

**EXPERT DECLARATION OF RICHARD J. SPONTAK, PH.D., IN
SUPPORT OF HUHTAMAKI FLEXIBLE PACKAGING GERMANY
GMBH & CO. KG'S PETITION FOR POST-GRANT REVIEW OF U.S.
PATENT NO. 11,260,624**

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

SCOPE OF THE ASSIGNMENT

1. I have been retained as an expert witness on behalf of Huhtamaki Flexible Packaging Germany GmbH & Co. KG ("Huhtamaki") for the above-captioned post-grant review ("PGR"). I am being compensated for my time in connection with this PGR through which Patterson Intellectual Property Law, P.C. has agreed to pay me for my services at a rate of \$500 per hour. My compensation is not contingent upon my opinion or testimony or the outcome of this PGR.
2. This report addresses the grounds of unpatentability that Huhtamaki asserts in its Petition for PGR to render claims 1–13 of U.S. Patent No. 11,260,624 (EX1001, the "'624 patent") unpatentable as indefinite, pursuant to 35 U.S.C. § 112(b), and unpatentable as obvious, pursuant to 35 U.S.C. § 103. This report details why the claims fail to particularly point out and distinctly claim the invention and why the prior art publications identified herein render obvious the claimed invention to a person having ordinary skill in the art ("POSITA").

3. I have been asked to provide my independent technical review, analysis, insights, and opinions regarding the '624 patent and the prior-art references that form the basis for the grounds of unpatentability in the Petition.
4. In preparing this declaration, I have reviewed and am familiar with all the documents cited herein. I have reviewed and am familiar with the '624 patent and its file history. I confirm that, to the best of my knowledge, the accompanying exhibits are true and accurate copies of what they purport to be, and that an expert in the field would reasonably rely on them to formulate opinions such as those set forth in this declaration.
5. The matters and opinions stated herein are true and correct to the best of my understanding. The facts set forth in this declaration are personally known to me and I have firsthand knowledge thereof. If called upon to do so, I could and would competently testify to these matters under oath.

QUALIFICATIONS AND RELEVANT EXPERIENCE

6. In forming the opinions expressed in this declaration, I have considered and relied upon my approximately thirty-nine years' experience, my education, and the knowledge in the relevant art. In addition, I have reviewed and relied upon additional materials in preparation of this declaration, as described below. In formulating my opinions, I have also considered the viewpoint of a POSITA

before the time of the invention, which I have been told to assume for this case is December 29, 2015.

7. My experience and education are detailed in my curriculum vitae (“CV”), a copy of which is provided as Exhibit (“Ex.” or “EX”) 1010. My CV also lists publications on which I am a named author, as well as patent applications and issued patents on which I am a named inventor.
8. I am presently a Distinguished Professor of Chemical & Biomolecular Engineering, Professor of Materials Science & Engineering, and Alumni Distinguished Graduate and Undergraduate Professor at North Carolina State University. On the basis of my research, teaching and service to my institution, the scientific community and the general populace, I rose through the ranks of tenure-track Assistant Professor and tenured Associate Professor before becoming full professor. I was named Distinguished Professor in 2016 (according to University regulations, the “number of Distinguished Professors...is capped for each college at 4% of the total number of tenured/tenure-track faculty”). I have also previously held the position of Lars Onsager Professor (named after the Nobel laureate) at the Norwegian University of Science & Technology in recognition of my research endeavors. I supervise the Macromolecular Materials & Morphology Group at North Carolina State University, and my Group

consisting of post-doctoral scholars, Ph.D. students, M.S. students, and outstanding undergraduates, aims to investigate a wide range of polymeric systems to elucidate fundamental principles and enable targeted technologies. My research has been widely applauded by the scientific and engineering communities, resulting in several national and international awards. This year alone, I received the Roy W. Tess Award in Coatings from the American Chemical Society (Polymeric Materials: Science & Engineering Division), the International Award from the Society of Polymer Science, Japan, the Global Research Project Award from the Institution of Chemical Engineers (UK), the R.J. Reynolds Tobacco Award for Teaching, Research & Extension from the North Carolina State University College of Engineering [the highest college-level award], and the Alexander Quarles Holladay Medal for Excellence from North Carolina State University [the highest institution-level award].

9. I have also been named as a co-inventor on several issued patents and pending patent applications. For example, I am a named co-inventor on U.S. Patent No. 7,658,989 on the subject of “Nano- and Micro-cellular Foamed Thin-Walled Materials, and Processes and Apparatuses for Making the Same,” issued on February 9, 2010. Several pending patents pertain specifically to polymer surfaces; for example, “Inherently Self-Disinfecting Coating Surfaces and

Method for Making Thereof,” “Bio-Secure Protective Surface and Methods for Making” and “Towards Universal Photodynamic Spray Coatings for Infection Control.” Although the properties of interest in these patent applications differ from those in the ’624 patent, many of the molecular-level design principles are comparable. Moreover, my experience in helping to write my own patents has greatly improved my ability to detect shortcomings in others.

10. During this time, I have also authored over 300 peer-reviewed journal publications, as well as over 30 book chapters and invited monographs, and delivered over 370 invited/keynote/plenary/award presentations addressing various aspects of polymer films, fibers, blends, and laminates, wherein factors such as interfacial adhesion and molecular transport frequently play important roles regarding ultimate property development.

11. My CV provides further details pertaining to my education, professional experience, publications, patents, presentations, and other qualifications. See EX1010.

MATERIALS CONSIDERED

12. In my study of this matter, I have received various materials from counsel for Huhtamaki (these are listed on the following page, along with their Exhibit Nos.),

and I have likewise searched for and examined relevant background material as I would with any project.

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

Exhibit No.	Description
1001	U.S. Patent No. 11,260,624 to Christensen <i>et al.</i>
1002	U.S. Patent No. 11,260,624 Prosecution History
1004	WIPO International Pub. No. 2015/123211 A1 to Riis <i>et al.</i>
1005	Wypych, G. (2012), Handbook of Polymers, ChemTec Publishing
1006	U.S. Pat. App. Pub. No. 2005/0037162 A1 to Adams
1007	U.S. Patent No. 6,120,860 to Bowen <i>et al.</i>
1008	U.S. Patent No. 9,452,593 to Tatarka <i>et al.</i>
1009	U.S. Patent Appl. No. 15/780,999 Application File History
1010	Curriculum Vitae of Richard J. Spontak, Ph.D.
1011	Dow NUCREL™ 3990 Product Data Sheet
1012	Dow LDPE 4012 Product Data Sheet

1013	U.S. Patent No. 8,003,179 to Merial <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

14. Lastly, and as detailed below, I relied on counsel for my legal understandings, particularly with respect to patent law. While I do not possess a detailed knowledge of or practical background in patent law, my opinions provided herein relate my expertise regarding polymer science and polymer engineering to the patentability of the '624 patent.

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

amplification of these conclusions will be addressed in supplemental reports or testimony, which I reserve the right to provide.

APPLICABLE LEGAL STANDARDS

16.I have been told the following legal principles apply to analysis of patentability.

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

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

18.I have been told that, in a PGR proceeding, a patent claim may be deemed unpatentable if it is shown by a preponderance of evidence that the claim is indefinite if the claim, read in light of the specification delineating the patent (and the prosecution history), fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

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

20.I understand that it is not sufficient that one can ascribe some meaning to a patent's claims, but reasonable efforts must result in a definition that provides

sufficient specificity and clarity to inform skilled artisans of the bounds of the claim.

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

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

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

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

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

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

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

1. *Graham* factors

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

28.With respect to determining the proper scope of prior art to examine, I understand that, for a prior art reference to be properly used in an obviousness ground under 35 U.S.C. § 103, the prior art reference must be analogous art to the claimed invention. I have been told that a reference is analogous art to the claimed invention only if: (1) the reference is from the same field of endeavor as the claimed invention; or (2) the reference is reasonably pertinent to the particular problem solved by the inventor.

29.I understand that factors relevant to determining the proper field of endeavor include the inventor’s explanations of the subject matter (including the patent

specification), as well as the claimed invention's structure and function. And I further understand that to be reasonably pertinent to the particular problem solved by the inventor, a prior art reference must logically commend itself to the inventor's attention in considering his or her problem.

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

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

- a. A combination of familiar elements according to known methods is likely to be obvious if it yields predictable results;
- b. The simple substitution of one known element for another is likely to be obvious if it yields predictable results;
- c. The use of a known technique to improve similar devices, products, or methods in the same way is likely to be obvious if it yields predictable results;

- d. The application of a known technique to a prior art reference that is ready for improvement is likely obvious if it yields predictable results;
- e. Any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed;
- f. A POSITA often will be able to fit the teachings of multiple references together like a puzzle; and
- g. The proper analysis of obviousness requires a determination of whether a POSITA would have a “reasonable expectation of success”—not “absolute predictability” of success—in achieving the claimed invention by combining prior art references.

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

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

34.I have been told there is no rigid rule prescribing that a reference or combination of references must contain a “teaching, suggestion, or motivation” to combine references. But I also have been told that the “teaching, suggestion, or motivation” test can be a useful guide in establishing a rationale for combining elements of the prior art. I have been told this test poses the question as to whether there is an express or implied teaching, suggestion, or motivation to combine prior art elements in a way that realizes the claimed invention, and that it seeks to counter impermissible hindsight analysis.

