

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG,

Petitioner,

v.

ADAPA FLEXIBLES DENMARK SLAGELSE A/S,

f/k/a DANAPAK FLEXIBLES A/S,

Patent Owner.

PGR2023-00008

Patent 11,260,624

**THIRD DECLARATION OF STEPHEN MCCARTHY, PH.D., IN
SUPPORT OF PATENT OWNER'S REPLY TO THE PETITIONER'S
OPPOSITION TO PATENT OWNER'S REVISED MOTION TO AMEND**

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I. INTRODUCTION

I, Stephen McCarthy, declare as follows:

1. I am making this Declaration in connection with ADAPA FLEXIBLES DENMARK SLAGELSE A/S's ("Patent Owner")¹ Reply to Petitioner's Opposition to Patent Owner's Revised Motion to Amend, which I understand is being submitted herewith.
2. I have previously provided a Declaration, signed on September 11, 2023, in this post grant review ("PGR") proceeding, PGR2023-00008, before the Patent Trial and Appeal Board ("Board"), in which I provided my independent expert opinions and expert knowledge regarding U.S. Patent No. 11,260,624 ("the '624 Patent") entitled, "Method for Providing an Extreme Chemical Resistant Film, a Film and Laminate Obtainable Therefrom" in response to HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG's ("Huhtamaki" or "the Petitioner") Petition for Post-Grant Review of the '624 Patent, and the arguments and references that form the basis for such grounds asserted by the Petitioner; the level of skill of a person of ordinary skill in the art ("POSITA") for the invention claimed in the '624 Patent; and Patent Owner's prior Motion to

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

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

3. I have previously provided a second Declaration, signed on January 16, 2024, in this PGR proceeding before the Board, in which I provided my independent expert opinions and expert knowledge regarding the level of skill of a person of ordinary skill in the art (“POSITA”) for the invention claimed in the ’624 Patent as well as the proposed revised substitute claims set forth in Patent Owner’s Revised Motion to Amend, and the general knowledge of such a person at the time of the invention; what one of ordinary skill in the art before the priority date of the ’624 Patent would have understood, including scientific and technical knowledge related to the ’624 Patent; and whether the proposed revised substitute claims set forth in Patent Owner’s Revised Motion to Amend add new matter not previously disclosed in the ’624 Patent and/or its related applications or are patentable in light of the arguments and references set forth in the Petitioner’s Opposition to Patent Owner’s Motion to Amend and the Board’s December 29, 2023, Preliminary Guidance (“Preliminary Guidance”)² regarding the same. I understand my second Declaration was submitted as Exhibit 2016 to this PGR proceeding. When making

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

reference to my second Declaration, I may refer to it as “Second Declaration” or “EX2016.”

4. I have been retained by Holland & Hart LLP on behalf of Patent Owner. In this Declaration, I have been asked to provide information and opinions on Petitioner’s Opposition to Patent Owner’s Revised Motion to Amend (“Opposition”) and the arguments and references that form the basis for such grounds contained therein.

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

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

7. I am being compensated at my standard rate of \$400.00 per hour for my work on this case. My compensation is in no way dependent upon the outcome

of this PGR or any issue therein, nor is it contingent upon the results of my study or the substance of my testimony. I have no stake in the outcome of this PGR.

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

II. SUMMARY OF OPINIONS

9. I understand that Petitioner's Opposition only asserts obviousness grounds to challenge the revised substitute claims. It is my opinion that the prior art and prior art combinations asserted in the Opposition do not render the proposed revised substitute claims obvious at least because the prior art and prior art combinations do not disclose, teach or suggest all of the features of the claims; a POSITA would not be motivated to modify or combine the references; a POSITA would not have a reasonable expectation of success in modifying or combining the references; the prior art lacks enablement; or a combination thereof.

III. BASIS FOR OPINIONS & MATERIALS CONSIDERED

10. 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 the Petitioner in this PGR proceeding. I have also carefully reviewed the Petitioner's Opposition to Patent Owner's Revised Motion

to Amend, the third declaration from Dr. Richard J. Spontak (EX1038), and each of the accompanying documents that are cited therein. In addition, I have conducted a search for, and examination of, relevant background material as I would with any matter in which I was asked to provide my opinions and analysis.

11. I understand that Patent Owner is submitting herewith a Reply to Petitioner's Opposition to Patent Owner's Revised Motion to Amend in response to additional arguments raised by Petitioner against Patent Owner's Revised Motion to Amend. As detailed below, it is my opinion that the prior art and prior art combinations do not render the proposed revised substitute claims obvious.

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

PGR Exhibit No.	Description
1001	U.S. Patent No. 11,260,624 to Christensen <i>et al.</i>
1002	U.S. Patent No. 11,260,624 Prosecution History
1003	Declaration of Richard J. Spontak, Ph.D.
1004	WIPO International Pub. No. 2015/123211 A1 to Riis <i>et al.</i>
1005	Wypych, G. (2012), Handbook of Polymers, ChemTec Publishing
1006	U.S. Pat. App. Pub. No. 2005/0037162 A1 to Adams
1007	U.S. Patent No. 6,120,860 to Bowen <i>et al.</i>
1008	U.S. Patent No. 9,452,593 to Tatarka <i>et al.</i>
1009	U.S. Patent Appl. No. 15/780,999 Application File History
1010	Curriculum Vitae of Richard J. Spontak, Ph.D.

1011	Dow NUCREL™ 3990 Product Data Sheet
1012	Dow LDPE 4012 Product Data Sheet
1013	U.S. Patent No. 8,003,179 to Merical <i>et al.</i>
1014	U.S. Patent Appl. Pub. No. 2006/0198973 to Jester
1015	U.S. Patent Appl. Pub. No. 2018/0354702 to Liu <i>et al.</i>
1016	Plastics News: Topas and MSM Make Progress on Barex Replacements
1017	Topas Advanced Polymers: TOPAS COC is Commercial Alternative to Barex
1018	Declaration of Julie Glascock
1019	Topas Cyclic Olefin Copolymers - March 2006 Brochure
1020	Declaration of Samuel A. Raque
1021	U.S. Patent Appl. Pub. No. 2009/0208685 to Rivers <i>et al.</i>
1022	Topas COC 8007F-400 Safety Data Sheet (2015)
1023	Topas COC 8007F-400 Safety Data Sheet (2017)
1024	Dr. Detlev Schulz Declaration
1025	WO 2012/037180 to Bonekamp <i>et al.</i>
1026	Reproduction of Fig. 2 – U.S. Patent No. 11,260,624 to Christensen <i>et al</i>
1027	Diagram #1 of 4-layer multilayer film
1028	Diagram #2 of 4-layer multilayer film
1029	PGR2022-00001 – EX1003 – Declaration of Stephen McCarthy Ph.D.
1030	U.S. Patent No. 10,889,093 to Wang
1031	U.S. Patent No. 6,903,161 to Morris
1032	Deposition of Dr. Stephen McCarthy
1033	U.S. Patent App. Pub. No. 2017/0348246 to Tohara <i>et al.</i>
1034	U.S. Patent App. Pub. No. 2008/0286512 to Holzmuller <i>et al.</i>
1035	WO 2009/105205 to Rivers <i>et al.</i>
1036	The Science and Technology of Flexible Packaging - Morris
1037	Second Declaration of Richard J. Spontak, Ph.D.
1038	Third Declaration of Richard J. Spontak, Ph.D.
1039	Second Deposition of Dr. Stephen McCarthy
N/A	Petition for Post-Grant Review of U.S. Patent No. 11,260,624
N/A	Patent Owner's Preliminary Response
2001	U.S. Patent No. 11,504,954 assigned to Huhtamaki Flexible
2002	U.S. Patent App. No. 16/425,067 Application File History (in-part)
2003	U.S. Patent App. Pub. No. 20150225151A1 to Osborn <i>et al.</i>
2004	Redline Comparison Between Riis and Osborn

