

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG,
Petitioner,

v.

DANAPAK FLEXIBLES A/S,
Patent Owner.

PGR2023-00008
Patent 11,260,624

DECLARATION OF STEPHEN MCCARTHY, PH.D.

TABLE OF CONTENTS

I.	Introduction	1
II.	Summary of Opinions	3
III.	Basis For Opinions & Materials Considered	3
IV.	Qualifications	6
V.	Legal Principles	8
	A. Indefiniteness	9
	B. Analogous Art	10
	C. Obviousness	11
	D. Written Description	14
	E. Enablement	15
VI.	Level Of Person Having Ordinary Skill In The Art	16
VII.	Overview of the '624 Patent	18
	A. Summary of the '624 Patent and Relevant Technology	18
	B. Prosecution History	28
VIII.	Summary Of The Asserted References	30
	A. Riis (WIPO International Pub. No. 2015/123211 A1)	30
	B. Wypych (Wypych, G. (2012), Handbook of Polymers, ChemTec Publishing)	46
	C. Tatarka (U.S. Patent No. 9,452,593)	46
IX.	Claim Construction	47
X.	The Claims Of The '624 Patent Are Not Indefinite or Obvious	50
	A. Ground 1: Petitioner Fails to Show that a POSITA Would Not Understand, With Reasonable Certainty, the Meaning of the Term “Aggressive Chemical- Resistant Film”	51

B. Ground 1: Petitioner Fails to Show that a POSITA Would Not Understand, With Reasonable Certainty, the Meaning of the Term “Loading”	58
C. Ground 2: The Challenged Claims are not Rendered Obvious by Riis	61
D. Ground 3: The Challenged Claims are not Rendered Obvious by Riis, Wypych and Tatarka, or any combination thereof.	80
XI. Motion to Amend	87
A. The Substitute Claims	87
XII. Conclusion.....	102

I. INTRODUCTION

I, Stephen McCarthy, declare as follows:

1. I have been retained by Holland & Hart LLP on behalf of Danapak Flexibles A/S (“Danapak” or “Patent Owner”) regarding the above-captioned post grant review (“PGR”) proceeding, PGR2023-00008, before the Patent Trial and Appeal Board. I have been retained to provide 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.”

2. 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, 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 grounds and references cited by the Petition render the invention claimed by the ’624 Patent indefinite and/or obvious. I understand that, in this PGR proceeding, Petitioner asserts that claims 1–13 of the ’624 Patent (“Challenged Claims”) are unpatentable. I also understand that the Patent Trial and Appeal Board issued a

decision instituting trial to determine the patentability of the Challenged Claims of the '624 Patent ("Decision").

3. I have been asked to provide my independent technical review, insights, analysis and opinions regarding the '624 Patent, the grounds asserted by Huhtamaki Flexible Packaging Germany GmbH & Co. KG ("Huhtamaki" or "Petitioner") in its Petition for Post-Grant Review of the '624 Patent, and the arguments and references that form the basis for such grounds asserted by Petitioner.

4. 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.

5. 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.

6. 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.

II. SUMMARY OF OPINIONS

7. It is my opinion that one of ordinary skill in the art would understand, with reasonable certainty, the scope of what is claimed by the '624 Patent, and that the '624 Patent provides clear and understandable methods by which to determine whether a film qualifies as an “aggressive chemical-resistant film”.

8. It is my opinion that one of ordinary skill in the art would understand, with reasonable certainty, the scope of what is claimed by the '624 Patent, and that the '624 Patent clearly informs how “loading” is determined.

9. It is my opinion that Riis does not render Claims 1-13 of the '624 Patent obvious.

10. It is my opinion that the combination of Riis, Wypych and Tatarka does not render Claims 1-13 of the '624 Patent obvious.

11. It is my opinion that the proposed substitute claims are supported by the '624 Patent and related applications.

III. BASIS FOR OPINIONS & MATERIALS CONSIDERED

12. 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 the Petition and the declaration from Dr. Richard J. Spontak (EX1003) which Petitioner submitted in support of its Petition in this PGR proceeding. I have also reviewed the Petition and each of the accompanying documents that are cited in the Petition, including those specifically mentioned in Grounds 1–3 of the Petition (noted below). I have also reviewed Danapak’s Preliminary Response and each of the accompanying documents cited in that Preliminary Response. I have reviewed the Decision Granting Institution of Post-Grant Review by the Patent Trial and Appeal Board in this PGR proceeding. Additionally, I have reviewed the transcript of the deposition of Dr. Spontak. For reference, below is a list of documents I have reviewed and analyzed as part of conducting my analysis and forming my opinions in this PGR proceeding:

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. Raque
1021	U.S. Patent Appl. Pub. No. 2009/0208685 to Rivers <i>et al.</i>
1022	Topas COC 8007F-400 Safety Data Sheet (2015)
1023	Topas COC 8007F-400 Safety Data Sheet (2017)
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

IV. QUALIFICATIONS

13. My qualifications relevant to this PGR and Declaration are summarized in this section, with additional detail provided in my *curriculum vitae*, which is attached as EX2013, hereto.

14. I earned a Bachelor of Science degree in Textile Chemistry from Southeastern Massachusetts University in 1978. Afterwards, I studied Chemical Engineering at Princeton University, where I earned a Master's Degree in 1980. After receiving my Master's Degree, I worked as an Advanced R&D Engineer at Owens Corning Fiberglas in Granville, Ohio. I went on to study Macromolecular Science at Case Western Reserve University, where I earned my Ph.D. in 1984. In 2005, I also received a Certificate from Worcester Polytechnic Institute in the field of Medical Device Management.

15. After earning my Ph.D. in 1984, I have worked as a professor in the field of polymer engineering. Throughout my nearly 40-year career, I have held a number of positions at the University of Massachusetts Lowell, where I am currently an Emeritus Professor in the Department of Plastics Engineering and the Department of Biomedical Engineering. As of the date of this declaration, I have over 40 years of directly relevant academic experience in the field of polymers.

16. My research focuses on, among other things, polymer material design and manufacture, and I have had numerous publications that are relevant to the

subject matter of the '624 Patent, a sampling of which are listed in my *curriculum vitae*. See EX2013. Examples include: (1) “Processing Blends of Biopolymers”; (2) “Rheological and Mechanical Properties of Immiscible Blends of EVOH and Styrene-Based Polymers”; (3) “Mechanical Testing and Characterization of Biopolymers”; (4) “‘Kinetic’ Welding of Plastic Parts”; (5) “Analysis of Adhesive Properties of Different Engineering Thermoplastics to Elastomers by a Two-Shot Injection Molding Process”; (6) “Analysis of Adhesive Properties of Different Engineering Thermoplastics to Elastomers by a Two-Shot Injection Molding Process”; and (7) “Effect of Glass Fiber Orientation on the Thermal Diffusivity and Thermal Conductivity of Polymer Melts”.

17. I served as an editor for the Journal of Polymers and the Environment from 1991 to 2016, and served on the Editorial Board of the Journal of Applied Polymer Science from 1995 to 2003. In addition, I am a member of numerous professional societies, including the Society of Plastics Engineers, the American Society for Engineering Education, the American Chemical Society, the American Society for Standards and Materials, and the Bio/Environmentally Degradable Polymer Society. I have also supervised 34 Ph.D. Dissertations and 126 Master’s Theses in the polymer field, including a Ph.D. Dissertation entitled “High Barrier Multilayer Packaging by the Coextrusion Method: The Effect of Nanocomposites

and Biodegradable Polymers on Flexible Film Properties” and a Master’s Thesis entitled “Coextrusion Barrier Modelling and Evaluation.”

18. I have received numerous awards throughout my career, including the SPE Education Award, Society of Plastics Engineers (2013), the Irish Education 100 Award (2012), and the BEPS James Hammar Memorial Lifetime Achievement Award (2008), among several others.

19. I have received numerous research contracts and grants throughout my career, including a grant from Polysar, Inc., entitled “Permeability of Coextruded Sheet.” Throughout my career, I have received over \$53,000,000.00 in polymer research contracts and grant support.

20. I am an inventor on fifteen patents or patent applications that are all related to polymer science, including U.S. Patent No. 6,770,230 “Surface Finishing Compression Molding with Multi-Layer Extrusion”, and U.S. Patent No. 6,093,792 “Bioresorbable Copolymers”.

21. I have over ten years of hands-on experience with polymer and copolymer extrusion and coextrusion techniques.

V. LEGAL PRINCIPLES

22. I am not a legal expert and offer no opinions of the law. However, I have been informed by counsel for Danapak that certain legal standards apply with

respect to determining patentability. I recite my understanding of the relevant legal principles below.

23. I understand that, in this PGR proceeding, the grounds for institution include only allegations that the Challenged Claims are indefinite and obvious. For purposes of the Contingent Motion to Amend, I have also considered enablement and written description.

A. Indefiniteness

24. 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.

25. 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.

26. 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.

27. 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.

B. Analogous Art

28. 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.

C. Obviousness

29. 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.

30. 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.

31. 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.

32. 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.

33. 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 likely to be obvious when it does no more than yield predictable 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.

34. 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.

35. 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.

36. For purposes of my independent analysis, I have assumed that all of the references cited by the Petition in this proceeding to be prior art. I have used a date of December 29, 2015, as the date of invention in my analyses.

D. Written Description

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

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

E. Enablement

43. 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.

44. 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.”

45. 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

46. Dr. Spontak provides 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.

47. 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.

48. 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.

49. 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.

50. 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.

51. I also 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, pp. 22, 23).

VII. OVERVIEW OF THE '624 PATENT

A. Summary of the '624 Patent and Relevant Technology

52. The '624 Patent is entitled "Method for Providing an Extreme Chemical Resistant Film, a Film and Laminate Obtainable Therefrom" and is related to a method for producing a multilayer film and laminate, referred to as an aggressive chemical-resistant film. EX1001 at Abstract.

53. An important quality of the disclosed aggressive chemical-resistant film is that it exhibits "resistance toward highly aggressive substances . . . [and has] [i]nert properties for ensuring that chemical compounds do not migrate from the exterior environment . . . through the laminate getting into contact with a sealed substance." *Id.* at 1:48-55. The '624 Patent defines a "film" as "a product comprising [either] a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or a base layer laminated with a tie layer and a contact layer." *Id.* at

11:64–67. The '624 Patent also defines a “laminate” as “the film to which a further layer [(e.g., an outer layer)] is laminated.” *Id.* at 12:6–8.

54. The '624 Patent goes on to disclose a multilayer film and laminate for use with aggressive chemicals, such as nicotine, fentanyl, lidocaine and rivastigmine. *Id.* at 2:24-30. Specifically, the '624 Patent discloses an aggressive chemical-resistant film that includes a tie layer, a contact layer, and a water and/or oxygen resistant base layer, where the tie layer and contact layer are coextruded to provide a coextrusion layer which is then coated to the base layer. *Id.* at 2:45–51. After the coextrusion layer coated to the base layer adheres to the base layer, the result is the aggressive chemical-resistant film. *Id.* at 2:52-56.

55. The '624 Patent also discloses that the contact layer “comprises a polymer selected from the group consisting of a cyclic olefin polymer (COC), a polyamide (PA), or an ethylene vinyl alcohol (EVOH).” *Id.* at 5:14-17.

56. With respect to a COC contact layer, the '624 Patent discloses that “COC has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates . . . [including] from a visual point of view . . . [and] it is very surprising that the inventors . . . have succeeded in providing a coextrusion layer comprising COC as a contact layer for sealing aggressive substances.” *Id.* at 6:1-13. The '624 Patent also discloses that “[i]t has surprisingly been found that when coextruding the tie layer and the contact layer . .

. the respective layers can be thinner while maintaining the overall mechanical and chemical robustness of the final film and laminates . . . made with the film.” *Id.* at 2:63-67. These thinner layers are disclosed in terms of the respective layers’ “loading.” As defined in the ’624 Patent, “loading” means “the amount of polymer left[] in the layer when the film has dried.” *Id.* at 6:38-39. For example, the ’624 Patent discloses that, “[i]n one embodiment the tie layer or plurality of layers constituting the tie layer has a loading in the range of 7 to 20 g/m² and/or the contact layer has a loading in the range of 4 to 20 g/m² and the loading of the laminate is not more than 40 g/m².” *Id.* at 6:32–37.

57. I agree with the assertion that the ’624 Patent’s success in providing a coextrusion layer consisting of a tie layer and a contact layer having the low loadings (and thus thin layers) as well as a contact layer that is both aesthetically appealing and has robust barrier properties disclosed in the ’624 Patent is very surprising. *See e.g.*, EX1008 (Tatarka) at 2:1-8 (“Cyclic olefin copolymers (COC) in particular are versatile transparent polymeric materials. The lack of mechanical durability or toughness in some aspects of COCs and COPs, especially brittleness (as opposed to durability) has somewhat limited adoption of the material in some applications. Imparting additional durability into cycloolefin containing material without significantly compromising transparency and chemical purity has proven to be very difficult.”).

58. The '624 Patent identifies three grades of COC polymer: Topas 6013M-07, Topas 8007F-600, and Topas 9506F-500. The corresponding glass transition temperatures of these three grades of COC polymer are 142° C, 78° C, and 64° C, respectively. As described in the '624 Patent, coextruding the COC involves heating the COC in an extruder to temperatures above the glass transition temperature to a “melt” temperature that balances the viscosity, which decreases with increasing temperature, with thermal degradation, which increases with increasing temperature and time. For Topas 8007F-600 and Topas 9506-500, the recommended temperature ranges in the extruder is 200° C to 210° C in Zones 1 to 4. For Topas 6013M-07, the recommended temperature ranges in the extruder are 230° C to 240° C in Zone 1 and 250° C to 260° C in Zones 2 to 4. For Topas 8007F-600 and Topas 9506-500, the recommended die temperatures are 220° C to 240° C. For Topas 6013M-07, the recommended die temperatures are 230° C to 240° C. These temperatures are used as a baseline guide, though adjustments are made to optimize the process.

59. As mentioned herein, the viscosity of the molten polymers decreases with increasing temperature, which Dr. Spontak acknowledges. EX1003 at 23. However, I disagree with Dr. Spontak's classification of this behavior as “shear thinning.” The decrease in viscosity with increasing temperature is a common phenomenon due to the increase in kinetic energy with increasing temperature. This

increase in energy results in an increase in volume and the distance between molecules, which results in a lower resistance to flow and lower viscosity.

60. Shear thinning, on the other hand, is the product of a different phenomenon that occurs with molten polymers, a decrease in viscosity with an increasing shear strain rate. This reduction in viscosity is due to the orientation of the long polymer chains in the direction of flow as the shear strain rate increases. As the orientation of the polymer chains in the direction of flow increases, it becomes easier for the polymer chains to “slide” past one another which results in a decrease in viscosity. However, this decrease in viscosity due to orientation comes with a price. The reduction in viscosity is directly proportional to an increase in “elastic” stress within the oriented polymer chains — polymer chains have the lowest stress when they are in a random coil configuration. As the polymer chains are oriented or “stretched” in a certain direction, there is a corresponding residual stress which exists in the polymer chains. This residual stress due to the orientation as a result of the flow of the molten polymer during extrusion can cause a great deal of problems.