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

OVERVIEW OF THE '624 PATENT

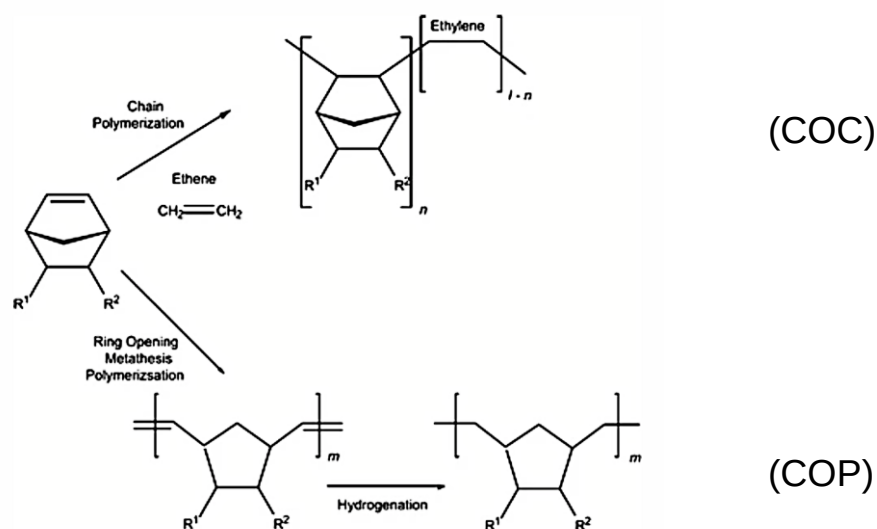
36.The '624 patent, entitled “Method for Providing an Extreme Chemical Resistant Film, a Film and Laminate Obtainable Therefrom,” is directed to a method for providing a multilayer film and a laminate suitable for packaging aggressive chemical substances. Ex. 1001, codes (54), (57), 2:44–62. The claims generally require providing “an aggressive chemical-resistant film” by coating a coextruded tie layer and contact layer to a base layer comprising aluminum. The claims further require that the contact layer—the layer that contacts the aggressive chemical—consist of a cycloolefin copolymer (COC) and that the tie layer have a particular loading range. The claims also generally require providing a laminate that includes the aggressive chemical-resistant film.

37.The '624 patent claims also recite a variety of ranges of loading and relative melting points among the layers of the aggressive chemical-resistant film. The '624 patent claims require that the tie layer or portions thereof have a loading in the range of 7–20 g/m² and the contact layer have a loading in the range of 4–20 g/m². The claims of the '624 patent further require that the melting point of the

tie layer differs from the melting point of the COC comprising the contact layer by 30 °C or less, more preferably 5–15 °C.

Technology Background – COCs and Systems Utilizing COCs

38. Seminal literature regarding the synthesis of COCs dates back to the early 1990s as metallocene chemistry began to capture the imagination of polymer chemists intrigued by the possibility of achieving surprising new material properties from cyclic precursors, such as cyclobutene, cyclopentene or norbornene. If the starting monomer is polymerized via ring-opening metathesis, the resulting homopolymer is referred to as a cycloolefin polymer (COP), whereas if a second monomer is introduced during chain polymerization, the macromolecule is a COC, as depicted below (from Shin *et al.*, *Pure Appl. Chem.* **2005**, 77, 801-814):



While research into the metallocene-catalyzed polymerization of this family of materials continued into the 2000s and beyond, applications benefiting from the unique property sets of COCs (*e.g.*, fibers, optics, microfluidics, and foams) started to appear in the open literature throughout the 2010s, thereby implying that the corresponding commercial efforts developed earlier. At this time, considerable interest arose regarding the use of COCs in polymer lab-on-a-chip constructs, which explicitly relied on the chemical resistance of COCs in contact with various chemical and biological species. Concurrently, efforts examined the melt processability of COCs by extrusion, injection molding and fiber spinning.

39. Skilled artisans began incorporating COC polymers in multilayer films at least as early as 2006. For example, U.S. Patent No. 8,003,179 to Merical *et al.* (“Merical”), filed on August 1, 2006, and assigned to Alcan Packaging Flexible France SAS described multilayer films wherein “[t]he product contact layer may be comprised of a substance that has been deemed acceptable to be in contact with a product such as a pharmaceutical.” Ex. 1013, 12:3-17. According to Merical, in one such embodiment “the product contact layer can include COC, HDPE or a blend of COC and HDPE. Blends of COC and HDPE in some embodiments can be approximately 70-90% COC and approximately 10-30%

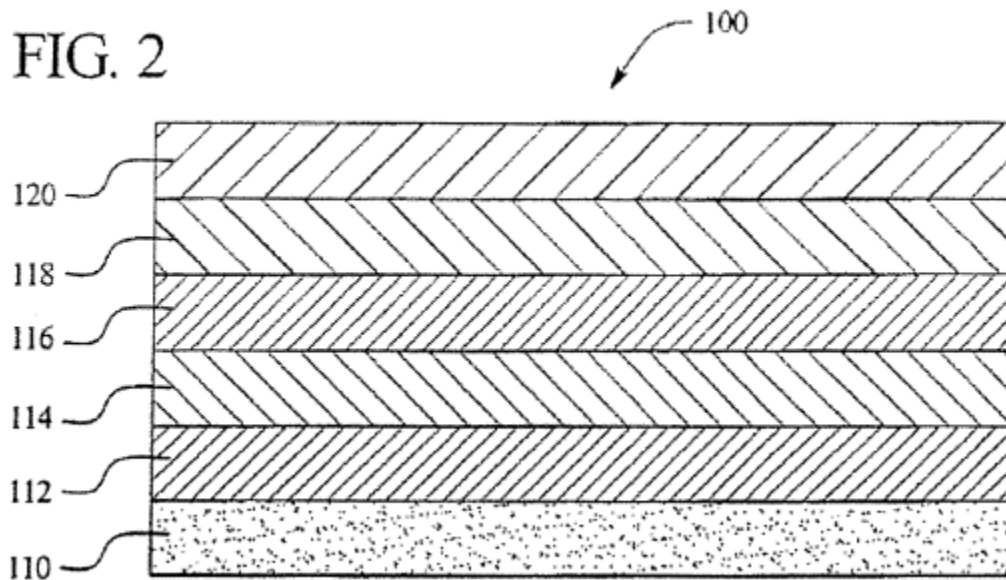
HDPE or approximately 80% COC and approximately 20% HDPE.” Merical, 12:3-17.

40. Merical further disclosed the structure of various embodiments of such films.

Describing Fig. 2, reproduced below, Merical taught that “film layer 110” is “a sealant layer or product contacting layer” that “may be adhered to a barrier layer 114 by a tie or adhesive layer 112.” Ex. 1013, 9:6-21.

41. Merical further explains that the tie or adhesive layer 112 “may be a coextrusion of LDPE and EAA.” Ex. 1013, 9:59-63. Merical states that the “barrier layer 114 may be a metal foil,” providing aluminum foil as an example. Ex. 1013, 10:13-22, 9:32-35, 4:53-64.

FIG. 2



42. In addition, U.S. Patent Appl. Pub. No. 2006/0198973 to Jester (“Jester”), filed on March 3, 2005, and assigned to Topas Advanced Polymers GmbH described the use of COC in contact layers of food and beverage packaging and other consumables since COC has a reduced effect on the flavor of packaged consumables as compared to standard polyethylene contact layers. Ex. 1014, ¶¶[0001]-[0003]. Jester explicitly recognizes that “[f]ilms employing a cycloolefin copolymers (“COC” or “COCs”) are well known in the art, and have been used to package consumables.” Ex. 1014, ¶[0004] (citing U.S. Pat. No. 6,607,423 to Hasumann, U.S. Pat. No. 5,912,070 to Miharuru et al., U.S. Pat. No. 6,680,094 to Kikuchi et al., U.S. Pat. No. 6,713,165 to Karsten, and U.S. Pat. No. 6,544,610 to Minami et al.). Notably, the prior art patents referenced in Jester are discussed as providing other preferred attributes of COC as used within films, such as heat seal strength. Jester utilizes commercially available cycloolefin copolymers, such as Topas® COC polymers that are copolymers of norbornene and ethylene. Ex. 1014, ¶¶[0038], [0051]. Jester also recognizes that such films are formed by ordinary processes, including coextrusion and lamination. Ex. 1014, ¶¶[0043]-[0044].

Technology Background – Aggressive Chemical-Resistant Films

43. Chemical-resistant polymer films and coatings have long been recognized as an important category of protective materials, that is, multicomponent materials wherein the purpose of one or more components is to protect the remainder of the material system (and its contents in the case of packaging) from environmental factors such as solvent penetration or degradation. As discussed in my book chapter by Soltani and Spontak (see my attached CV), several strategies are available to improve what is typically referred to as “barrier performance.” The chemical route involves the incorporation of moieties (*e.g.*, fluorine units, as in the case of Teflon[®]) that prevent penetration or degradation. In this example, a highly fluorinated surface becomes (super)hydrophobic and prevents water from dissolving in and diffusing through a protective contact layer. Alternatively, diffusive barriers such as solid additives (*e.g.*, nanoclay, graphene and various minerals) and polymer crystals can likewise enhance barrier performance. Additives can be dispersed throughout a polymer insofar as such dispersion is spatially uniform with acceptable levels of aggregation, and the size and population of polymer crystals can be controllably modulated through the use of thermal treatment and/or nucleating agents. In contrast, the COCs tend to be glassy (amorphous) materials that are transparent and possess glass transition

temperatures (T_g s) that depend on the chemistry of each COC. In general, a higher T_g translates into closer molecular packing, which, in turn, means a better barrier to penetrant diffusion. However, as is well-established for polycarbonates, a glassy polymer subjected to an organic vapor can crystallize so that an initially transparent polymer film can become progressively opaque (since the crystals become sufficiently large to diffract light). As with many inherently hydrophobic polyolefins, COCs are resistant to the penetration of various polar compounds, but are chemically susceptible to a number of organic solvents such as toluene. Another consideration with respect to chemical resistance is polymer degradation wherein a chemical reaction caused by a chemical species alters the chemical nature of a polymer. Since COCs are hydrophobic, strong aqueous acids or bases, as well as alcohols, do not interact with COCs to the point of inducing a substantial degradation within a reasonable time frame. This level of chemical resistance is one reason why polyolefins are beneficial in many technologies.

44. As the '624 patent acknowledges, it was known in the art that some drugs, such as fentanyl and nicotine, can be properly dosed through a transdermal patch applied to the skin of a patient. Ex. 1004, ¶[0003]. These patches, and other similar drug delivery systems, are contained in packaging that is designed to contain the patch and its drug within the package. Ex. 1004, ¶[0003]. The

packaging serves various functions, including resisting the migration of the drug compounds from the patch to the packaging, as well as protecting the patch from contamination and from adverse effects from the external environment. Ex. 1004, ¶¶[0003]-[0004]. This is especially true for drugs administered through transdermal patches that include aggressive pharmaceuticals such as fentanyl and nicotine.

45. It was also known that the film used for the packaging of aggressive chemical substances is typically suited to be heat-sealed and provide a hermetic barrier, that is, the film packaging is folded and heat-sealed (welded) along the edges to form a pouch containing the active pharmaceutical ingredient. Ex. 1004, ¶[0003]. In a recently settled injury litigation involving the death (by fentanyl overdose) of a young woman, I examined the packaging of transdermal fentanyl patches and discovered evidence of insufficient welding, which led to fatal leakage.