2005	U.S. Patent 11,504,954 NFOA Response dated 11 March 2021
2006	U.S. 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 Patent App. No. 15202962.5 – '624 Priority Application
2013	Curriculum Vitae – Dr. Stephen McCarthy
2014	Declaration of Dr. Stephen McCarthy
2015	Deposition Transcript – Dr. Richard Spontak
2016	Second Declaration of Dr. Stephen McCarthy
2017	U.S. Patent No. 11,504,954 Assigned to Huhtamaki Flexible – Application File History
2018	U.S. Patent No. 11,504,954 FOA Response dated 12 August 2021
2019	U.S. Patent No. 11,504,954 Declaration of Huhtamaki Inventor Manuella Herb dated 12 August 2021
2020	U.S. Patent App. Pub. No. 2017/0136747 to Torradas <i>et al.</i>
2021	Second Deposition Transcript – Dr. Richard Spontak
N/A	Decision Granting Institution of Post-Grant Review
N/A	Patent Owner's Motion to Amend
N/A	Petitioner's Opposition to Patent Owner's Motion to Amend
N/A	Board's December 29, 2023, Preliminary Guidance Regarding Patent Owner's Motion to Amend

IV. QUALIFICATIONS

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

V. LEGAL PRINCIPLES

14. I have been asked, in this Declaration, whether the proposed revised substitute claims are patentable over the relevant prior art. I offer my opinions from the perspective of one of ordinary skill in the art.

15. I understand that in response to Patent Owner's Revised Motion to Amend, Petitioner asserted solely obviousness grounds alleging that the proposed revised substitute claims are unpatentable as obvious over the Petitioner's identified prior art references. I understand that Petitioner has not challenged the statutory requirements of the proposed revised substitute claims in its Opposition thereto.

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

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

A. Analogous Art

18. 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.

B. Obviousness

19. 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.

20. I understand that, in a PGR proceeding, a patent claim is deemed unpatentable if it is shown by a preponderance of the evidence that the claim is rendered obvious by one or more prior art references. I understand that a petitioner has the burden to show unpatentability in a PGR proceeding.

21. 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.

22. 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.

23. To be obvious in light of a single prior art reference or multiple prior art references, there must be a reason to modify the single prior art reference, or combine two or more references, in order to achieve the claimed invention. This reason may come from a teaching, suggestion, or motivation to combine, or may come from the reference or references themselves, the knowledge or “common sense” of one skilled in the art, or from the nature of the problem to be solved and may be explicit or implicit from the prior art as a whole. I have also been informed that the combination of familiar elements according to known methods is not obvious when it yields unexpected results. I also understand that it is improper to

rely on hindsight in making the obviousness determination. Moreover, to show a patent claim is obvious in light of prior art, the POSITA must have had a reasonable expectation of success that modifying and/or combining the prior art would have resulted in the claimed invention. I understand that a claim is not obvious if there is no suggestion or motivation to modify the reference or combine the references or a lack of some articulated reasoning with a rational underpinning to support the combination of references.

24. 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.

25. 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.

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

C. Enablement

27. 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.

28. 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."

29. 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 to practice the claimed invention without such undue experimentation.

30. It is my understanding that there are many factors to be considered when determining whether there is sufficient evidence to support a determination

that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” These factors include but are not limited to the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. I understand that these factors can be referred to as the *Wands* factors.

VI. LEVEL OF PERSON HAVING ORDINARY SKILL IN THE ART

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

It is my opinion that a POSITA with respect to the subject matter of the '624 patent at the time of its invention can fairly be described as someone with at least a bachelor's degree (or equivalent) in Chemical Engineering, Polymer Science and Engineering, Materials Science and Engineering, or the like, and 2-3 years of experience in laminate or film manufacture or similar packaging manufacture. Less hands-on experience may be necessary with additional education and vice versa.

EX1003 at ¶ 72.

32. As stated in my Original Declaration and my Second Declaration, given my review of the '624 Patent, and its file history, I disagree with Dr. Spontak's formulation of a person of ordinary skill in the art applicable to the analyses related to this dispute.

33. 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.

34. I provided a thorough analysis and discussion section regarding why a definition of the level of ordinary skill requires hands-on experience with coextrusion techniques, which I reaffirm but do not reproduce here.

35. In my opinion, Dr. Spontak's Second Declaration (EX1037) and Third Declaration (EX1038) provide further support for my position that a person of ordinary skill in the art of the '624 Patent should have hands-on experience. Specifically, Dr. Spontak's positions that a POSITA can simply combine or modify first film structures with the properties and components of other film structures that have significant polymeric and structural differences, and that are formed from significantly different manufacturing processes, plainly exposes the limitations of his purely theoretical understanding of film manufacturing.

36. In my hands-on experience, I have found the specific material being used for one layer of a coextrusion often significantly and, in some cases, unpredictably affects the composition and dimensions of the other layers in the coextrusion that are needed to achieve a successful film, especially as the quantity of layers in the coextrusion increases. Similarly, in my hands-on experience, I have found that for the same materials, the dimensions and properties that are achievable for the layers of a film is significantly affected by the processes used to form that film. Indeed, a significant motivation for the development and use of different processes has been, and is, to successfully form films with different dimensions and properties for particular material combinations.

37. Accordingly, in my opinion, only a person with a purely academic understanding of film manufacturing would suggest that the dimensions of films having significant polymeric and structural differences, and that are formed from significantly different manufacturing processes, can be effortlessly combined with one another. Only by ignoring these differences and the practical consequences of them would one appreciate the difficulty and sometime impossibility of combining such references. As such, a person with a purely academic understanding of film manufacturing would be unable to appreciate the nuances and realities required by the '624 Patent, especially when considering items such as a motivation to combine

or modify film structures and whether there is a reasonable expectation of doing so.

VII. OVERVIEW OF THE '624 PATENT

A. Summary of the '624 Patent and Relevant Technology

38. I provided a thorough analysis and technical overview section regarding the '624 Patent and the relevant technology related thereto in my Original Declaration, which I reaffirm here but do not reproduce here.

