

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.

PGR2023-00008

Patent 11,260,624

**SECOND DECLARATION OF STEPHEN MCCARTHY, PH.D., IN
SUPPORT OF PATENT OWNER'S REVISED MOTION TO AMEND**

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I. INTRODUCTION

I, Stephen McCarthy, declare as follows:

1. I am making this Declaration in connection with Adapa Flexibles Denmark Slagelse A/S's ("Adapa" or "Patent Owner")¹ Revised Motion to Amend, which I understand is being submitted herewith.

2. I have previously provided a Declaration, signed on September 11, 2023, in this post grant review ("PGR") proceeding, PGR2023-00008, before the Patent Trial and Appeal Board ("Board"), in which I provided my independent expert opinions and expert knowledge regarding U.S. Patent No. 11,260,624 ("the '624 Patent") entitled, "Method for Providing an Extreme Chemical Resistant Film, a Film and Laminate Obtainable Therefrom" in response to Huhtamaki Flexible Packaging Germany GmbH & Co. KG's ("Huhtamaki" or "Petitioner") Petition for Post-Grant Review of the '624 Patent, and the arguments and references that form the basis for such grounds asserted by Petitioner, as well as Adapa's prior Motion to Amend.

¹ Since the time I prepared my Original Declaration, Danapak Flexibles A/S changed its name to adapa flexibles Denmark Slagelse A/S. I understand that this name change has been registered with the United States Patent and Trademark Office ("USPTO"). *See* Reel/frame 065266/0645.

3. I understand my prior Declaration was submitted as Exhibit 2014 to this PGR proceeding. When making reference to my prior Declaration, I may refer to it as “Original Declaration” or “EX2014.”

4. I have been retained by Holland & Hart LLP on behalf of Adapa. In this Declaration, I have been asked to provide information and opinions regarding the level of skill of a person of ordinary skill in the art (“POSITA”) for the invention claimed in the ’624 Patent as well as the proposed substitute claims set forth in Adapa’s Revised Motion to Amend, and the general knowledge of such a person at the time of the invention. I have been asked to consider what one of ordinary skill in the art before the priority date of the ’624 Patent would have understood, including scientific and technical knowledge related to the ’624 Patent, and whether the proposed substitute claims set forth in Adapa’s Revised Motion to Amend add new matter not previously disclosed in the ’624 Patent and/or its related applications or are patentable in light of the arguments and references set forth in Petitioner’s Opposition to Patent Owner’s Motion to Amend (“Opposition”) and the Board’s December 29, 2023, Preliminary Guidance (“Preliminary Guidance”)² regarding the same.

² I understand that the Board’s Preliminary Guidance is not binding on the Board when rendering a final written decision. *See* Preliminary Guidance at 3.

5. As stated in my Original Declaration, the '624 Patent describes multilayer films and laminates, and methods of producing the same, that are resistant to aggressive pharmaceutical chemicals. I am familiar with the technology described in the '624 Patent as of its earliest possible priority date, December 29, 2015.

6. I have reviewed and analyzed, and am familiar with, the '624 Patent and its file history. I confirm that to the best of my knowledge, the exhibits accompanying this declaration are true and correct copies of what they purport to be, and that an expert in the relevant field would reasonably rely on such exhibits to formulate opinions such as the opinions I set forth herein.

7. I am being compensated at my standard rate of \$400.00 per hour for my work on this case. My compensation is in no way dependent upon the outcome of this PGR or any issue therein, nor is it contingent upon the results of my study or the substance of my testimony. I have no stake in the outcome of this PGR.

8. This Declaration supplements aspects of my Original Declaration, and as such, I do not repeat all materials included therein.

II. SUMMARY OF OPINIONS

9. It is my opinion that the proposed substitute claims do not enlarge the scope of their corresponding original claims.

10. It is my opinion that the proposed substitute claims are supported by the '624 Patent and related applications, and thus, do not add new subject matter.

11. It is my opinion that the proposed substitute claims are responsive to grounds raised in the Petitioner, Opposition to Patent Owner's Motion to Amend, and/or the Board's Preliminary Guidance.

12. It is my opinion that the prior art and prior art combinations do not render the proposed substitute claims obvious.

III. BASIS FOR OPINIONS & MATERIALS CONSIDERED

13. My opinions and analysis set forth in this Declaration are based on my personal knowledge and experience, including my education, training, and work experience in polymer engineering and the analysis, design, and manufacturing of the same. In addition, I have reviewed the '624 Patent, its prosecution history, and the references identified by Petitioner in this PGR proceeding. I have also carefully reviewed Petitioner's Opposition to Patent Owner's original Motion to Amend, the second declaration from Dr. Richard J. Spontak (EX1037), and each of the accompanying documents that are cited therein. I have also carefully reviewed the Board's December 29, 2023, Preliminary Guidance addressing both Adapa's original Motion to Amend and Petitioner's Opposition thereto. In addition, I have conducted a search for, and examination of, relevant background material as I would with any matter in which I was asked to provide my opinions and analysis.

14. I understand that Adapa is submitting herewith a Revised Motion to Amend that would add certain limitations to the challenged claims of the '624 Patent

should they be found invalid or unpatentable. I have reviewed the support from the application leading to the '624 Patent, the '624 Patent's file history, and the relevant related applications. As detailed below, it is my opinion that a POSITA would have known that Adapa was in possession of the substitute claims as of the filing date of the application leading to the '624 Patent.

15. In addition to the documents mentioned above, and those I listed as having reviewed and analyzed in my Original Declaration, I have reviewed each of the listed documents below as part of conducting my analysis and forming my opinions in this PGR proceeding and this Declaration:

PGR 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
1003	Declaration of Richard J. Spontak, Ph.D.
1004	WIPO International Pub. No. 2015/123211 A1 to Riis <i>et al.</i>
1005	Wypych, G. (2012), Handbook of Polymers, ChemTec Publishing
1006	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. Rague
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 Ph.D.
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
1037	Second Declaration of Richard J. Spontak, Ph.D.
N/A	Petition for Post-Grant Review of U.S. Patent No. 11,260,624
N/A	Patent Owner's Preliminary Response
2001	US Patent 11,504,954 assigned to Huhtamaki Flexible
2002	U.S. Patent Appl. No. 16425,067 Application File History (in-part)
2003	US Patent App. Pub. No. 20150225151A1 to Osborn <i>et al.</i>
2004	Redline Comparison Between Riis and Osborn
2005	US Patent 11,504,954 NFOA Response dated 11 March 2021
2006	US Patent 11,504,954 FOA Response dated 3 August 2022
2007	Huhtamaki Parent Website - Business Segments
2008	Huhtamaki Parent Website - Contact Us
2009	Huhtamaki Parent Website - Executive Team
2010	Huhtamaki Parent Annual Report 2021
2012	EP Application No. 15202962.5 – '624 Priority Application
2015	Deposition Transcript – Dr. Richard Spontak
N/A	Decision Granting Institution of Post-Grant Review

N/A	Patent Owner's Motion to Amend
N/A	Petitioner's Opposition to Patent Owner's Motion to Amend
N/A	Board's December 29, 2023, Preliminary Guidance Regarding Patent Owner's Motion to Amend

IV. QUALIFICATIONS

16. My qualifications relevant to this PGR and Declaration are summarized in Section IV of my Original Declaration, with additional detail provided in my *curriculum vitae*, which is attached as EX2013, thereto, and as such, are not reproduced here.

V. LEGAL PRINCIPLES

17. I have also been asked whether substitute claims 14-24 enlarge the scope of the original claims of the '624 Patent, are supported by the original description of the '624 Patent and related applications, whether the substitute claims would add "new matter," whether the substitute claims are responsive to Petitioner's Petition, Petitioner's Opposition to Patent Owner's Motion to Amend and/or the Board's Preliminary Guidance, and whether the substitute claims are patentable over the relevant prior art. I offer my opinions from the perspective of one of ordinary skill in the art.

18. I understand that in response to Adapa's original Motion to Amend, Petitioner asserted that the originally submitted contingent substitute claims were unpatentable as either obvious over Petitioner's identified prior art references or indefinite.

19. As stated in my Original Declaration, I am not a legal expert and offer no opinions of the law. However, I have been informed by counsel for Adapa that certain legal standards apply with respect to contingent motions to amend claims and the grounds raised in Petitioner's Opposition to Patent Owner's original Motion to Amend and the Board's Preliminary Guidance regarding the same. I recite my understanding of the relevant legal principles below, however, other portions of this Declaration may also be relevant to, and contain my understanding of, the relevant legal standards as I applied such to my analysis.

20. I understand that concurrently herewith, Adapa is filing a Revised Motion to Amend the claims of the '624 Patent that is contingent upon a finding by the Board that one or more challenged claims of the '624 patent are found to be unpatentable. Thus, the following discussion necessarily assumes that this contingency has occurred. However, for the reasons detailed in my Original Declaration, I believe that the Petitioner has not demonstrated that any of the challenged claims to be unpatentable, and nothing contained in this Declaration should be construed otherwise.

A. Contingent Amendments

21. I have been informed and understand that if the Board should accept Petitioner's arguments set forth in its Petition and cancel any of the originally issued claims of the '624 Patent, Adapa is making a motion to amend to, contingently,

substitute the canceled claims(s) with corresponding proposed amended claims. I understand that Adapa previously submitted an original Motion to Amend, Petitioner filed its Opposition to Patent Owner's original Motion to Amend, and the Board issued its Preliminary Guidance related thereto.

22. I further understand that in PGR proceedings where a patent owner has filed a motion to amend, patent owners have the option to file a revised motion to amend, and in such instances, any new amendments, arguments, or evidence submitted therewith should be responsive to issues raised in a petitioner's opposition to the original motion to amend and/or the Board's preliminary guidance.

23. I have been informed and understand that for the proposed substitute claims to be accepted, a patent owner must show, among other things, that the substitute claims are supported by the written description of the original disclosures of the patent-at-issue and related applications, including the drawing figures, specifications, and claims.

24. I have been informed and understand that to satisfy the written description requirement, the substitute claims must be disclosed in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention as of the filing date sought. I understand that the patent owner can show possession of the claimed invention by pointing to such

descriptive means as words, structures, figures diagrams, and formulas that fully set forth the claimed invention.