61. In coextrusion, each individual layer is extruded through a channel in the feed block. During this time, the polymer chains are being oriented in the direction of flow directly proportional to the shear strain rate. The shear strain rate is highest at the top and bottom internal surfaces of the feed block channel and consequently results in the highest orientation, the lowest viscosity, and the highest

elastic stresses in the polymer chains close to these surfaces. The shear strain rate is proportional to the velocity gradient and since the velocity is close to zero at the surface of the top and bottom of the internal surfaces of the feed block channel, the velocity gradient is the highest close to these surfaces. At the center of the channel, the velocity is a maximum and the velocity gradient is close to zero which results in the minimum value of the shear strain rate for that cross section. Because the shear strain rate is minimum at the center of the channel, the orientation of the polymer chains at the center will be minimized, the viscosity will be the highest, and the elastic stresses will be the lowest at the center for that cross section.

62. At the exit of the feedblock channel, the polymer chains closest to the feedblock's internal top and bottom surfaces are brought together with those from the adjacent feed block channels. When these two surfaces meet, it is these regions with the highest orientation and stresses which are matched together. These highly oriented chains with high elastic stress will relax as they exit the feedblock resulting in an increase in thickness, commonly referred to as "die swell." In many processes, the coextrusion can be "stretched" in the machine direction by increasing the takeoff speed, to counterbalance this swelling. However, this "stretching" is not a solution for the coextrusion of multilayer films which contain an Aluminum foil layer. The nonuniform relaxation of these stresses and orientation can cause instabilities and problems in uniformity and quality of the coextruded material.

63. Moreover, the coextrusion of thinner layers of the tie layer and the contact layer becomes even more difficult (relative to thicker layers) due to problems with flow instability along the width and length of the die, resulting in variations in the thicknesses and separation of the two layers.

64. Furthermore, the lack of mechanical durability or toughness for the COC polymers, especially brittleness, further increases the difficulty of successfully coextruding thin, uniform layers. For the COC polymers listed in the '624 Patent, the elongation to break values are as follows: COC 6013M-07 = 2.6%, COC 8007F-600 = 3.4%, and COC 9506F-500 = 3.1%. These low elongation to break values indicate a “brittle” fracture. At the time of the invention, it was recognized that polymers which exhibit brittle fracture are subject to the problems listed in the '624 Patent. Using COCs in a coextrusion layer presents many problems in the context of aggressive chemical-resistant films, including the inability to maintain a desirable aesthetic in the final product and degradation of the barrier properties for the layer in which the COC appears.

65. In light of the above challenges known at the time of the invention, the achievement of coextruding very thin tie and COC contact layers that exhibit acceptable aesthetic, uniform, strength, and barrier properties, as evidenced by the '624 Patent, would be very surprising and the result of inventive effort. Additionally, the thin layer of COC coextruded adjacent to the tie layer, as disclosed in the '624

Patent is advantageous from a mechanical performance perspective because polymers below their glass transition temperatures show an increase in ductility as the thickness is decreased as well as an increase in brittleness as the thickness is increased. This phenomena is explained by the increasing thickness leading to a plane strain fracture condition while the decreasing thickness leads to a plane stress fracture condition.

66. The '624 Patent further discloses that “[t]o obtain a satisfactory coextrusion layer it is important that the polymer constituting a contact layer and a copolymer constituting a tie layer are compatible with respect to the melting characteristic of the polymers and the copolymer.” *Id.* at 6:24-28. One of ordinary skill in the art would understand that the term melting characteristic is interpreted to mean the change from a physical solid to a viscous liquid state. Thus, for the semicrystalline materials of the tie layer, the melting characteristic would correspond to the melting point and for the amorphous COC polymers and blends, the melting characteristic would correspond to the glass transition temperature.

67. The '624 Patent discloses that an improved processing of COC can be achieved “when COC is coextruded with a tie layer having a glass transition temperature higher than or equal to that of a COC polymer such as a terpolymer of ethylene, acrylic ester, and maleic anhydride.” *Id.* at 6:13-17. As noted above, the term glass transition temperature is used correctly with respect to the COC layer in

this disclosure, as the COC is amorphous. Further, the '624 Patent discloses an embodiment in which “the tie layer has a melting point that differs from COC with 30°C, or less.” *Id.* at 6:19-20. As noted above, the term melting point is used correctly with respect to the tie layer, as it contains semicrystalline materials. The '624 Patent further discloses that when coextruding a tie layer and COC contact layer with similar melting characteristics, the respective layers can be thinner while maintaining the overall desired mechanical, and structural qualities as well as the chemical effectiveness of the final film. *Id.* at 2:63-67.

68. Therefore, as disclosed in the '624 Patent, a coextrusion of a tie layer with a COC or COC blend, where the tie layer has a melting point similar to the glass transition temperature of the COC or COC blend, that is coated to the base layer would result in the production of a thinner extreme chemical resistant film with lower stress, improved visual appearance, and improved processability.

69. As disclosed in the '624 Patent, matching the melt viscosities of these two polymers is an important criteria for success. Matching the melt viscosities yields a synergistic behavior at the interphase of the COC and the tie layers when coextruded with a similar COC glass transition temperature and tie layer melting point, which allows the COC / tie layer coextrusion to be thinner, more uniform, and contains less residual stress while maintaining the overall desired mechanical, and structural qualities as well as the chemical effectiveness of the final film.

70. Taking these disclosures together, the '624 Patent discloses that by matching the melt viscosities of the tie layer and the COC contact layer during coextrusion, for example by selecting a tie layer with a melting point that is near the glass transition temperature of the COC contact layer, the resulting coextrusion layer had a thin tie layer (*e.g.*, having a loading within the range of 7 to 20 g/m²), a thin and also uniform COC contact layer (*e.g.*, having a loading within the range of 4 to 20 g/m²), and maintained its structural, mechanical properties and desired resistance to aggressive chemicals. Based on this knowledge, the inventors of the '624 Patent further contemplated blending polymers to manufacture a contact layer that has melting characteristics that comply with the melting characteristics of the tie layers. For example, by mixing two of the COC polymers disclosed in the application (*e.g.*, COC 6013M-07 and COC 8007F-600), resulting COC blends having a wide range of glass transition temperatures may be obtained.

71. The coextrusion processes at the time of the invention did not match the melt viscosities of the tie layer and the COC contact layer, but actively sought to avoid such matching, as admitted by Dr. Spontak. *See* EX1003 at 22 (“The thickness of each layer can be independently controlled, and interlayer mixing is commonly avoided by sufficient viscosity contrast (*i.e.*, differences in melt viscosity).”) I agree that individually controlling the thickness of each layer and avoiding interlayer mixing being commonly avoided by sufficient viscosity contrast (*i.e.*, differences in

melt viscosity) is valid and commonly used in coextrusion, which further evidences the inventive efforts disclosed in the '624 Patent.

72. As for the method of producing the disclosed aggressive chemical-resistant film, the '624 Patent discloses coating a coextrusion layer that includes a tie layer and a COC contact layer to one side of a base layer. *Id.* at 12:67-13:3. Specifically, “the coextrusion layer may be coated to [an] aluminum [base] layer by a coextrusion system.” *Id.* at 13:11-15. “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 or simply wrapped around the film to provide a laminate.” *Id.* at 13:51-54. “The first outer layer . . . and the base layer side . . . may be laminated together . . . after the coextrusion layer . . . is applied/coated to the base layer.” *Id.* at 13:57-61.

B. Prosecution History

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

74. During examination, the Examiner issued two non-final Office Actions and one final Office Action. In the first non-final Office Action (which issued on

February 9, 2021), the application's claims were rejected under § 102 or § 103 over Adams and under § 103 over Bowen in view of Adams. EX1002 at 201-05. In the first non-final Office Action, the Examiner found that "Adams is silent regarding the loading and melting point of the layers." EX1002 at 202. The Examiner also found that "Bowen in view of Adams is silent regarding the loading and melting point of the layers." EX1002 at 204. Petitioner admits Riis is silent as to these same elements. *See, e.g.*, Petition at 40, 46.

75. The application's claims were allowed on January 12, 2022, via a Notice of Allowance. In the Notice of Allowance, the Examiner found that Adams "fails to teach making a film consisting only of a base layer comprising aluminum and a coextrusion layer consisting only of a tie layer and a contact layer, [] wherein the contact layer consists of only COC." EX1002 at 21. The Examiner also found that Adams fails to teach "an aggressive chemical-resistant film which is resistant to a chemical selected from nicotine, fentanyl, rivastigmine or lidocaine." *Id.* Riis is also silent as to a film resistant to rivastigmine.

76. The Examiner further found that Adams failed to teach a loading in the loading range of 7–20 g/m². *Id.* With respect to Bowen, the Examiner found that Bowen "fails to teach making a film consisting only of a base layer comprising aluminum and a coextrusion layer consisting only of the tie layer and the contact layer, [] wherein the contact layer consists of only COC." *Id.* at 22. The Examiner

further acknowledged that Bowen fails “to teach [an] aggressive chemical film selected explicitly from nicotine, fentanyl, rivastigmine or lidocaine.” *Id.*

VIII. SUMMARY OF THE ASSERTED REFERENCES

77. Petitioner asserts three references as the basis for its asserted grounds of unpatentability based on obviousness (Grounds 2 and 3). I include a brief summary of each reference in this section, with more a detailed discussion of each accompanying my relevant opinions below.

A. Riis (WIPO International Pub. No. 2015/123211 A1)

78. Riis, a PCT application filed on February 10, 2015, claims priority to U.S. Patent App. No. 14/178,005, filed on February 11, 2014. It is my understanding that Riis was disclosed by Patent Owner during the prosecution of the '624 Patent and considered by the Examiner during prosecution. EX1002 at 216.

79. Riis's parent application is US Pub. No. 2015/0225151 to Osborn et al. (“Osborn”) is entitled “Anti-Scalping Transdermal Patch Packaging Film.” Osborn names two of the same inventors as Riis and discloses the eight-layer film of Riis's example five that is being relied on by the § 103 allegations in the Petition. It is important to note that Petitioner, during the prosecution of a separate application, identified that the eight-layer film disclosed in Osborn (which corresponds to the eight-layer film disclosed in Riis) includes a separate base and sealant film. EX2005 at 8 (“[E]xample 5 ... refers to the identity of the *base films of examples 5* and 2, this can only refer to the structure OPET/primer/LDPE/EAA/Al-foil which forms

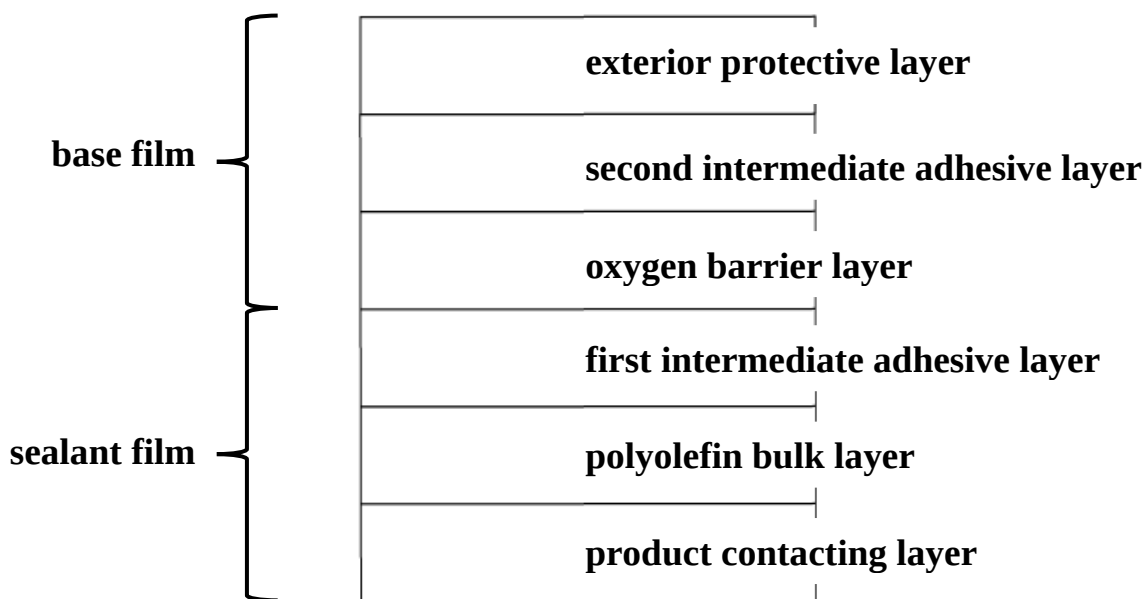
the base film of example 2 . . . Contrary to example 2, the layer structure on the inner, product-contacting side of the aluminum foil is EAA/LDPE/COC. Consequently, ***in example 5 the sealant layer*** mLLDPE of example 2 is replaced by a layer of COC.”) (emphasis added).

80. Like Riis, Osborn was also submitted in an information disclosure statement during examination of the '624 Patent. EX1002 at 214. It is my understanding that Osborn was also considered and dismissed in an application related to the '624 Patent. See Preliminary Response at 7.

81. Riis relates to a multilayer film for packaging products containing pharmaceutically active agents. EX1004 at Abstract. The inventors of Riis claimed to have discovered a way to predict whether a COC film would have desirable resistance to specific pharmaceutical chemicals (not including rivastigmine). Specifically, the inventors of Riis “believed that a combination of Hansen Solubility Parameter of the pharmaceutical active agent and a film or layer comprising the ethylene norbornene copolymer and the glass transition temperature of the film or layer can be used to predict whether an ethylene norbornene copolymer film will have a suitable anti-scalping properties for a given pharmaceutical active agent.” *Id.* at ¶ [0009].

82. Riis depicts several examples of multilayer films. One such example is depicted in FIG. 1 of Riis. This example is of a multilayer film having six layers (10)

that includes a contact layer (1), a polyolefin bulk layer (2), a first intermediate adhesive layer (3), an oxygen barrier layer (4), a second intermediate adhesive layer (5), and an exterior protective layer (6). *Id.* at FIG. 1. An annotated FIG. 1 of Riis is included below:



EX1004 at FIG. 1 (annotated); *see also*, Preliminary Response at 45.

83. As acknowledged by Dr. Spontak regarding his discussion of multilayer films, “each layer of the laminate [or multilayer film] serves a particular purpose that is relevant to the target application.” EX1003 at ¶ 69. As it relates to Riis’s disclosures, I agree with Dr. Spontak in this regard. Moreover, one skilled in the art would refer to a layer in a film in accordance with that layer’s primary purpose. For example, one skilled in the art would refer to a layer primarily used to adhere layers together as a “tie” layer, a layer primarily used to improve stiffness or heat sealability or cost as a “bulk” layer, and so on.