B. Prosecution History

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

40. I provided a thorough analysis and discussion section regarding the '624 Patent's prosecution history in my Original Declaration and my Second Declaration, which I reaffirm but do not reproduce here.

VIII. SUMMARY OF THE ASSERTED REFERENCES

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

42. I understand that, in its Opposition to Patent Owner's original Motion to Amend, the Petitioner identified additional prior art references as forming the bases of its obviousness grounds relating to the originally proposed substitute claims: Tohara (U.S. Patent App. No. 2017/0348246); Holzmuller (U.S. Patent App. No. 2008/0286541); and Rivers (WIPO International Pub. No. 2009/105205). I provided a thorough analysis and discussion section regarding these references in my Second Declaration. In addition to this information, which I reaffirm but do not reproduce here, I provide information supplemental to the analysis and discussion of Holzmuller below.

43. I understand that, in its Opposition to Patent Owner's Revised Motion to Amend, the Petitioner identifies Riis, Wypych, Holzmuller, and Rivers as forming the bases of its obviousness grounds relating to the proposed revised

substitute claims. In addition to my analysis of these references in my Original Declaration and my Second Declaration, which I reaffirm but do not reproduce here, I provide information supplemental to that analysis and discussion in the sections detailing the patentability of the proposed revised substitute claims below.

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

44. In my opinion, Holzmuller discloses a laminate formed using significantly different processes and significantly different materials than those disclosed in the '624 Patent—namely with Holzmuller disclosing jointly extruding (*i.e.*, extruding in a back-to-back or one-after-the-other fashion) layers of an intermediate layer material onto a barrier (aluminum) layer and failing to consider COC materials entirely. Also, in my opinion, Holzmuller suggests that, after the layers of the intermediate layer are jointly extruded to the barrier layer, the separately formed oriented coextruded protective layer is attached by a lamination procedure to the intermediate layer in a manner that preserves the orientation of the oriented coextruded protective layer.

IX. CLAIM CONSTRUCTION

45. I provided a thorough analysis and discussion section regarding claim construction in my Original Declaration and my Second Declaration, which I reaffirm but do not reproduce here.

X. PATENT OWNER'S REVISED MOTION TO AMEND

46. In its Revised Motion to Amend, I understand that Patent Owner seeks to unconditionally cancel Claims 2 and 3 of the '624 Patent. I also understand that Patent Owner seeks a contingent amendment with respect to Claims 1 and 4–13. In my Second Declaration, I provided a thorough analysis and discussion section regarding the compliance of Patent Owner's Revised Motion to Amend with the requirements for revised motions to amend, which I reaffirm but do not reproduce here.

47. In my Second Declaration, I also provided a thorough analysis and discussion section regarding the patentability of the proposed revised substitute claims over the Petitioner's identified prior art. In addition to this information, which I reaffirm here but do not reproduce, I provide information supplemental to this analysis and discussion in the sections detailing the proposed revised substitute claims below.

48. For the reasons discussed in my Original Declaration, my Second Declaration, and below, it is my opinion that the proposed revised substitute claims are patentable over the Petitioner's identified prior art.

A. The Proposed Revised Substitute Claims

49. I have been informed that Patent Owner proposed the following revised substitute claims in its Revised Motion to Amend:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing less than 10% of the chemical to migrate into the aggressive chemical-resistant film.

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

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

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

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

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

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

the chemical is provided in a first patch, and
the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing 90% to 110% of the chemical in the first patch to migrate into a first pouch formed by the aggressive chemical-resistant film relative to an amount of the chemical in a second patch allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises polyacrylonitrile.

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

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

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

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

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

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

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

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

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

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

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

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

B. Riis and Wypych, alone and in combination, fail to disclose, teach, or suggest features of the proposed revised substitute claims.

61. In my Original Declaration and Second Declaration, I have provided a thorough analysis explaining Riis's, and Riis in view of Wypych's, failure to disclose, teach, or suggest features of the proposed revised substitute claims, which I reaffirm but do not reproduce in full here. I provide information supplemental to that analysis and discussion below.

1. Riis and Wypych, alone and in combination, fail to disclose, teach, or suggest a "coextrusion layer consisting of [a] tie layer [comprising a first layer and a second layer] and [a] contact layer," as recited in Substitute Claim 14.

62. I understand that the Petitioner again alleges that Riis discloses an exemplary film having a multi-layer tie layer made with two individual "tie" layers: an EAA "tie" layer and an LDPE "tie" layer. Opposition, 2. As noted in my Original Declaration, Riis explicitly discourages the use of multi-layer tie layers in multi-layer films made under Riis. Specifically, Riis defines a tie layer as a multifunctional layer (1) that serves the primary purpose of providing sufficient adhesion between adjacent layers; (2) that has properties (*e.g.*, thickness properties) known by a POSITA as being consistent with serving that purpose; and (3) for which a primary reason for including the layer in the film was to serve that purpose. Thus, in my opinion, in Riis, for polyolefins (such as polyethylenes) to be used as a tie layer, the polyolefin must be modified. *See* EX1004 ¶ [0071]

(providing “adhesive layers may include modified *e.g.* anhydride modified polymers *e.g.* polyolefins such as [anhydride modified] polyethylenes.”)

63. As further noted in my Original Declaration, based at least on Riis’s disclosure, the structure of the film, the material properties of the layers, and a POSITA’s knowledge, a POSITA would identify the 0.17 mil EAA layer in the film disclosed in Riis’s Example 5 as a “tie” layer and the 0.65 mil LDPE layer in the film disclosed in Riis’s Example 5 as a “bulk” layer.

64. Regarding the film disclosed in Riis’s Example 5, and as noted in my Original Declaration, the sealant film of Riis’s Example 5 includes a single 0.17 mil EAA “tie” layer that is used to tie a 0.65 mil LDPE “bulk” layer to a 0.35 mil Al “barrier” layer of the base film of Riis’s Example 5. Though the 0.65 mil LDPE layer naturally adheres to the 0.43 mil COC “contact” layer as a result of these layers sharing material properties, the 0.65 mil LDPE layer’s primary purpose (*i.e.*, the reason for including the 0.65 mil LDPE layer in the Film) is not to tie the 0.43 mil COC layer to the 0.17 mil EAA layer. Instead, consistent with the primary purpose of a bulk layer, the 0.65 mil LDPE layer’s primary purpose is to improve the structural, heat sealability, barrier, and cost properties of Riis’s Example 5.

65. Thus, in my opinion, Riis’s sealant film fails to disclose, teach, or suggest a “coextrusion layer consisting of [a] tie layer [comprising a first layer and a second layer] and [a] contact layer,” as recited in Substitute Claim 14.

66. I understand that Wypych is simply used by the Petitioner to provide material properties for the Film. Thus, in my opinion, Riis, in view of Wypych, similarly fails to disclose, teach, or suggest this feature.

2. In other proceedings before the USPTO, the Petitioner has advanced a position consistent with my understanding that Riis's 0.65 mil LDPE layer is a "bulk" layer.