25. I have been informed by counsel and understand that for the proposed substitute claims to be entered, a patent owner must show, among other things, that the substitute claims do not introduce new subject matter.

26. I understand that new matter is any addition to the claims without support in the original disclosure.

27. I have been informed by counsel and understand that for the proposed substitute claims to be entered, patent owner must show, among other things, the proposed substitute claims do not broaden the scope of the original claims.

B. Indefiniteness

28. I understand that, in a PGR proceeding, a patent claim is deemed unpatentable if it is shown by a preponderance of the evidence that the claim is indefinite.

29. I understand that a patent claim is indefinite if it fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. I also understand that patent claims must particularly and distinctly set out what is claimed so that the public has fair notice of the claimed invention. I understand that the claim must be read in light of the disclosure of the application (including the prosecution history), the teachings of the prior art, and the knowledge of a POSITA at the time

of the invention of the claim. Further, I understand that each term in a patent claim must find clear support or antecedent basis in the specification.

30. I have been informed by counsel that claims are not indefinite merely because they present a difficult task of claim construction. Instead, if the meaning of the claim is discernible, then the claim is sufficiently clear to avoid invalidity on indefiniteness grounds, even though the claim construction task may be formidable and reasonable minds may disagree. I further understand that a patent is definite if it is precise enough to afford clear notice of which is claimed and apprises the public of what is still open to them. Claims that, when read in light of the specification and the prosecution history, provide objective boundaries for those of skill in the art are definite.

31. It is my understanding that a patent's written description can set forth more than one definition of a claim term and that just because a term has multiple definitions does not, by itself, make the term indefinite.

C. Analogous Art

32. It is my understanding that a prerequisite to determining whether a reference or combination of references renders a claimed invention obvious is determining the scope and content of the prior art and determining whether a given reference properly falls within that scope. Further, it is my understanding that a reference qualifies as prior art for an obviousness determination only when it is

analogous to the claimed invention. It is my understanding that a reference is analogous art to the claimed invention 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. I understand that the field of endeavor of a patent is determined by looking to the patent itself—including the written description and claims, and including the structure and function of the invention. I further understand that a reference is “reasonably pertinent” if it would logically commend itself to the inventor’s attention in considering the problem solved by the claimed invention.

D. Obviousness

33. I understand that during a post grant review, the claims of a patent are to be given their ordinary and customary meaning as understood by a person of ordinary skill in the art (“POSITA”) at the time of the alleged invention in light of the claims, the specification of the patent, the prosecution history, and other relevant extrinsic information. I have been informed by counsel that in the obviousness inquiry, once the patent claims have been construed (if necessary), the claim language is compared to the prior art references on a limitation-by-limitation basis.

34. I understand that, in a PGR proceeding, a patent claim is deemed unpatentable if it is shown by a preponderance of the evidence that the claim is

rendered obvious by one or more prior art references. I understand that a petitioner has the burden to show unpatentability in a PGR proceeding.

35. I have been informed by counsel that a patent claim is invalid as “obvious” under 35 U.S.C. § 103 in light of one or more prior art references if it would have been obvious to a POSITA, taking into account (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) any so called “secondary considerations” of nonobviousness, which include: (i) “long felt need” for the claimed invention, (ii) commercial success attributable to the claimed invention, (iii) unexpected results of the claimed invention, and (iv) “copying” of the claimed invention by others. I understand that such evidence must have a nexus, or causal relationship to the elements of a claim, in order to be relevant to the obviousness or non-obviousness of the claim.

36. I have been informed by counsel that a claim can be obvious in light of a single prior art reference or multiple prior art references, and that a claim is not obvious if the reference or combined references do not disclose, teach or suggest at least one element of the claim.

37. To be obvious in light of a single prior art reference or multiple prior art references, there must be a reason to modify the single prior art reference, or combine two or more references, in order to achieve the claimed invention. This

reason may come from a teaching, suggestion, or motivation to combine, or may come from the reference or references themselves, the knowledge or “common sense” of one skilled in the art, or from the nature of the problem to be solved, and may be explicit or implicit from the prior art as a whole. I have also been informed that the combination of familiar elements according to known methods is not obvious when it yields unexpected results. I also understand that it is improper to rely on hindsight in making the obviousness determination. Moreover, to show a patent claim is obvious in light of prior art, the POSITA must have had a reasonable expectation of success that modifying and/or combining the prior art would have resulted in the claimed invention. I understand that a claim is not obvious if there is no suggestion or motivation to modify the reference or combine the references or a lack of some articulated reasoning with a rational underpinning to support the combination of references.

38. A claim is not proved obvious merely by demonstrating that each of the elements was independently known in the prior art. Most, if not all, inventions rely on building blocks long since uncovered, and claimed discoveries, almost of necessity, will likely be combinations of what is already known. It is important to identify whether a reason existed at the time of the invention that would have prompted a POSITA in the relevant field to combine the known elements in the way the claimed invention does. In assessing obviousness, one should consider the

distortion caused by hindsight bias, guard against slipping into the use of hindsight, be cautious of arguments that rely upon after-the-fact reasoning, and avoid the temptation to read into the prior art the teachings of the invention at issue.

39. Dependent claims include all the limitations of the independent claim upon which they are based. Therefore, if a reference or combination of references fails to properly disclose, teach, or suggest a limitation of an independent claim, they also fail to do so when that limitation is deemed incorporated into all the dependent claims.

40. For purposes of my independent analysis, I have assumed that all of the references cited by the Petition and Opposition to Patent Owner's original Motion to Amend to be prior art. I have used a date of December 29, 2015, as the date of invention in my analyses.

E. Written Description

41. It is my understanding that patent law requires a patent applicant to provide an adequate written description of the invention.

42. It is my understanding that the test for sufficiency of a written description is whether the disclosure of the application reasonably conveys to a person of skill in the art at that time that the inventor had possession of the claimed subject matter as of the filing date. Specifically, the written specification must

describe an invention understandable to a person of skill in the art at the time and make it clear that the inventor had actually invented the claimed invention.

43. It is my understanding that the specification must provide written description support for each and every limitation of the claims. The full scope of the claim, read as a whole, must have written description support within the specification.

44. It is also my understanding that the written description requirement applies to both original and amended claims, and that a patent claim is not entitled to the filing date of a patent application unless that patent application as filed contains a written description of that claim.

45. It is my understanding that a patent claim is valid if the specification of the patent in which the claim appears contains a written description of the invention of the claim.

46. It is my understanding that a patent claim is valid if it contains subject matter that was added to the claim by amendment and is supported by the as-filed patent application leading to the patent in which the claim appears.

F. Enablement

47. It is my understanding that patent law requires the description of the invention in the application to be adequate to enable the invention. Specifically, the description must possess such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

48. I also understand that the enablement requirement is met “when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.”

49. It is my understanding that a patent claim is invalid for lack of enablement if a POSITA, based on the written description, would not be able practice the claimed invention without such undue experimentation.

VI. LEVEL OF PERSON HAVING ORDINARY SKILL IN THE ART

50. In his original declaration, Dr. Spontak provided the following definition for a person of ordinary skill in the art:

It is my opinion 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.

EX1003 at ¶ 72.

51. As stated in my Original Declaration, given my review of the '624 Patent, and its file history, I disagree with Dr. Spontak's formulation of a person of ordinary skill in the art applicable to the analyses related to this dispute. Specifically, Dr. Spontak's definition is overly broad and fails to account for the narrow

proficiency called for by the '624 Patent and its claims—namely, coextrusion processing techniques, such as coextrusion lamination and coextrusion coating. *See* EX1001 at Abstract “The method may include providing a base layer, wherein the base layer is resistant to one or more of water or oxygen; **coextruding** a tie layer and a contact layer to provide a coextrusion layer...” (emphasis added); *id.* at Claims 1-13.

52. Indeed, Dr. Spontak’s definition’s inclusion of “2-3 years of experience in laminate or film manufacture or similar packaging manufacture” in his definition of a POSITA would encompass techniques irrelevant to the '624 Patent, such as rotogravure printing, flexographic printing, etc., which may be used in the manufacturing of laminates or films. These other techniques involve vastly different processes, techniques, materials and considerations of chemical properties, and thus, experience in such manufacturing techniques does not imply experience with the relevant, coextrusion processing techniques. Instead, the '624 Patent discloses and claims narrow coextrusion processing techniques. An understanding of coextrusion processing techniques requires hands-on experience in order to appreciate the intricacies involved therewith, and without such, one would not appreciate the invention of the '624 Patent. Purely academic knowledge of coextrusion processing does not accurately reflect the intricacies and difficulties experienced during manufacturing of a coextruded film.

53. As such, it is my opinion that a person of ordinary skill in the art of the '624 Patent at the time of the invention would instead have had a relevant technical degree in Plastics Engineering, 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. Less experience may be necessary with additional education and vice versa. However, in no event, would one skilled in the art have less than one (1) year of experience in manufacturing flexible films using coextrusion processing techniques.

54. In his second declaration, submitted with Petitioner's Opposition to Patent Owner's original Motion to Amend, Dr. Spontak does not disagree with my proposed definition of a POSITA, nor demonstrate that he meets such definition. EX1037 at ¶¶ 51-54. Instead, Dr. Spontak opines that, in his opinion, "both proposed definitions of a POSITA are not substantially different and overlap significantly," and that "the difference in the levels of skill do not change the analysis [] in determining the unpatentability of the proposed substitute claims." *Id.* at ¶ 54.

55. I disagree with Dr. Spontak's opinion that the competing proposed definitions of a POSITA in this proceeding would not change the analysis in determining the patentability of the proposed substitute claims. It is my opinion that purely academic knowledge of coextrusion processing does not accurately reflect

the intricacies and difficulties experienced during manufacturing of a coextruded film, especially when analyzing the different loading ranges and COC material at issue in the proposed substitute claims. In order to be able to properly opine as to whether or not the proposed substitute claims would have been obvious to a POSITA in light of the prior art references identified in Petitioner's Opposition to Patent Owner's original Motion to Amend, and/or whether or not a POSITA would have been motivated to combine such references or had a reasonable expectation of success when doing so, a POSITA would need to understand and appreciate the effects and consequences associated with modifying loading ranges, layer thicknesses and coextrusion techniques relative to the multi-layer films at issue in the PGR proceeding.