84. The film disclosed in Riis includes a product-contacting sealing layer, including at least 90 wt. % of an ethylene norbornene copolymer, which is a cyclic olefin copolymer (COC). *Id.* Riis discloses that the pharmaceutically active agent is selected from a group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine. EX1004 at ¶ [0011]. Riis does not disclose a multilayer film, or contact layer, for use with rivastigmine. Riis discloses that the product contacting layer (1) in this example “comprises an ethylene norbornene copolymer.” *Id.* at ¶ [00135]. With respect to the contacting layer, and unlike the discovery disclosed in the '624 Patent, Riis discloses that blending the COC with other polymers “may undesirabl[y] affect the anti-scalping properties of this layer and ... may be unacceptable for many applications of the film for packaging drugs or drug articles such as transdermal patches.” *Id.* at ¶ [0055].

85. Riis also discloses, in the section discussing barrier layers, that a bulk layer is “provided to provide additional functionality such as stiffness or heat sealability or to improve machinability, cost, flexibility, barrier properties, etc.” *Id.* at ¶ [0065]. Riis discloses that “[p]referred bulk layers comprise one or more polyolefins such as polyethylene, ethylene-alpha olefin copolymers (EAO), polypropylene, polybutene, ethylene copolymers having a majority amount by weight of ethylene polymerized with a lesser amount of a comonomer such as vinyl

acetate [(EVA)].” *Id.* at ¶ [0065]. Riis also provides additional uses for LDPE in multilayer films, such as an oxygen barrier layer and a moisture barrier layer. *Id.* at ¶¶ [0062], [0087].

86. With respect to tie layers, Riis discloses that adhesive layers (or tie layers) “promote the adherence of **adjacent layers** to one another in a multilayer film.” *Id.* at ¶ [0071] (emphasis added). Thus, Riis discloses that a tie layer serves the purpose of promoting the adherence of the two films immediately next to it. In addition, Riis discloses that the minimal number of tie layers are preferred. Specifically, with respect to a tie layer, Riis discloses 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** by virtue of the compatibility of the materials in that layer to the first and second layers” *Id.* (emphasis added). Indeed, the 0.17 mil EAA layer disclosed in example 5 of Riis, upon which Petitioner heavily relies, is a multifunctional tie layer as defined by Riis because it is formulated to adhere to both the 0.65 mil LDPE layer and the 0.35 Al foil layer. Specifically, the 0.17 mil EAA layer has a nonpolar polyolefin component as well as a polar acrylic acid component. The 0.17 mil EAA layer “ties” the nonpolar 0.65 mil LDPE layer to the polar 0.35 mil Al foil film. It is important to note that an EAA layer could also serve as a multifunctional tie layer between a COC contact layer and an aluminum layer, as it adheres to both of those layers as well. As such, Petitioner’s reading of the 0.65

mil LDPE layer disclosed in example 5 of Riis as serving the purpose of an additional tie layer to the 0.17 mil EAA layer is inconsistent with Riis's express teachings to use a multifunctional tie layer and to minimize the number of tie layers.

87. Riis also discloses a thin adhesive layer in relation to the overall thickness of the multilayer film. Specifically, Riis discloses that the adhesive (or tie) layer is “preferably between 2% and 10% of the overall thickness of the multilayer film.” *Id.* Riis goes on to disclose that “adhesive resins are often more expensive than other polymers so the tie layer thickness is usually kept to a minimum consistent with the desired effect.” *Id.* (emphasis added). And, in one embodiment of Riis that omits a bulk layer, a multilayer structure includes a “a first adhesive layer positioned between and in direct contact with [an] exterior layer and a core oxygen barrier layer . . . and a second tie layer between and in direct contact with the same core oxygen barrier layer and the interior layer to produce a five layer film.” *Id.*

88. As noted in Riis, “a film as described herein may have any number of one or more [of the] layers.” *Id.* at ¶ [00135]. In such cases, in some embodiments of Riis, a “polyolefin bulk layer can serve as an adhesive or tie layer.” *Id.* While Riis discloses that multilayer films can comprise any suitable number of tie or adhesive layers (¶ [0072]), Riis does not disclose a multilayer film wherein two tie layers are positioned adjacent to each other. Moreover, Riis does not disclose that an LDPE

layer that primarily serves the purpose of a bulk layer can serve as an adhesive or tie layer.

89. Petitioner relies heavily on the fifth example disclosed in Riis with respect to its obviousness arguments. Riis's fifth example discloses a sealant film having a three-layer coextrusion of EAA, LDPE and ethylene-norbornene copolymer (COC). *Id.* at ¶ [00174]. The sealant film is made of a 0.17 mil EAA layer/ a 0.65 mil LDPE layer/ and a 0.43 mil COC layer which is extrusion coated onto the aluminum foil surface of the multilayer base film to produce an eight-layer film having the structure: 0.92 mil OPET layer /primer layer/ 0.42 mil LDPE layer/ 0.1 mil EAA layer/ 0.35 mil foil layer/ 0.17 mil EAA layer/ 0.65 mil LDPE layer/ and a 0.43 mil COC layer, totaling 3.04 mils (76 microns) thick (the thickness of the primer layer is not given). *Id.* at ¶ [00174].

90. Riis discloses that the primer layer is an “anchor coating of a water-based polyethyleneimine (PEI) primer (Layer 2) that was contact coated onto the corona treated side of the OPET film.” *Id.* at ¶ [0163]. A primer is similar to a tie layer in that it promotes adhesion between layers. *Id.* at ¶ [0071]. A primer is typically applied using a smooth roll applicator or a gravure applicator, and the typical primer thickness is less than 0.002 mil after drying. Thus, Riis discloses that the thickness of the primer layer is ~0.002 mil.

91. In summary, Riis's example 5 discloses an eight-layer film made of (1) a base film that includes a 0.35 mil Al foil layer (that primarily serves the purpose of an oxygen barrier layer) and several other layers; and (2) a sealant film that includes a 0.17 mil EAA layer (that primarily serves the purpose of a first intermediate adhesive/tie layer), a 0.65 mil LDPE layer (that primarily serves the purpose of a polyolefin bulk layer), and a 0.43 mil COC layer (that primarily serves the purpose of a contact layer). Furthermore, the 0.17 mil EAA, layer, the 0.65 mil LDPE layer, and the 0.43 mil COC layer of the sealant film are coextrusion coated (by way of a three-layer coextrusion) to the foil layer of the base film.

92. Riis describes, "a bulk layer [is] provided to provide additional functionality such as stiffness or heat sealability or to improve machinability, cost, flexibility, barrier properties, etc." *Id.* ¶ [0065]. Example 5 of Riis does not disclose that the 0.65 mil LDPE layer functions as the tie layer and/or adhesive layer. Instead, Riis's disclosures suggest that the 0.65 mil LDPE layer functions as a bulk layer, as evidenced by (1) the presence of the multipurpose 0.17 mil EAA layer (and Riis's teaching away from multiple adhesive layers); (2) the multipurpose 0.17 mil EAA layer's purpose of promoting adherence between the layers (thus rendering the LDPE layer redundant in terms of adhesive functionality); and (3) Riis's disclosure of the tie layer being between 2% and 10% of the multilayer film's total thickness (taking the 0.17 mil EAA layer and the 0.65 mil LDPE layer together, amounts to

0.82 mil of the overall 3.04 mil multilayer film in Riis's example 5—or **26.97%**).¹ See also, EX1004 at Claim 18 (claiming “a polyolefin **bulk layer**” positioned between the COC contact layer and the first intermediate adhesive layer) (emphasis added).

93. When read in light of Riis's disclosures, if the 0.17 mil EAA layer is properly considered the adhesive layer, the thickness of this adhesive layer of the eight-layer film would be no more than 5.59% of the overall thickness—and thus in line with Riis's disclosure of a tie layer having a thickness of 2% to 10% of the multilayer film's total thickness. Petitioner's argument that the 0.65 mil LDPE layer is a tie layer goes against Riis's express teachings. If the 0.17 mil EAA layer and the 0.65 mil LDPE layer are both considered a multi-layer adhesive layer, then the thickness of the adhesive layer would be 26.97% of the overall thickness of the multilayer film. As such, Petitioner's argument is unworkable in light of Riis's disclosure as, in order for the 0.65 mil LDPE and 0.17 mil EAA layers to achieve a 10% overall thickness, one would have to ignore the express teachings of Riis.

94. In addition, the relative thickness of Riis's 0.65 mil LDPE layer to the 0.17 mil EAA layer, with the 0.65 mil LDPE layer being almost four times as thick as the 0.17 mil EAA layer, further indicates that it is serving as a bulk layer rather

¹ Even taking the 0.65 mil LDPE layer alone, it accounts for 21.38% of the thickness of the 3.04 mil multilayer film in example 5, thus falling outside of Riis's disclosure.

than a tie layer. One skilled in the art would understand that a bulk layer that is primarily serving a tying purpose, on its own or in a multi-layer tie layer, would be thinner — e.g., closer to the thickness of the 0.17 mil EAA layer. And that a bulk layer that is primarily serving a bulk purpose would be thicker than an adjacent tie layer, as is the case here in Riis. In fact, if one were to remove the 0.65 mil LDPE bulk layer, the EAA would serve as a tie layer between the 0.35 mil Foil and the 0.43 mil COC contact layer. The adhesion between the remaining layers would not be compromised, and in fact would be improved, by removing the 0.65 mil LDPE bulk layer. However, the bulk properties such as stiffness and heat sealability would be compromised by removing the 0.65 mil LDPE bulk layer. Therefore, the primary purpose of the 0.65 mil LDPE bulk layer is to improve stiffness and heat sealability at a low cost, which is a bulk material.

95. Moreover, the 0.65 mil LDPE layer is a low-cost polyolefin which extends the thickness of the COC contact layer at a much lower cost and such a material use is a “bulk material”.

96. A depiction of Riis’s example 5 of Riis is included below:

base film	{	.92 mil OPET – Exterior Protective Layer
		(Not Given) mil PEI – Primer Layer
		.42 mil LDPE – Bulk Layer
		.1 mil EAA – 2nd Intermediate Adhesive Layer
		.35 mil Foil – Barrier Layer
sealant film	{	.17 mil EAA – First Intermediate Adhesive Layer
		.65 mil LDPE – Bulk Layer
		.43 mil COC – Contact Layer

See, Preliminary Response at 46 (Figure 1).

97. With reference to the above discussion of the disclosure Riis (including the correspondence between the six-layer film described in FIG. 1 of Riis and the eight-layer film disclosed in example 5 of Riis) and the knowledge of one skilled in the art at the time of the '624 Patent, one skilled in the art would understand the primary purposes of the layers of the eight-layer film to be as follows.

98. One skilled in the art would understand that the 0.92 mil OPET layer to be primarily serving an exterior protective layer purpose and would, thus, refer to the 0.92 mil OPET layer as an “exterior protective” layer. Importantly, Petitioner does not challenge that the 0.92 mil OPET layer primarily serves as an exterior protective layer in Riis.

99. One skilled in the art would understand that the PEI layer is primarily serving a primer purpose (which is given in paragraph [00174] of Riis) and would,

thus, refer to the PEI layer as a “primer” layer. Importantly, Petitioner does not challenge that the PET layer primarily serves as a primer layer in Riis.

100. One skilled in the art would also understand that the 0.42 mil LDPE layer is primarily serving a bulk purpose and would, thus, refer to the 0.42 mil LDPE layer as a “bulk” layer. Importantly, Petitioner does not challenge that the 0.42 mil LDPE layer primarily serves as a bulk layer in Riis. *See* Petition at 38 (depicting this layer as “LDPE-Bulk Layer”); EX1003 at ¶ 144 (same). And this is in line with what one of skill in the art would understand in light of Riis’s disclosures. Specifically, one skilled in the art would understand that a bulk layer that is primarily serving a bulk purpose would be thicker than an adjacent tie layer. In addition, the bulk properties such as stiffness and heat sealability would be compromised by removing the 0.42 mil LDPE bulk layer. Therefore, the primary purpose of the 0.42 mil LDPE bulk layer is to improve stiffness and heat sealability at a low cost, which is a bulk material.

101. One skilled in the art would also understand that the 0.1 mil EAA layer is a primarily serving a tying purpose and would, thus, refer to the 0.1 mil EAA layer as an “adhesive” or “tie” layer. Importantly, Petitioner does not challenge that the 0.1 mil EAA layer primarily serves as a tie layer in Riis.

102. One skilled in the art would also understand that the 0.35 mil Al foil layer is a primarily serving a barrier purpose and would, thus, refer to the 0.35 mil

Al foil layer as a “barrier” layer. Importantly, Petitioner does not challenge that the 0.35 mil Al foil layer primarily serves as a barrier layer in Riis.

103. One skilled in the art would also understand that the 0.17 mil EAA layer is a primarily serving a tying purpose and would, thus, refer to the 0.17 mil EAA layer as an “adhesive” or “tie” layer. Importantly, Petitioner does not challenge that the 0.17 mil EAA layer primarily serves as a tie layer in Riis.

104. As detailed more fully below, and for the same reasons one of ordinary skill in the art would understand that the 0.42 mil LDPE layer primary serves as a bulk layer in Riis, one skilled in the art would also understand that the 0.65 mil LDPE layer is a primarily serving a bulk purpose and would, thus, refer to the 0.65 mil LDPE layer as a “bulk” layer. *See also*, ¶¶ 94, 156.

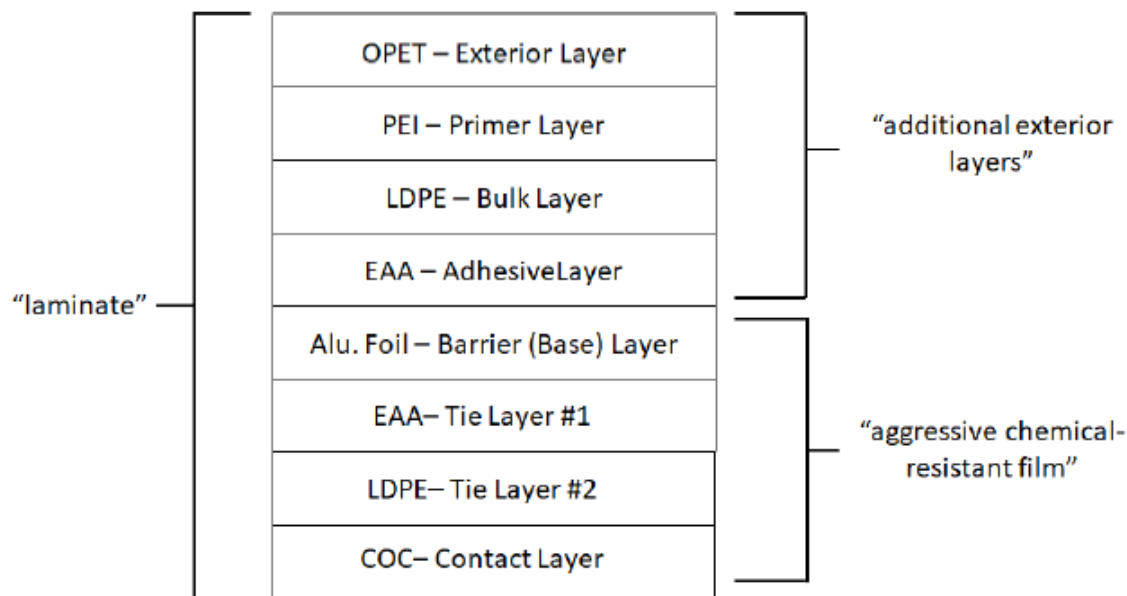
105. One skilled in the art would also understand that the 0.43 mil COC layer is a primarily serving a contacting purpose and would, thus, refer to the 0.43 mil COC layer as a “contact” layer. Importantly, Petitioner does not challenge that the 0.43 mil COC layer primarily serves as a contact layer in Riis.