67. In my analysis, I have identified positions taken by the Petitioner in other proceedings before the USPTO (in U.S. App. No. 16/516,792) that are consistent with my above understanding of Riis in the Petitioner's analysis of Osborn (US2015/0225151). Riis claims priority to Osborn and shares many similarities to Osborn. For example, Riis's Examples 2 and 5 are identical to those disclosed in Osborn. EX2003 ¶¶ [0097], [0100]. Additional similarities between Riis and Osborn can be found in the redline comparison of Riis and Osborn provided in EX2004.

68. Particularly, in U.S. App. No. 16/516,792, in the Response filed on August 3, 2022 ("Second FOA Response") in response to the Final Office Action dated April 7, 2022, Petitioner provided a table (reproduced below as Table 1 on page 10 of EX2006) indicating that, consistent with my understanding, Petitioner also understands the 0.65 mil LDPE layer to be a bulk layer. EX2006, 12:11,12.

69. Table 1 illustrates, in respective columns, structures of the prior art films and the invention claimed in U.S. App. No. 16/516,792. In my opinion, Table

1 is constructed to illustrate the structures of the prior art films and Petitioner's allegedly inventive films relative to the eight-layer films of Osborn such that layers in the different film structures that are similar to one another are positioned next to (*i.e.*, in a same row as) one another. As illustrated in Table 1, if a film structure does not have a layer comparable to a particular layer of the eight-layer films of Osborn, the omission of that layer from that film structure is indicated using an "XXX" designation.

70. In Table 1, the Petitioner reproduces Riis's Example 2 in the first column (as Osborn1) and Riis's Example 5 in the second column (as Osborn2). In the first column, the Petitioner explicitly identifies, in the sealant film of Riis's Example 2, the layer (of PE, LLDPE, or m-LLDPE) between a PE or EVA "tie" layer and a COC "contact" layer as a polyolefin bulk layer. In the second column and in the same row as the layer (of PE, LLDPE, or m-LLDPE), the Petitioner identifies, in the sealant film of Riis's Example 5, the layer (of LDPE) between an EAA "tie" layer and a COC "contact" layer. In my opinion, the layout of Table 1 suggests that the layer represented by the third-to-last row (including this layer (of LDPE)) represents the polyolefin bulk layer in each of the comparable film structures illustrated in Table 1.

71. Furthermore, in my opinion, this layer of LDPE directly corresponds to the 0.65 mil LDPE layer in Riis's Example 5, which shares the same structure as

the second column: OPET/PE/LDPE/EAA/Al/EAA/LDPE/COC. As further evidence that the Petitioner understands the LDPE layer in Riis's Example 5 to be a bulk layer, the Petitioner explicitly identifies, later in its response, that "the 'bulk' layer in Osborn [] is a polyolefin such as PE or LLDPE." EX2006, 12:11,12. LDPE is another example of a polyolefin.

Osborn 1	Osborn 2	Toft	Invention Claim 38	Invention Claim 42	Invention Claim 50
exterior	exterior	exterior	exterior	exterior	exterior
OPET/ Paper	OPET/ Paper	PE	XXX*	XXX	XXX
PE	Primer / PE	Paper	XXX	XXX	Paper or plastic/ OPET
LDPE	LDPE	LDPE	XXX	XXX	XXX
EVA	EAA	XXX	XXX	XXX	XXX
O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)	O2 barrier (Al foil)
PE or EVA	EAA	EAA	EAA/EVA	EAA/EVA	EAA/EVA
Polyolefin Bulk: PE, LLDPE, m-LLDPE	LDPE	COC + mLLDPE	PE	PE inc. C ₈ m-LLDPE	PE, LLDPE, m-LLDPE
COC	COC	m-PE/ m-LLDPE	COC	COC	COC
Interior	Interior	interior	interior	Interior	interior

Table 1

72. Moreover, the Petitioner has explicitly identified (when explaining the correspondence between the structure layer in U.S. Pub. No. 2017/0136747 to

Torradas *et al.* (“Torradas”) (EX2020) with a layer in Osborn) that the “structure layer in Osborn is the ‘bulk’ layer which is a polyolefin.” EX2006, 12:11,12. The definition of the term “structure layer” is derived from Torradas, which describes a structure layer as a layer that can be combined with a barrier layer (as separate layers or as a single layer) to provide effective barriers to moisture and oxygen as well as bulk mechanical properties suitable for processing and/or packaging the products, such as clarity, toughness, and puncture-resistance. EX2020 ¶ [0121]. Accordingly, Petitioner’s description of a polyolefin bulk layer is consistent with Riis’s definition and my opinion that the 0.65 mil LDPE “bulk” layer’s primary purpose is to improve structural, heat sealability, cost, and barrier properties.

3. In other proceedings before the USPTO, the Petitioner has advanced a position consistent with my understanding that Riis’s 0.65 mil LDPE layer is not a “tie” layer.

73. In the Response dated August 12, 2021 (“First FOA Response”) to the Final Office Action dated May 13, 2021 for U.S. App. No. 16/516,792, the Petitioner submitted that the LDPE layer allows a multilayer structure to be created. EX2018, 9:5–15. The Petitioner further submitted that the bond between a regular LDPE layer and a COC layer is weak such that the COC layer easily delaminates from the neighboring LDPE layer. EX2018, 9:5–15. Based on the poor bond between the regular LDPE layer and the COC layer, Petitioner proposes to use a metallocene C8 LLDPE layer instead of the regular LDPE layer to

“increase[] the ties (lamination forces) between the polyethylene layer and the COC layer . . . without destroying the multilayer structure.” EX2018, 9:5–15.

74. In U.S. App. No. 16/516,792, Petitioner submitted the Inventor Declaration dated August 12, 2021 (EX2019), on behalf of an inventor of U.S. App. No. 16/516,792, Manuella Herb, to support this assertion. In this Declaration, the inventor represented that laboratory testing showed that the COC layer “more or less easily delaminates or can be peeled off the neighboring regular LDPE-layer.” EX2019 ¶ 10. Specifically, the inventor represented that the bond between a regular LDPE layer and a connected COC layer in a laminate structure including “aluminum/ethylene acrylic acid [(EAA)] copolymer/LDPE/COC [(the same layer combination as Riis)] has a strength per length of 0.5 N per 15 mm.” EX2019 ¶ 10.

75. The inventor further represented that when C8 mLLDPE was used in place of the regular LDPE, the adhesion between the metallocene C8 LLDPE layer and the COC layer was surprisingly up to 3.3 N per 15 mm, the inventor stating the “adhesion between [the] metallocene C8 LLDPE-layer and [the] COC layer [was] significantly greater than the cohesion of the respective material within each layer[, and that] this effect was neither known, nor could it be expected.” EX2019 ¶ 11.

76. Thus, in my opinion, according to the Petitioner's reasoning, from a delamination performance perspective, it would be better to omit such LDPE layers (*e.g.*, the 0.65 mil LDPE layer) from a multilayer structure entirely unless

such layers are providing the structure required (and primarily included) for the successful creation of the multilayer structure.