46. Typically, as-received polymeric materials are extruded by the manufacturer and cut into small beads or pellets using a “chopper,” which cuts long strands of extrudate into more manageable and packable beads or pellets. All of this is done on a dry basis, even for highly hydrophilic polymers, which must remain dry or purposefully dried prior to final product processing by, for example, extrusion, injection/blow molding or fiber spinning. During extrusion, the as-received solid

beads or pellets are added to a hopper, from which they are controllably metered into the extruder barrel where they are heated to form a polymer melt (*i.e.*, a viscoelastic liquid) to permit flow and, if desired, mixing. This process was well-known in the art of polymer processing at the time of the '624 patent (I've actually taught this topic in one of my graduate courses since the late 1990s) and closely resembles the making of pasta in a home kitchen. Information regarding temperature profiles within the extruder barrel is frequently provided by manufacturers, who often work with customers to achieve a successful product. Coextrusion is a more elaborate form of extrusion in which two or more polymer melt streams are controllably combined to yield a layered construct, or laminate. This process technology developed as a result of the packaging industry, which required polymer films possessing multiple property sets unattainable with a single polymer. The different streams can be brought together in the feed ("feed block" coextrusion) or at the exit ("die" coextrusion). 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). In all cases, the beads or pellets entering the extruder must be dry to avoid liquid evaporation inside the barrel (which could lead to undesirable pressure build-up in the equipment, as well as bubbling in the melt, otherwise known as foaming).

47. As previously mentioned, it is critically important for polymers to flow during conventional processes such as (co)extrusion, injection/blow molding and fiber spinning. The flow profile, typically presented in terms of melt viscosity as a function of shear rate at different temperatures, must be known prior to processing to avoid problems that could result in excessive equipment damage and/or unsafe working conditions. The term “melt” refers to a polymeric liquid, which typically differs from a simple liquid exhibiting Newtonian behavior (for which viscosity is independent of shear rate). Polymeric melts exhibit Newtonian behavior at low shear rates (in the so-called “zero-shear” limit) but then their melt viscosities generally decrease with increasing temperature, a flow characteristic referred to as “shear-thinning.” Since melt viscosity plays a crucial role in the transport of polymer through the extruder, its temperature dependence must be well-established, and this information is often provided by the manufacturer.
48. Thermoplastic polymers, such as polyolefins including COCs, can possess two very different solid forms as semi-crystalline solids (recognizing that no synthetic polymer of commercial relevance can ever be 100% crystalline) or glassy solids. Crystals require the three-dimensional registry of adjacent polymer chains to generate long-range order that can be detected by the presence of Bragg diffraction peaks in wide-angle X-ray scattering (WAXS). Solid crystals

transform into a liquid at the melting temperature (or normal melting temperature if the pressure is 1 atm), commonly designated as T_m . This is a first-order phase transition wherein the chemical potentials of the two phases (solid and liquid) are equal, and the melting temperature is manifested as a peak in thermal tests such as differential scanning calorimetry (DSC). Since not all of the polymer chains are involved in the formation of crystals in polymers, the remaining chain population remains in the melt (liquid) state until sufficiently cooled below its T_g , at which the large-scale molecular mobility of the chains ceases and the material vitrifies. For example, linear low-density polyethylene (here, density provides an indicator of how crystalline the polymer is, since crystals are more dense than the amorphous part of the polymer) typically possesses a low degree of crystallinity, in which case it is primarily liquid (but held together by crystalline crosslinks and chain entanglements). The value of T_m is quantitatively related to the thickness of the lamellae comprising crystals by the well-known Gibbs-Thomson equation (as T_m increases, the lamellae become thinner).

49. When glassy solids are heated, they also transform into melts (liquids) at the T_g , but the process is a second-order phase transition wherein volume and the state of entropy remain the same (this is not true in the case of first-order phase transitions for which these properties become discontinuous and a jump occurs).

The T_g provides a valuable measure of chain packing (but not into three-dimensional registry) and free volume (*i.e.*, the volume unoccupied by polymer chains at sub-molecular length scales) and can be easily affected by the presence of other species, surfaces or interfaces, pressure, and even heating/cooling rate. In DSC thermograms, the T_g appears as a discontinuity, not an endothermic peak, and is often independent of heating *versus* cooling. In marked contrast, the crystallization temperature (T_c) measured by cooling is always lower than T_m measured by heating for conventional linear polymers. Another means of detecting T_g is through a dynamic (oscillatory) test capable of yielding a loss modulus (G'' or E'' , depending on the deformation mode) as a function of temperature. In this case, the loss modulus exhibits a maximum, which is also responsible for a maximum in $\tan\delta$ (where δ is the dissipation factor or loss angle, given by the ratio of the loss modulus divided by the storage modulus). Thus, it follows that T_m and T_g refer to thermal properties arising from fundamentally different solid forms and must be lower than the (co)extrusion temperature.

50. One other thermal characteristic that must be considered during (co)extrusion of any thermoplastic polymer reflects thermal decomposition of the long polymer chains fragmenting into smaller units. For linear polyolefins such as polyethylene and polypropylene, this range extends from about 330 °C to just over 410 °C,

which means that any measured or reported thermal transitions (*e.g.*, T_m) within this range are suspect or altogether erroneous. Since the COCs of interest here contain ethylene repeat units, they would most likely have comparable degradation characteristics. This is why the temperature profiles for COC (co)extrusion are limited to below 320 °C.

51. Materials for constructing such packaging intended for use as transdermal patches typically possessed an interior layer most immediate to the transdermal patch that is aimed to resist migration of chemicals between the patch and the package. This is what is typically known in the art as “scalping.” Ex. 1004, ¶[0004].

52. One common material used in the packaging of the interior layer for transdermal patches was a material sold under the trademark Barex[®]. Although Barex[®] possessed favorable antiscalping properties, other characteristics such as high cost, poor tear properties, and limited availability make Barex[®] a less desirable choice for packaging. Ex. 1004, ¶[0004].

53. The reference to Barex[®] in the past tense here is purposeful. In October 2014, Ineos Group announced that it would end production of Barex[®] polyacrylonitrile

(PAN) resin at its only global plant in Lima, Ohio.¹ Polymer producers looked to fill that void, promoting their polymers for use in such films and packaging. These producers included Topas Advanced Polymers, which promoted its cyclic olefin copolymer (COC) and MSM Poly LLC, which promoted its acrylonitrile methyl acrylate copolymer.

54. By at least November 2015, Topas Advanced Polymers announced that its COC could provide a successful alternative to Barex[®].² As its announcement stated, “[t]he pharmaceutical packaging industry is already familiar with COC through its use in semi-rigid and container applications.... While not a 1-for-1 replacement for PAN, COC delivers effective chemical resistance and low adsorption rates, exhibiting low reactivity with medical-grade chemical contents such as nicotine for patches.... Topas’ converter customers have developed innovative nicotine patch packaging solutions utilizing COC for the transdermal industry.”

55. Topas touted the advantages of the use of its COC products for food contact and medical uses. “Unlike PAN, Topas COC can be melt processed by all common

¹ <https://www.plasticsnews.com/article/20151119/NEWS/151119853/topas-and-msm-make-progress-on-barex-replacements>

² <https://topas.com/company/news/topas%C2%AE-coc-commercial-alternative-barex>

thermoplastic processing methods including mono and multi-layer film, sheet, and extrusion coating, along with injection and extrusion blow molding.”

56. Topas described its COC as “a key component in a broad range of global Barex[®] replacement products from leading healthcare packaging companies including Bemis Healthcare Packaging, Oshkosh, Wis., Rollprint Packaging Products, Addison, Ill., Tekni-Films Division of Tekni-Plex, Inc., Wayne, Pa, and other suppliers.”

57. Thus, it is not surprising that, by that time Bemis had already filed a patent application on films and packaging utilizing Topas COCs.³ Specifically, Bemis is the assignee of WO 2015/123211 A1, to Riis *et al.*, upon which the obviousness grounds discussed in this declaration rely.

Summary of the '624 Patent

58. As discussed above, the '624 patent teaches a method for generating a multilayer film and a laminate suitable for packaging aggressive chemical substances. It states that the requirements for such a package, film, or laminate typically include the following: (1) resistance towards highly aggressive substances; (2) inert

³ Bemis filed international application PCT/US2015/015246 on February 10, 2015, which claims priority to U.S. Patent App. No. 14/178,005, filed on February 11, 2014.

properties to prevent migration of chemical compounds to an exterior environment of the film or laminate; and (3) adding additional exterior protections, such as childproofing, to increase the safety associated with packaging of hazardous materials. Ex. 1001, 1:58-2:20.

59. Specifically, the '624 patent identifies Barex[®] as a polymer capable of satisfying the requirements of being chemically resistant toward highly aggressive substances and possessing inert properties to prevent migration. Ex. 1001, 1:58-62. The '624 patent recognizes the wide use of Barex[®] in drug and food applications due to its increased barrier properties compared to other polymers, and further for its chemical resistance toward a number of functional groups, including nicotine. Ex. 1001, 1:58-2:2. Finally, the '624 patent states that, since Barex[®] is heat stable, it can be welded at increased temperatures such that the material can form flexible packaging. Ex. 1001, 2:2-4.

60. The '624 patent discusses a method for providing an aggressive chemical resistant film by providing a base layer resistant to water and/or oxygen, coextruding a tie layer and a contact layer onto the base layer, where the contact layer is made of a COC. Ex. 1001, claim 1, 11:9-25, 13:34-41. Additionally, the loading of the tie layer is in a range from 7 to 20 g/m². Ex. 1001, claim 1, 6:33-

35. The specific layers of the aggressive chemical resistant film identified in the '624 patent are depicted schematically in Figure 2.