56. Specifically, a POSITA would need at least one (1) year of experience in manufacturing flexible films using coextrusion processing techniques in order to accurately opine on whether modifications to a layer's loading range would have been obvious, because such modification, when viewed in light of the entirety of the multi-layered film in which it appears, can affect, among other things, the overall efficacy of the film, the mechanical stability of the film, the laminate strength of the film, and the heat sealability of the film. Without such experience, a person would not appreciate the intricacies involved with such changes, nor the processing and/or

mechanical problems related thereto enough to opine on whether or not making those changes would have been obvious at the time of the invention.

57. It is my opinion that Dr. Spontak's lack of hands-on experience with coextrusion renders him unable to appreciate the difficulties associated with achieving successful coextrusion layers with such thin layers (especially when the intricacies of COC resins are involved). As such, his opinions should be given little weight as they relate to the difficulty of achieving layers within the loading ranges of the proposed substitute claims when coextruding with COC resins, whether the processing parameters of the proposed substitute claims would be obvious, whether the coextrusion described in the proposed substitute claims would be successful, and whether considering the foregoing, it would have been obvious to change loading parameters of individual layers (and if so, which layer, how, and by how much).

58. Furthermore, I agree with Dr. Spontak's assessment that he does not have hands on experience in coextrusion film manufacturing, and thus do not consider Dr. Spontak to be a person of ordinary skill in the art of the '624 Patent. (EX2015 at 23:11-24:3).

59. My opinion on the level of ordinary skill in the art is based on the relevant art of the '624 Patent and my own experiences. Given that I held the above-referenced degree and had the above-reference experience by December 29, 2015, I was and am a person of ordinary skill in the art of the '624 Patent.

VII. OVERVIEW OF THE '624 PATENT**A. Summary of the '624 Patent and Relevant Technology**

60. I provided a thorough analysis and technical overview section regarding the '624 Patent and the relevant technology related thereto in my Original Declaration. In addition to this information, which I reaffirm here but do not reproduce, I provide information supplemental to that technical overview in the sections detailing the proposed substitute claims below.

B. Prosecution History

61. As detailed in my Original Declaration, the '624 Patent issued from U.S. Application No. 16/835,018 (erroneously detailed as U.S. Application No. 16/835,108 in my Original Declaration), which was filed on March 30, 2020, as a continuation of the Parent Application (U.S. App. No. 15/780,999), which was filed on June 1, 2018, as a 371 of Int'l Application No. PCT/EP2016/082876 ("Int'l Application"). The Int'l Application was filed on December 29, 2016, and claimed benefit to EP Application No. 15202962.5, which was filed on December 29, 2015.

62. I provided a thorough analysis and discussion section regarding the '624 Patent's prosecution history in my Original Declaration. In addition to this information, which I reaffirm but do not reproduce here, I provide information supplemental to that discussion in the sections detailing the proposed substitute claims below.

VIII. SUMMARY OF THE ASSERTED REFERENCES

63. In its Petition, Petitioner identified three prior art references as forming the bases for its obviousness challenges to the original claims of the '624 Patent: Riis (WIPO International Pub. No. 2015/123211 A1); Wypych (Wypych, G. (2012), Handbook of Polymers, ChemTec Publishing); and U.S. Patent No. 9,452,593 ("Tatarka"). I provided a thorough analysis and discussion section regarding these prior art references in my Original Declaration. In addition to this information, which I reaffirm but do not reproduce here, I provide information supplemental to that analysis and discussion in the sections detailing the proposed substitute claims below.

64. I understand that, in its Opposition to Patent Owner's original Motion to Amend, Petitioner identifies additional prior art references as forming the bases of its obviousness grounds relating to the originally proposed substitute claims. I provide a summary of these additional references in this section, with additional information and analysis provided in the sections of this Declaration regarding the proposed substitute claims.

A. Tohara (U.S. Patent App. No. 2017/0348246)

65. Tohara, is a United States patent application entitled "Packaging Body for Patch and Method of Packing Patch." EX1033 at 1. Tohara was published as US

2017/0348246 on December 7, 2017, and claims the benefit of PCT/JP2015-082476, which was filed on November 18, 2015.

66. Tohara relates to a “packaging body for a patch exhibiting excellent temporal stability of a drug, a patch product equipped with the patch and a packaging bag, and a method of manufacturing the patch product.” EX1033 at Abstract. Tohara further discloses a “patch product equipped with a packaging bag formed of a laminate composed of at least three or more layers including a cyclic polyolefin film and a lidocaine- or rivastigmine containing patch housed in the packaging bag, a method of the patch product, and a packaging body for a patch formed of a laminate including a cyclic polyolefin film.” *Id.*

67. While Tohara discloses patches and packaging for use with lidocaine and rivastigmine, Tohara does not disclose a film, laminate or packaging for use with either fentanyl or nicotine. In addition, the patch product disclosed in Tohara uses “pressure sensitive adhesive layer[s],” which are relatively thin, flexible layers used to promote adhesion between the layers against which they are placed. However, unlike the tie or adhesion layers described in the ’624 Patent, pressure sensitive adhesive layers do not require the higher temperatures required in coextrusion coating in order to exhibit their adhering properties. Instead, as its name makes obvious, pressure is applied to the layers between which the pressure sensitive adhesive layer is placed, in order to promote adhesion thereto. Furthermore, pressure

sensitive adhesive layers are made with material that is permanently tacky on at least one side and that adhere at room temperature permanently.

68. Tohara also discloses a different product than that described in the '624 Patent. Namely, Tohara describes a patch product that contains the relevant drug, including rivastigmine. For example, claim 2 of Tohara discloses a patch product that includes “a support, a pressure sensitive adhesive layer provided on at least one surface of the support, and a drug-containing layer which contains a drug and is provided on the pressure sensitive adhesive layer.” As such, because the patch in Tohara contains the drug at issue, room temperature processing temperatures would be employed to create the claimed patch in order to prevent destruction of the drug contained therein.

69. The processing methods disclosed in Tohara are different than those claimed in the '624 Patent and the proposed substitute claims. Specifically, Tohara discloses that the patch [0039] includes: “a support, drug-containing layer which contains a drug and is provided on at least one surface of the support, and a pressure sensitive adhesive layer provided on the drug-containing layer,” [0040], or “a support, a pressure sensitive adhesive layer provided on at least one surface of the support, and a drug-containing layer which contains a drug and is provided on the pressure sensitive adhesive layer” [0041], or “a support and a drug-containing layer provided on at least one surface of the support” [0042]. With respect to

manufacturing the disclosed patch, Tohara discloses that the “pressure sensitive adhesive (plaster) obtained by the above method is extruded through a die head portion of which the temperature is controlled at from 100° C. to 150° C. by using a hot melt coating machine and spread on the separator layer so as to have a coating amount of from 100 g/m² to 250 g/m².” *Id.* at ¶ [0239].

70. Processing laminates using the disclosed methods in Tohara, namely pressure sensitive adhesives, are significantly different than those disclosed in the ’624 Patent (coextrusion coating) and the proposed substitute claims. As would have been known to a POSITA at the time of the invention of the ’624 Patent, in dry lamination, the adhesive is applied to one substrate and dried prior to the second substrate being introduced, as opposed to the simultaneous processing method disclosed in the coextrusion process of the ’624 Patent. *See, e.g.*, EX1036 (Morris) at 42.

71. Furthermore, a POSITA would understand that lamination “involves combining films or substrates typically using either an adhesive lamination or extrusion lamination process. In adhesive lamination, solvent-based, water-based, or liquid solventless adhesives are used to bind the substrates together. Heat is applied after lamination to dry or cure the adhesive. In extrusion lamination, molten polymer is used as the adhesive. Cooling solidifies the polymer and locks the layers in place.” *Id.* at 12. Morris goes on to describe the differences in lamination processing and

coextrusion processing, noting that when deciding between the two in a multilayer film, lamination involves combining the two films with an adhesive or polymer melt, whereas in coextrusion, layers are combined while in the melt during the film-converting process. *Id.* at 14.

72. Given the lamination-specific processes disclosed in Tohara, a POSITA would appreciate that Tohara discloses the processing of a film at much lower temperatures than those required by the '624 Patent. Specifically, lamination processes which involve pressure sensitive adhesives usually occur at room temperature. At these lower temperatures, LDPE does not contain any polar groups, and as such would not exhibit the multifunctional tie properties required by Riis. *See e.g.*, Morris at 89 (“When [LDPE is] extruded at temperatures above 300°C, oxidation occurs, producing polar groups such as aldehydes, acids, and ketones. These provide a moderate level of adhesion to polar substrates”).

B. Holzmuller (U.S. Patent App. No. 2008/0286541)

73. Holzmuller is a United States patent application entitled “Multilayered Laminate for Tubes having an Embedded Aluminum Layer, a Process for the Production thereof and a Tube Produced therefrom.” EX1034 at 1. Holzmuller was published on November 20, 2008, and filed on May 15, 2008.

74. Holzmuller relates to laminate tubes. Specifically, Holzmuller discloses a “multilayered laminate for tubes having an embedded aluminum layer . . .

surrounded on each side by an oriented co-extruded protective layer[,] which is in each case joined to the aluminum layer by means of an intermediate layer material.” EX1034 at Abstract. Holzmuller’s oriented co-extruded layer forms the innermost layer of the tube and protects the aluminum layer by increasing the diffusion resistance in the path from the substance to the aluminum layer. *Id.* at ¶ [0011].