4. Under Dr. Spontak's definition of a "tie" layer, the 0.65 mil LDPE layer is not a "tie" layer.

77. I understand that Dr. Spontak's definition of a tie layer is "a layer that is used to adhere two other components that wouldn't adhere sufficiently and one that prevents those layers from delaminating" and that such a tie layer a tie layer would not easily delaminate or peel away from an adjoining layer. EX2021, 183:23–189:4. As noted above, Dr. Manuella Herb—Petitioner's employee and an inventor on U.S. App. No. 16/516,792 assigned to Petitioner—observed, in the context of Riis's Example 5³, that an LDPE layer easily delaminates from a neighboring COC layer. As also noted above, Dr. Manuella Herb further reported testing results confirming the poor lamination performance between the LDPE and COC layer. Accordingly, under Dr. Spontak's definition of a tie layer, the 0.65 mil LDPE layer would not be a tie layer.

5. Accordingly, in this and other proceedings before the USPTO, the Petitioner has advanced a position consistent with my understanding of Riis's 0.65 mil LDPE layer is a "bulk" layer and is not a "tie" layer.

78. Accordingly, in previous proceedings in front of the USPTO, the Petitioner has also identified that the 0.65 mil LDPE layer in the sealant film of Riis's Example 5 is primarily used to provide structure and to enable Riis's

³ Citing Osborn's identical disclosure of Riis's Example 5.

Example 5 film to be created, not to tie the 0.17 mil EAA layer to the 0.43 mil COC layer. Petitioner has further identified that the regular LDPE layer is used for this “bulking” purpose in spite of its poor secondary “tying” functionality. Thus, Petitioner has similarly identified that, consistent with a traditional bulking purpose, the primary purpose of the 0.65 mil LDPE layer in the sealant film of Riis’s Example 5 is to provide structure that allows Riis’s Example 5 film to be created and to improve barrier properties. As such, the Petitioner has indicated that, from a delamination performance perspective, it would be preferred to omit the 0.65 mil LDPE layer entirely except that the LDPE layer is required for the successful creation of Riis’s Example 5. Given this necessity, the Petitioner proposes replacing the LDPE “bulk” layer with an m-LLDPE “bulk” layer whose primary purpose is still to enable the successful creation of a film but that allegedly exhibits an improved secondary tie performance relative to regular LDPE.

79. Therefore, the Petitioner’s own representations to the Office and this proceeding confirm my understanding that the 0.65 mil LDPE layer is a “bulk” layer, not a “tie” layer, and not a layer of a multi-layer “tie” layer.

6. Riis and Wypych, alone and in combination, fail to disclose, teach, or suggest “[a] tie layer, or each of [a] first layer of the tie layer and the second layer of the tie layer, ha[ving] a loading in the range of 7 to 20 g/m²,” as

recited in Substitute Claim 14, and “a loading of an entirety of the tie layer [] in the range of 7 to 20 g/m²,” as recited in Substitute Claim 16.

80. Since, in my opinion, the sealant film of Riis’s Example 5 discloses a single-layer tie layer (*i.e.*, the 0.17 mil EAA layer), and in accordance with the Petitioner’s calculations, the 0.17 mil EAA layer has a loading of 3.94 g/m² to 4.15 g/m², it follows that the single-layer tie layer in Riis fails to disclose, teach, or suggest “[a] tie layer, or each of [a] first layer of the tie layer and the second layer of the tie layer, ha[ving] a loading in the range of 7 to 20 g/m²,” as recited in Substitute Claim 14, or “a loading of an entirety of [a] tie layer [that] is in the range of 7 to 20 g/m²,” as recited at least in Substitute Claim 16.

7. Even if, assuming arguendo, the sealant film of Riis were to include a multi-layer tie layer, Riis and Wypych, alone and in combination, fails to disclose, teach, or suggest “a loading of the first layer of the tie layer . . . and a loading of the second layer of the tie layer [] in the range of 1 to 14 g/m²,” as recited in Substitute Claim 16.

81. According to the Petitioner’s calculations, the 0.65 mil LDPE layer has a loading range of 15.11 g/m² to 15.34 g/m², which fails to disclose “a loading of . . . [a] tie layer [that] is in the range of 1 to 14 g/m²,” as recited in Substitute Claim 16.

82. As noted in my Original Declaration and my Second Declaration, in my opinion, in light of Riis and a POSITA’s knowledge, a POSITA would be discouraged from decreasing the thickness of the 0.65 mil LDPE layer since a

POSITA would expect doing so would compromise the structural, heat sealability, barrier, and cost properties of the film.

8. Even if, assuming arguendo, the sealant film of Riis were to include a multi-layer tie layer, Riis and Wypych, alone and in combination, fails to disclose, teach, or suggest “a loading of the first layer of the tie layer is in the range of 5 to 19 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m²,” as recited in Substitute Claim 17.

83. According to the Petitioner’s calculations, the 0.17 mil EAA layer has a loading of 3.94 g/m² to 4.15 g/m², and the 0.65 mil LDPE layer has a loading range of 15.11 g/m² to 15.34 g/m², which fails to disclose, teach, or suggest, respectively, “a loading of the first layer of the tie layer is in the range of 5 to 19 g/m² and a loading of the second layer of the tie layer is in the range of 1 to 14 g/m²,” as recited in Substitute Claim 17.

84. As noted in my Original Declaration and my Second Declaration, in my opinion, in light of Riis and a POSITA’s knowledge, a POSITA would be discouraged from increasing the thickness of the 0.17 mil EAA layer since a POSITA would expect doing so would compromise the delamination strength of the film. As also noted in my Second Declaration, Dr. Spontak has similarly expressed the importance of maintaining as thin a tie layer as possible.

85. As noted in my Original Declaration, my Second Declaration and herein, in my opinion, in light of Riis and a POSITA’s knowledge, a POSITA would be discouraged from decreasing the thickness of the 0.65 mil LDPE layer

since a POSITA would expect doing so would compromise the structural, heat sealability, barrier, and cost properties of the film.

9. Even if, assuming arguendo, the sealant film of Riis were to include a multi-layer tie layer, Riis and Wypych, alone and in combination, fails to disclose, teach, or suggest “a loading of the first layer of the tie layer . . . and a loading of the second layer of the tie layer is in the range of 7 to 20 g/m²,” as recited in Substitute Claim 18.

86. According to the Petitioner’s calculations, the 0.17 mil EAA layer has a loading of 3.94 g/m² to 4.15 g/m², which fails to disclose, teach, or suggest, “a loading of [a] tie layer [] in the range of 7 to 20 g/m²,” as recited in Claim 18.

87. As noted in my Original Declaration, my Second Declaration and herein, in my opinion, in light of Riis’s disclosures and a POSITA’s knowledge, a POSITA would be discouraged from increasing the thickness of the 0.17 mil EAA layer since a POSITA would expect doing so would compromise the delamination strength of the film.