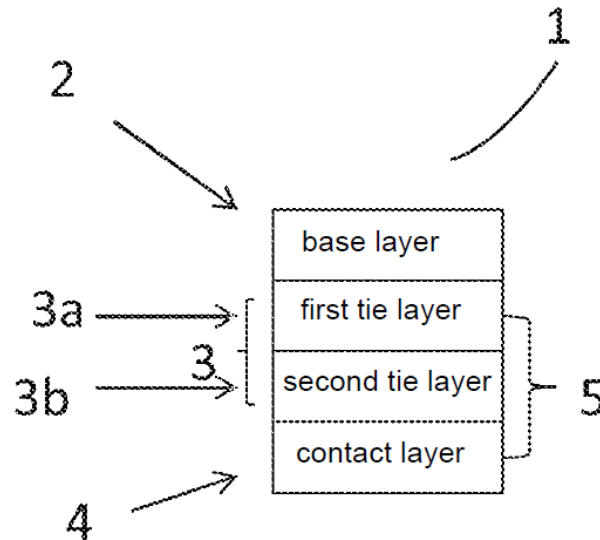


Fig. 2

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

61. According to the '624 patent, forming a coextrusion layer by coextruding the tie layer and the contact layer allows the respective layers to be relatively thinner while still maintaining overall mechanical and chemical robustness, including resulting in better adhesion of the layers that do not separate in a laminated film. EX1001, 2:63–3:3.

62. The '624 patent does not purport to identify the coextrusion process as novel over the prior art. Instead, the '624 patent provides that the coextrusion layer maybe

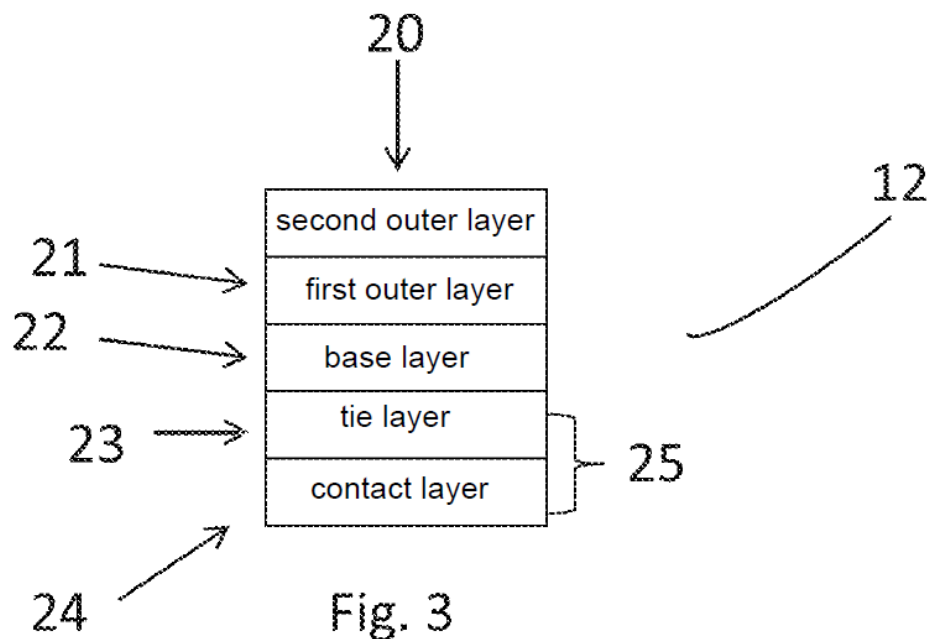
coated to the aluminum surface of the base layer “by a coextrusion system generally known in the art.” Ex. 1001, 13:11-14.

63. The purportedly innovative aspects of the film, according to the ’624 patent, include that COC “has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates,” and that the processing of COC is improved when COC is coextruded with a tie layer polymer “compatible with respect to the melting characteristic” of each of the COC layer and tie layer polymer. Ex. 1001, 6:1–27.

64. I disagree with this supposedly innovative aspect since Topas Advanced Polymers fully recognized and advocated the use of COCs in a variety of polymer processes, including extrusion, and specifically address aspects associated with welding, adhesive bonding and metallization in their 2006 20-page technical brochure. In terms of potential applications, Topas explicitly mentions both pharmaceutical and food packaging.

65. The ’624 patent also provides a method of providing a laminate for packaging an aggressive chemical substance. The laminate includes an outer layer, typically composed of a mechanically wear-resistant material, and the aggressive chemical-resistant film described above. Ex. 1001, 7:54–63. The outer layer can be laminated to the film to provide a laminate “which is easy to wrap, and, it is

ensured that the individual parts of the laminate do not fall apart.” Ex. 1001, 8:3–7. The ’624 patent also provides that the laminate can include a second outer layer on an exterior of the first outer layer, and the second outer layer may be a printed paper layer, for example including the “name, color and/or logo of the product and manufacturer of the product.” Ex. 1001, 8:8–13. The first and second outer layers may have adhesive layers applied therebetween, such as the same material used in the tie layer of the aggressive chemical resistant film. Ex. 1001, 8:14–23, 9:8–13. The specific layers of the laminate are schematically depicted in Figure 3 below.



(’624 patent, Fig. 3 (annotated))

LEVEL OF ORDINARY SKILL IN THE ART

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

67. The claims are generally directed to a method of providing an aggressive chemical resistant film and a laminate including the film. The method provides an oxygen and/or water-resistant base layer including aluminum, coextruding a tie layer and a contact layer of COC, collectively as a coextrusion layer, onto the base layer, where the tie layer has a loading ranging from 7-20 g/m². I have considered the level of skill in the art as it pertains to the claimed invention as a whole and the accompanying specification.

68. By late 2015, the types of problems solved by the claims had already been solved by numerous companies in the industry using known methods of manufacture,

including film (co)extrusion, lamination and heat-sealing of films including COC. Potential problems that could have benefited from additional solutions at that time include, for example, nonuniform wetting (patchy adhesion) of the coextruded layers resulting in long-term thermal instability due to delamination (“peeling”) of the layers during storage and/or application.

69. Even by 2005-06, a decade before the '624 patent, prior-art solutions sought to utilize COC in films used for packaging of food and pharmaceutical articles – articles which might be negatively affected or may otherwise negatively affect their surroundings should volatile components be absorbed by the packing. By then, packaging thin films utilized suitable multilayer film constructs that combined suitable barrier layers, article contact layers, intermediate adhesive layers, and others to provide a reduced scalping effect to ensure product safety. These packaging films utilized COC within the article contact layer, which could have been coextruded with adjacent layers and could have also been present in a heat-sealing layer for making a finished pouch or package from a heat-sealed film or laminate. This design paradigm is expectedly versatile since it can be applied to a wide variety of packaging technologies. The ultimate design of coextruded laminates is that each layer of the laminate serves a particular purpose that is relevant to the target application. Thus, the design in the '624 patent is obvious.

70. The concept of combining polymers with different (and complementary) property sets to achieve a multifunctional material is not new, as polymer blends, physical mixtures of two or more polymers, have been processed and commercialized long before the '624 patent. Most commercially relevant blends are, however, thermodynamically metastable, and their properties can evolve over time as the components strive to reach thermodynamic equilibrium. One way to overcome this problem involves the use of compatibilizing agents (copolymers or other additives) to reduce interfacial tension and/or stabilize the interface dividing chemically dissimilar constituents. This introduces a new challenge associated with the time-dependent competition between self-assembly or aggregation and interfacial restructuring during processing. Another solution to the problem is more engineering-oriented and relies on spatially modulating the different constituent polymers during processing instead of relying on thermodynamic considerations to achieve phase separation. This paradigm has yielded established processes such as coextrusion and bi/tricomponent fiber spinning, which is comparable to coextrusion in fiber, rather than film, form. I have firsthand experience with bi/tricomponent fiber spinning (see my CV) in 2015 and, at that time, the technology was already mature. I believe that it is safe to say that the coextrusion polymer process preceded bi/tricomponent fiber

spinning, as evidenced by the earliest recorded journal publications in 1958 and 1967, respectively. Since the compatibility of adjacent polymer layers can preclude interfacial mixing (thereby reducing, of not eliminating, adhesion), an adhesive (or tie) layer is often included to ensure the stability of the laminate.

71. In assessing the sophistication of the technology and educational level of workers in the field, I considered the educational background of former co-workers and colleagues, as well as (under)graduate students and conference delegates, in relation to the invention of the '624 patent and what the requisite skill set would have looked like.

72. 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.

CLAIM CONSTRUCTION

73. I understand that it is a basic principle of patent law that assessing the validity of a patent claim involves a two-step analysis. In the first step, the claim language

must be properly construed to determine its scope and meaning. In the second step, the claim, as properly construed, must be compared to the alleged prior art to determine whether the claim is valid.

74. My methodology for determining the meaning of claim phrases was first to study the patent carefully. In particular, I studied the claims themselves, followed by the background, detailed specification, figures, and other patent content. Next, I reviewed the prosecution history looking for any clarifications or limitations that might be attached to claim terms. In some circumstances, I looked at other documents, such as references applied by the patent office, for example US Pat. No. 6,120,860 to Bowen and US Pat. App. Pub. No. 2005/0037162 to Adams.

75. I understand that in a post grant review, claim terms are to be given their ordinary and customary meaning as understood by a person of ordinary skill in the art in the context of the entire disclosure at the time of the invention. I understand that one must be careful not to read a specific embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. I further understand that any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision.

76. I understand that this standard is the same as that used in United States district courts, in which claim terms are given their plain and ordinary meaning as would

be understood by a person of ordinary skill in the art at the time of the invention having taken into consideration the language of the claims, the specification, and the prosecution history of record under the Phillips claim construction standard.

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

SUMMARY OF THE APPLIED REFERENCES

Riis (EX. 1004)

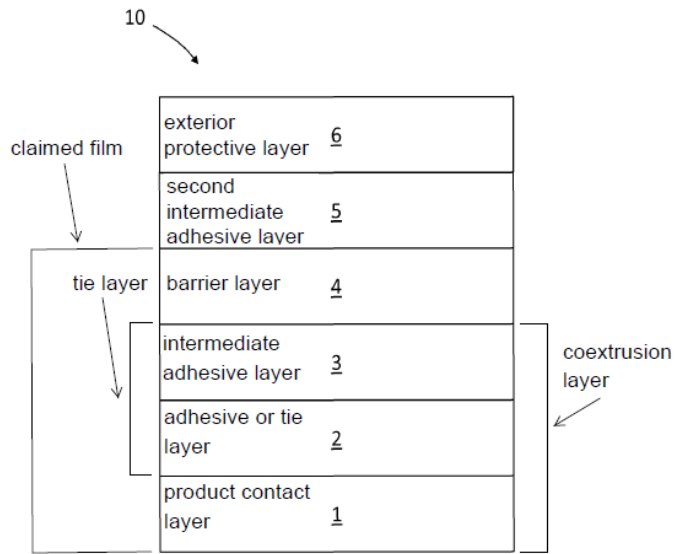
78. Riis is entitled “Anti-Scalping Pharmaceutical Packaging Film,” and provides for a film for packaging and product that has a pharmaceutical active agent. Riis is generally directed to the field of suitable packaging for a physiologically active substance such as transdermal drug-delivery patches. EX. 1004, ¶¶ [0002]-[0003], [0011] (disclosing suitable packaging for transdermal patches for pharmaceutical agents such as fentanyl, nicotine, and lidocaine, wherein the packaging should contain the pharmaceutical ingredient while protecting the patch from contamination and deleterious effects from the external environment).