106. With respect to the process of producing the eight-layer film of Riis’s example 5, Riis discloses the following process: (1) providing the base film including, a protective layer, a primer layer, a bulk layer a second intermediate adhesive layer, and an oxygen barrier layer; (2) providing the sealant film including a product contacting layer, a polyolefin bulk layer, and a first intermediate adhesive

layer; and (3) coextrusion coating (by way of a three-layer coextrusion) the product contacting layer, the polyolefin bulk layer, and the first intermediate adhesive layer of the sealant film onto the foil layer of the base film to complete the eight-layer film. EX1004 at ¶¶ [00163]–[00174].

107. The coextrusion process disclosed in Riis (including with respect to example 5) does not contemplate any processing parameters such as relative melting points and loading ranges of the layers involved in the coextrusion process. *Id.*; Petition at 30-31. As such, Riis is silent on, and does not disclose, a coextrusion process that would achieve the unexpected benefits associated with matching relative melting profiles and loading ranges during the coextrusion process that improve the processability of multilayer films. For example, one of skill in the art would understand that using the coextrusion process disclosed in example 5 of Riis would result in thicker layers with more residual stress, more brittle, and less desirable mechanical and structural qualities.

108. I have read and reviewed Petitioner's summary and characterization of Riis, and, as detailed more fully below, I disagree with Petitioner as to many of Riis's alleged disclosures. For ease of reference, a copy of Petitioner's summary depiction of Riis is reproduced below:

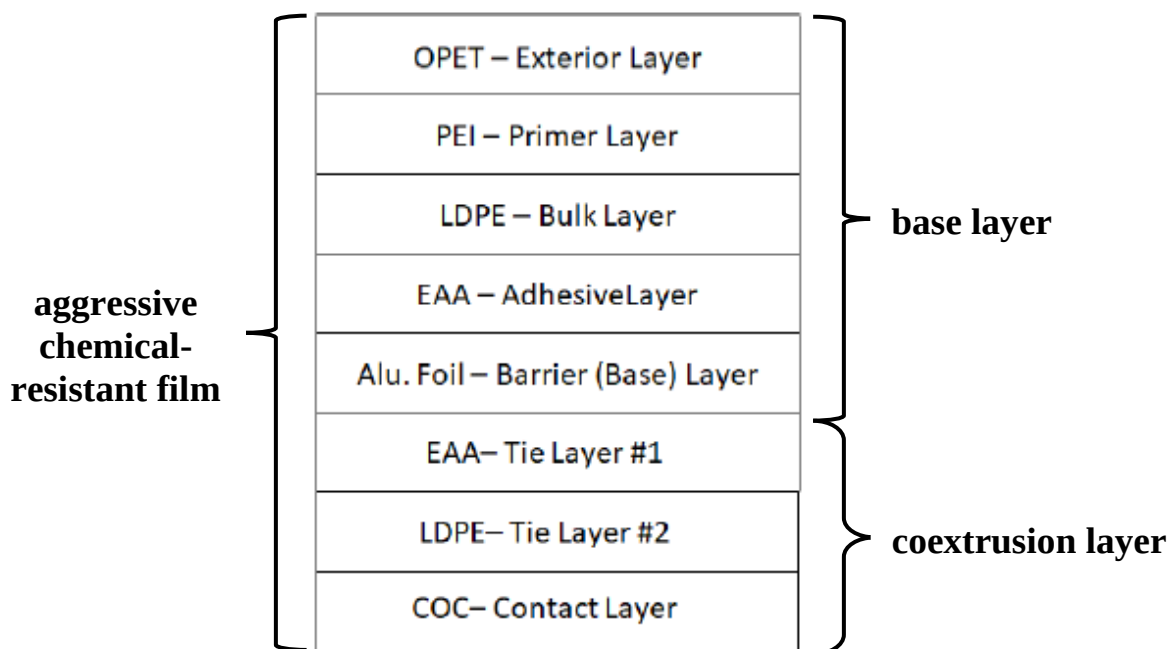


See Petition at 38.

109. As detailed above, and against Riis’s express teachings, Petitioner summarizes the eight-layer film in Riis as disclosing an aggressive chemical-resistant film made up of (1) a COC layer (serving the primary purpose of a contact layer), (2) an LDPE layer (serving the primary purpose of a tie layer), (3) an EAA layer (also serving the primary purpose of a tie layer), and (4) an aluminum foil layer (serving the primary purpose of a barrier or base layer). Additionally, Petitioner summarizes the eight-layer film in Riis as disclosing “additional exterior layers” made up of (1) an EAA layer (serving the primary purpose of a tie layer), (2) an LDPE layer (serving the primary purpose of a bulk layer), (3) a PEI layer (serving the primary purpose of a primer layer), and (4) an OPET layer (serving the primary purpose of an exterior layer). *Id.* Put simply, Petitioner alleged that the foil layer of

the base film of Riis and the tie layer, bulk layer, and contact layers of the sealant film of Riis compose the aggressive chemical-resistant film of a laminate, while the remaining layers compose the exterior layers.

110. Petitioner also summarizes an “alternative” summary of the disclosures in Riis. Specifically, Petitioner alleges that, in the event “the exterior and intermediate / adhesive layers are considered part of the ‘base layer,’” Petitioner characterizes, Riis’s eight-layer film as follows:



See Petition at 39.

111. In this alternative characterization, Petitioner asserts that the base film and the tie layer, bulk layer, and contact layers of the sealant film of Riis compose the aggressive chemical-resistant film of a laminate.

B. Wypych (Wypych, G. (2012), Handbook of Polymers, ChemTec Publishing)

112. The Wypych reference relied upon by Petitioner appears to be a, and is entitled, “Handbook of Polymers,” authored by George Wypych. EX1005 at 1. Wypych includes information on various polymers, including “all major polymeric materials used by the plastics and other branches of the chemical industry as well as specialty polymers used in the electronics, pharmaceutical, medical and space fields.” *Id.* at 4. As Wypych acknowledges, the information included in it includes “data from different sources” and such data “vary in a broad range and they have to be reconciled. In such cases, values closest to their average and values based on testing of the most current grades of materials are selected...” *Id.* Wypych acknowledges that it rejected older data. *Id.* Wypych includes information related to COC, EAA and LDPE. *Id.* at 6-12, 20-25.

C. Tatarka (U.S. Patent No. 9,452,593)

113. U.S. Patent No. 9,452,593 (“Tatarka”) is entitled “Melt Blends of Amorphous Cycloolefin Polymers and Partially Crystalline Cycloolefin Elastomers with Improved Toughness.” EX1008 at 1. Tatarka was filed on April 7, 2011, and purports to claim priority to U.S. Provisional Patent Application No. 61/342,527, filed on April 15, 2010. *Id.* at 1:10-14. Tatarka relates to “melt blends of amorphous cycloolefin containing polymers with partially crystalline cycloolefin containing

elastomers.” *Id.* at 1:18-20. Tatarka discloses physical properties of cyclic olefin copolymers and other materials, such as polyolefins and polymers. *Id.* at 3:45-60.

114. Tatarka’s claims relate generally to melt-blending different ratios of polymers having characteristics of localized stress whitening, relative high speed impact strengths within a certain range, certain haze values, etc. *See* EX1008 at Claims 1-20.

IX. CLAIM CONSTRUCTION

115. I have been informed that the construction/definition of a patent claim term should be made from the perspective of a person of ordinary skill in the art 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 person of ordinary skill in the art in question at the time of the invention, here as of December 29, 2015. A person of ordinary skill in the art 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.

116. I am informed by counsel that the patent specification, under the 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.

117. 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.

118. 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.

119. 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.

120. 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.

121. Except as discussed below regarding the terms “aggressive chemical-resistant film” and “loading”², I applied the plain and ordinary meaning for the remaining terms of the '624 Patent 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 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.

² I understand that Petitioner, in an entirely speculative nature, asserted that the term “melting point” could potentially be found indefinite if Danapak “in an effort to avoid Tatarka’s disclosure, argues that Tatarka’s ‘melting point’ means something different than the ‘melting point’ recited in the claims,” and thus claims 2 and 3 of the '624 Patent would be unpatentable. Petition at 30. However, given Danapak’s cancellation of claims 2 and 3, such an argument is now moot, as none of the remaining Challenged Claims contain the term “melting point.”

X. THE CLAIMS OF THE '624 PATENT ARE NOT INDEFINITE OR OBVIOUS

122. In Ground 1 of the Petition, Petitioner alleged that the Challenged Claims are indefinite for allegedly failing to inform one of ordinary skill in the art as to the scope of the term “aggressive chemical-resistant film” with reasonable certainty. Petition at 24. Petitioner also alleges that independent Claims 1 and 13 and dependent Claims 5 through 7 are indefinite for allegedly failing to inform one of ordinary skill in the art how the term “loading” is determined. Petition at 29. As discussed below, it is my opinion that the Challenged Claims are not indefinite.

123. In Grounds 2 and 3 of the Petition, Petitioner alleges that the Challenged Claims are obvious under 35 U.S.C. § 103. As discussed below, it is my opinion that the Challenged Claims are not rendered obvious by the asserted references, alone or in combination.

124. A summary of the asserted grounds is as follows:

<u>Ground</u>	<u>Challenged Claims</u>	<u>Basis</u>
1	Claims 1-13; Claims 1, 5-7, and 13	§ 112 (“aggressive chemical-resistant film”); § 112 (“loading”)
2	Claims 1-13	§ 103 (Riis)
3	Claim 1-13	§ 103 (Riis, Wypych and Tatarka)

125. For the reasons set forth in this Declaration, it is my opinion that Grounds 1-3 of the Petition fail.

A. Ground 1: Petitioner Fails to Show that a POSITA Would Not Understand, With Reasonable Certainty, the Meaning of the Term “Aggressive Chemical-Resistant Film”

126. In Ground 1 of the Petition, Petitioner alleges that the Challenged Claims are indefinite for failing to inform a person of ordinary skill in the art as to the scope of the term “aggressive chemical-resistant film” with reasonable certainty. Petition at 24.

127. Claims 1 and 13 are reproduced below.

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

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

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

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

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

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

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

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

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

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

the base layer comprising the aluminum, and the coextrusion layer consisting of the tie layer, and the contact layer consisting of COC, wherein the aggressive chemical-

layer, and the contact layer consisting of COC,	resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine,
wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m ² .	wherein the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m ² .

128. Claim 1 recites “a method for providing an aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine.” EX1001 at 18:11-13. Claim 13 recites “a method for providing a laminate, wherein the laminate comprises an aggressive chemical-resistant film ... wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine.” *Id.* at 18:61-63, 19:13-16.

129. Reading these claims in light of the specification, which sets forth ways in which to determine whether a film qualifies as an “aggressive chemical-resistant film,” it is my opinion that (1) a person of ordinary skill in the art would understand that this term means a film where less than 10% of the original amount of active pharmaceutical ingredient (“API”) (nicotine, fentanyl, rivastigmine, or lidocaine) to be packaged is absorbed into the film after 24 weeks. It is further my opinion that (2) a person of ordinary skill in the art would understand that this term means a film that, when used to package an amount of API (nicotine, fentanyl, rivastigmine, or

lidocaine) in a patch product results in an amount of API remaining (after storage) in the resultant patch product that is 90% to 110% of a corresponding amount of the API that remains in an equivalent patch product packaged with a Barex® film.

130. Petitioner alleges that because there are supposedly three different definitions of the “aggressive chemical-resistant film” term, the Challenged Claims are indefinite because each definition recites a different amount of permissible migration of the aggressive chemical into the film. *See* Petition at 25.

131. Petitioner’s First Definition: Petitioner’s first alleged definition for an “aggressive chemical-resistant film” is as follows: a film that allows no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) to migrate into the packaging material after 24 weeks. *See* Petition at 25; EX1001 at 5:8-13. But Petitioner’s “definition” attempts to look at this singular disclosure and ignores the context in which it appears, including the immediately preceding text—text that details that the acceptable “degree of absorption for a given substance is typically dictated by the manufacturer but often the accepted values lie in the range of 0 to 1 % (w/w). For some products up to 10% (w/w) is acceptable.” *See* EX1001 at 5:1-5.

132. Petitioner’s Second Definition: Petitioner’s second alleged definition for an “aggressive chemical-resistant film” is as follows: a film which when in contact with an aggressive substance does not allow more than 10%, such as 5%

w/w/ or 1.5% w/w based on the nominal content of the aggressive chemical to migrate into the packaging material. Petition at 25; EX1001 at 7:21-25.

133. Petitioner's Third Definition: Petitioner's third alleged definition for an "aggressive chemical-resistant film" is as follows: a film which when in contact with an aggressive substance does not allow more than 1.3% w/w of nominal content to migrate to the packaging material or that 90-110% w/w of the aggressive chemical substance remains in the product when compared to Barex® as index 100. Petition at 25; EX1001 at 12:16-22. Petitioner acknowledges that this third definition provides an alternative testing methodology using Barex® as a comparison standard. Petition at 26.

134. As acknowledged by the Patent Trial and Appeal Board ("Board") in its Institution Decision, the percentages used to describe an "aggressive chemical-resistant film" are internally consistent. PGR 2023-0008, Paper 14 at 21. As further noted in the Institution Decision, Petitioner fails to show that the "latter 'Barex' definition would take the absorption above the 10% upper limit specified in Definitions 1 and 2." *Id.* (the Institution Decision noting that "the location of Definition 3 within the 'Detailed Description' section of the '624 Patent indicates that it is directed to a more specific example than the more general Definitions 1 and 2 and stating that Petitioner fails to show that the "latter 'Barex' definition would take the absorption above the 10% upper limit specified in Definitions 1 and 2.").