88. Here, and in conflict with a POSITA’s general understanding of tie layers, a POSITA would need to nearly double the thickness of the 0.17 mil EAA layer to meet the loading ranges claimed in Substitute Claim 18.

10. In other proceedings before the USPTO, the Petitioner has advanced a position consistent with my understanding that Riis does not disclose, teach, or suggest the loading ranges claimed in Substitute Claims 16–18.

89. In my analysis, I have identified positions taken by the Petitioner in other proceedings before the USPTO (in U.S. App. No. 16/516,792) that are consistent with the above understanding of Riis in the Petitioner’s analysis of

Osborn (US2015/0225151). Specifically, in the Petitioner's Second FOA Response (while addressing the layer thicknesses claimed in U.S. App. No. 16/516,792), the Petitioner stated "[t]he Examiner does not, and cannot, point out any clear teaching or suggestion of the claimed thickness layer ranges in the Osborn reference . . . because such teaching is not there." EX2006, 13:10–12.

90. Claim 58 of U.S. App. No. 16/516,792 recited a film having an acrylic acid-containing joining layer, a polyethylene layer, and a COC layer, each having "layer thickness[es] in the range from about 7 μm [0.28 mils] to about 15 μm [0.59 mils]." EX2006, 6. Using Petitioner's calculation to convert thickness to loading, the layer thicknesses in the '792 Application correspond to EAA and LDPE loadings from $\sim 6.5 \text{ g/m}^2$ to $\sim 13.8 \text{ g/m}^2$.

91. Regarding Substitute Claims 16–18, I agree with the Petitioner that there is no clear teaching or suggestion of the loading ranges claimed in Substitute Claims 16–18 in Osborn or Riis.

92. In the Second FOA Response, the Petitioner went on to state that "[e]ven assuming *arguendo* that the extrapolation from Osborn leads to the same layer thicknesses as those instantly claimed, there is simply no teaching or suggestion in Osborn . . . that leads to the claimed relative thicknesses in present claims (58–62)." EX2006, 13:15–18.

93. Claim 58 of U.S. App. No. 16/516,792 further recited that “the thickness values of [the acrylic acid-containing joining, the polyethylene, and the COC] layers . . . differ by no more than 15%.” EX2006, 6.

94. Regarding Substitute Claim 18, I agree with the Petitioner that there is no clear teaching or suggestion of the relative loading ranges claimed in Substitute Claim 18 in Osborn or Riis. Specifically, with reference to Substitute Claim 18, there is no clear teaching or suggestion in Osborn or Riis of a relative loading range between a first layer (*e.g.*, the 0.17 mil EAA layer) and a second layer (*e.g.*, the 0.65 mil LDPE layer) in a three-layer coextrusion that is between 1 (7/7) to 2.85 (20/7).

C. Riis, Wypych, and Holzmuller, alone and in combination, fail to disclose, teach, or suggest features of the proposed revised substitute claims.

1. The fact that the .65 mil LDPE layer is not a “tie” layer fundamentally undermines Petitioner’s arguments for combining Riis and Holzmuller.

95. In Dr. Spontak’s Third Declaration, he alleges that the intermediate bonding layers in Holzmuller are tie layers. EX1038 ¶ 103 (stating “Holzmuller teaches relative interacting thickness for intermediate bonding layers (*i.e.*, tie layers)").

96. In his Third Declaration, Dr. Spontak further provides:

It is my opinion that, similar to Riis, Holzmuller recognizes using polymers like EAA and polyethylene provide suitable bonding layers for use in such laminates. Based on this disclosure, Holzmuller would

have motivated a skilled artisan to tailor and optimize the thicknesses, and thus the loadings, of the **intermediate bonding layers** as applied to Riis's LDPE and EAA **tie layers** to achieve desired synergistic properties of the multilayered intermediate tie layers.

EX1038 ¶ 99 (emphasis added; in-line citations omitted).

97. In his Third Declaration, Dr. Spontak further provides:

Holzmuller would have motivated a skilled artisan to tailor and optimize the thicknesses, and thus the loadings, of the **intermediate bonding layers** as applied to Riis's LDPE and EAA tie layers to achieve desired synergistic properties of the **multilayered intermediate tie layers**.

EX1037 ¶ 126 (emphasis added).

98. Accordingly, it is my opinion, that the Petitioner's combination of Riis and Holzmuller hinges on the 0.65 mil LDPE layer in Riis's Example 5 being a tie layer to maintain compatibility with the intermediate bonding layers in Holzmuller.

99. As noted above, in my opinion—which is supported by evidence in Riis (*e.g.*, EX1004 ¶ [0065]); Morris (EX1036, 196); Dr. Spontak's statements (*e.g.*, EX2015, 83:16–22), and Petitioner's own statements (EX2006, Table 1 & 12:11,12)—the 0.65 mil LDPE layer is a bulk layer.

100. As further noted above, in my opinion—which is supported by evidence in Riis (*e.g.*, EX1004 ¶ [0071]); Dr. Spontak's statements (*e.g.*, EX2021,

183:23–189:4), and Petitioner’s own *sworn* statements (*e.g.*, EX2019 ¶ 10)—the 0.65 mil LDPE layer is not a tie layer.

101. Accordingly, in my opinion, and in addition to the lack of motivation and reasonable expectation of success described below, Petitioner’s combination of Riis and Holzmuller fails at least for the fact that the 0.65 mil LDPE layer is not a tie layer.

2. A POSITA would not be motivated to combine Riis and Holzmuller because Riis’s and Holzmuller’s films are structurally, functionally, and polymerically different and are formed using fundamentally different processes.

102. In my Second Declaration, I have provided a thorough analysis explaining that the structural, functional, and polymeric differences undermine a motivation to modify or combine Riis with Holzmuller. In addition to this information, which I reaffirm but do not reproduce here, I provide information supplemental to my analysis on this matter here.

103. In my opinion, the Petitioner is taking a backwards approach to applying Holzmuller to Riis. Specifically, Petitioner identifies a completed film created under Riis (Riis’s Example 5) and then suggests applying the thickness ranges in Holzmuller to the completed film. However, Riis’s Example 5 represents an end point of experimentation. Riis’s Example 5 represents a film that has been completed in light of the principles disclosed in Riis—*e.g.*, to have tie layer thicknesses kept to a minimum consistent with a desired effect, bulk layer

thicknesses sufficient to provide the structure needed to allow the creation of Riis's Example 5, and so on. Thus, in my opinion, a POSITA would not begin experimentation anew with Riis's Example 5, randomly modifying thicknesses of Riis's Film, but would instead adhere closely to the specifications of Riis's Example 5—*i.e.*, maintaining a similar structure, similar relative thicknesses, and the like.

3. A POSITA would not have a reasonable expectation of success in modifying or combining Riis with Holzmuller because Riis's and Holzmuller's films are structurally, functionally, and polymerically different and are formed using fundamentally different processes.