79. Riis also recognizes a common material employed for the interior surface layer of such transdermal patch packaging includes Barex[®]. Riis similarly recognizes the antiscalping properties of Barex[®] but also identifies various deficiencies of Barex[®] such as the poor tear resistance, high cost, and limited availability. Although the precise reason for the termination of Barex[®] is not known to me other than what I have read on internet sources, I offer some considerations that might have entered into consideration, in addition to the property deficiencies listed above and mentioned by Riis. The Barex[®] resin was a copolymer of acrylonitrile, methyl acrylate and nitrile rubber, modeled in similar fashion as ABS plastic comprised of acrylonitrile, butadiene rubber and styrene. While ABS is used extensively in the automotive industry, acrylonitrile polymers are suited for high-tech applications. In fact, carbonized PAN yields carbon fiber that is used as a stiff, high-strength additive in ubiquitous technologies. A challenging aspect of pure PAN is that it frequently degrades before reaching its T_m at about 320 °C and so it is nontrivial to process in the melt. Alternatively, it dissolves in polar solvents and several aqueous solutions, which is why it is often used as a copolymer in textiles. While the process temperature for Barex[®] with a Vicat softening point of 83 °C is listed as 200 °C, the thermal properties of the copolymer can vary depending on the consistency of the copolymerization.

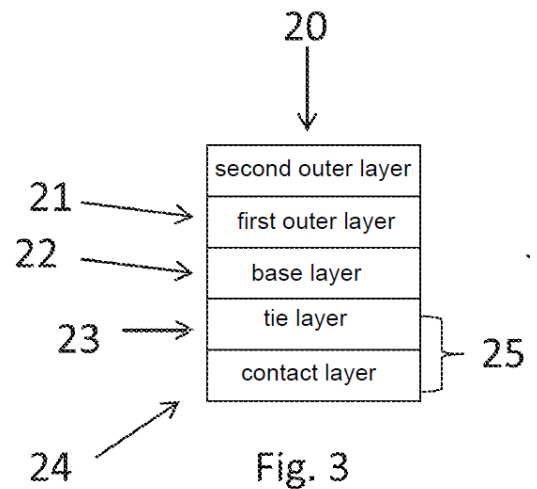
Whatever the reason for Barex[®] termination, it is clear that packaging manufacturers in the pharmaceutical and food industries were quickly searching for alternative materials when the termination was unexpectedly announced.

80. Riis provides a flexible multilayer packaging film suitable for physiologically active substances such as transdermal drug delivery patches. In particular, Riis teaches a chemical-resistant film that can be created through a coextrusion process by coating a coextruded tie layer(s) and a contact layer (also referred to in Riis as a “product contact layer” or an “article contact layer) onto a base layer comprising aluminum, such as aluminum foil (also referred to in Riis as a “barrier layer”). Riis, ¶¶[0012], [0021], and [0052]-[0055], ¶¶[0057]-[0059], [00157]-[00158], [00174]. Riis discusses the various layers that make up the multilayer packaging, including the inner product contact layer, various intermediate and tie layers, barrier layers, and abuse resistant outer layers. Riis also discusses methods of manufacture and various examples.

81. Figure 1 of Riis depicting an exemplary laminate is provided below. Figure 3 of the '624 patent depicts a virtually identical laminate also provided below.



(EX. 1004, Figure 1 (annotated))



('624 patent, Fig. 3 (annotated))

82. Figure 1 of Riis depicts a schematic drawing of a cross section of the multilayer film of Riis including six layers. The multilayer film includes a product contacting layer including an ethylene norbornene copolymer, a polyolefin bulk layer as an adhesive or tie layer adjacent and in contact with the product contacting layer, an intermediate adhesive layer, and an oxygen barrier layer, a second intermediate adhesive layer and exterior protective layer adjacent and in contact with the oxygen barrier layer. EX. 1004, ¶ [0135].

83. The film of Riis is described as having an ethylene norbornene copolymer product contact layer, ethylene norbornene copolymer is a cyclic olefin copolymer (COC). EX. 1004, ¶ [0052]. Further regarding commercially available resins, Riis provides the product contact layers “can also include one or more other properties of Topas[®] cyclic olefin copolymer described in a March 2006 brochure Topas[®] Cyclic Olefin Copolymers’ available from Topas[®] advanced polymers website.” EX. 1004, ¶ [0054]. Riis also mentions that where the contact layer functions as a heat sealing or heat sealable layer the article contact layer comprises only polyethylene norbornene COC. EX. 1004, ¶ [0055].

84. Riis also provides intermediate layers and tie layers of multilayer films, including any layer between the exterior and interior layer. EX. 1004, ¶ [0059]. The tie layers are selected to promote adherence of adjacent layers to one another in the

multilayer film, thus preventing undesirable delamination. EX. 1004, ¶[0071].

Riis further provides materials of table for disclosed intermediate or tie layers.

85. Riis provides a barrier layer that functions as a gas and moisture barrier layer. In discussing the barrier layers oxygen resistance, Riis specifically mentions oxygen sensitive articles and substances such as nicotine or fentanyl transdermal patches to be packaged. EX. 1004, ¶¶ [0058]-[0060]. Riis also provides that the suitable material for the barrier layer includes aluminum foil. EX. 1004, ¶¶ [0062]-[0063].

86. Riis also provides an abuse resistant outer layer, most commonly associated with the exterior layer of any package, bag, or pouch made from the inventive film. EX. 1004, ¶¶ [0066]-[0067].

87. Regarding methods of manufacture Riis provides the multilayer film is made by conventional processes. EX. 1004, ¶ [0082].

88. Riis provides for the manufacture of several example films, with Example 5 according to the film of the present invention and Examples 1-4 providing comparative films (not of the invention). Riis notes that the layers of the example films may be formed by any suitable method, including coextrusion, extrusion coating, and lamination. EX. 1004, ¶¶ [00156]-[00158].

89. The multilayer film of Example 5 includes a base film and connected sealant film, the sealant film including a surface layer designed to contact the article and

provide heat sealing of the multilayer film to form a pouch. Notably, Riis provides the layers of the sealant layer “were either extrusion coated or adhesively laminated.” EX. 1004, ¶ [00160]. Riis provides the “multilayer base film having the following structure: OPET / Primer / PE / EAA / Foil was made and only the connected sealant film was varied.” EX. 1004, ¶ [00160].

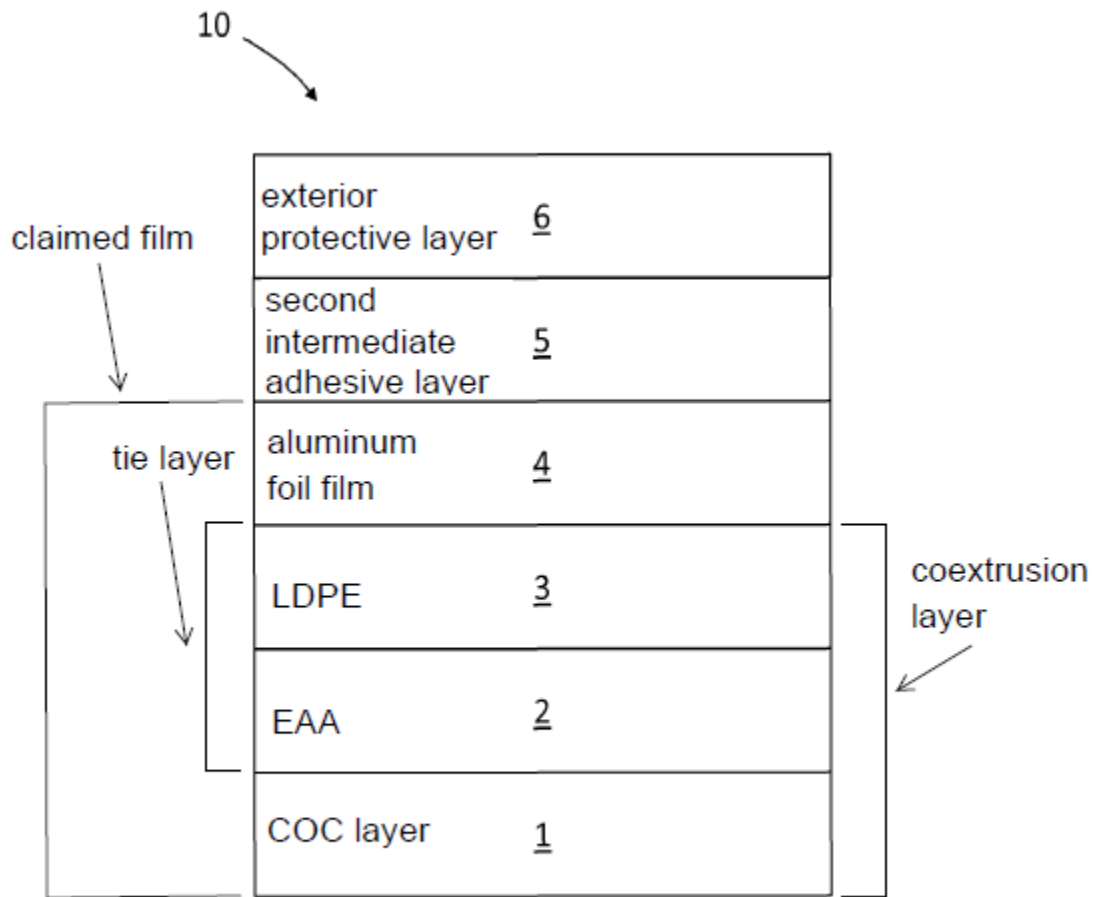


FIG. 1

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

Wypych (EX. 1005)

90. The handbook of polymers, by George Wypych, includes information on all major polymeric materials used in the plastics industry, including material properties of COC, EAA, and LDPE as disclosed polymers of Riis. Wypych provides that data included in the Handbook of Polymers come from literature available from manufacturers or various grades of polymers, plastics, and finished products among other sources. EX. 1005, 4.