135. I agree with the Board’s finding (and reasoning for the same) that the percentages used to describe an “aggressive chemical-resistant film” are consistent and that the Petitioner has failed to show that the latter Barex® definition is inconsistent with the percentages. As explained to me by counsel, the mere fact that two definitions are provided for a claim term does not render the claim term indefinite. Instead, and as noted in pages 3 and 4 of Danapak’s Preliminary Response, the ’624 Patent provides two, non-exclusive definitions of an aggressive chemical-resistant film that are internally consistent and that work in tandem to provide objective boundaries for those of skill in the art to understand, with reasonable certainty, what is still open to them. And that is exactly what those two definitions do. The first definition ((1) above in Paragraph 129 refers to the properties of the film product whereas definition (2) refers to the properties of the packaged patch product).

136. Specifically, the ’624 Patent discloses a first definition of an aggressive chemical-resistant film: films that allow less than 10% of the active pharmaceutical ingredient (API) in a packaged nicotine, fentanyl, rivastigmine, or lidocaine product to be absorbed into the film after 24 weeks. *See, e.g.*, EX1001 at 5:1-12, Claim 1. And, in the detailed description section of the ’624 Patent, a second definition of an aggressive chemical-resistant film: films that, when used to package a nicotine, fentanyl, rivastigmine, or lidocaine **patch** product, with respect to API absorption,

yield packaging that performs within 10% of equivalent packaging manufactured with a Barex® film. *Id.* at 7:5-9, 17:50-67. This is in line with what a person of ordinary skill in the art at the time of the invention would understand, as the Barex® standard. The amount of API remaining in a packaged patch product would depend on the dimensions, layer thicknesses and compositions, API amount, and design of the packaged patch product. This is why a comparison to an identical packaged patch product made with Barex® is needed as a reference.

137. A person of ordinary skill in the art would understand that the first definition of an “aggressive chemical-resistant film” provides a film-centric definition for an “aggressive chemical-resistant film” that is relative to the film itself: *a film that allows less than 10% API absorption*. A person of ordinary skill in the art would also understand that the second definition provides a packaged product-centric definition for an aggressive chemical-resistant film that is relative to a product packaged in a packaging product made from the film: *a film that, when used to package an amount of API in a patch product, results in an amount of API remaining, after storage, in the resultant patch product that is 90% to 110% of a corresponding amount of the API that remains in an identical patch product packaged with a Barex® film*. In other words, one skilled in the art would understand that an implemented film is an aggressive chemical-resistant film if the film allows

less than 10% API absorption or if a film used to package a patch product performs comparably with a Barex® film used to package an equivalent patch product.

138. Indeed, Petitioner's own reference, Riis, provides further evidence that one skilled in the art would find these two definitions to be consistent with one another and understand the utility of the Barex® standard. Specifically, Riis discloses that a film has anti-scalping properties if an amount of a pharmaceutical active agent allowed to migrate into the film is less than 15% of an amount of the pharmaceutical active agent allowed to migrate into a Barex® film. EX1004 ¶ [00129]. Riis further discloses a method for determining whether a film is anti-scalping is to prepare commonly-dimensioned pouches with each test film and comparing the amount of eluted drug for each of the pouches after a certain amount of time has passed. *Id.* ¶ [00134].

139. It is my opinion that, given the widespread use of Barex® in the industry at the time, a person of ordinary skill in the art at the time of the invention would recognize Barex® as a suitable reference material with respect to aggressive chemical-resistant films.

140. As such, it is my opinion that the '624 Patent provides one skilled in the art objective boundaries for understanding the scope of the term "aggressive chemical-resistant film." Thus, a person of ordinary skill in the art, when reading the

disclosures of the '624 Patent in their full context and not in a vacuum, would readily understand the meaning of the term, an “aggressive chemical-resistant film.”

141. In forming my opinions, I have evaluated the contentions set forth in the Petition, Dr. Spontak's Declaration, and the documents cited therein. It is my opinion, as detailed in the analysis above, the Preliminary Response and the concurrently submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that a person of ordinary skill in the art would understand, with reasonable certainty, the meaning of this term.

B. Ground 1: Petitioner Fails to Show that a POSITA Would Not Understand, With Reasonable Certainty, the Meaning of the Term “Loading”

142. In Ground 1 of the Petition, Petitioner also alleges that Claims 1, 5-7 and 13 of the '624 Patent are indefinite for failing to inform a person of ordinary skill in the art as to the scope of the term “loading” with reasonable certainty. Petition at 29. Specifically, Petitioner alleges that the '624 Patent fails to inform a person of ordinary skill in the art how a layer's “loading” is determined. *Id.*

143. As shown above, Claim 1 recites that “the tie layer comprises one or more layers, [] wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m².” EX1001 at 18:30-32. Claims 5-7, which are dependent upon Claim 1 provide for varying loading ranges of the tie layer(s). *Id.* at

18:41-48. Claim 13 recites that “the tie layer comprises one or more layers, and wherein the tie layer [] has a loading in the range of 7 to 20 g/m². *Id.* at 19:17-19.

144. The '624 Patent discloses that “loading means the amount of polymer left[] in the layer when the film has dried.” *Id.* at 6:38-39. The '624 Patent further provides that “in one embodiment[,] the tie layer or plurality of layers constituting the tie layer has a loading in the range of 7 to 20 g/m².” *Id.*, at 6:33-35. As such, given the clear designation of units of measure, namely g/m², a person of ordinary skill in the art would understand that the '624 Patent provides that the loading of a layer is determined based on an areal density of a polymer in the layer, where the mass of the polymer is measured in grams and the unit area is a square meter. Put simply, in the '624 Patent's disclosures, the loading of a layer refers to a mass of the polymer in the layer that is measured in a square meter section of the layer after the film is completed.

145. As such, it is my opinion that a person of ordinary skill in the art would understand that the term “loading” refers to an areal density of a layer. In addition, the disclosures of the '624 Patent provide a person of ordinary skill in the art with the means to determine the areal density of a polymer in a layer — *e.g.*, based on a density of the polymer resin used to create the layer, based on measuring a mass of the polymer (in grams) in the layer within a square meter, which may be referred to as grammage. Petitioner's acknowledgement of the same is telling. Specifically,

Petitioner's arguments regarding its § 103 obvious arguments with respect to the term "loading," Petitioner itself states that "[b]y knowing the thickness of the layer and the density of the polymer used, g/m² can be calculated" such that "'loading' as that term is used in the '624 Patent can be determined by (1) multiplying thickness in cm by density in g/cm³ and (2) converting g/cm³ to g/m²." Petition at 41. This concession describes without issue the exact method a person of ordinary skill in the art would use, in light of the '624 Patent's disclosures, to determine the loading in a layer and for determining whether the loading in the layer satisfies the claimed loading range. The use of the loading in g/m² would produce an "average thickness" across the area of the section of film weighed.

146. Indeed, the Board, in its Institution Decision, found that Petitioner has failed to show the "loading" term is indefinite. PGR 2023-0008, Paper 14 at 22. I agree with the Board's finding and the reasonings therefor.

147. As such, it is my opinion that the '624 Patent provides one skilled in the art objective boundaries for calculating and understanding the scope of the term "loading." Thus, a person of ordinary skill in the art, when reading the disclosures of the '624 Patent, including the clear units of measure associated with this term, would readily understand the meaning of the term, "loading."

148. In forming my opinions, I have evaluated the contentions set forth in the Petition, Dr. Spontak's Declaration, and the documents cited therein. It is my

opinion, as detailed in the analysis above, the Preliminary Response and the concurrently submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that a person of ordinary skill in the art would understand, with reasonable certainty, the meaning of this term.

C. Ground 2: The Challenged Claims are not Rendered Obvious by Riis

149. As detailed above, Riis relates to a film for packaging a product that has a pharmaceutical active agent and that includes a product-contacting sealing layer including at least 90 wt. % of an ethylene norbornene copolymer (COC). EX1004 at Abstract.

150. Contrary to Petitioner's assertions, Riis fails to render the Challenged Claims of the '624 Patent obvious for at least the reasons set forth below.

1. Claim 1: Riis Fails to Disclose, Teach or Suggest a "coextrusion layer consisting of [a] tie layer [that] . . . has a loading in the range of 7 to 20 g/m²," as recited in Claim 1.

151. Riis's example 5 discloses an eight-layer film that includes (in part) a 0.35 mil foil layer, a 0.17 EAA layer, a 0.65 mil LDPE layer, and a 0.43 mil COC layer (in that order). EX1004 at FIG. 1, ¶ [00174]. Riis also generally discloses another, six-layer film that includes (in part) an oxygen barrier layer, a first intermediate adhesive layer, a polyolefin bulk layer, and product contacting layer (in that order). EX1004, FIG. 1.

152. When you compare the two films disclosed in Riis, the foil layer of the eight-layer film corresponds to the oxygen barrier layer of the six-layer film, the EAA layer of the eight-layer film corresponds to the first intermediate adhesive layer of the six-layer film, the 0.65 mil LDPE layer of the eight-layer film corresponds to the polyolefin bulk layer of the six-layer film, and the COC contact layer of the eight-layer film corresponds to the product contacting layer of the six-layer film. The side-by-side comparison of Riis's eight-layer and six-layer films depicts this correspondence:

exterior protective layer 6	.92 mil OPET – Exterior Protective Layer
second intermediate adhesive layer 5	(Not Given) mil PEI – Primer Layer
oxygen barrier layer 4	.42 mil LDPE – Bulk Layer
first intermediate adhesive layer 3	.1 mil EAA – 2nd Intermediate Adhesive Layer
polyolefin bulk layer 2	.35 mil Foil – Barrier Layer
product contacting layer 1	.17 mil EAA – First Intermediate Adhesive Layer
	.65 mil LDPE – Bulk Layer
	.43 mil COC – Contact Layer

Response, FIG. 2 (side-by-side comparison)

153. Paragraph [00135] of Riis provides that, in some embodiments, a polyolefin bulk layer can serve as an adhesive or “tie” layer. However, many types of polymers qualify as polyolefins, as exemplified in paragraph [0022] of Riis. Riis also discloses that a “bulk layer may be of any suitable thickness from 0.1 to 7 mils or may even be omitted for use in certain applications.” EX1004 ¶ [0065]. Given the

large variety of polyolefin polymer and the large thickness range, Riis discloses nearly limitless combinations of polyolefin materials and thicknesses for forming a polyolefin bulk layer. Not all of these combinations would be suitable to serve as a tie layer. For example, any combinations that include thicknesses relative to the overall thickness of the film that exceed 10% would be inconsistent with Riis's preferred tie layer (a thickness of which is "kept to a minimum") and with the knowledge of one skilled in the art that thinner layers are preferred for tying purposes. The 0.65 mil LDPE layer is one such layer that has a thickness that is inconsistent with Riis's definition of a tie layer and with the known-in-the-art preference for using thinner layers for tying purposes. Moreover, any combinations that include polyolefins that are not suitable to bond polar materials (such as Aluminum) and non-polar materials (such as COCs) would be unable to directly bond the 0.35 mil Al layer to the 0.43 mil COC layer and would thus be inconsistent with Riis's preference for a multi-functional tie layer. Again, the 0.65 mil LDPE layer is one such layer that is not suitable to bond polar materials to non-polar materials.

154. Riis notes that adhesive layers (also known as tie layers) are "selected to promote the adherence of **adjacent** layers to one another in a multilayer film and to prevent undesirable delamination." *Id.* ¶ [0071] (emphasis added). "A multifunctional [adhesive] layer is preferably formulated to aid in the adherence of

one layer to another layer ***without the need of using separate adhesives*** by virtue of the compatibility of the materials in that layer to the first and second layers [— *i.e.*,] adhesive layers comprise materials found in both the first and second layers.” *Id.* (emphasis added). Riis discloses that “[t]he adhesive layer may suitably be less than 10% and preferably between 2% and 10% of the overall thickness of the multilayer film.” *Id.* (emphasis added). Riis additionally discloses that “adhesive resins are often more expensive than other polymers so the tie layer thickness is usually ***kept to a minimum consistent with the desired effect.***” *Id.* (emphasis added). And in one embodiment of Riis that omits a bulk layer, a multilayer structure includes a “a first adhesive layer positioned between and in direct contact with [an] exterior layer and a core oxygen barrier layer . . . and a second tie layer between and in direct contact with the same core oxygen barrier layer and the interior layer to produce a five layer film.” *Id.*

155. Although I note that Riis, in paragraph [00135], does disclose that a bulk layer theoretically can serve as a tie layer, the films in its examples do not disclose this. Specifically, Riis does not disclose that the 0.65 mil LDPE layer is being used as a tie layer in the context of example 5’s eight-layer film. EX1004 at ¶¶ [00172]-[0173]. Nor do Petitioner or Dr. Spontak provide any evidence that the 0.65 mil LDPE layer is serving its primary purpose as a tie layer in the context of this eight-layer film. See EX1003 at ¶¶ [82], [214], [216], [233].

156. Instead, as one of ordinary skill in the art would readily understand, the express disclosure of Riis teaches that the 0.65 mil LDPE layer is serving the purpose of a bulk layer. Indeed, Petitioner acknowledges that the 0.42 mil LDPE layer adjacent to the 0.1 mil EAA layer in the base film is a bulk layer (and not a tie layer). Petition at 38 (annotated figure). Put simply, Petitioner puts forth no explanation as to why, in light of Riis's disclosures, the 0.42 mil LDPE layer in the base film is a bulk layer while the analogous, but thicker, 0.65 mil LDPE layer in the sealant film is not. Looking at the 0.42 mil LDPE layer and the 0.65 mil LDPE layer, it is my opinion, given Riis's disclosures, their material similarities, structural similarities, and both being adjacent to a thin EAA layer (that primarily serves as a tie layer), that the primary function of both of these LDPE layers would be the same. More specifically, it is my opinion that both of these LDPE layers serve primarily as bulk layers and would be referred to as such. A multifunctional tie layer is used between two materials that do not bond to each other on their own and is preferred by Riis. In fact, if one were to remove the 0.65 mil LDPE bulk layer, the EAA would serve as a tie layer between the 0.35 mil Al layer and the 0.43 mil COC contact layer. The bulk properties such as stiffness and heat sealability would be compromised by removing the 0.65 mil LDPE bulk layer. Therefore, the primary purpose of the 0.65 mil LDPE bulk layer is to improve stiffness and heat sealability at a low cost, which is a bulk material. As noted above, a comparison of Riis's disclosures confirms that

that the 0.65 mil LDPE layer of the eight-layer film is in fact serving the primary purpose of a bulk layer, not a tie layer as Petitioner asserts.

157. In addition, the 0.65 mil LDPE is nearly four times as thick as the 0.17 mil EAA layer in the eight-layer film. I also note that the 0.42 mil LDPE layer in the base film shares a similar relationship with the adjacent 0.1 mil EAA layer in the base film (also being around four times as thick as the EAA layer).

