that a POSITA would have been motivated to modify the method of providing an aggressive chemical-resistant film of Riis and Wypych to be additionally chemically resistant to rivastigmine as taught by Tohara to prevent oxidation, decomposition, and adsorption of susceptible packaged patch products—such as lidocaine and rivastigmine patches.

173. Further, it is my opinion that a POSITA would have had a reasonable expectation of success in modifying the method of providing a film of Riis and Wypych with Tohara's resistance to rivastigmine, because Tohara provides the suitability of using a COC product contact layer, specifically from Topas, to prevent the adsorption of such products. Both Tohara and Riis appreciate the use of COCs, and specifically mention commercially available COCs from Topas, for use in product contact layers of multilayer films. *See* EX1004, ¶¶52, 54, 97 (recommending commercially available COCs from Topas due to their beneficial properties, including high transparency and gloss, excellent barrier properties, etc.); EX1033, ¶¶87-89, 94-95, 102 (disclosing COCs capable of suppressing adsorption of lidocaine or rivastigmine are commercially available from Topas). Both Riis and Tohara are directed to ultimately providing multilayer films for use in packaging

such patch products containing chemicals susceptible to degradation over time. *See e.g.*, EX1033, ¶128-130 (providing a multilayer film for a packaging body); EX1004, ¶135 (same). Accordingly, a POSITA would reasonably expect that incorporating Tohara's resistance to rivastigmine into the method of providing a film of Riis and Wypych would be successful.

iii. The combination of Riis, Wypych, Tohara, and Holzmuller renders obvious the claimed loading ranges.

174. As discussed in my Original Declaration and above in this Second Declaration, a POSITA would be able to determine the loading of any layer of material by multiplying the thickness of the layer by the mass density to yield an area density. EX1003, ¶152; *see also supra* § IX.E. I utilize the same methodology to ascertain loading ranges in this Second Declaration.

175. As discussed in my Original Declaration, a first layer of the tie layer is the LDPE layer and a second layer of the tie layer is the EAA layer. EX1003, ¶¶194, 253. As also discussed in my Original Declaration, the 0.65 mil LDPE layer disclosed in the three-layer coextrusion sealant film of Example 5 of Riis has a loading range of 15.11-15.34 g/m², which falls outside of the newly claimed range of 7 to 14 g/m² as recited in Substitute Claim 21. EX1003, ¶¶150-159, 226-234. As further discussed in my Original Declaration, Riis discloses that the polyolefin bulk layer, which may be a tie layer, “may be of any suitable thickness from 0.1 to 7 mils,” which provides a broad loading range beyond the approximate 15 g/m²

disclosed by the combination of Riis and Wypych. EX1003, ¶233 (citing EX1004, ¶65). A POSITA would thus be motivated to alter the thickness of the LDPE layer to be of any suitable thickness disclosed by Riis.

176. As additionally discussed in my Original Declaration, the 0.17 mil EAA layer disclosed in the three-layer coextrusion sealant film of Example 5 of Riis has a loading range of 3.97-4.15 g/m², which falls outside the newly claimed range of 7 to 14 g/m² as recited in Substitute Claim 21. EX1003, ¶¶150-159, 226-234.

177. However, Holzmuller teaches multilayered laminates which have varying disclosed and preferred ranges of thicknesses of intermediate bonding layers in order to produce a synergistic effect of both high mechanical and chemical stability along with other added benefits. *See supra* §§ VIII.D, IX.E. In particular, Holzmuller teaches that adequate protection of a sandwiched aluminum barrier layer can be obtained while also balancing haptic properties and costs by utilizing more than one intermediate bonding layers of varying thicknesses to yield an “additive effect.” EX1034, ¶¶18-20. Additional benefits of this approach include “high tear resistance, a high level of resistance to diffusion and the possibility of achieving good drive [and] good haptic properties.” EX1034, ¶20.

178. It is my opinion that a POSITA would appreciate Holzmuller’s teaching that varying the thicknesses of intermediate bonding layers would produce an additive effect, yielding multiple positive benefits for the end laminate or film, including high

mechanical stability and high chemical stability,” and also provides “a high degree of stretchability combined at the same time with high tear resistance, a high level of resistance to diffusion and the possibility of achieving good drive [and] good haptic properties.” EX1034, ¶20. Thus, a POSITA would be motivated to modify and optimize the interacting thicknesses of the layers that make up the tie layer to promote adhesion, prevent undesirable lamination, and otherwise produce an additive effect through routine experimentation.

179. As discussed above, Holzmuller teaches various thicknesses of intermediate bonding layers, including an allowable layer thickness, a preferred layer thickness, and an especially preferred layer thickness. EX1034, ¶¶19, 23. Thus, a POSITA would be motivated to start with the broad allowable ranges taught by Holzmuller and experiment within those ranges, including into the narrower preferred and especially preferred layer thickness ranges, to determine which thicknesses produce the desired additive effect.

180. Regarding intermediate bonding layers, Holzmuller teaches that such layers may be formed from polyolefins, like polyethylene, and from EAA. EX1034, ¶19. Holzmuller teaches exemplary thicknesses of bonding layers formed from polyolefins like polyethylene to 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.

181. As discussed above, a POSITA would be able to determine the loading of any layer of material by multiplying the thickness of the layer by the mass density to yield an area density. EX1003, ¶152. For Holzmuller, a POSITA would understand to take the thickness of each polymer layer as disclosed in microns and convert it to centimeters, then multiply its thickness in centimeters by the mass density (typically expressed in grams per cubic centimeter), and finally convert to an area of square meters. Table 1 is provided below summarizing the dimensional analysis of allowable loading, preferred loading, and especially preferred loading of Riis's LDPE layer as taught by Holzmuller's polyethylene layers.