91. Wypych notes that “[f]requently, data from different sources vary in a broad range” and must be reconciled by selecting “values closest to their average and values based on testing of the most current grades of materials” in order to provide information characteristic of currently available products. EX. 1005, 4.

Tatarka (EX. 1008)

92. U.S. Patent No. 9,452,593 (“Tatarka”) discloses cyclic olefin copolymers (COC) which are durable and can be used in coextrusion processes with other polymers in “flexible packaging applications.” Tatarka discloses and teaches a variety of cyclic olefin copolymers along with their physical and chemical properties. Tatarka specifically identifies ethylene norbornene copolymer including its melting point.

93. Tatarka further discloses the use of COCs in “flexible packaging applications,” specifically stating that “Durable cycloolefin films can be used alone or coextruded with other polymers, especially polyolefins, to satisfy growing sustainably and resource conservation requirements for new flexible packaging applications, such as bags, pouches, forming films, and form-fill-and-seal films and the like.” Ex. 1008, 3:55-60.
94. With respect to COCs, Tatarka also identifies that COC elastomers, such as those including ethylene norbornene copolymer, “are suitable for device and packaging applications” especially those subject to cold storage environments. Ex. 1008, 13:65-67.
95. Tatarka goes on to disclose that the cyclic olefin copolymers can be combined with other polyolefin layers to create packaging films, which includes polyethylenes, polypropylenes, polybutenes, polymethylpentenes, and others well known in the art. Tatarka specifically discloses the use of different polyethylenes, including LDPE (low density polyethylene), LLDPE (linear low density polyethylene), MDPE (intermediate density polyethylene), and HDPE (high density polyethylene).

PATENTABILITY OF THE CHALLENGED CLAIMS OVER THE APPLIED REFERENCES

Ground 1: Claims 1–13 Are Unpatentable Under 35 U.S.C. § 112(b) As Indefinite

- 1. The '624 fails to inform a POSITA as to the scope of “aggressive chemical-resistant film” with reasonable certainty because it fails to provide any way to determine whether a film is “aggressive chemical-resistant”**

96. In my opinion, the term “aggressive chemical resistant film” renders the claims

indefinite because a POSITA would be unable to determine what types of films meet the claimed aggressive chemical resistant film.

97. I understand the claims are indefinite where (1) different known methods exist

for calculating a claimed parameter, (2) nothing in the record suggests using one method in particular, and (3) application of the different methods results in materially different outcomes for the claim’s scope.

98. I understand that the specification may set forth a special definition given to a

claim term by the patentee that differs from the meaning it would otherwise possess. I also understand that where the special definition is set forth clearly and unmistakably, that definition should control over others.

99. The term “aggressive chemical resistant film” does not have an ordinary and

customary meaning in the art. According to Riis, there is no standardized test for determining whether a film is “aggressive chemical resistant.” Ex. 1004,

¶[00128] (providing that “[w]hether a product contacting layer of a film performs effectively as an anti-scalping layer can be a subjective determination, with differing amounts of migrations of a pharmaceutical active agent into a layer of a film being considered acceptable depending on, among other things, the active agent, the amount that the active agent migrates into layers of other films, and the like).

100. It is my understanding that, in and of itself, does not render the term indefinite if the patent provides sufficient information that a skilled artisan could determine whether the limitation is met. In my opinion, however, it does not provide the necessary information.

101. The '624 patent provides several definitions of what the term “aggressive chemical resistant film” means within the scope of the '624 patent. Each definition is provided below.

- Definition 1: “In the context of the present disclosure aggressive chemical resistant film means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks.” EX. 1001, 5:8-13.
- Definition 2: “The term ‘aggressive chemical resistant film’ means 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 to the packaging material.” EX. 1001, 7:21-25.

- Definition 3: “[T]he term ‘aggressive chemical resistant film’ means a film which when in contact with an aggressive substance does not allow more than 1.5% 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.” EX. 1001, 12:16-22.

102. Each definition requires a determination of whether a film is resistant to aggressive chemical substances by measuring a weight percentage absorption of the aggressive substance into the packaging. EX 1001, 5:5–7. However, each definition measures aggressive chemical resistance by a different percentage.

103. Definition 1 requires that no greater than 1% or 10%—it is unclear which percentage—of the aggressive chemical substance migrate into the packaging after a period of 24 weeks.

104. Definition 2 requires that no greater than 10%, 5%, or 1.5%—it is unclear which percentage—of the aggressive chemical substance migrate into the packaging material.

105. Definition 3 identifies alternative options to meet an aggressive chemical resistant film. Under the first option, Definition 3 requires that no greater than 1.5% of the aggressive chemical substance migrate into the packaging. Alternatively, Definition 3 requires that at least 90% weight of the aggressive chemical substance remain in the packaging when compared against the absorption rate of Barex® as index 100.
106. In my opinion, the term “aggressive chemical resistant film” is indefinite because, in view of the various alternate thresholds define by the patent, would be unable to determine whether the claim limitation is met. The ’624 patent fails to expressly identify which, if any, of the definitions should take priority over the other in determining whether a film is an aggressive chemical resistant film. And a skilled artisan would not recognize any guidepost within the intrinsic evidence from which to determine which definition would take priority. The most unrestrictive level of allowed transfer is $\leq 10\%$ w/w, whereas the most restrictive level is $\leq 1\%$ w/w. It immediately follows that, if the transfer level is $\leq 10\%$ w/w, then any transfer level below 10% w/w would also be allowed. Clearly, though, this expectation is not generally observed in the table below, which summarizes the results presented in the ’624 patent. Thus, the definitions are not consistent with each other. Moreover, within the scope of each definition, additional

inconsistencies are apparent (e.g., being allowed at $\leq 10\%$ w/w by Definition 2 but being unclear at $\leq 1\%$ w/w). Due to the self-contradictory nature of these definitions, a POSITA would be unable to select a single and unambiguous protocol that provides the necessary performance evaluation.

Definition of “aggressive chemical- resistant film”	Amount of transfer to packaging material allowed				
	$\leq 1\%$ w/w	$\leq 1.5\%$ w/w	$\leq 5\%$ w/w	$\leq 10\%$ w/w	90-110% w/w remains vs. Barex® as 100
Definition 1 (after 24 weeks)	Allowed	Unclear	Unclear	Sometimes Allowed	Unclear
Definition 2	Unclear	Sometimes Allowed	Sometimes Allowed	Allowed	Unclear
Definition 3	Unclear	Allowed	Unclear	Unclear	Allowed

107. Applying different definitions of the term “aggressive chemical resistant film” also leads to different outcomes. For example, based on Figure 4, laminate 2 (60% EVOH blend) would not be an “aggressive chemical resistant-film” under Definition 1 because more than 1% of the rivastigmine has migrated to the packaging after only eight weeks. However, laminate 2 would be an “aggressive chemical resistant-film” under any of the limits of Definitions 2 ($<10\%$, $<5\%$, or $<1.5\%$) since Definition 2 provides no time limit of absorption, or Definition 3 ($<1.5\%$).

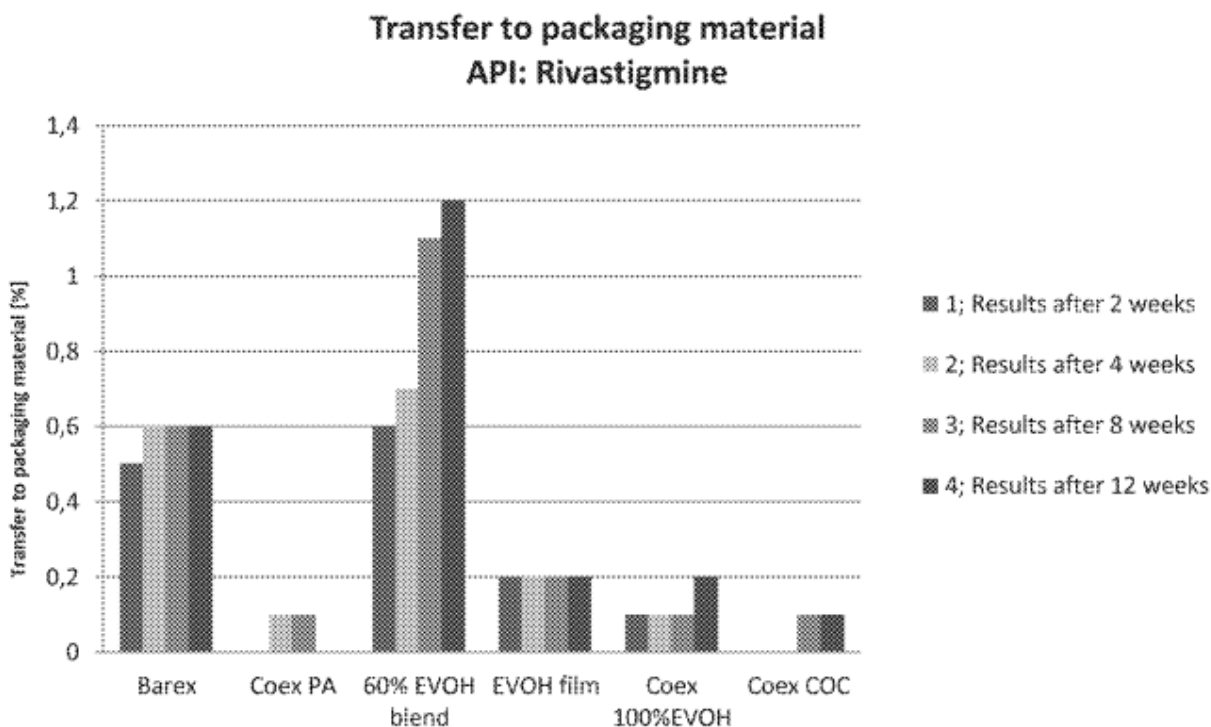
108. In my opinion, the term “aggressive chemical resistant film” is also indefinite because, even if the patent defined the term using consistent thresholds, a skilled artisan would be unable to determine whether the claim limitation is met because the patent fails to provide sufficient parameters to perform testing. In addition to the different testing definitions set forth by the ’624 patent, the ’624 patent fails to provide other necessary information to test exemplary aggressive chemical substances and films. Information necessary to test for an aggressive chemical resistant film includes the following: (1) form of the aggressive chemical substance being tested, such as what form of nicotine, fentanyl, rivastigmine, or lidocaine should be used in the test laminate; (2) concentration of aggressive chemical substance being tested; (3) time of testing and ambient conditions present during testing, such as temperature and humidity, especially with respect to sample storage before determining the amount of aggressive chemical that has migrated into the packaging; and most importantly, (4) the uniformity of which the aggressive substance to be tested is loaded onto the testing packaging. Chemical resistance is fundamentally based on the transfer of a chemical species into a polymer, and this absorption process depends on both the diffusion of the species into the polymer and the solubility of the species within the polymer. The chemical make-up of the species establishes its solubility, whereas factors such

as concentration and environmental conditions (e.g., temperature) determine the diffusivity of the species. Since absorption is a dynamic process, the time of exposure must be constant for comparative purposes. An often neglected consideration is the uniformity of the migrating species, since absorption is the result of unbalanced chemical potentials. If this imbalance spatially varies, then the extent of absorption will likewise vary. To this point, I have personally witnessed considerable variations in transdermal patches containing fentanyl gel wherein the gel was heterogeneously distributed within its patch. This situation would, in turn, affect the rate of transfer to the skin.