158. Moreover, paragraph [0071] of Riis discloses that an adhesive layer is preferably less than 10% of the overall thickness of the multi-layer film. In the context of the eight-layer film of Riis, if the 0.17 mil EAA layer and the 0.65 mil LDPE layer are both considered layers of a multi-layer adhesive layer, then the combined 0.82 mil thickness would make up 26.97% of the overall thickness of the 3.04 mil eight-layer film. Accordingly, Riis's disclosure mandates that the 0.65 mil LDPE layer would not be considered an adhesive layer but instead must be acknowledged as a bulk layer—otherwise, the thickness of the multi-layer tie layer would far exceed the disclosed thickness of this layer with the overall film.

159. Also, in light of Riis's disclosures, a person of ordinary skill in the art would know that the 0.65 mil LDPE layer in Riis's example 5 serves its primary purpose as a bulk layer, as bulk layers are formed as thicker layers to improve machinability, flexibility, structural integrity and barrier properties of a film. The 0.65 mil LDPE layer comprises 21% of the overall thickness of the film disclosed in

example 5 of Riis, which is consistent with a layer that is primarily being used as a bulk layer. Moreover, bulk layers typically include low-cost material to provide structural performance at a low cost. LDPE is a significantly more cost-effective material than COC and provides structural integrity for a film.

160. Furthermore, a person of ordinary skill in the art would know that an adhesive (tie) layer is formed as a thinner layer (relative to the overall thickness of a film) to provide adhesion between two adjacent layers of a film. The primary function of the adhesive (tie) layer is to provide a sufficient adhesive bond between two layers. A very common scenario is the bonding of a nonpolar material with a polar material, such as polyolefins to aluminum. Common multifunctional tie layers are copolymers of polyethylene with polar comonomers such as acrylic acid, acrylic ester, methacrylic acid, maleic anhydride, vinyl acetate, etc. One skilled in the art would further understand that a thinner adhesive (tie) layer results in improved adhesion performance between two layers and reduction in cost. Therefore, a reduction in the thickness of the tie layer would reduce the cost. Also, as disclosed in Riis (¶ [0071]), adhesive layer thickness is often kept to a minimum consistent with the desired effect for cost reasons. In addition, thick layers of the tie layer are prone to cohesive failure where the failure occurs within the thickness of the tie layer due to a lower tensile strength of the tie layer material. Accordingly, one skilled in the art would find the relative thickness of the 0.65 mil LDPE layer (around 21% of

the thickness of the overall film) to be inconsistent with the desired thickness of a tie layer in the context of the film disclosed in example 5 of Riis.

161. This understanding of the 0.17 mil EAA tie layer and the 0.65 mil LDPE bulk layer is consistent with the disclosure of Riis itself. Paragraph [0071] of Riis discloses that a multifunctional adhesive layer is preferred to aid in adherence of one layer to another layer “***without the need of using separate adhesives.***” *Id.* Thus, Riis discloses that the use of a single multifunctional adhesive layer is preferred. In the context of the eight-layer film of Riis, EAA serves as the single multifunctional adhesive layer of example 5 that can bond to both an Al layer and a polymer layer. Using LDPE as an additional adhesive would be inconsistent with Riis’s stated preference for a single multifunctional adhesive layer. Moreover, LDPE cannot, on its own, serve as the multifunctional adhesive layer preferred by Riis. Specifically, LDPE cannot, on its own, be used to bond a polar Al foil layer to a non-polar COC layer. Other types of polyolefins, such as EVA, can be used to adhere to polar materials and to non-polar materials.

162. Furthermore, this understanding of the EAA and LDPE layer is consistent with the Petitioner’s own statements. For example, in his declaration, Dr. Spontak acknowledged that each layer in a coextrusion layer must serve a purpose that is relevant to the target application. EX1003, p. 34. So, if the LDPE layer of Riis is not primarily serving an adhesive purpose, one skilled in the art would understand

the LDPE layer to be serving some other purpose — in this case, a purpose that is consistent with a bulk layer, strengthening and extending the thickness of the COC layer.

163. Given the correlation between the polyolefin bulk layer of the six-layer film and the LDPE layer of the eight-layer film, Riis's disclosures regarding tie layers and the relative thicknesses of the 0.17 mil EAA and 0.65 mil LDPE layers, it is evident that the thicker 0.65 mil LDPE layer of Riis's eight-layer film is primarily serving as a bulk layer (not a tie layer), while the thinner 0.17 mil EAA layer is primarily serving as a multifunctional tie layer between the 0.65 mil LDPE layer and the 0.35 mil Al foil layer. The surface of the 0.35 mil Al foil layer is polar due to the aluminum oxide. Thus, the portion of the 0.17 mil EAA layer with the acrylic acid functionality will bond well to the surface of the 0.35 mil Al foil layer. And the portion of the 0.17 mil EAA layer with the ethylene functionality is able to adhere to the 0.65 mil LDPE layer and provide good adhesion to the 0.65 mil LDPE layer. That portion of the 0.17 mil EAA layer with the ethylene functionality is also able to provide good adhesion to the 0.43 mil COC layer.

164. Contrary to Petitioner's assertion, Riis discloses an eight-layer film that includes a coextrusion layer having a 0.17 mil EAA layer (that primarily serves a tying purpose), a 0.65 mil LDPE layer (that primarily serves a bulk purpose), and a 0.43 mil COC layer (that primarily serves a contacting purpose). Petitioner asserts

that EAA has a density within the range of .92–.96 g/cm³ and that LDPE has a density within the range of .915–.929 g/cm³. Petition at 41–42. Thus, by Petitioner’s own calculations, Riis discloses a tie layer with a loading of 3.97–4.15 g/m² and a bulk layer with a loading of 15.11 g/m² to 15.34 g/m², for a combined loading of 19.08 g/m² to 19.49 g/m². *Id.* at 42.

165. As I note above, the 0.65 mil LDPE layer of Riis primarily serves the purpose of a bulk layer rather than a tie layer. Accordingly, the loading of the 0.65 mil LDPE layer cannot be included in the calculation of the loading of the tie layer in the coextrusion layer of the eight-layer film disclosed in example 5 of Riis. As such, Riis fails to disclose, teach or suggest a “coextrusion layer consisting of [a] tie layer [that] . . . has a loading in the range of 7 to 20 g/m²,” as recited in Claim 1.

166. I have evaluated the contentions set forth in the Petition and in Dr. Spontak’s declaration regarding the allegation that Riis renders obvious the invention set forth in the Challenged Claims, specifically Claim 1. It is my opinion, as detailed in the analysis above, the Preliminary Response and the concurrently submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that Riis fails to disclose the above-identified element recited in the Challenged Claims.

2. Claim 1: Riis fails to disclose, teach or suggest a “coextrusion layer consisting of [a] tie layer[] and . . . [a] contact layer,” as recited in Claim 1.

167. As I note above, Riis discloses a sealant film having a 0.17 mil EAA layer (primarily serving a tying purpose), a 0.65 mil LDPE layer (primarily serving a bulk purpose), and a 0.43 mil COC layer (primarily serving a contacting purpose). that are coextrusion coated (by way of a three-layer coextrusion) onto the 0.35 mil foil layer of a base film (primarily serving a barrier purpose).

168. But a coextrusion layer that includes a tie layer, a bulk layer, and a contacting layer fails to teach or suggest “a coextrusion layer **consisting of** [a] tie layer[] and [a] contact layer,” as recited in Claim 1 (emphasis added). Specifically, it is my understanding that when a patent claim includes the phrase “consisting of” in a clause of the body of a claim, it is presumed that the claim term set off with the “consisting of” phrase is closed to unrecited elements. With this understanding, Claim 1’s recitation of “a coextrusion layer **consisting of** [a] tie layer[] and [a] contact layer,” excludes other layers, such as a bulk layer. Therefore, Riis fails to disclose, teach or suggest this element of Claim 1 of the ’624 Patent.

169. I have evaluated the contentions set forth in the Petition and in Dr. Spontak’s declaration regarding the allegation that Riis renders obvious the invention set forth in the Challenged Claims, specifically Claim 1. It is my opinion, as detailed in the analysis above, the Preliminary Response and the concurrently

submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that Riis fails to disclose the above-identified element recited in the Challenged Claims.

3. Claim 1: Petitioner Fails to Provide a Motivation to Modify Riis.

170. Petitioner does not provide a valid reason for why a POSITA would have modified Riis's example 5 to come to the invention of Claim 1 of the '624 Patent. Specifically, the Petition states "a skilled artisan would have been motivated to follow Riis's disclose to **recreate** the film of Example 5 and would have had a reasonable expectation of doing so to arrive at the claimed invention." Petition at 43 (emphasis added). But Petitioner's argument is simply a summary of its obviousness arguments, **without modification**. *Id.* at 43-45; EX2015 at 129:18-23.

171. Petitioner's assertion that one of skill in the art would simply apply Riis to come to the invention of the '624 Patent as set forth in the Challenged Claims also ignores Riis's express teachings away from using multiple adjacent adhesive layers. In light of this teaching away, it is my opinion that a person of ordinary skill in the art would not be motivated to modify Riis to come to the invention of the '624 Patent as set forth in the Challenged Claims.

172. Specifically, Petitioner is silent with regard to modifying the tie layer of Riis to meet the loading range claimed for the tie layer in independent claim 1. Petitioner relies on the knowledge of one skilled in the art solely to "**recreate** [not

modify] the film of Example 5 . . . to [allegedly] arrive at the claimed invention.” Petitioner at 43 (emphasis added). Thus, Petitioner provides no arguments in support of modifying the processing parameters (*e.g.*, including the loadings and melting points) of Riis, and Petitioner’s arguments rise and fall on whether the recreation of the film of Example 5 discloses the claimed features Claim 1, which, as shown above, it does not.

173. After the film is recreated, Petitioner does not discuss any modification to any aspect of the film. For example, Petitioner does not discuss any changes to the loading ranges or melting characteristics of the layers of the film outside of those loading ranges and melting characteristics that are disclosed in Riis. Moreover, Petitioner does not consider any changes to the configuration of the film, such as the addition or removal of layers. Nor does Petitioner consider how such changes would affect the other layers, or the overall performance, of the film. When manufacturing a multi-layer film, the material properties and configurations of the layer are intentionally, carefully, and painstakingly selected to optimize the manufacture and performance for the target application, and minor changes in those material properties and configurations can significantly affect the manufacture and performance of the multi-layer film.

174. For example, removing the 0.65 mil LDPE layer would hinder the manufacture and performance of the film disclosed in example 5 of Riis, causing

(among other issues) a reduction in stiffness of the film and a decrease in heat sealability of the film. Moreover, if the 0.65 mil LDPE layer were removed, other layers of the film would then need to be modified to compensate for the removal of the 0.65 mil LDPE layer. Reducing the thickness of the 0.65 mil LDPE layer would result in similar negative effect. Thus, absent a motivation to modify a multi-layer film, one skilled in the art would remain true to the specifications of the multi-layer film when recreating a multi-layer film for its target application.

175. As such, and for the reasons set forth above, Petitioner's arguments do not put forth any argument as for why a POSITA would have modified Riis's example 5 to come to the disclosure of Claim 1 of the '624 Patent, including a "coextrusion layer consisting of [a] tie layer [that] . . . has a loading in the range of 7 to 20 g/m²," or "coextrusion layer consisting of [a] tie layer[] and . . . [a] contact layer."

4. Claim 13: Riis fails to disclose, teach or suggest a "coextrusion layer consisting of [a] tie layer [that] . . . has a loading in the range of 7 to 20 g/m²," as recited in Claim 13.

176. This element also appears in Claim 1, and as such, I incorporate my above discussion, analysis and opinions, herein as if set forth in full. As noted above, Riis's example 5 discloses a coextrusion layer including a 0.17 mil EAA layer (primarily serving a tying purpose) with a loading of 3.97–4.15 g/m² and a 0.65 mil LDPE layer (primarily serving a bulk purpose) with a loading of 15.11 g/m² to 15.34

g/m². The 0.17 mil EAA layer disclosed in Riis having a loading of 3.97–4.15 g/m², fails to disclose, teach or suggest a “tie layer . . . [that] has a loading in the range of 7 to 20 g/m²,” as recited in Claim 13.

177. I have evaluated the contentions set forth in the Petition and in Dr. Spontak’s declaration regarding the allegation that Riis renders obvious the invention set forth in the Challenged Claims, specifically Claim 13. It is my opinion, as detailed in the analysis above, the Preliminary Response and the concurrently submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that Riis fails to disclose the above-identified element recited in the Challenged Claims.

5. Claim 13: Riis fails to disclose, teach or suggest a “coextrusion layer consisting of [a] tie layer[] and . . . [a] contact layer,” as recited in Claim 13.

178. This element also appears in Claim 1, and as such, I incorporate my above discussion, analysis and opinions, herein as if set forth in full. As I note above, Riis discloses a sealant film having a 0.17 mil EAA layer (primarily serving a tying purpose), a 0.65 mil LDPE layer (primarily serving a bulk purpose), and a 0.43 mil COC layer (primarily serving a contacting purpose). that are coextrusion coated (by way of a three-layer coextrusion) onto the 0.35 mil foil layer of a base film.

179. But a coextrusion layer that includes a tie layer, a bulk layer, and a contacting layer fails to teach or suggest “a coextrusion layer **consisting of** [a] tie

layer[] and [a] contact layer,” as recited in Claim 1 (emphasis added). Specifically, it is my understanding that when a patent claim includes the phrase “consisting of” in a clause of the body of a claim, it is presumed that the claim term set off with the “consisting of” phrase is closed to unrecited elements. With this understanding, Claim 1’s recitation of “a coextrusion layer **consisting of** [a] tie layer[] and [a] contact layer,” excludes other layers, such as a bulk layer. Therefore, Riis fails to disclose, teach or suggest this element of Claim 1 of the ’624 Patent.

180. I have evaluated the contentions set forth in the Petition and in Dr. Spontak’s declaration regarding the allegation that Riis renders obvious the invention set forth in the Challenged Claims, specifically Claim 13. It is my opinion, as detailed in the analysis above, the Preliminary Response and the concurrently submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that Riis fails to disclose the above-identified element recited in the Challenged Claims.

6. Claim 13: Petitioner Fails to Provide a Motivation to Modify Riis.

181. As noted above with respect to Claim 1, my discussion of which is incorporated herein as if set forth in full, Petitioner does not provide a valid reason for why a POSITA would have modified Riis’s example 5 to come to the invention of Claim 13 of the ’624 Patent. Specifically, the Petition states “a skilled artisan would have been motivated to follow Riis’s disclose to **recreate** the film of Example

5 and would have had a reasonable expectation of doing so to arrive at the claimed invention.” Petition at 52 (emphasis added). But Petitioner’s argument is simply a summary of its obviousness arguments, ***without modification***. *Id.* at 52-53; EX2015 at 131:15-20.