75. More specifically, it is my opinion that Holzmuller discloses a film that requires an oriented coextruded protective layer obtained by stretching (especially biaxially) the oriented coextruded protective layer after its initial formation. Accordingly, it is my opinion that, for a film to be formed according to Holzmuller, manufacturing processes for forming the film would be limited to manufacturing processes that preserve the orientation of the oriented coextruded protective layer. This would preclude manufacturing processes involving high temperatures that would destroy the orientation of the oriented coextruded protective layer, such as coextrusion coating. Accordingly, the intermediate layer material and oriented coextruded protective layer cannot be coextruded together since coextrusion requires all the layers in a coextrusion to be coextruded together at a same high temperature, 200° C to 260° C, that would destroy the orientation of the oriented coextruded protective layer. Instead, other, lower-temperature manufacturing techniques (such as extrusion lamination) would be required that use temperatures below the melting point of the oriented polymer in the oriented coextruded protective layer. For

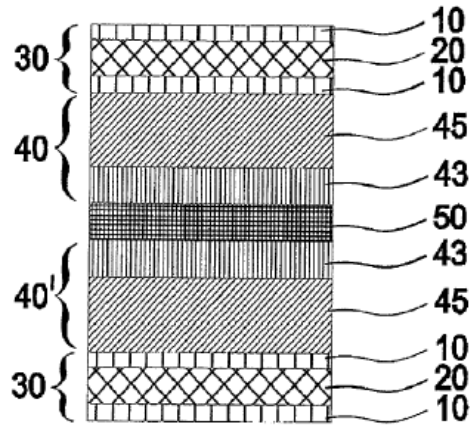
example, to preserve the orientation of the oriented coextruded protective layer, the layers of the intermediate layer can be coextruded onto the aluminum layer and, after providing the intermediate layer time to cool, the oriented coextruded protective layer can be applied to the molten (though cooled) intermediate layer. Once the molten intermediate layer cools, the oriented coextruded protective layer would be fixed to the aluminum by the intermediate layer.

76. Holzmuller discloses a representative multilayer laminate which includes cover layers 10, oriented polymer layers 20, first bonding layers 43, second bonding layers 45, and the aluminum layer 50. *Id.* at FIG. 2; ¶¶ [0042]–[0052]. Holzmuller goes on to list, without identifying any preferred combination, possible materials and thicknesses for the different layers it discloses. *Id.* at ¶¶ [0018], [0019]. For example, for the cover layers 10 (layers that are in contact with the subject substance), Holzmuller lists “polyethylene (PE), polypropylene (PP), polyethylene terephthalate (PETP), polyethylene terephthalate glycol (PETG), and mixtures of the afore-mentioned” as possible materials. *Id.* As such, the contact layers disclosed in Holzmuller could include any of the above-mentioned materials, and/or any combination of one of more said materials. Holzmuller does not disclose COC in any of its list of materials for any of its disclosed layers. For the first bonding layers 43, Holzmuller lists, “[m]aleic acid anhydride (MSA), ethylene methacrylate (EMA), ethyleneacrylic acid copolymers (EAA), ionomers, terpolymers

(ethyleneacrylic acid-maleic acid ester anhydrides), ethylene vinyl acetates (EVA), modified olefins, mixtures [thereof].” *Id.* For the second bonding layers 45, Holzmuller lists MSA, EMA, EAA, ionomers, terpolymers (ethyleneacrylic acid-maleic acid ester anhydrides), EVA, polyolefins (especially PE), PP, modified olefins, and mixtures thereof. *Id.*

77. Holzmuller separately references “bonding” and “adhesive” layers but does not expressly define these terms. It is my opinion that a “bonding layer” in Holzmuller is a polymer layer that is used to support a low-temperature lamination of an oriented coextruded protective layer to the aluminum layer. It is further my opinion that an “adhesive layer” in Holzmuller is an adhesive layer that is used to support the lamination of adjacent layers. As known in the art, lamination involves combining films or substrates using either (co)extrusion lamination or adhesive lamination. EX1036 at 12. (Co)extrusion lamination uses molten polymer as an adhesive, where cooling solidifies the polymer and locks the adjacent layers in place. *Id.* Adhesive lamination uses a solvent-based, water-based, or liquid solventless adhesive to bind substrates together. Thus, it is my opinion, that Holzmuller discloses (co)extruding the intermediary bonding layers as molten polymers such that the molten (though cooled) intermediary bonding layers can be used to laminate the oriented coextruded protective layer to the aluminum layer at temperatures that preserve the biaxial orientation.

78. Figure 2 of Holzmuller further discloses that the disclosed multilayer laminate includes an upper coextruded protective layer 30, a lower coextruded protective layer 30, the intermediate layer material A 40, and the intermediate layer material I 40'.



EX1034 at FIG. 2; ¶ [0036]

79. In Holzmuller, the oriented coextruded protective layer (*e.g.*, the upper/lower coextruded protective layers 30) is produced by stretching, especially biaxially, coextrusion of an oriented polymer layer 20 with the cover layer(s) 10. *Id.* at ¶ [0025]. Also, in Holzmuller, the intermediate layer materials (*e.g.*, the intermediate layer materials A/I 40/40') can be coated to both sides of the aluminum layer in back-to-back or joint extrusion steps. *Id.* at ¶ [0024]. Holzmuller describes that layers forming the intermediate layer material are coextruded and/or extruded immediately one after the other. *Id.* at ¶ [0026]. Holzmuller does not expressly disclose how the oriented coextruded protective layer is fixed to the intermediate layer material, but it is my opinion that the oriented coextruded protective layer is

likely fixed to the intermediate layer material by an extrusion lamination procedure using the bonding layer(s) as adhesives, at a temperature low enough to retain the orientation in the oriented coextruded protective layer.

80. Holzmuller provides a partial reduction to practice of the laminate disclosed in FIG. 2, where the first bonding layers 43 have a layer thickness of 14 μm and the second bonding layers 45 have a layer thickness of 34 μm . *Id.* at ¶ [0036]. However, Holzmuller does not disclose the materials used for these layers, leaving a POSITA with a large number of choices among the numerous materials and combinations of materials disclosed for said layers. Holzmuller provides no guidance as to what materials should be selected among the aforementioned list of materials and combinations that could result from combining one or more of the same.

81. Assuming, *arguendo*, given the relevant context of the '624 Patent and the proposed substitute claims, that Figure 2's first bonding layers 43 use EAA and the second bonding layers 45 use LDPE, applying by Petitioner's conversions detailed in its Opposition to Petitioner's Motion to Amend (at 17-18), the first bonding EAA layers would have a loading of 13.08 g/m^2 , and the second bonding LDPE layers 45 would have a loading of 32.69 g/m^2 .

82. In addition, Holzmuller discloses a laminate coextruded with a significantly different process, significantly different materials and with entirely

different ranges than that disclosed in the '624 Patent—namely with Holzmuller disclosing a coextruded intermediate layer and a separately formed oriented coextruded protective/contacting layer adjacent to the coextruded intermediate layer, both having loading ranges outside of those claimed in the proposed substitute claims.

C. Rivers (WIPO International Pub. No. 2009/105205)

83. Rivers is a PCT application entitled “Packaging Film” filed on February 18, 2009, and published on August 27, 2009.

84. Rivers relates to “plastic films that have a sealant layer and/or a layer adjacent to a sealant layer that minimally scalps essential oils, flavor compounds, antibacterial additives, antifungal additives, insecticides, and the like from products packaged using the disclosed films, and related methods and packaged products.” EX1035 at 1.

85. Rivers generally discloses the use of cyclic olefin copolymers (COCs) in the packaging of essential oils, flavor compounds, antibacterial additives, antifungal additives, insecticides to prevent scalping of the same. *Id.* at 1-2. Rivers does not disclose the use of COCs in relation to the aggressive chemicals disclosed in the '624 Patent, including nicotine, fentanyl, lidocaine, or rivastigmine.

IX. CLAIM CONSTRUCTION

86. As set forth in my Original Declaration, I have been informed that the construction/definition of a patent claim term should be made from the perspective of a POSITA at the time of the invention. I understand that one can look to two types of evidence to guide claim construction: intrinsic evidence (*e.g.*, patent claims, specification, and prosecution history) and extrinsic evidence (*e.g.*, technical dictionaries and expert testimony). I understand the words (or terms) of a claim are generally given their ordinary and customary meaning to a POSITA in question at the time of the invention, here as of December 29, 2015. A POSITA reads the claim term not only in the context of the claim in which it is a part, but also in the context of the entire patent, including the patent specification.

87. I am informed by counsel that the patent specification, under the relevant legal principles, has been described as the single best guide to the meaning of a claim term, and is thus highly relevant to the interpretation of claim terms. And I understand for terms that do not have a customary meaning within the art, the specification usually supplies the best context of understanding the meaning of those terms.

88. I am further informed by counsel that other claims of the patent in question can be valuable sources of information as to the meaning of a claim term. Because the claim terms are normally used consistently throughout the patent, the

usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms, including that different words or phrases are presumed to have different meanings.

89. I understand that the prosecution history can further inform the meaning of the claim language by demonstrating how the inventors understood the invention and whether the inventors limited the invention in the course of prosecution, making the claim scope narrower than it otherwise would be. Extrinsic evidence may also be consulted in construing the claim terms, such as my expert testimony.

90. I have been informed by counsel that, in PGR proceedings, a claim of a patent shall be construed using the same claim construction standard that would be used to construe the claim in a civil action filed in a U.S. district court (which I understand is called the “*Phillips*” claim construction standard), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.

91. In forming my opinions in this Declaration, I have reviewed and analyzed the patent claims, the patent specification, the patent figures, the prosecution history and documents included therein to help determine the meaning of the ’624 Patent’s claim limitations.

92. Except as discussed in my Original Declaration regarding the terms “aggressive chemical-resistant film” and “loading”, I applied the plain and ordinary meaning for the remaining terms of the ’624 Patent and the proposed substitute claims as a person of ordinary skill in the art would understand them at the time of the invention. It is my opinion that the words of the remaining terms of the ’624 Patent and proposed substitute claims are easily understood by a person of ordinary skill in the art without the need for construction beyond the plain and ordinary meaning of those terms. My understanding of the plain and ordinary meanings for these additional terms is informed by my review of the materials listed above, in combination with my education and experience in the art and what one of ordinary skill in the art would understand the undisputed claim terms to mean.

93. I understand that, with the exception of the “aggressive chemical-resistant film” and “loading” terms, Dr. Spontak agrees that the ’624 Patent does not use any other unusual claim terms, nor do any claim terms aside from those two terms appear to be used outside their plain and ordinary meaning, as understood by a POSITA. EX1037 at ¶¶ 55-57.

X. PATENT OWNER’S REVISED MOTION TO AMEND

94. In its Revised Motion to Amend, I understand that Patent Owner seeks to unconditionally cancel Claims 2 and 3 of the ’624 Patent. I also understand that Patent Owner seeks a contingent amendment with respect to Claims 1 and 4–13.