104. In my Second Declaration, I have provided a thorough analysis explaining that the structural, functional, and polymeric differences undermine a reasonable expectation of success for modifying or combining Riis with Holzmuller. In addition to this information, which I reaffirm here but do not reproduce, I provide information supplemental to my analysis on this matter here.

105. Holzmuller describes a joint extrusion lamination process that involves extrusion coating a first bonding layer and a second bonding layer to an aluminum foil layer followed by lamination of an oriented coextruded protective layer to the second bonding layer without disruption of the orientation in the oriented protective layer. Holzmuller also provides a wide range of thicknesses for the first bonding layer and the second bonding layer. EX1034 ¶ [0019]. As noted in my Second Declaration, apart from listing possible materials for the bonding layers

and providing the wide thickness ranges, Holzmuller fails to provide a working example of a film with specific materials and thicknesses, and I do not believe that Holzmuller enables the production of a film having EAA and LDPE bonding layers with loadings within the loading ranges claimed in the proposed revised substitute claims.

106. That said, in the event the above deficiencies of Holzmuller are overlooked, I do not believe a POSITA would have a reasonable expectation of success in applying the thicknesses provided for the bonding layers in Holzmuller to the EAA layer and the LDPE layer in Riis.

107. Riis contemplates performing a three-layer coextrusion coating of EAA, LDPE, and COC to an Al foil layer. In my opinion, there is no reason to believe that thickness ranges achievable for the layers in a joint extrusion can simply be applied to two layers in a three-layer coextrusion, regardless of whether the layers share a function or the same material. For example, in my experience, there is no reason to believe that the EAA and LDPE layers in a three-layer coextrusion of EAA, LDPE, and COC can be successfully extruded using the same thickness ranges achievable for a joint extrusion of EAA and LDPE followed by a lamination. The thicknesses of the first bonding layer and the second bonding layer in Holzmuller will decrease as both layers cool and crystallize. The thickness of each of these layers will continue to decrease during the lamination process where

these layers will be “squeezed” during the compression of lamination to ensure bonding between the oriented cover layer / protective layer composite without destroying the orientation within the oriented cover layer / protective layer composite. This low temperature lamination will determine the final thicknesses of the first bonding layer and the second bonding layer. The trial and error process of obtaining specific thicknesses for the joint extrusion followed by low temperature lamination in Holzmuller is very different and not equivalent to the trial and error process of obtaining specific thicknesses in a three layer coextrusion process in Riis where all of the layers are coextruded together at the same time and cooled together. Moreover, the expectation of success would be even lower when using thickness ranges provided for a joint extrusion using different or unknown materials, as in Holzmuller. In other words, in my experience, there is no reason to believe that thickness ranges achieved for two layers in a joint extrusion can automatically be achieved for a corresponding two layers in a three-layer coextrusion.

108. Indeed, a three-layer coextrusion of EAA, LDPE, and COC is a significantly more complicated coextrusion process than a joint extrusion of EAA and LDPE and it is significantly more difficult to form a successful three-layer coextrusion across a wide range of thicknesses than it is to form a successful joint extrusion of EAA and LDPE followed by lamination. Additionally, applying the

smaller thicknesses of Holzmuller to the EAA and LDPE layers in Riis's Example 5 would further complicate the coextrusion process relative to a joint extrusion of EAA and LDPE followed by lamination. Moreover, the thinness of the COC layer in Riis's Example 5 would even further complicate the coextrusion process relative to a joint extrusion of EAA and LDPE followed by lamination. Together, these added complexities would lead a POSITA to believe that modifying or combining Riis with the thickness ranges disclosed in Holzmuller would be unlikely to result in success.

4. Petitioner relies solely on conclusory statements regarding the motivation to combine or modify Riis with Holzmuller and a POSITA's expectation of success.

109. In my opinion, Dr. Spontak disregards the structural, polymeric, and functional differences between Riis and Holzmuller and merely provides conclusory statements regarding a POSITA's motivation to combine or modify Riis with Holzmuller. Specifically, Dr. Spontak's primary support for the motivation to combine or modify Riis with Holzmuller is that Holzmuller discloses "preferred ranges of thicknesses of intermediate bonding layers to produce a 'synergistic' effect of both high mechanical and chemical stability along with other added benefits." EX1038 ¶ 87 (referring to EX1034 ¶¶ [0018]–[0020]). And similarly, that Holzmuller teaches that "varying the thicknesses of intermediate

bonding layer would produce an additive effect, yielding multiple positive benefits for the end laminate or film.” EX1038 ¶ 88.

110. However, in my opinion, the cited paragraphs of Holzmuller, or any other disclosure in Holzmuller for that matter, do not disclose, teach, or suggest varying the thicknesses of intermediate bonding layers to produce an additive effect. Instead, Holzmuller states that:

[b]y virtue of the multilayered construction of the intermediate layer material, it is possible to **combine materials** the positive properties of which have an additive effect and in that way offer an intermediate layer material which, on the one hand, has both high mechanical stability and high chemical stability. In particular, mention should be made in this connection of a high degree of stretchability combined at the same time with high tear resistance, a high level of resistance to diffusion and the possibility of achieving good grip and, at the same time, good haptic properties.

EX1034 ¶ [0020] (emphasis added). It is my opinion that “combining materials” refers to the “mixtures of the afore mentioned materials” which occurs at the end of the list of first bonding layer materials and at the end of the list of second bonding layer materials. Blending of polymer materials is well known in the art to “have an additive effect in producing an intermediate layer material which has high mechanical stability and high chemical stability.” Polymer blends are successful in producing high degree of stretchability combined at the same time with high tear

resistance. Polymer blends are also successful in producing a high level of resistance to diffusion and the possibility of achieving good grip and, at the same time, good haptic properties. The versatility of polymer blends in achieving these additive properties surpasses the property changes due to variations in thicknesses suggested by Dr. Spontak.

111. In my opinion, Dr. Spontak similarly disregards the structural, polymeric, and functional differences between Riis and Holzmuller and merely provides conclusory statements regarding a POSITA's expectation of success in combining or modifying Riis with Holzmuller.

112. Specifically, Dr. Spontak's primary support for the position that a POSITA would have a reasonable expectation of success in combining or modifying Riis with Holzmuller is his conclusory and unsupported opinion regarding the alleged structural, functional, and polymeric similarities between these films (EX1038 ¶ 100). However, as I have set forth the films in Riis and Holzmuller are significantly different in terms of structure, functionality, polymer composition, and the process for forming the respective films.

113. Dr. Spontak also provides that "a POSITA would have a reasonable expectation of success in modifying the individual tie layer thicknesses of the combination of Riis . . . with Holzmuller's teachings of varying thicknesses to employ among the intermediate bonding layers to achieve the additive effects

benefitting the end resulting film.” EX1038 ¶ 102. As noted above, I did not find in Holzmuller any disclosure, teaching, or suggestion that varying the thicknesses of intermediate bonding layers produces an additive effect. Moreover, in my opinion, even if Holzmuller did teach varying the thicknesses of the intermediate bonding layers leads to an additive effect in Holzmuller, I disagree that this supports the position that the thicknesses of the 0.17 mil EAA layer and the 0.65 mil LDPE layer in Riis’s Example 5 can be similarly varied with a reasonable expectation of success (at least due to the structural, functional, polymeric, and manufacturing differences in Riis and Holzmuller).