182. As such, and for the reasons set forth above, Petitioner’s arguments do not put forth any argument as for why a POSITA would have modified Riis’s example 5 to come to the disclosure of Claim 13 of the ’624 Patent, including a “coextrusion layer consisting of [a] tie layer [that] . . . has a loading in the range of 7 to 20 g/m²,” or “coextrusion layer consisting of [a] tie layer[] and . . . [a] contact layer.”

7. *Claims 4-12³: render obvious dependent Claims 2 through 12.*

183. I incorporate my above discussion, analysis and opinions, herein as if set forth in full, including those related to non-obviousness and motivations to combine.

184. Claims 4 through 12 all depend at least from independent Claim 1, and as such, Riis fails to render these dependent claims obvious at least for their dependence on Claim 1.

³ I understand that Petitioner asserts that Riis also renders Claims 2 and 3 of the ’624 Patent obvious. However, given Danapak’s cancellation of claims 2 and 3, such an argument is now moot, and as such, I do not address it in this Declaration.

185. I have evaluated the contentions set forth in the Petition and in Dr. Spontak's declaration regarding the allegation that Riis renders obvious the invention set forth in the Challenged Claims, specifically Claims 4-12. It is my opinion, as detailed in the analysis above, the Preliminary Response and the concurrently submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that Riis fails to render these claims obvious.

8. *Claim 4: Riis fails to render obvious dependent Claim 4.*

186. In addition to the reasonings above, Riis fails to render Claim 4 of the '624 Patent obvious for additional reasons.

187. Specifically, and as noted above, Riis discloses an eight-layer film that includes a coextrusion layer having a 0.17 mil EAA layer (primarily serving a tying purpose), a 0.65 mil LDPE layer (primarily serving a bulk purpose), and a 0.43 mil COC layer (primarily serving a contacting purpose). As also noted above, the disclosure of Riis suggests that the 0.65 mil LDPE layer of the eight-layer film primarily serves the purpose a bulk layer based on the desired thickness of the disclosed tie layers, the relative thicknesses of the 0.17 mil EAA layer and the 0.65 mil LDPE layer. As previously noted, the 0.65 mil LDPE layer is instead used as a low-cost means for extending and strengthening the 0.43 mil COC contacting layer and, thus, would be referred to by one skilled in the art as a "bulk" layer.

188. It is further noted that given the primary purpose of the 0.65 mil LDPE layer as a bulk layer, if one skilled in the art were asked to characterize the LDPE layer as a layer of either the tie layer or the contact layer in light of Riis's express teachings, one skilled in the art would characterize the 0.65 mil LDPE as a layer of the contact layer (not the tie layer).

189. As further noted above, Petitioner provides that EAA has a density within the range of 0.92–0.96 g/cm³ and that LDPE has a density within the range of 0.915–0.929 g/cm³. Petition at 41, 42. Thus, by Petitioner's calculations, Riis discloses that the 0.17 mil EAA layer (primarily serving a tying purpose) has a loading of 3.97–4.15 g/m² and that the 0.65 mil LDPE layer (primarily serving a bulk purpose) has a loading of 15.11 g/m² to 15.34 g/m², for a combined loading of 19.08 g/m² to 19.49 g/m². *Id.* at 42.

190. Petitioner further provides that COC has a density in the range of 1.00–1.08 g/cm³. *Id.* at 48. Thus, by Petitioner's calculations, Riis discloses that the 0.43 mil COC layer (primarily serving a contacting purpose) has a loading of 10.92–11.80 g/m². *Id.* at 48. It is noted that a combined loading of the 0.65 mil LDPE layer and the 0.43 mil COC layer is between 26.03 g/m² and 27.14 g/m².

191. As noted above, the coextrusion layer of Riis including the 0.17 mil EAA layer (that primarily serves a tying purpose) having a loading of 3.97–4.15 g/m², as described in Riis, fails to teach or suggest a “coextrusion layer consisting

of [a]tie layer . . . [that] has a loading in the range of 7 to 20 g/m²,” as recited in dependent claim 4 (by way of incorporation of independent Claim 1). Furthermore, if the 0.65 mil LDPE layer is construed as a layer of the 0.43 mil COC layer, a contact layer having a combined loading of 26.03 g/m² to 27.14 g/m², as described in Riis, fails to teach or suggest a “contact layer [that] has a loading in the range of 4 to 20 g/m²,” as recited in Claim 4.

192. As also noted above, a coextrusion layer that includes a tie layer, a bulk layer, and a contacting layer fails to teach or suggest “a coextrusion layer **consisting of** [a] tie layer[] and ... [a] contact layer,” as recited in Claim 4 (by way of incorporation of Claim 1) (emphasis added). Riis also fails to teach “a coextrusion layer consisting of [a] tie layer [having a loading in the range of 7 to 20 g/m²] and . . . [a] contact layer [having a loading in the range of 4 to 20 g/m²],” as recited in Claim 4 (by way of incorporation of Claim 1).

D. Ground 3: The Challenged Claims are not Rendered Obvious by Riis, Wypych and Tatarka, or any combination thereof.

193. Petitioner alleges the combination of Riis with Wypych and Tatarka renders the Challenged Claims obvious under 35 U.S.C. § 103. Petition at 53. Contrary to Petitioner’s assertions, the combination of Riis with Wypych and Tatarka fails to render the Challenged Claims of the ’624 Patent obvious for at least the reasons set forth below.

1. Claims 1 and 13: Riis, Wypych, and Tatarka — alone or in any combination — fail to render Claims 1 and 13 obvious.

194. For at least the reasons I stated with respect to Ground 2 above, Riis fails to disclose teach or suggest several features recited in the Challenged Claims. As Petitioner acknowledges, Wypych and Tatarka are simply cited in combination with Riis to provide material properties for the film disclosed in therein. Petition at 80. However, because the addition of the alleged material properties in Wypych and Tatarka does not supplement Riis in such a way as to fill in Riis's holes with respect to the '624 Patent, it follows that Riis, Wypych, Tatarka, or any combination thereof similarly fail to render obvious the Challenged Claims.

2. Claims 1 and 13: Riis, Wypych, and Tatarka — alone or in any combination — fail to disclose, teach or suggest a “tie layer [that] . . . has a loading in the range of 7 to 20 g/m²,” as recited in Claims 1 and 13.

195. For at least the reasons I stated with respect to Ground 2 above, which I incorporate herein as if set forth in full, Riis fails to disclose teach or suggest this element. Specifically, the sealant film of Riis's eight-layer film includes the 0.17 mil EAA (serving the primary purpose of a *single, multifunctional tie layer*) with a loading of 3.97–4.15 g/m² (as calculated by Petitioner using a density range of .92 g/cm³–.96 g/cm³ for EAA disclosed in Wypych) and the 0.65 mil LDPE layer (serving the primary purpose of a *bulk layer*) with a loading of 15.11 g/m² to 15.34 g/m².

196. However, because the 0.17 mil EAA layer has a loading of 3.97–4.15 g/m², Riis fails to disclose, teach or suggest a “tie layer . . . [that] has a loading in the range of 7 to 20 g/m²,” as recited in Claims 1 and 13.

197. Petitioner does not cite to Tatarka with respect to loading ranges of the tie layer.

3. Claims 1 and 13: Riis, Wypych, and Tatarka — alone or in any combination — fail to disclose, teach or suggest “a coextrusion layer consisting of [a] tie layer[] and [a] contact layer,” as recited in Claims 1 and 13.

198. For at least the reasons I stated with respect to Ground 2 above, which I incorporate herein as if set forth in full, Riis fails to disclose teach or suggest this element. Specifically, Riis’s coextrusion layer includes a 0.17 mil EAA layer (primarily serving a tying purpose), a 0.65 mil LDPE layer (primarily serving a bulk purpose), and a 0.43 mil COC layer (primarily serving a contacting purpose). But a coextrusion layer that includes a “tie” layer, a “bulk” layer, and a “contacting” layer fails to teach or suggest “a coextrusion layer **consisting of** [a] tie layer[] and [a] contact layer,” as recited in Claims 1 and 13 (emphasis added).

199. As I note above, Petitioner admits that Wypych and Tatarka are simply used to provide properties of specific materials used in the film disclosed in Riis and thus, their combination with Riis does not disclose, teach or suggest “a coextrusion layer consisting of [a] tie layer[] and [a] contact layer,” as recited in Claims 1 and 13.

4. *Claims 1 & 13: Petitioner Fails to Provide a Motivation to Combine Riis, Wypych and Tatarka.*

200. Petitioner does not provide a valid reason for why a POSITA would have combined Riis, Wypych and Tatarka to come to the invention of Claims 1 and 13 of the '624 Patent. Specifically, and as noted above, the Petitioner relies on Wypych and Tatarka exclusively to provide material properties for the film disclosed in Riis but do not otherwise alter the arguments made in the first 35 U.S.C. § 103 allegation. See Petition at 80 (stating “the rationale to combine the disclosure of Riis with the material properties provided by Wypych and Tatarka is simply to provide relevant and applicable material properties one of ordinary skill in the art would look to”). But Wypych and Tatarka do not disclose, teach or suggest either that “tie layer [that] . . . has a loading in the range of 7 to 20 g/m²,” or “coextrusion layer consisting of [a] tie layer[] and . . . [a] contact layer” as neither of those elements relate to a material property.

201. As such, and for the reasons set forth above, Petitioner’s arguments do not put forth any argument as for why a POSITA would have combined Riis, Wypych and Tatarka to come to the disclosure of Claims 1 and 13 of the '624 Patent, including a “tie layer [that] . . . has a loading in the range of 7 to 20 g/m²,” or “coextrusion layer consisting of [a] tie layer[] and . . . [a] contact layer.”

5. Claims 4-12⁴: Riis, Wypych, and Tatarka — alone or in any combination — fail to disclose, teach or suggest “a coextrusion layer consisting of [a] tie layer[] and ... [a] contact layer,” as recited in Claims 1 and 13.

202. I incorporate my above discussion, analysis and opinions, herein as if set forth in full, including those relating to nonobviousness and motivation to combine.

203. Claims 4 through 12 all depend at least from independent Claim 1, and as such, no combination of Riis, Wypych, or Tatarka renders these dependent claims obvious at least for their dependence on Claim 1.

6. Riis, Wypych, and Tatarka — alone or in any combination — fail to render obvious Claim 4.

204. In addition to the reasonings above, the combination of Riis, Wypych and Tatarka fail to render Claim 4 obvious for additional reasons.

205. As noted above, Riis discloses an eight-layer film that includes a coextrusion layer having a 0.17 mil EAA layer (primarily serving a tying purpose), a 0.65 mil LDPE layer (primarily serving a bulk purpose), and a 0.43 mil COC layer (primarily serving a contacting purpose). As previously noted, Petitioner’s only reliance on Wypych and/or Tatarka is simply to provide properties of specific materials used in the film disclosed in Riis. As also noted above, the disclosure of

⁴ I understand that Petitioner asserts that the combination of Riis, Wypych and Tatarka also renders Claims 2 and 3 of the ’624 Patent obvious. However, given Danapak’s cancellation of claims 2 and 3, such an argument is now moot, and as such, I do not address it in this Declaration.

Riis teaches away from and suggests that the 0.65 mil LDPE layer of the eight-layer film is serving its primary purpose as a bulk layer based on Riis's desired thickness of a tie layer with respect to the overall film, and the relative thicknesses of the 0.17 mil EAA layer and the 0.65 mil LDPE layer. As previously noted, the 0.65 mil LDPE layer is instead used as a low-cost means for extending and strengthening the 0.43 mil COC contacting layer and, thus, is a bulk layer.

206. It is further noted that (given the thickness of the 0.65 mil LDPE layer, the purpose of the 0.65 mil LDPE layer, and the common material properties of the 0.65 mil LDPE layer and the 0.43 mil COC layer) if one skilled in the art were asked to characterize the 0.65 mil LDPE layer as a layer of either the tie layer or the contact layer, one skilled in the art would characterize the 0.65 mil LDPE as a layer of the contact layer (not the tie layer).

207. Petitioner provides that EAA has a density within the range of 0.92–0.96 g/cm³ and that LDPE has a density within the range of 0.915–0.929 g/cm³. Petition at 41, 42. Thus, by Petitioner's calculations, Riis discloses that the 0.17 mil EAA layer (primarily serving a tying purpose) has a loading of 3.97–4.15 g/m² and that the 0.65 mil LDPE layer (primarily serving a bulk purpose) has a loading of 15.11 g/m² to 15.34 g/m², for a combined loading of 19.08 g/m² to 19.49 g/m². *Id.* at 42.

208. Petitioner further provides that COC has a density in the range of 1.00-1.08 g/cm³. *Id.* at 48. Thus, by Petitioner’s calculations, Riis discloses that the 0.43 mil COC layer has a loading of 10.92-11.80 g/m². *Id.* at 48. It is noted that a combined loading of the 0.65 mil LDPE layer and the 0.43 mil COC layer is between 26.03 g/m² and 27.14 g/m².

209. As I note above, the coextrusion layer of Riis including the 0.17 mil EAA layer (that primarily serves a tying purpose) having a loading of 3.97–4.15 g/m², as described in Riis (in combination with Wypych), fails to teach or suggest a “coextrusion layer consisting of [a] tie layer . . . [that] has a loading in the range of 7 to 20 g/m²,” as recited in Claim 4 (by way of incorporation of Claim 1). Furthermore, if the 0.65 mil LDPE layer is construed as a layer of the 0.43 mil COC layer, a contact layer having a combined loading of 26.03 g/m² to 27.14 g/m², as described in Riis (in combination with Wypych), fails to teach or suggest a “contact layer [that] has a loading in the range of 4 to 20 g/m²,” as recited in Claim 4.

210. As I further note above, a coextrusion layer that includes a tie layer, a bulk layer, and a contacting layer fails to teach or suggest “a coextrusion layer **consisting of** [a] tie layer[] and . . . [a] contact layer,” as recited in Claim 4 (by way of incorporation of independent claim 1) (emphasis added). Let alone “a coextrusion layer consisting of [a] tie layer [having a loading in the range of 7 to 20 g/m²] and

... [a] contact layer [having a loading in the range of 4 to 20 g/m²],” as recited in Claim 4 (by way of incorporation of Claim 1).

211. I have evaluated the contentions set forth in the Petition and in Dr. Spontak’s declaration regarding the allegation that this combination renders obvious the invention set forth in the Challenged Claims, specifically Claims 4-12. It is my opinion, as detailed in the analysis above, the Preliminary Response and the concurrently submitted Response, that, based upon my knowledge and experience in this field and my review of the relevant materials, it is readily apparent that this combination fails to render these claims obvious.

XI. MOTION TO AMEND

212. 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, 6–10, and 13. I have reviewed the support cited in Patent Owner’s Motion to Amend, and it is my opinion that a POSITA would know that Patent Owner was in possession of the Substitute Claims as of December 29, 2015.