A. The Proposed Substitute Claims

95. I have been informed that Adapa proposes the following substitute claims in its Revised Motion to Amend:

96. **Substitute Claim 14 (contingently replacing Claim 1):**

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

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

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

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

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

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

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

97. **Substitute Claim 15 (contingently replacing Claim 4):**

15. The method according to claim ~~[[1]]~~ 14, wherein the contact layer has a loading in the range of 4 to 20 g/m².

98. **Substitute Claim 16 (contingently replacing Claim 5):**

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

99. **Substitute Claim 17 (contingently replacing Claim 6):**

17. ~~[[A]]~~ The method according to claim ~~[[1]]~~ 14, wherein a loading of at least a portion of the entirety of the tie layer is in the range of 7 to 20 g/m², wherein the first layer of the tie layer is adjacent to the base layer, wherein the second layer of the tie layer is adjacent to the first layer and the contact layer, and wherein a loading of the first layer of the tie layer is in the range of 5 to 19 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m².

100. **Substitute Claim 18 (contingently replacing Claim 7):**

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

101. **Substitute Claim 19 (contingently replacing Claim 8):**

19. The method according to claim [[1]] 14, wherein:
~~the one or more layers of the tie layer consists of two layers,~~
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.

102. **Substitute Claim 20 (contingently replacing Claim 9):**

20. The method according to claim [[1]] 14, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.

103. **Substitute Claim 21 (contingently replacing Claim 10):**

21. The method according to claim [[1]] 14, wherein at least one of the ~~one or more layers~~ first layer of the tie layer and the second layer of the tie layer comprises an acrylic acid layer or a polyethylene layer.

104. **Substitute Claim 22 (contingently replacing Claim 11):**

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

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

105. **Substitute Claim 23 (contingently replacing Claim 12):**

23. The method according to claim [[11]] 22, wherein the acrylic acid layer comprises ethylene acrylic acid.

106. **Substitute Claim 24 (contingently replacing Claim 13):**

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

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

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

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

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

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

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

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

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

B. The Substitute Claims Do Not Enlarge the Scope of the Original Claims

107. I have been informed that it is prohibited for substitute claims to enlarge the scope of the original claims that they are intended to replace. It is my opinion that the substitute claims set forth above do not enlarge the scope of the original claims of the '624 Patent. Generally speaking, in my opinion, the substitute claims do not remove or broaden any of the elements appearing in the original claims of the '624 Patent, but instead, add limitations that either clarify or further narrow the scope thereof.

108. Substitute Claim 14: The proposed amendments set forth in Substitute Claim 14 clarify antecedent basis of claim terms (*e.g.*, clarifying that “the film” in the original claim is the “aggressive chemical-resistant film”), add narrowing features (*e.g.*, replaces “the tie layer comprises one or more layers” with the narrower claim language “the tie layer comprises a first layer and a second layer,” and replaces “the base layer comprises aluminum” with the narrower claim language, “the base layer consists of aluminum.”), and address grammatical informalities relative to original Claim 1. I note that with respect to similar amendments made in Adapa’s original Motion to Amend, the Board found that such amendments did not enlarge

the scope of the original claims. *See* Preliminary Guidance at 5. Given that these amendments narrow the language relating to the claimed layers of the tie layer, it is my opinion that Substitute Claim 14 narrows rather than expands the scope of original Claim 1.

109. Substitute Claims 15, 20, and 23: The proposed amendments set forth in Substitute Claims 15, 20, and 23 merely update the dependencies of original Claims 4, 9, and 12, respectively, to depend on Claim 14. Since Claim 14 is narrowed relative to original Claim 1, it is my opinion that Substitute Claims 15, 20, and 23 narrows rather than expands the scope of original Claims 4, 9, and 12, respectively.

110. Substitute Claims 16, 17, and 18: The proposed amendments set forth in Substitute Claims 16, 17, and 18 clarify antecedent basis of claim terms (*e.g.*, replacing “A method” with “The method” and replaces “a loading” with “the loading”), add narrowing features (*e.g.*, providing explicit per-layer loading ranges), and remove certain features relative to original Claim 5, 6, and 7, respectively. These removed features only involve updating the dependency, improving consistency with the narrowed scope of Claim 14, and narrowing ranges. In addition, these amendments add narrowing features by requiring loading ranges for both of the layers of the tie layer. Given that these amendments narrow the originally claimed loading range, clarify prior claim language and add in a further limiting loading

range, it is my opinion that Substitute Claims 16, 17, and 18 narrows rather than expands the scope of original Claims 5, 6, and 7, respectively.

111. Substitute Claim 21: The proposed amendments set forth in Substitute Claim 21 replace the broader “one or more layers of the tie layer” language with the narrower “first layer of the tie layer and the second layer of the tie layer” language relative to original Claim 10. Thus, it is my opinion that Substitute Claim 21 narrows rather than expands the scope of original Claims 10.

112. Substitute Claims 19 and 22: The proposed amendments set forth in Substitute Claims 19 and 22 add narrowing features which clarify when a film qualifies as the claimed “aggressive chemical-resistant film” of original Claims 8 and 11, respectively. Given that these amendments provide narrowing clarity to the claimed “aggressive chemical-resistant film,” it is my opinion that Substitute Claims 19 and 22 narrow rather than expand the scope of original Claims 8 and 11, respectively.

113. Substitute Claim 24: The proposed amendments set forth in Substitute Claim 24 add similar narrowing and clarifying features and remove certain additional features relative to original Claim 13, as those discussed above with respect to Substitute Claim 14. As such, and for the reasons provided above with respect to Substitute Claim 14, it is my opinion that Substitute Claim 24 narrows rather than expands the scope of original Claim 13.

114. As discussed above, I have reviewed the Substitute Claims, the original disclosure of the patent, the earlier-filed disclosures, and the Challenged Claims, and it is my opinion that none of the proposed Substitute Claims enlarge the scope of the current, Challenged Claims.

C. The Substitute Claims Are Supported in the Original Description & Do Not Add New Matter

115. The '624 Patent issued from U.S. Application No. 16/835,018 ("the '018 App."), which was filed on March 30, 2020, as a continuation of U.S. Application No. 15/780,999 (the "Parent Application"). The Parent Application was filed on June 1, 2018, as a 371 of Int'l Application No. PCT/EP2016/082876 ("Int'l Application"). The Int'l Application was filed on December 29, 2016, and claimed benefit to EP Application No. 15202962.5 ("the '962 App."), which was filed on December 29, 2015.

116. The '018 App. is reproduced in EX1002 at 309 (page 134 of EX1002, Part 3)). The '962 App. is reproduced in EX2012.

117. For each element of the substitute claims, I have been asked to analyze whether certain portions of the original description of the '018 App. and/or '962 App. provide adequate written description support. My analysis was guided by the legal principles as set forth previously herein.

118. I have reviewed the above-referenced applications, including the portions identified below, and in my opinion, a POSITA reading these original

disclosures would have understood that the inventors of the '624 Patent would have been in possession of the inventions as recited in the proposed substitute claims at least as of the filing dates of the applications. Given that each of the substitute claims are fully supported by the original descriptions of these applications, the substitute claims also do not introduce new subject matter. I believe that each element of each substitute claim is fully and adequately supported by the original description of these applications by at least the following portions thereof, as identified in the table appearing below:

Claim Lim. ³	Support in the '018 and '962 Apps.
[14A]	<p>“In a first aspect this [the “needs” described in the preceding paragraph] is solved by a method for providing, e.g., an aggressive chemical-resistant film.” EX1002 ¶ [0010]; EX2012, 2:34-35.</p> <p>“In an embodiment of the disclosure, the film is used to wrap a composition comprising a chemical selected from nicotine, fentanyl, loricine [sic], and rivastigmine.” EX1002 ¶ [0050].</p> <p>“In an embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl, and lidocaine.” EX2012, 2:34-35.</p>
[14B]	<p>The disclosure contemplates “a method for providing the packaging [of] the chemical substance, said method comprising the steps of: a) providing a base layer.” EX1002 ¶ [0066]; EX2012, 10:23–27.</p> <p>The disclosure provides that the “base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil.” EX1002 ¶ [0023]; EX2012, 9:9-10.</p>

³ The alphanumeric labels for each proposed substitute claim element contained in this chart are consistent with the labels set forth in Adapa’s Revised Motion to Amend.

	<p>“The coextrusion layer may be coated to the aluminium layer by a coextrusion system.” EX1002 ¶ [0117]; EX2012, 14:12-13.</p> <p>“To further improve the mechanical wear resistance of the film a first outer layer may be laminated to the base layer side of the film.” “Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the disclosure, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.” EX1002 ¶ [0123]; EX2012, 15:6–12.</p>
[14C]	<p>The disclosure contemplates “a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . b) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer.” EX1002 ¶ [0066]; EX2012, 10:28-29.</p> <p>“In one preferred embodiment, the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer (COC), a polyamide (PA), or[] an ethylene vinyl alcohol.” EX1002 ¶ [0034]; EX2012, 6:30-31.</p>
[14D]	<p>The disclosure contemplates “a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . c) coating the coextrusion layer to the base layer.” EX1002 ¶ [0066]; EX2012, 10:30.</p> <p>The disclosure provides that the “base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil.” EX1002 ¶ [0023]; EX2012, 9:9-10.</p> <p>“The coextrusion layer may be coated to the aluminium layer by a coextrusion system.” EX1002 ¶ [0117]; EX2012, 14:12-13.</p>
[14E]	<p>The disclosure contemplates “a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . d) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide a chemical resistant film comprising the tie layer and the contact layer formed as an [sic] coextrusion layer coated to the base layer.” EX1002 ¶ [0066]; EX2012, 10:31–34.</p>
[14F]	<p>“In one embodiment the tie layer is made of 1, 2, 3, 4, or 5 layers.” “All the layers are coextruded with the contact layer for a simplified processing.” EX1002 ¶¶ [0028], [0029]; EX2012, 6:3–9.</p>