114. Dr. Spontak also provides that a “POSITA would further have a reasonable expectation of success as Holzmuller similarly relates to multilayer films exposed to chemicals that may leach through the film laminate.” EX1038 ¶ 102. As previously noted in my Second Declaration, the films disclosed in Riis are functionally different than the films disclosed in Holzmuller—the films disclosed in Riis being concerned with limiting uptake of a pharmaceutical ingredient to a threshold amount and the films in Holzmuller merely being concerned with slowing the diffusion of an aggressive substance to the aluminum layer. In my opinion, though the functional differences are important in determining whether a POSITA would be motivated to combine Riis with Holzmuller, the structural, polymeric, and manufacturing differences carry more weight when determining

whether the film structures disclosed in Riis can be combined with the film structures disclosed in Holzmuller. In other words, a POSITA with the requisite hands-on experience would not have a reasonable expectation of success for combining, with first film structures, significant aspects of other film structures that are structurally and polymerically different, and that result from significantly different manufacturing procedure.

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

115. In my Second Declaration, I have provided a thorough analysis explaining Holzmuller's failure to enable its disclosure. In addition to this information, which I reaffirm here but do not reproduce, I provide information supplemental to my analysis on this matter here.

116. In my opinion, the following *Wands* factors: (1) the nature of the invention, (2) the level of predictability in the art; (3) the amount of direction provided by the inventor; (4) the existence of working examples; and (5) the quantity of experimentation needed to make or use the invention point toward Holzmuller not being enabled. Specifically, Holzmuller is related to processes for film manufacturing with thin layers. In my experience, manufacturing films with thin layers is subject to unpredictability—*i.e.*, small changes (especially as at smaller thicknesses) to the layers of a film can result in unpredictable behavior or

failure of the film. Additionally, Holzmuller does not provide a single, complete working example—*i.e.*, Holzmuller never describes a full film structure, or sub-structure for that matter, with designated materials and thicknesses. Moreover, as noted above and as previously noted in my Second Declaration, Holzmuller discloses nearly limitless combinations.

6. As Holzmuller cannot be combined with Riis, the Petitioner has failed to disclose ranges that include or overlap with the claimed ranges in the proposed revised substitute claims.

117. It is my opinion that there would not be a reasonable likelihood of success in modifying Riis with Holzmuller. Accordingly, I understand that the Petitioner has failed to establish that a POSITA would modify Riis's 0.17 mil EAA layer and Riis's 0.65 mil LDPE layer to meet the claimed ranges in the proposed revised substitute claims. I also understand that the Petitioner fails to provide ranges for the 0.17 mil EAA layer and Riis's 0.65 mil LDPE layer that overlap with or include the claimed ranges in the proposed revised substitute claims. Thus, I understand that the proposed revised substitute claims are allowable over Riis and Holzmuller even in the absence of evidence of criticality.

118. Specifically, I understand that no evidence of criticality is required if the claimed ranges do not overlap with ranges disclosed in the identified prior art combination. Regardless, as detailed above, I have identified evidence of criticality

of the claimed ranges. See EX1001 at 2:63–67; 6:1–13, 24–28; EX2014 at ¶¶ 57–65, 68–70 (which discuss the surprising results achieved in the '624 Patent).

7. In other proceedings before the USPTO, Petitioner itself has provided evidence of criticality of the loading ranges claimed in Substitute Claims 16–18.

119. In U.S. App. No. 16/516,792, Petitioner submitted the Inventor Declaration dated August 12, 2021, (well after the priority date at issue in this PGR proceeding) on behalf of an inventor of U.S. App. No. 16/516,792, Manuella Herb, to support the assertion that there is a poor bond between a regular LDPE layer and a COC layer. In this Declaration, the inventor represented that laboratory testing showed that the COC layer “more or less easily delaminates or can be peeled off the neighboring regular LDPE-layer.” EX2019 ¶ 10. Specifically, the inventor represented that a laminate structure including “aluminum/ethylene acrylic acid [(EAA)] copolymer/LDPE/COC” has a strength per length of 0.5 N per 15 mm.” EX2019 ¶ 10.

120. The inventor further represented that when C8 mLLDPE was used in place of the regular LDPE, the adhesion between the metallocene C8 LLDPE layer and the COC layer was surprisingly up to 3.3 N per 15 mm, the inventor stating the “adhesion between [the] metallocene C8 LLDPE-layer and [the] COC layer [was] significantly greater than the cohesion of the respective material within each layer[, and that] this effect was neither known, nor could it be expected.” EX2019 ¶ 11.

121. Claim 58 of U.S. App. No. 16/516,792 recited a film having an acrylic acid-containing joining layer, a polyethylene layer, and a COC layer, each having “layer thickness[es] in the range from about 7 μm [0.28 mils] to about 15 μm [0.59 mils].” EX2006, 6. Using Petitioner’s calculation to convert thickness to loading, the layer thicknesses in the ’792 Application correspond to EAA and LDPE loadings from $\sim 6.5 \text{ g/m}^2$ to $\sim 13.8 \text{ g/m}^2$. Thus, the films disclosed in U.S. App. No. 16/516,792 disclosed similar loadings as those claimed in the ’624 Patent.

122. Accordingly, evidence of criticality can be found throughout the ’624 Patent, my Original Declaration, my Second Declaration, and in Petitioner’s own representation to the USPTO, which confirm that achieving a film including a coextrusion having a tie layer (*e.g.*, a multi-layer tie layer having an EAA and polyethylene layer) and a COC contact layer with the low loadings obtained in the ’624 Patent, while maintaining overall mechanical and chemical robustness of the film, was an unexpected result.

XI. CONCLUSION

123. I submit this Declaration in support of Patent Owner’s Reply to the Petitioner’s Opposition to Patent Owner’s Revised Motion to Amend. The statements set forth in this Declaration are based upon my personal knowledge, and where I lacked such personal knowledge, I have undertaken efforts to verify the information to confirm the information contained herein is true and correct. If

called upon to do so, I could competently testify to the matters set forth herein under oath.

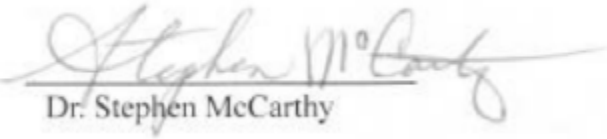
124. This Declaration is based on the information presently available to me as of the date of this Declaration. To the extent any additional information is provided at a later time that could further support or modify the conclusions and opinions I have reached to date, I reserve the right to amend or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

125. 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.

126. 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 25th day of March 2024.



Dr. Stephen McCarthy