109. In some instances, the '624 patent sets forth examples of testing conditions to be used. However, these examples are inconsistent.

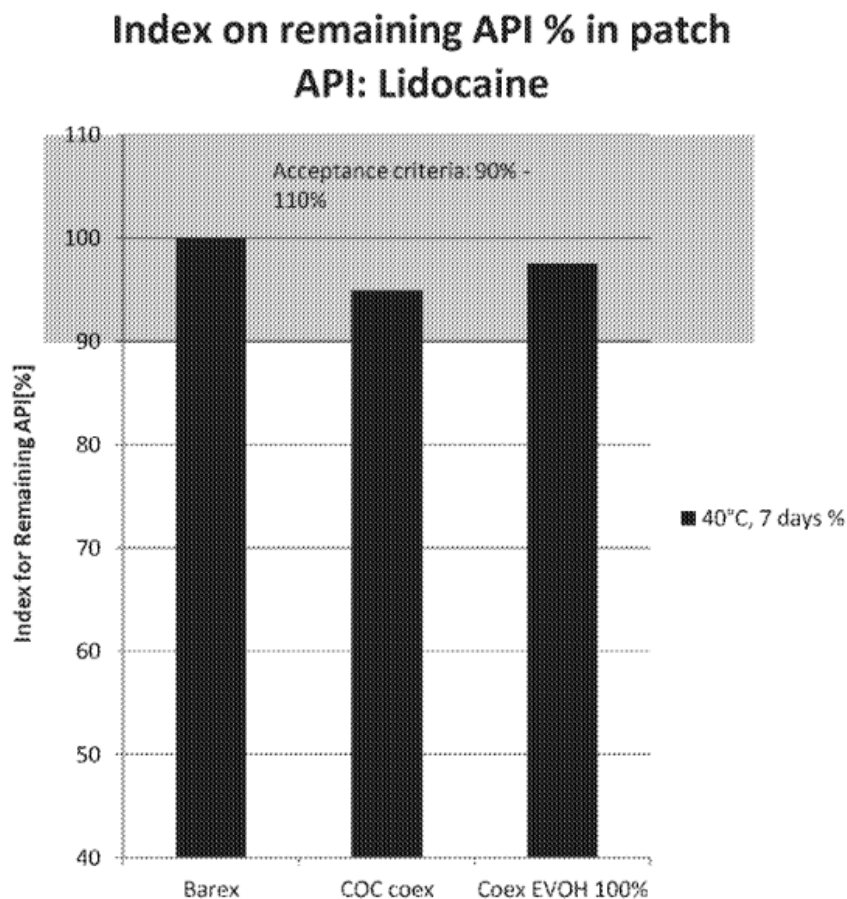
110. In example 1, the '624 patent discloses testing of a patch containing 9.5 mg rivastigmine stored at 40°C for intervals of 2, 4, 8, and 12 weeks. The absorption study results of rivastigmine in example 1 are depicted in Figure 4 below. It is surprising that the tests were performed at different times that are significantly shorter than the 24 weeks required by Definition 1. These results are therefore inconclusive with regard to Definition 1. According to Definitions 2 and 3, there absorption is not time-dependent (since no fixed time is identified), which is clearly contradictory with respect to the experimental results presented in Figure

4 and the physical process of absorption as it is known. In a simple polymer, this process typically follows a saturation curve wherein the saturation limit at long absorption times corresponds to the solubility. Multicomponent polymers including layered materials, can exhibit more complex curves with multiple solubility regimes. Without consistent results evaluated at a fixed time (24 weeks), it remains ambiguous if the results presented in Figure 4 satisfy the requirements of the '624 patent.



('624 patent, Figure 4)

111. In example 2, the '624 patent discloses testing of a patch containing 40 mg of lidocaine at 40°C for seven days. The results of determining a remaining amount of lidocaine are depicted in Figure 5 below.



('624 patent, Figure 5)

112. Neither example 1 nor example 2 of the '624 patent utilize the required time period of 24 weeks required by Definition 1. The time periods set forth in example 1 demonstrate that storage time of the aggressive chemical substance affects the weight percent absorption into the packaging. It is unclear why the

examples provided by the '624 patent would fail to utilize the only time period set forth in a definition yet measure absorption of the aggressive chemical substance at time intervals less than the minimum 24 weeks.

2. The '624 patent fails to inform how “loading” is to be determined

113. Independent claims 1 and 13 and dependent claims 5–7 recite limitations including the “loading” of the tie layer, or portions thereof, falling within a range of “7 to 20 g/m².” Ex. 1001, 18:30–32, 41–49. Similarly, claim 4 recites “the contact layer [having] a loading in the range of 4 to 20 g/m².” Ex. 1001, 18:39–40.

114. “Loading” does not have an ordinary and customary meaning in the art. The term is normally used as a means by which to express composition in a multicomponent polymer system and is often accompanied by “level” to yield “loading level.” More specifically, it frequently refers to the incorporation of additives such as fillers, dyes or pigments into a polymer and is expressed in terms of a fraction, ratio or percent on a mass basis. It is not uncommon to see the loading level alternatively expressed in terms of mass per unit volume of host material (*e.g.*, g/m³). Since the target loading levels of additives inherently depend on the measured mass or the mass density of the constituent species, all species to be considered must be dry (*i.e.*, without any solvent, including water,

present). Therefore, a POSITA would expect that calculated loading levels needed to design the layered extrudates would be based on dry materials and would need to know how the loading levels are calculated prior to coextrusion. Within the scope of the '624 patent, loading means "the amount of polymer left, in the layer when the film has dried." EX1001, 6:38-39. However, this brief definition of loading fails to explain how loading is determined.

115. The '624 patent fails to identify any test methodology or parameters (*e.g.*, time, temperature, humidity) to determine loading. Without such instruction, the only way to ascertain the loading is from calculation of the thickness of each dry polymer layer. The '624 patent also fails to set forth any examples of determining the loading of film layers.

116. The characteristics of a layered construct, a laminate, are routinely expressed in terms of the thickness of each layer in the dry state. As stated earlier, the constituent polymers enter into the extruder in the form of solid-state beads or pellets and they are subsequently heated to transform from the solid- to liquid-state, the latter of which is generically referred to as the melt. Molten polymers proceed through the extruder alone or spatially modulated during coextrusion until they reach the exit die. At this point, the extrudate is subjected to tension to reduce die swell and cooled to induce solidification either through crystallization

or vitrification. The volume of each polymer within a layered extrudate depends on the relative flowability of the polymer (*i.e.*, its viscosity), as well as any remaining die swell, and the cooling rate, which can alter both T_m and T_g .

117. The '624 patent fails to indicate a standard dryness of each polymer layer being measured, only providing that loading is the amount of polymer left “when the film has dried.” It is unclear if the polymer layer is oven dry, dry shortly after extrusion cooling, or dry after 24 weeks of storing an aggressive chemical substance.

118. Without disclosed conditions at the time of polymer layer formation and at the time loading is measured, a POSITA would be unable to determine if a polymer layer has a loading within the ranges provided by the '624 patent.

3. To the extent Patent Owner argues that the construction of “melting point” differs from the ordinary and customary meaning, “melting point” is indefinite

119. Dependent claims 2 and 3 recite “wherein [a / the] melting point of the tie layer differs from a melting point of COC by [30°C / 5-15°C] or less.” EX1001, 18:33-38. Tatarka explicitly recites a “melting point” for COCs. To the extent Patent Owner, 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, claims 2 and 3 are indefinite because a POSITA would not have

understood which of the temperature properties of COC polymers is equivalent to “melting point.”

Ground 2: Riis Renders Claims 1–13 Obvious

120. Riis, although generally directed to anti-scalping pharmaceutical packaging films, provides a specific example multilayer film that substantially mirrors the claimed method for providing an extreme chemical resistant film and laminate. as discussed below, Riis’s inventive film of Example 5 renders the claims of the ’624 obvious.

1. Claim 1

- i. [1.a] “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:”*

121. Riis relates to films resistant to migration of chemicals (anti-scalping films) as used in packaging for products containing a pharmaceutical active agent. EX. 1004, ¶ [0005]. Examples of products containing a pharmaceutical active agent include transdermal patches containing nicotine, fentanyl, and lidocaine. EX. 1004, ¶¶ [0002], [0004]-[0005], [0011]. Riis includes methods of manufacture of the film and additionally provides illustrative film examples utilizing conventional processing techniques for available resins and additives. EX. 1004, ¶¶ [0081]-[0089], [0156]-[0158].

122. Riis also discusses the standard for determining whether the film made is considered effective for anti-scalping purposes, providing for an amount of pharmaceutical chemical migration through the film of no more than 1% as compared to Barex®. EX. 1004, ¶¶ [0127]-[0133]. As discussed in Ground 1 above, the term “aggressive chemical resistant film” as disclosed in the ’624 patent has several definitions that allow for materially different outcomes, one of which limits the nominal content of migration of the aggressive chemical substance to the packaging material to be no more than 1.5% w/w when compared to Barex®. EX. 1001, 12:16-22.