	<p>“[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.” EX1002 ¶ [0043]; EX2012, 8:12–15.</p> <p>“In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b.” EX1002 ¶ [0121] & FIG. 3; EX2012, 14: 34–15:2.</p> <p>“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.” EX1002 ¶ [0147]; EX2012, 19:1–6.</p> <p>See also, the additional analysis provided following this table.</p>
[15A]	See claim elements 14A and 14F, <i>supra</i> .
[16A]	See claim elements 14A and 14F, <i>supra</i> .
[17A]	See claim elements 14A and 14F, <i>supra</i> .
[18A]	See claim elements 14A and 14F, <i>supra</i> .
[19A]	See claim element 14A, <i>supra</i> .
[19B]	See claim element 14F, <i>supra</i> .
[19C]	<p>“Hence, in the context of the present disclosure aggressive chemical-resistant film means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks. Typically, the degree of uptake is complete after 12 weeks or less.” EX1002 ¶¶ [0033]; EX2012, 6:26–29.</p>
[20A]	See claim elements 14A and 14D, <i>supra</i> .
[21A]	See claim elements 14A and 14F, <i>supra</i> .
[22A]	See claim element 14A, <i>supra</i> .
[22B]	See claim element 14F, <i>supra</i> .
[22C]	<p>“In a particular embodiment . . . wherein the composition is provided as a patch, the amount of the aggressive chemical substance remaining . . . [is compared] to a Barex® patch as index 100.” EX1002 ¶ [0051].</p> <p>“A lidocaine patch containing 40 mg lidocaine was wrapped in the pouch, packaged and stored at 40°C for seven days.” EX1002 ¶ [0157]; EX2012, 20:9–11.</p>
[22D]	<p>“Stability of the API is important . . . [a] value of 90% - 110% of the original does after one week when stored at 40°C using Barex® as index</p>

	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.” EX1002 ¶¶ [0158], [0159] & FIG. 5; EX2012, 20:16–26. “A known polymer that fulfils the requirements of extreme chemical resistance and inert properties is a polyactyllonitrile [sic] (PAN) based film, which is sold for example as resins under the trademark Barex®.” EX1002 ¶ [0005], EX2012, 1:30-31.
[23A]	See claim elements 14A and 14F, <i>supra</i> .
[24A]	See claim elements 14A through 14F, <i>supra</i> .
—	
[24G]	

119. Given that the elements of the Substitute Claims are supported in the original disclosure of the patent and/or the earlier-filed disclosure, it is my opinion that the proposed Substitute Claims do not introduce any new subject matter.

120. I have reviewed Petitioner’s arguments that certain proposed substitute claim limitations add new subject matter and the Board’s Preliminary Guidance regarding the same, and agree with the Board’s analysis and reasoning. *See* Preliminary Guidance at 5-8. Specifically, for substitute claim elements relating to limitations regarding the loading ranges of the first and second layers of the claimed tie layers, in addition to the above-identified support, I agree with the Board’s analysis in finding that similar and broader amendments (namely originally-proposed substitute claim limitations [16B], [17B], and [21F]) find support in the relevant applications.

121. With respect to the minimum endpoints of both 7 g/m² and 9 g/m², and as the Board found, support appears in at least [0043] of the '018 App. Similarly, with the maximum endpoints of both 14 g/m² and 18 g/m², and as the Board found, support appears in at least [0147] of the '018 App.

122. Contrary to Petitioner's arguments, the narrower range proposed in these substitute claims is not new matter in light of the existing disclosures of a "plurality of tie layers constituting the tie layer," having "a loading in the range of 7 to 20 g/m²," and that "the loading of the tie layers was between 4-18 g/m²." Preliminary Guidance at 7. And, with respect to Petitioner's arguments that there is no support for each tie layer having the claimed substitute loading range, as the Board pointed out, support for such limitations appear in at least [0043] of the '018 App., which discloses "the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m²." As the Board found, the disclosed "the tie layer" applies to each layer of the claimed tie layer. *Id.*

123. Furthermore, in both the '018 App and the '962 App, the total loading range of a tie layer, or plurality of tie layers, is expressly stated as being in the range of 7 to 20 g/m², which supports a per-tie layer loading of 7 to 20 g/m². Moreover, when the disclosed range of 7 to 20 g/m² is directed to a single tie layer/multi-layer tie layer, I understand that the disclosed range supports per-layer loading ranges that meet a total multi-layer tie layer loading range between 7 and 20 g/m² (some

example per-layer ranges for a two-layer tie layer supported by such a total multi-layer tie loading range include examples where the combined loadings of the individual layers add up to a value that is within the total multi-layer tie loading range : 3 g/m² and 4 g/m² (total loading of 7 g/m²); .01 g/m² and 19.99 g/m² (loading of 20 g/m²); 7 g/m² and 13 g/m² (total loading of 20 g/m²); 7 g/m² and 7 g/m² (total loading of 14 g/m²); etc.).

124. The claimed per-layer loading ranges of 1 to 14 g/m² (in Substitute Claim 15), 7 to 20 g/m² (in Substitute Claim 18), and respective per-layer loading ranges of 1 to 14 g/m² and 5 to 19 g/m² (Substitute Claim 17) fall within the disclosed per-layer loading ranges. Accordingly, support for each substitute claim can be found in the original disclosure of the patent and the earlier-filed disclosure for which benefit of the filing date is sought.

D. The Substitute Claims Are Responsive to a Ground of Unpatentability From the Petition and/or Are Additionally Responsive to Issues Raised in Petitioner's Opposition and/or the Board's Preliminary Guidance.

125. I have been asked to compare Adapa's originally proposed substitute claims set forth in its original Motion to Amend with the proposed substitute claims set forth in Adapa's concurrently submitted Revised Motion to Amend. It is my opinion, as is readily apparent from a simple comparison of the original proposed substitute claims with the revised proposed substitute claims, that the revised proposed substitute claims make substantively similar proposed amendments to the

original claims of the '624 Patent. As such, and for the same reasons previously discussed in my Original Declaration, it is also my opinion that the revised proposed substitute claims each respond to one or more of the grounds asserted in the Petition.

126. While the revised proposed substitute claims make substantively similar amendments as those set forth in Adapa's original Motion to Amend, there are differences, as discussed below. I have been asked to opine on whether these differences address issues raised in Petitioner's Opposition to Adapa's original Motion to Amend and/or the Board's Preliminary Guidance. As discussed below, it is my opinion that the revised proposed substitute claims (addressing, among other issues, the per-layer loading ranges discussed in Petitioner's Opposition to Adapa's original Motion to Amend and/or the Board's Preliminary Guidance) are responsive to arguments and positions set forth in either Petitioner's Opposition to Adapa's original Motion to Amend and/or the Board's Preliminary Guidance.

127. Substitute Claim 14: As discussed above, the proposed amendments set forth in Substitute Claim 14 clarify antecedent basis of claim terms, add narrowing features, and address grammatical informalities of original Claim 1. Adapa's originally proposed substitute claim 14 also sought to make similar amendments (additionally replacing the broader "comprising" language with the narrower "consisting of" language relating to the claimed base layer), but did not seek to

narrow the tie layer to two layers, as does the current revised proposed Substitute Claim 14.

128. In both Petitioner's Opposition, and the Board's Preliminary Guidance, arguments and positions included therein address the originally claimed per-layer loading ranges and allegations/preliminary guidance that the same are obvious in light of the prior art cited therein. *See* Preliminary Guidance at 8-19. As such, because Adapa's revised proposed Substitute Claim 14 directly addresses arguments regarding the claimed loading range at issue in at least Adapa's originally proposed substitute claims 14 and 17, it is my opinion that the amendments included in revised proposed Substitute Claim 14 are responsive to Petitioner's Opposition to Patent Owner's original Motion to Amend and/or the Board's Preliminary Guidance regarding the same.

129. Substitute Claims 15, 20, and 23: The proposed amendments set forth in Substitute Claims 15, 20, and 23 merely update the dependencies of original Claims 4, 9, and 12, respectively, to depend on Claim 14.

130. Substitute Claims 16–18: Substitute Claims 16–18 add narrowing features (*e.g.*, narrowing loading ranges) and remove certain features relative to original Claims 5–7. The removed features only involve updating dependencies.

131. In both Petitioner's Opposition, and the Board's Preliminary Guidance, arguments and positions included therein address the originally claimed loading

ranges and allegations/preliminary guidance that the same is obvious in light of the prior art cited therein. *See* Preliminary Guidance at 8-19. As such, because Adapa's any amendments to revised proposed Substitute Claim 16–18 directly addresses arguments regarding the claimed loading ranges at issue, it is my opinion that the amendments included in revised proposed Substitute Claims 16–18 are responsive to Petitioner's Opposition to Patent Owner's original Motion to Amend and/or the Board's Preliminary Guidance regarding the same.

132. Substitute Claims 19 and 22: The proposed amendments set forth in Substitute Claims 19 and 22 add narrowing features which clarify when a film qualifies as the claimed “aggressive chemical-resistant film” of original Claims 8 and 11. Adapa's originally proposed substitute claim 18 (which sought to replace original claim 8) provided such amendments to clarify the definition of the claimed “aggressive chemical-resistant film” based on how much of the chemical was allowed to migrate and Adapa's originally proposed substitute claim 20 (which sought to replace original claim 11) provided such amendments to clarify the definition of the claimed “aggressive chemical-resistant film” based on a comparison with a Barex® film.

133. In both Petitioner's Opposition, and the Board's Preliminary Guidance, arguments and positions included therein address the originally proposed substitute definitions and allegations/preliminary guidance that the same were obvious and/or

indefinite. *See* Preliminary Guidance at 8-19. As such, because Adapa’s revised proposed Substitute Claims 19 and 22 directly address these arguments by further clarifying said definitions, it is my opinion that the amendments included in revised proposed Substitute Claims 19 and 22 are responsive to Petitioner’s Opposition to Patent Owner’s original Motion to Amend and/or the Board’s Preliminary Guidance regarding the same.

134. Substitute Claim 21: As discussed above, the proposed amendments set forth in Substitute Claim 21 replace the broader “one or more layers of the tie layer” language with the narrower “the first layer of the tie layer and the second layer of the tie layer” language.