A. The Substitute Claims

213. The ’624 Patent issued from U.S. Application No. 16/835,108 (the “’108 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.

214. The ’108 App. is reproduced in EX1002 at 309 (page 134 of EX1002, Part 3)). The ’926 App. is reproduced in EX2012. I have reviewed the ’108 App. and the ’926 App. and it is my opinion that support for each Substitute Claim appears in these applications, as shown in the table below:

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

	foil, preferably aluminum foil.” ’108 App ¶ [0023]; ’962 App, p. 9, lns. 9, 10. “The coextrusion layer may be coated to the aluminium layer by a coextrusion system.” ’108 App ¶ [0117]; ’962 App, p. 14, lns. 12, 13. “To further improve the mechanical wear resistance of the film a first outer layer may be laminated to the base layer side of the film.” “Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the disclosure, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.” ’108 App ¶ [0123]; ’962 App, p. 15, lns. 6–12.
[14C] coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	The disclosure contemplates “a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . b) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer.” ’108 App ¶ [0066]; ’962 App, p. 10, lns. 28, 29. “In one preferred embodiment, the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer (COC), a polyamide (PA), or[] an ethylene vinyl alcohol.” ’108 App ¶ [0034]; ’962 App, p. 6, lns. 30, 31.
[14D] coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer consisting of the aluminum; and	The disclosure contemplates “a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . c) coating the coextrusion layer to the

	base layer.” ’108 App ¶ [0066]; ’962 App, p. 10, lns. 30. The disclosure provides that the “base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil.” ’108 App ¶ [0023]; ’962 App, p. 9, lns. 9, 10. “The coextrusion layer may be coated to the aluminum layer by a coextrusion system.” ’108 App ¶ [0117]; ’962 App, p. 14, lns. 12, 13. “To further improve the mechanical wear resistance of the film a first outer layer may be laminated to the base layer side of the film.” “Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the disclosure, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.” ’108 App ¶ [0123]; ’962 App, p. 15, lns. 6–12.
[14E] allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of: the base layer consisting of the aluminum, and the coextrusion layer consisting of the tie layer and the contact layer consisting of the COC,	The disclosure contemplates “a method for providing the packaging [of] the chemical substance, said method comprising the steps of . . . d) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide a chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer.” ’108 App ¶ [0066]; ’962 App, p. 10, lns. 31–34.
[14F] wherein: the tie layer comprises one or more layers, and wherein the tie layer, or the one or more layers of the tie	“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

layer, has a loading in the range of 7 to 20 g/m²	simplified processing.” ’108 App ¶¶ [0028], [0029]; ’962 App, p. 6, lns. 3–9. “[I]n one embodiment, the tie layer or plurality of tie layers constituting the tie layer, has a loading in the range of 7 to 20 g/m² and/or the contact layer has a loading in the range of 4 to 20 g/m², and the loading of the laminate is not more than 40 g/m².” ’108 App ¶ [0043]; ’962 App, p. 8, lns. 12–15. “In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b.” ’108 App ¶ [0121] & FIG. 3; ’962 App, p. 14, ln. 34 – p. 15, ln. 2. “For the co-extrusion layers, the loading of the tie layers was between 4–18 g/m² and the loading of the contact layer was 8–12g/m².” ’108 App ¶ [0147]; ’962 App, p. 19, lns. 1–6.
[15A] The method according to claim 19, wherein:	See <i>supra</i> claim element 14A.
[15B] at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer, and	“The tie layer may be made of a material selected from but not limited to a copolymer made of a material selected from a copolymer of ethylene and acrylic acid.” ’108 App ¶ [0135]; ’962 App, p. 17, lns. 6–8. “In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b.” ’108 App ¶ [0121] & FIG. 3; ’962 App, p. 14, ln. 34 – p. 15, ln. 2.
[15C] the method further comprises laminating, after the aggressive chemical-resistant film is formed by coating the	See <i>supra</i> claim element 14D and 14E. “To further improve the mechanical wear resistance of the film a first outer layer may

coextrusion layer to the base layer consisting of the aluminum, a first outer layer to the base layer of the aggressive chemical-resistant film.	be laminated to the base layer side of the film.” “Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the disclosure, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.” ’108 App ¶ [0123]; ’962 App, p. 15, lns. 6–12.
[16A] The method according to claim 14,	See <i>supra</i> claim element 14A.
[16B] wherein a loading of a first layer of the tie layer is in the range of 7 to 18 g/m ² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m ²	See <i>supra</i> claim element 14F.
[17A] The method according to claim 14,	See <i>supra</i> claim element 14A.
[17B] wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of a first layer of the plurality of layers is in the range of 7 to 14 g/m ² and a loading of a second layer of the plurality of layers is in the range of 7 to 14 g/m ² .	See <i>supra</i> claim element 14F.
[18A] The method according to claim 14, wherein:	See <i>supra</i> claim element 14A.
[18B] the one or more layers of the tie layer consists of two layers, and	See <i>supra</i> claim element 14F.
[18C] wherein the aggressive chemical-resistant film is	“Hence, in the context of the present disclosure aggressive chemical-resistant film

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.	means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks. Typically, the degree of uptake is complete after 12 weeks or less.” ’108 App ¶¶ [0033]; ’962 App, p. 6, lns. 26–29.
[19A] The method according to claim 14,	See <i>supra</i> claim element 14A.
[19B] wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating of the coextrusion layer directly to the base layer consisting of the aluminum.	See <i>supra</i> claim element 14D.
[20A] The method according to claim 14, wherein:	See <i>supra</i> claim element 14A.
[20B] the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer,	See <i>supra</i> claim element 15B.
[20C] the chemical is provided in a first patch, and	“In a particular embodiment . . . wherein the composition is provided as a patch, the amount of the aggressive chemical substance remaining . . . [is compared] to a Barex® patch as index 100.” ’108 App ¶ [0051]. “A lidocaine patch containing 40 mg lidocaine was wrapped in the pouch, packaged and stored at 40°C for seven days.” ’108 App ¶ [0157]; ’962 App, p. 20, lns. 9–11.
[20D] the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing 90% to 110% of the chemical in the first patch to	“Stability of the API is important . . . [a] value of 90% - 110% of the original does after one week when stored at 40°C using Barex® as index 100 is considered acceptable.” “As can be seen from figure 5,

migrate into a first pouch formed by the aggressive chemical-resistant film relative to an amount of the chemical in a second patch allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises Barex®.	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.” ’108 App ¶¶ [0158], [0159] & FIG. 5; ’962 App, p. 20, lns. 16–26.
[21A] A method for providing a laminate, wherein the laminate comprises an aggressive chemical-resistant film, said method comprising:	See <i>supra</i> claim element 14A.
[21B] providing a base layer, wherein the base layer consists of aluminum and is resistant to one or more of water or oxygen;	See <i>supra</i> claim element 14B.
[21C] coextruding a tie layer and a contact layer to provide a coextrusion layer, wherein the contact layer consists of a cycloolefin copolymer (COC);	See <i>supra</i> claim element 14C.
[21D] coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer consisting of the aluminum; and	See <i>supra</i> claim element 14D.
[21E] allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of: the base layer comprising the aluminum, and the coextrusion layer consisting of the tie layer and the contact layer consisting of the COC,	See <i>supra</i> claim element 14E.

[21F] wherein: the tie layer comprises a first tie layer having a loading in the range of 7 to 14 g/m ² and a second layer having a loading in the range of 7 to 14 g/m ² , and	See <i>supra</i> claim elements 14F and 17B.
[21G] [wherein] the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine.	See <i>supra</i> claim element 14A.

215. 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.

216. 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.

217. Substitute Claim 14: Substitute independent Claim 14 clarifies antecedent basis of claim terms (including “the film”), adds narrowing features, and removes certain features relative to independent Claim 1. The removed features only involve replacing claim terms with more narrow claim terms or addressing grammatical informalities. Specifically, this claim clarifies that “the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine,” replaces the claim language “the base layer comprises

aluminum” with the more narrow claim language “the base layer consists of aluminum,” and removes a stray comma.

218. Substitute Claim 15: Substitute dependent Claims 15 adds narrowing features and removes certain features relative to dependent Claim 10. Specifically, the removed features only involve updating the dependencies.

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

220. Substitute Claim 17: Substitute dependent Claim 17 adds narrowing features and removes certain features relative to dependent Claim 7. The removed features only involve updating the dependency or replacing claim terms with more narrow claim terms. Specifically, this claim replaces the claim term “in the range of 7 to 20 g/m²” with the narrower claim term “in the range of 7 to 14 g/m².”

221. Substitute Claims 18-20: Substitute dependent Claims 18, 19, and 20 add narrowing features and remove certain features relative to dependent Claims 8, 9 and 11. The removed features only involve updating the dependencies.

222. Substitute Claim 21: Substitute independent Claim 21 adds narrowing features and removes certain features relative to independent Claim 13. The removed features only involve replacing claim terms with more narrow claim terms, improving consistency with the added narrowing features (by their removal), or narrowing the scope of the claims (by their removal). Specifically, this claim: replaces the claim language “comprising” with the more narrow claim language “consisting”; replaces the claim language “the tie layer comprises one or more layers” with the more narrow claim language “the tie layer comprises a first layer . . . and a second layer”; replaces the claim language “wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²” with the more narrow claim language, “a first layer having a loading . . . and a second layer [each] having a loading in the range of 7 to 18 g/m²”; and clarifies that “the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine.”.

223. As such, it is my opinion that none of the proposed Substitute Claims enlarge the scope of the current, Challenged Claims.

224. It is also my opinion that the proposed Substitute Claims each respond to one or more of the grounds asserted in the Petition. Specifically, the Petition asserts that Claims 1 through 13 are unpatentable on the grounds of indefiniteness under 35 U.S.C. § 112 and that Claims 1 through 13 are unpatentable on the grounds of obviousness under 35 U.S.C. § 103 over Riis and/or the combination of Riis, Wypych and Tatarka.

225. I have addressed Grounds 1-3 of the Petition in detail above, and in light of my discussion, analysis and opinions thereof, it is my opinion that the proposed Substitute Claims are responsive to one or more grounds of unpatentability at issue in this proceeding at least because the amendments enhance clarity of the claims (Ground 1) and/or introduce additional distinguishing features that are not disclosed, taught, or suggested by any of Riis, Wypych and/or Tatarka (Grounds 2-3).

226. I have also reviewed the proposed Substituted Claims in light of the arguments Petitioner makes with respect to Grounds 1-3 of the Petition. It is my opinion that the proposed Substitute Claims are definite (for the reasons set forth above with respect to Ground 1) and non-obvious over Riis (Ground 2) and/or the combination of Riis, Wypych and Tatarka (Ground 3).

227. Substitute Claim 14: As detailed above, Riis discloses a five-layer base film and a three-layer sealant film, where the materials (EAA, LDPE, and COC) of

the sealant film are coextruded to the aluminum foil surface of the five-layer base film in a three-layer coextrusion. In Riis, the three-layer sealant film is coated to the aluminum foil surface of the five-layer base film.

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

229. In addition, in Riis, after the three-layer coextrusion, the three-layer coextrusion layer is allowed to adhere to the five-layer base film to form the eight-layer film. Allowing a three-layer coextrusion to adhere to a five-layer base film to form an eight-layer film, as described in Riis, fails to teach or suggest “allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film, wherein the aggressive chemical-resistant film consists of: the base layer consisting of the aluminum, and the coextrusion layer consisting of the tie layer and the contact layer consisting of the COC,” as recited in substitute independent Claim 14. In Riis, after the three-layer coextrusion adheres to the five-layer base film, the result is an eight-layer film that includes a 0.92 mil OPET “exterior” layer, a PEI “primer” layer, a 0.42 mil LDPE “bulk” layer, a 0.1 mil EAA “adhesive” layer,

a 0.35 mil Al “barrier” layer, and the coextrusion layer, which does not “consist[] of [a] base layer consisting of [] aluminum[] and [a] coextrusion layer,” as recited in substitute independent Claim 14.

230. Substitute Claim 15: Because Riis discloses coating the sealant film to the aluminum foil surface of the five-layer base film in a three-layer coextrusion, it follows that Riis does not teach or suggest “laminating, after the aggressive chemical-resistant film is formed, a first outer layer to the base layer,” as recited in Substitute Claim 15. In Riis, the base film includes all of its outer layers prior to the three-layer coextrusion and, thus, does not contemplate laminating any outer layers to the base film after the three-layer coextrusion.

231. Substitute Claim 16: 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. Petitioner, alleges that the 0.17 mil EAA/ 0.65 mil LDPE/ 0.43 mil COC form a coextrusion layer, the EAA and LDPE layers allegedly being tie layers. *See* Petition, at 38-39. In accordance with Petitioner’s calculations, the 0.17 mil EAA layer has a loading within the range of 3.97–4.15 g/m² and the 0.65 mil LDPE layer has a loading within the range of 15.11–15.34 g/m². Petition at 41-42.

232. Assuming *arguendo* that the EAA and LDPE layers are both tie layers, the 0.17 mil EAA layer having a loading of 3.97–4.15 g/m² and the 0.65 mil LDPE

tie layer having a loading of 15.11–15.34 g/m², as described in Riis, does not teach or suggest that “a loading of a first layer of the tie layer is in the range of 7 to 18 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m²,” as recited in substitute dependent claim 16. Only one of the alleged tie layers (the LDPE layer) of Riis has a loading that falls within the claimed range of 7 to 18 g/m².

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

234. Substitute Claim 17: In accordance with Petitioner’s calculations, the 0.17 mil EAA layer has a loading within the range of 3.97–4.15 g/m² and the .65 mil LDPE layer has a loading within the range of 15.11–15.34 g/m². Petition at 41-42.

235. Again, assuming *arguendo* that the EAA and LDPE layers are both tie layers, the 0.17 mil EAA layer having a loading of 3.97–4.15 g/m² and a 0.65 mil LDPE layer has a loading of 15.11–15.34 g/m², as described in Riis, does not teach or suggest that “a loading of a first layer of the tie layer is in the range of 7 to 14 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 14 g/m²,”

as recited in substitute dependent Claim 16. Neither of the alleged tie layers of Riis has a loading that falls within the claimed range of 7 to 18 g/m².

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

XII. CONCLUSION

237. I submit this Declaration in support of Patent Owner's Response and Motion to Amend.

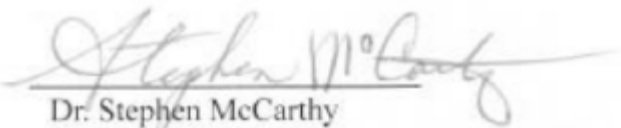
238. This Declaration is based on the information presently available to me as of the date of this report. To the extent any additional information is provided at a later time that could further support or modify the conclusions and opinions I have reached to date, I reserve the right to amend or supplement 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.

239. 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.

240. 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 11th day of September 2023.



Dr. Stephen McCarthy