Layer	Thickness	LDPE Density	Square Meter Conversion
Allowable	5-140 μm = 0.0005-0.014 cm	$\frac{(0.915-0.929) \text{ g}}{1 \text{ cm}^3}$	$\frac{10,000 \text{ cm}^2}{1 \text{ m}^2}$
Preferred	8-95 μm = 0.0008-0.0095 cm		
Especially Preferred	10-50 μm = 0.001-0.005 cm		

Table 1

182. According to the methodology employed in my Original Declaration for determining loading, Holzmuller teaches loading ranges of Riis's LDPE from 4.6-130.1 g/m², preferably from 7.3-88.3 g/m², and especially preferably from 9.2-46.4 g/m² (keeping to one decimal place for consistency). I note that a POSITA would understand LDPE to be a polyethylene. See *e.g.*, EX1004, ¶69, 74 ("The interior, exterior, intermediate or tie layers may be formed of any suitable thermoplastic

materials, for example . . . polyolefins, and in particular members of the polyethylene family such as . . . LDPE.”).

183. Holzmuller thus teaches an allowable loading range of LDPE that encompasses the claimed range recited in Substitute Claim 21. Holzmuller’s preferred and especially preferred ranges overlap with the new claimed range recited in Substitute Claim 21. Accordingly, it is my opinion that Holzmuller’s LDPE layer loading ranges render obvious the claimed range of “a first tie layer having a loading in the range of 7 to 14 g/m².”

184. Holzmuller further teaches exemplary thicknesses of bonding layers (such as a first bonding layer) formed from EAA to be in the same 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.

185. Table 2 is provided below summarizing the dimensional analysis of allowable loading, preferred loading, and especially preferred loading of Riis’s EAA layer as taught by Holzmuller’s EAA layers.

Layer	Thickness	EAA Density	Square Meter Conversion
Allowable	5-140 µm = 0.0005-0.014 cm	$\frac{(0.92-0.96) \text{ g}}{1 \text{ cm}^3}$	$\frac{10,000 \text{ cm}^2}{1 \text{ m}^2}$
Preferred	8-95 µm = 0.0008-0.0095 cm		
Especially Preferred	10-50 µm = 0.001-0.005 cm		

Table 2

186. According to the methodology employed in my Original Declaration for determining loading, Holzmuller teaches loading ranges of Riis's EAA of an allowable range of 4.6-134.4 g/m², preferred ranges of 7.4-91.2 g/m², and especially preferred ranges of 9.2-48.0 g/m² (keeping to one decimal place for consistency).

187. Holzmuller thus teaches an allowable loading range of EAA that encompasses the claimed range recited in Substitute Claim 21. Holzmuller's preferred and especially preferred ranges overlap substantially with the new claimed range recited in Substitute Claim 21. Accordingly, it is my opinion that Holzmuller's EAA layer loading ranges render obvious the claimed range of "a second layer having a loading in the range of 7 to 14 g/m²."

188. As discussed above, Holzmuller's teachings of not only allowable ranges of bonding layer thicknesses, but also of preferred and especially preferred thickness ranges would have motivated a POSITA to tailor the thicknesses, and thus the loadings, of the intermediate bonding layers to achieve the desired additive effects. It is thus my opinion that a POSITA would optimize the ranges of intermediate bonding layers taught by Holzmuller to the LDPE and EAA tie layers of the combination of Riis, Wypych, and Tohara to achieve desired synergistic properties of intermediate layers and thus impart the associated beneficial characteristics upon the resultant film or laminate, including high mechanical stability and high chemical stability, a high degree of stretchability combined at the same time with high tear

resistance, a high level of resistance to diffusion, the possibility of achieving good drive, and good haptic/mechanical properties.

189. It is my opinion that a POSITA would have a reasonable expectation of success in modifying the individual tie layer thicknesses of the combination of Riis, Wypych, and Tohara with Holzmuller's teachings of varying thicknesses to employ among the intermediate bonding layers to achieve the additive effects benefitting the end resulting film or laminate. A POSITA would further have a reasonable expectation of success as Holzmuller similarly relates to multilayer films exposed to chemicals that may leach through the film laminate. EX1034, ¶¶2-3; EX1004, ¶¶3-4, 91-92. Both Holzmuller and Riis contain aluminum foil layers that may be sandwiched between intermediate adhesive or bonding layers formed of polyethylene and EAA and exterior layers aimed to protect against external environments and chemicals. EX1034, ¶¶8, 10; EX1004, ¶59. Due to the similarity in structure, function, and polymeric materials considered, a POSITA would have a reasonable expectation of success in implementing Holzmuller's teachings into the method of providing a film with the combination of Riis, Wypych, and Tohara.

190. Accordingly, it is my opinion that absent any criticality, the specific dimensional ranges in Substitute Claim 21 are obvious as a matter of design choice, especially because such ranges were known in the prior art of Holzmuller. *See supra* § IX.E (citing EX1029) (discussing obviousness of claimed thickness ranges as a

matter of design choice).

X. CONCLUSION

191. In signing this declaration, I recognize that this declaration will be filed as evidence in a PGR before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required, I will appear for cross-examination within the United States during the time allotted.

I hereby declare that all statements made herein are made of my own knowledge and are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on this 5th day of December 2023.



Richard J. Spontak, Ph.D.