135. In both Petitioner’s Opposition, and the Board’s Preliminary Guidance, arguments and positions included therein address the originally claimed per-layer loading ranges and allegations/preliminary guidance that the same are obvious in light of the prior art cited therein. *See* Preliminary Guidance at 8-19. As such, because Adapa’s revised proposed Substitute Claim 21 directly addresses arguments regarding the claimed loading range at issue in at least Adapa’s originally proposed substitute claims 14 and 17, it is my opinion that the amendments included in revised proposed Substitute Claim 21 are responsive to Petitioner’s Opposition to Patent Owner’s original Motion to Amend and/or the Board’s Preliminary Guidance regarding the same.

136. Substitute Claim 24: As discussed above, the proposed amendments set forth in Substitute Claim 24 add similar narrowing and clarifying features and remove certain additional features relative to original Claim 13, as those discussed above with respect to Substitute Claim 14. As such, and for the reasons provided above with respect to Substitute Claim 14, it is my opinion that the amendments included in revised proposed Substitute Claim 24 are responsive to Petitioner's Opposition to Patent Owner's original Motion to Amend and/or the Board's Preliminary Guidance regarding the same.

E. The Substitute Claims are Not Obvious Over the Relevant Prior Art

137. I have also reviewed the proposed Substituted Claims in light of the arguments Petitioner makes with respect to the obviousness thereof and the Board's Preliminary Guidance regarding the same with respect to Adapa's originally proposed substitute claims. It is my opinion that the revised proposed Substitute Claims provide additional clarifying and narrowing amendments to those originally proposed, and as discussed below, are therefore patentable over Petitioner's identified prior art.

1. A POSITA would not be motivated to combine Riis and Holzmuller because Riis's and Holzmuller's films are structurally,

functionally, and polymerically different and are formed using fundamentally different processes.

138. As detailed in the Summary of the Asserted References Section above, Holzmuller discloses a significantly different processing technique than that disclosed in Riis. Specifically, Holzmuller discloses a two-layer coextrusion of a multi-layer bonding layer and separately, an oriented coextruded protective layer formed by a two/three-layer coextrusion, where the multi-layer bonding layer is used to laminate the oriented coextruded protective layer to the aluminum layer while preserving the orientation of the oriented coextruded protective layer. In addition, the intermediate layer and the oriented coextruded protective layer are intended to protect an Al layer, slowing, not stopping the diffusion of a packaged substance to an embedded Al layer. I note that Holzmuller is silent on including COC in any layer, much less the innermost oriented coextruded protective layer that is intended to contact a substance.

139. By contrast, and as detailed in my Original Declaration, Riis discloses a three-layer coextrusion of an EAA layer, an LDPE layer, and a COC layer (known for its processing difficulty) that is intended to be the innermost layer that contacts a substance. Specifically, Riis provides that the “EAA/LDPE/COC sealant layer of the invention and the comparative sealant layers were either extrusion coated or adhesively laminated.” EX1004 at ¶ [00160]. In Riis, the COC layer is intended to

limit the uptake of an active pharmaceutical ingredient in the substance to a threshold amount.

140. Accordingly, it is my opinion that, in light of these differences, Holzmuller and Riis disclose “structurally” and “polymerically” different coextrusion layers, and as such, a POSITA would not have a reasonable expectation of success in applying the thickness ranges for the layers of the polymerically and structurally different two-layer coextrusion in Holzmuller to the 0.17 mil EAA layer and the 0.65 mil LDPE layer of the three-layer coextrusion in Riis’s Example 5. Indeed, it appears that Petitioner’s only evidence that the thickness ranges in Holzmuller can be applied to the 0.17 mil EAA layer and the 0.65 mil LDPE layer in Riis is Dr. Spontak’s conclusory statements (EX1037 at ¶ 127), which give no consideration to the different coextrusion processes in Holzmuller and Riis or the additional complexity associated with coextruding COC—something which, in my opinion, a person with the requisite hands-on experience would readily understand and appreciate.

141. Moreover, as discussed in my Original Declaration, Riis explicitly discourages the use of multi-layer tie layers, providing that a “multifunctional layer is preferably formulated to aid in the adherence of one layer to another layer without the need of using separate adhesives.” EX1004 ¶ [0071]. Thus, in my opinion, a POSITA would be discouraged from modifying Riis to include a multi-layer

bonding layer from Holzmuller, at least because doing so would introduce separate adhesives and would not be cost effective.

142. It is also my opinion that Holzmuller and Riis disclose “functionally” different films. Specifically, and as detailed above, Holzmuller is concerned with protecting an embedded aluminum layer from a packaged substance by slowing diffusion of the substance to the aluminum layer instead of limiting a diffusion of the substance below a threshold as is required by Riis. This is confirmed by Holzmuller’s focus on orientation properties like stretchability. *Id.* at ¶ [0020].

143. As such, Riis and Holzmuller are structurally, functionally, and polymerically different, and, in my opinion, a POSITA would not be motivated to combine Riis and Holzmuller and would not have a reasonable expectation of success in doing so.

2. Holzmuller’s superficial disclosure does not enable a POSITA to make the modified film alleged by Petitioner, and thus does not support an obviousness rejection.

144. As detailed in the Summary of the Asserted References section above, Holzmuller discloses a single functional example in which a first bonding layer 43 has a thickness of 14 μm and a second bonding layer 45 has a thickness of 34 μm . Holzmuller further lists, for the first bonding layer 43, at least 7 possible materials that may be used alone, or in combination with one another, and, for the second bonding layer 45, at least 9 possible materials that may be used alone, or in

combination with one another. Holzmuller further discloses that mixtures of these materials can be used. EX1034 at ¶ [0018].

145. Taking this listing of materials and combinations of materials, Holzmuller describes sixty-three⁴ possible material combinations.⁵ Holzmuller also lists thickness ranges for the first bonding layer 43 and the second bonding layer 45 that, most preferably, range from 10 to 50 μm . Thus, Holzmuller describes, within the most preferable range, at least 1,600⁶ possible thickness combinations. Together, Holzmuller encompasses at least 100,800⁷ material/thickness combinations. Given the high number of material/thickness combinations, the iteration required to achieve the claimed loading range⁸, and the likely effect of changing one layer thickness on other layer thicknesses, it is my opinion that it would require undue experimentation for a POSITA to modify Holzmuller to arrive at Petitioner's modified film, which includes a coextrusion layer that has EAA and LDPE layers with the claimed loading ranges.

⁴ (7 material options) x (9 material options) = 63.

⁵ Holzmuller's disclosure that "mixtures of the afore-mentioned materials" introduces countless possibilities in the materials selected for these layers, as innumerable concentrations/blends of the same could be achieved. Holzmuller provides no guidance on the selection of suitable mixtures.

⁶ (40 thickness options) x (40 thickness options) = 1,600; assuming a 1 μm granularity.

⁷ (63 material option combinations) x (1,600 thickness combinations) = 100,800

⁸ Which, I note, would require the thickness of the second bonding layer 45 to be reduced by 40%.

146. Indeed, in light of my thorough review of the Holzmuller reference, it is my opinion that Holzmuller provides no meaningful guidance to a POSITA on the selection of materials, layer thicknesses thereof, or the combination/selection of both. As such, it is my opinion that a POSITA could not have successfully made a film including a coextrusion layer that includes an EAA layer and an LDPE layer at the per-layer loading ranges in light of Holzmuller's disclosures, especially in light of the numerous possible combinations detailed above. Thus, it is my opinion that Holzmuller amounts to no more than a listing of possible materials for adjacent bonding layers and a disconnected and unsupported statement of per-layer thickness ranges for the adjacent bonding layer. As such, it is my opinion that Riis, in view of Holzmuller, fails to render obvious the per-layer loading ranges in the Substitute Claims.

3. As Holzmuller cannot be combined with Riis, Petitioner has failed to disclose ranges that include or overlap with the claimed ranges in the Substitute Claims.

147. It is my opinion that there would not be a reasonable likelihood of success in modifying Riis with Holzmuller. Accordingly, I understand that Petitioner has failed to establish that a POSITA would modify Riis's 0.17 mil EAA layer and Riis's 0.65 mil LDPE layer to meet the claimed ranges in the Substitute Claims. I also understand that Petitioner fails to provide ranges for the 0.17 mil EAA layer and Riis's 0.65 mil LDPE layer that overlap with or include the claimed ranges in the

Substitute Claims. Thus, I understand that the Substitute Claims are allowable over Riis and Holzmuller even in the absence of evidence of criticality.

148. Specifically, I understand that no evidence of criticality is required if the claimed ranges do not overlap with ranges disclosed in the identified prior art combination. Regardless, as detailed above, I have identified evidence of criticality of the claimed ranges. *See* EX1001 at 2:63–67; 6:1–13, 24–28; EX2014 at ¶¶ 57–65, 68–70 (which discuss the surprising results achieved in the '624 Patent).

4. Riis and Holzmuller fail to teach or suggest a “coextrusion layer consisting of [a] tie layer [comprising a first layer and a second layer] and [a] contact layer.”

149. I provided thorough analysis and opinions regarding Riis in my Original Declaration, which I reaffirm but do not reproduce here.

150. Riis discloses an eight-layer film having the following structure: 0.92 mil OPET/ primer/ 0.42 mil LDPE/ 0.1 mil EAA/ 0.35 mil foil/ 0.17 mil EAA/ 0.65 mil LDPE/ 0.43 mil COC. Riis's 0.17 mil EAA layer, 0.65 mil LDPE layer, and 0.43 mil COC layer form a three-layer coextrusion layer. EX1004 at ¶¶ [0160], [0165], [0168], and [0174].

151. It is my opinion that the 0.17 mil EAA layer is primarily serving a tying purpose (*i.e.*, as a tie layer) and the 0.65 mil LDPE layer as primarily serving a bulking purpose (*i.e.*, as a bulk layer, not a tie layer). Moreover, it is my opinion that the 0.65 mil LDPE layer is not a layer of a multi-layer tie layer that includes the 0.17

mil EAA layer and the 0.65 mil LDPE layer (which, I note, is four times thicker than the 0.17 mil EAA layer). Specifically, I agree with Dr. Spontak that if the 0.65 mil LDPE layer was being used to contribute to machinability and mechanical properties, it would be thicker relative to the 0.17 mil EAA layer and that if the 0.65 mil LDPE layer was being used together with the 0.17 mil EAA layer as an adhesive, it would be on the thinner side. EX2015 at 83:16–22. Thus, and as confirmed by Dr. Spontak’s testimony regarding this point, it is my opinion that the three-layer coextrusion layer of Riis does not disclose a “coextrusion layer consisting of [a] tie layer [comprising a first layer and a second layer] and [a] contact layer,” as recited in Claim 14.

152. As I discuss above, Holzmuller requires low-temperature processes to form Holzmuller’s laminates in order to preserve the orientation of the oriented coextruded protective layer. As such, manufacturing processes for incorporating the oriented coextruded protective layer into the film that expose this layer to high temperatures, such as coextrusion processing, cannot be successfully used. As such, it is my opinion that Holzmuller fails to disclose a “coextrusion layer consisting of [a] tie layer [comprising a first layer and a second layer] and [a] contact layer,” as recited in Substitute Claim 14. Instead, Holzmuller discloses a coextruded intermediate material layer having multiple bonding layers (being silent as to a COC

contact layer), and a separate oriented coextruded protective contacting layer having one or more cover layers and an oriented polymer layer (but no tie layer).

5. Riis fails to disclose, teach or suggest a tie layer comprising multiple layers having the per-layer loading ranges in the Substitute Claims.

153. If I were to apply Petitioner's own calculations, Riis's 0.17 mil EAA layer has a loading in the range of 3.97 to 4.15 g/m² and Riis's 0.65 mil LDPE layer has a loading in the range of 15.11 to 15.34 g/m². Petition, 41, 42. Even if the 0.17 mil EAA and 0.65 mil LDPE layers are interpreted as tie layers or layers of a multi-layer tie layer, which they should not be (*see* Petition at 38, 39), the 0.17 mil EAA layer (calculated as having a loading in the range of 3.97 to 4.15 g/m²) and the 0.65 mil LDPE layer (calculated as having a loading in the range of 15.11 to 15.34 g/m²) fail to disclose a tie layer that comprises a first layer and a second layer "wherein a loading of the first layer of the tie layer is in the range of 1 to 14 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m²," as recited in Substitute Claim 16; a tie layer that comprises a first layer and a second layer "wherein a loading of the first layer of the tie layer is in the range of 5 to 19 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m²," as recited in Substitute Claim 17; or a tie layer that comprises a first layer and a second layer "wherein a loading of the first layer of the tie layer is in the range of 7 to 20

g/m² and a loading of the second layer of the tie layer is in the range of 7 to 20 g/m²,” as recited in Substitute Claim 18.

154. While Dr. Spontak opines that a “POSITA would [] be motivated to alter the thickness of the LDPE layer to be of any suitable thickness disclosed by Riis,” I note that this opinion directly contradicts his prior testimony that a POSITA would not modify Riis’s films to allegedly render the original claims of the ’624 Patent obvious. EX1037 at ¶ 134; EX2015 at 129:8-23.

155. Also, in my opinion, it would not be obvious for a POSITA to modify Riis, on its own, so that the thicknesses of the layers in Riis’s Example 5 teach or suggest the per-layer ranges of the Substitute Claims. Indeed, given a POSITA’s knowledge at the time of the ’624 Patent, it is my opinion that a POSITA would not modify Riis, on its own, so that the layers of Riis’s Example 5 meet the per-layer loading ranges of the Substitute Claims in the course of routine experimentation.

156. In addition, it is my opinion that a POSITA would be discouraged from increasing the thickness of the 0.17 mil EAA layer during routine experimentation because the effect of increasing the thickness of the 0.17 mil EAA layer would be to hinder both the adhesion and mechanical properties of Riis’s Example 5, as well as drive up costs, which Riis counsels against. To that end, I agree with Dr. Spontak statements that “the adhesive layer in any laminated . . . structure, for the purpose of adhesion, should be relatively thin”; EX2015 at 75:10–20, “you want to . . . ensure

that you're getting the . . . most use of the polymer *with as little polymer as possible*;" EX2015 at 76:7–20 (emphasis added); "if you start to make that . . . adhesive layer thicker and thicker, you might find that now the mechanical properties can be compromised;" EX2015 at 79:24–81:7. I note that Riis is consistent with this understanding stating that "the tie layer thickness is usually kept to a minimum consistent with the desired effect". EX1004 at ¶ [0071]. Accordingly, and contrary to Dr. Spontak's opinions, increasing the thickness of the 0.17 mil EAA layer to fall within the loading ranges of the Substitute Claims would go against the purpose of the tie layer, which is to "promote adhesion of layers and to prevent undesirable lamination." Opposition at 17.

157. Similarly, in my opinion, a POSITA would not be motivated to decrease the thickness of the 0.65 mil LDPE layer during routine experimentation because the effect of decreasing the thickness of the 0.65 mil LDPE layer would cause a decrease in the structural, heat sealable, or barrier properties imparted by the 0.65 mil LDPE layer. To that end, I agree with Dr. Spontak that "if you wanted to contribute to machinability, mechanical properties, et cetera, then you might want [a bulk layer] to be slightly thicker". EX2015 at 83:9–22.

158. As such, it is my opinion that absent undue experimentation, a POSITA would not (1) increase the 0.17 mil EAA tie layer thickness, or (2) decrease the 0.65 mil LDPE bulk layer thickness, of Riis's Example 5 to arrive at the per-layer loading

ranges of the Substitute Claims. As discussed herein, it is also my opinion that Holzmuller does not cure these deficiencies, and furthermore, a POSITA would not be motivated to combine Riis with Holzmuller.

a) A POSITA would not be motivated to combine Riis and Tohara.

159. It is also my opinion that a POSITA would not be motivated to combine Tohara and Riis, because Tohara also discloses a significantly different processing technique than that disclosed in Riis, including the use of pressure sensitive adhesive layers and layers actually containing the target drug—both of which demand much lower, near-room temperature processing techniques than those disclosed in Riis.

160. Specifically, and as discussed above, Tohara discloses that the disclosed laminate “can be manufactured by dry lamination, extrusion lamination, or coextrusion lamination.” *Id.* at ¶ [0122]. In addition, Tohara discloses that the “respective layers are directly laminated or laminated via an adhesive or the like.” *Id.* With respect to manufacturing the disclosed patch, Tohara discloses that the “pressure sensitive adhesive (plaster) obtained by the above method is extruded through a die head portion of which the temperature is controlled at from 100° C. to 150° C. by using a hot melt coating machine and spread on the separator layer so as to have a coating amount of from 100 g/m² to 250 g/m².” *Id.* at ¶ [0239].

161. As would have been known to a POSITA at the time of the invention of the '624 Patent, in dry lamination, the adhesive is applied to one substrate and

dried prior to the second substrate being introduced, as opposed to the simultaneous processing method disclosed in the coextrusion process of the '624 Patent. *See, e.g.*, EX1036 (Morris) at 42.

162. Furthermore, a POSITA would understand that lamination “involves combining films or substrates typically using either an adhesive lamination or extrusion lamination process. In adhesive lamination, solvent-based, water-based, or liquid solventless adhesives are used to bind the substrates together. Heat is applied after lamination to dry or cure the adhesive. In extrusion lamination, molten polymer is used as the adhesive. Cooling solidifies the polymer and locks the layers in place.” *Id.* at 12. Morris goes on to describe the differences in lamination processing and coextrusion processing, noting that when deciding between the two in a multilayer film, lamination involves combining the two films with an adhesive or polymer melt, whereas in coextrusion, layers are combined while in the melt during the film-converting process. *Id.* at 14.

163. Given the lamination-specific processes disclosed in Tohara, and the reliance on pressure sensitive adhesive layers, it is my opinion that a POSITA would know that Tohara discloses the processing of a film at much lower temperatures than those required by the processes disclosed in Riis. At these lower temperatures, LDPE does not contain any polar groups, and as such would not exhibit the multifunctional tie properties required by Riis. *See e.g.*, Morris at 89 (“When [LDPE is] extruded at

temperatures above 300°C, oxidation occurs, producing polar groups such as aldehydes, acids, and ketones. These provide a moderate level of adhesion to polar substrates”).

164. In addition, while Tohara discloses patches and packaging for use with lidocaine and rivastigmine, Tohara uses “pressure sensitive adhesive layer[s],” which are relatively thin, flexible layers used to promote adhesion between the layers against which they are placed and do not require the higher temperatures required in coextrusion coating in order to exhibit their adhering properties. Furthermore, Tohara describes a patch product that *actually contains the relevant drug*, which is opposite from the goal of the films disclosed in Riis—to prevent the target drug from being absorbed by the layers of the films disclosed therein. As a POSITA at the relevant time would know, both the use of pressure sensitive adhesive layers and the relation to a patch actually containing the drug demand much lower, near-room temperature processing techniques than those disclosed in Riis.

165. Given the use of pressure sensitive adhesive layers and the different processing techniques disclosed in Tohara, including the accompanying effects such as processing techniques have on the material properties of at least the LDPE layer disclosed in Riis, a POSITA would not be motivated to combine these two references nor would a POSITA reasonably expect to succeed in doing so.

XI. CONCLUSION

166. I submit this Declaration in support of Patent Owner's Revised Motion to Amend. The statements set forth in this Declaration are based upon my personal knowledge, and where I lacked such personal knowledge, I have undertaken efforts to verify the information to confirm the information contained herein is true and correct. If called upon to do so, I could competently testify to the matters set forth herein under oath.

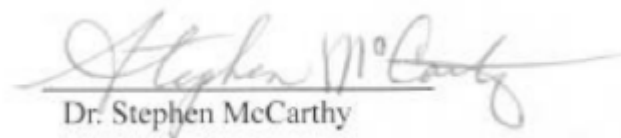
167. This Declaration is based on the information presently available to me as of the date of this Declaration. To the extent any additional information is provided at a later time that could further support or modify the conclusions and opinions I have reached to date, I reserve the right to amend or supplement this Declaration, and/or provide an updated Declaration based on that information. I further reserve the right to consider and comment/opine on any additional positions taken by Petitioner or Petitioner's experts and testimony of such provided in this proceeding.

168. In signing this declaration, I recognize that this declaration will be filed as evidence in this PGR proceeding 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 this PGR proceeding 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.

169. 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 willfully made 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 16th day of January 2024.



Dr. Stephen McCarthy