123. A POSITA would understand that films resistant to the migration an active pharmaceutical agent through the film in the amounts of no more than 1% as compared to Barex® would be considered as “and aggressive chemical-resistant film.”

ii. [1.b] “providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;”

124. Riis provides several example films, the first four being comparative examples and Example 5 is an exemplary film according to the inventive film disclosed in Riis, all examples including a base film. The base film has a layered structure including aluminum foil which provides an oxygen and moisture barrier. EX. 1004, ¶¶ [0159]-[0163]. Riis further provides that suitable barriers

including aluminum foil function both as a gas (e.g., oxygen) barrier layer and as a moisture (e.g., water) barrier to protect the package article from undesirable deterioration, oxidative effects, and the deleterious effects of moisture. EX. 1004, ¶¶ [0058]-[0062].

125. A POSITA would understand that Riis discloses a film having a base layer (barrier layer) that includes aluminum foil which provides resistance to both water and oxygen.

iii. [1.c] “coextruding a tie layer and a contact layer to provide a coextrusion layer,”

126. The example films provided in Riis contain a sealant film connected to the base film, the sealant film includes “a surface layer which is designed to contact the article to be packaged e.g. a transdermal patch article.” EX. 1004, ¶¶ [0021], [0160]. The example sealant films “were either extrusion coated or adhesively laminated” to the base film to form the overall film structure. EX. 1004, ¶ [0160]. Regarding Example 5 of the inventive film, the sealant film is a three-layer coextrusion of three polymers, EAA, LDPE, and Ethylene-norbornene copolymer (COC). Ex. 1004, ¶[00174]. The three-layer coextrusion is coated onto the base film. EX. 1004, ¶ [00174].

127. Riis also provides that the layers of the example films can be formed by any suitable method known in the art, including coextrusion. EX. 1004, ¶ [00157].

Regarding the processing of polymers used in the layered film, Riis provides that extruder and coextrusion die temperatures can be selected based on the polymers being used and mixtures being processed. EX. 1004, ¶ [00158].

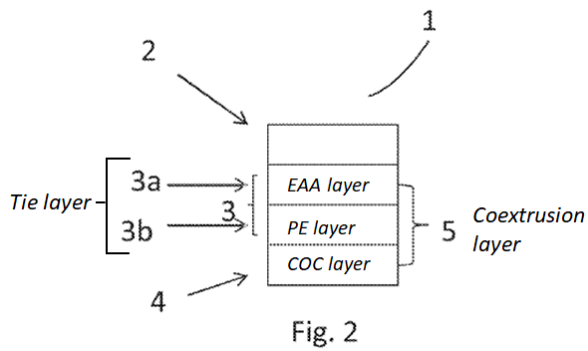
128. Regarding the specific layers coextruded in Example 5 of Riis, Riis confirms that the coextruded ethylene-norbornene copolymer (COC) is the product contact layer. EX. 1004, ¶ [0052] (“[t]he films described herein have a product contact layer containing ethylene norbornene copolymer, which is a cyclic olefin copolymer (COC).”).

129. Regarding the EAA and LDPE layers of the Example 5’s three-layer coextrusion, Riis lists a variety of suitable chemicals to be used in the film adhesive tie layers, including LDPE and EAA as polymeric resins falling in the “olefin” family. EX. 1004, ¶¶ [0068]-[0069] (discussing that an intermediate layer may include a tie layer and may include adhesive, adhesive polymers, and suitable polyolefins, such as polyethylene and polymeric olefin resins like LDPE and EAA). These tie layers are selected to be included as one or more adhesive layers which are used “promote the adherence of adjacent layers to one another in a multilayer film and prevent undesirable delamination,” which aligns with the disclosure of the ’624 patent that “the tie layer is selected provide sufficient adhesion between the base layer and the coextrusion layer.” EX. 1004, ¶ [0071];

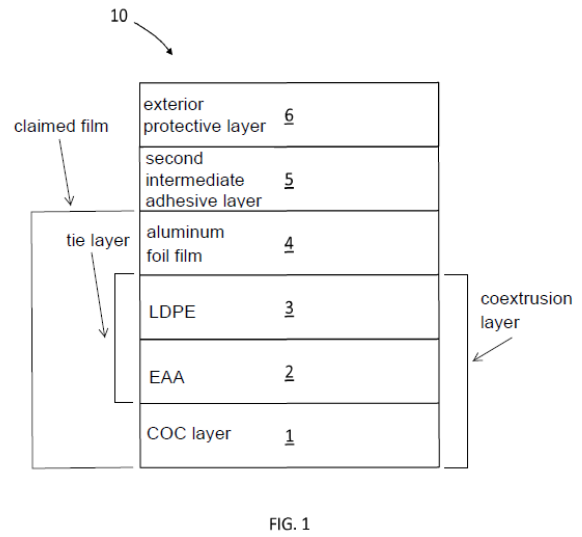
EX. 1001, 4:35-37. Riis also provides the configuration of the tie layer can include “any suitable number of tie or adhesive layers” in the inventive film and that the location of the tie layer can be “between and in direct contact with the barrier layer and the interior layer.” EX. 1004, ¶¶ [0071]-[0072]. Thus, a POSITA would understand that EAA and LDPE as provided in the sealant layer three-layer coextrusion of Example 5 constitute a tie layer selected to act as intermediate adhesive layers.

130. In the '624 patent, Fig. 2 illustrates the claimed film which includes a base layer “2” (containing the aluminum foil) onto which is coextruded the “tie layer” comprising two separate layers, the EAA layer “3a” (tie layer #1) and the LDPE layer “3b” (tie layer #2), and the coextrusion further including the COC layer “4.” Together, the tie layers and contact layer (COC layer) form the “coextrusion layer.” One of skill in the art would recognize that Riis’s example 5, as provided above, include an aluminum foil base layer, EAA, LDPE as tie layers, and a contact layer containing COC, where the tie layer and contact layer are coextruded onto the base layer.

131. An annotated Figure 2 of the '624 patent and an annotated Figure 1 of Riis are provided below as depicting substantially identical configurations of the coextrusion layer on the aluminum foil base layer.



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



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

iv. [1.d] “wherein the contact layer consists of cycloolefin copolymer (COC);”

132. Regarding the specific layers coextruded in Example 5 of Riis, Riis confirms that the coextruded ethylene-norbornene copolymer (COC) is the product contact layer. EX. 1004, ¶ [0052] (“[t]he films described herein have a product contact layer containing ethylene norbornene copolymer, which is a cyclic olefin copolymer (COC).”). Riis provides that commercially available COCs are “available from [Topas®] as an amorphous, transparent copolymer.” EX. 1004, ¶¶ [0052], [0054] (incorporated by reference a March 2006 brochure “Topas® Cyclic Olefin Copolymers”); *see also* EX1019 (Topas Cyclic Olefin Copolymers - March 2006 Brochure). Riis also notes that such COC’s “have previously been used for pharmaceutical, medical and food packaging applications . . . and maybe blended with polyethylene.” EX. 1004, ¶ [0052].

133. I understand that the transitional phrase “consisting of” means “including the following and excluding others and excludes any element, step, or ingredient not specified in the claim.

134. In discussing the additional function of the contact layer as a heat-sealing layer for forming hermetically sealed packages, Riis provides that “[t]he article contact

layer comprises at least 90 wt.% of ethylene norbornene COC, more preferably at least 95 wt.%, endmost preferably 100 wt.%.” EX. 1004, ¶ [0055].

135. Because the only polymer component of the contact layer as disclosed in Riis’s Example 5 is COC, a POSITA would have understood that the contact layer of Example 5 consists of COC.

v. ***[1.e] “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”***

136. As discussed in limitation [1.c] above, Example 5 of Riis’s inventive film provides the sealant film (the claimed coextrusion layer) as a “three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene copolymer (COC) . . . extrusion coated onto the aluminum foil surface of the multilayer base film.” EX. 1004, ¶ [0174]. As explained in limitation [1.c], identifying EAA and LDPE as the tie layer and COC as the contact layer, and [1.d], explaining contact layer consisting of COC, the sealant film of Riis consists of the tie layer and the COC of the contact layer. A POSITA would understand the sealant film three-layer coextrusion being extrusion coated “directly” onto the aluminum surface of the base film.

vi. ***[1.f] “allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,”***

137. Regarding allowing the coextrusion layer to adhere, the '624 patent explains that “[a]fter coating of the aluminum layer and subsequently cooling, the coextrusion layer is adhered to the side of the tie layer facing away from the aggressive chemical substance.” EX. 1001, 13:11-18. The '624 patent also provides “[t]he adhering step iv) preferably occurs instantly for example by cooling the co-extrudate in cooling cylinders during the lamination process.” EX. 1001, 6:65-67.

138. Regarding the processing of resins during coextrusion, Riis provides the following:

Typically the resins and any desired additives are mixed and introduced to an extruder where the resins are melt plastified by heating and then transferred to an extrusion (or coextrusion) die. Extruder and die temperatures will generally depend upon the particular resin or resin containing mixtures being processed and suitable temperature ranges for commercially available resins are generally known in the art, or are provided in technical bulletins made available by resin manufacturers. EX. 1004, ¶ [00158].

139. A POSITA would recognize that product material references provide relevant information concerning physical and processing properties of each material. Thus, a POSITA would look to these references in regard to the polymers used by Riis.

140. One such common reference is The Polymer Handbook authored by Wypych, which provides processing temperatures involved in coating of the coextrusion layer to the base layer. These processing temperatures are well above ambient room temperature. For instance, Wypych teaches that typical extrusion processing temperatures for these materials are 193-288°C for EAA, 199-232°C for LDPE, and 190-240°C for COC. Ex. 1005 at 9, 12, 25. These processing temperatures are all well above room temperature (~20°C). Thus, a POSITA would have found it obvious to cool the coextrusion of Riis's Example 5 to cause it to adhere to form an aggressive chemical-resistant film. Indeed, a POSITA would have understood that the three-layer coextrusion and base layer of Example 5 would have cooled subsequent to coextrusion, causing the coextrusion layer and base layer to adhere. As recognized by the '624 patent, the coextrusion process is known in the art. Tatarka similarly discusses that within the known coextrusion process for forming multilayer plastic films, the coextruded molten materials are "fused together into a layered structure and are allowed to cool." EX. 1008, 19:34-42.

vii. ***[1.g] “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;”***

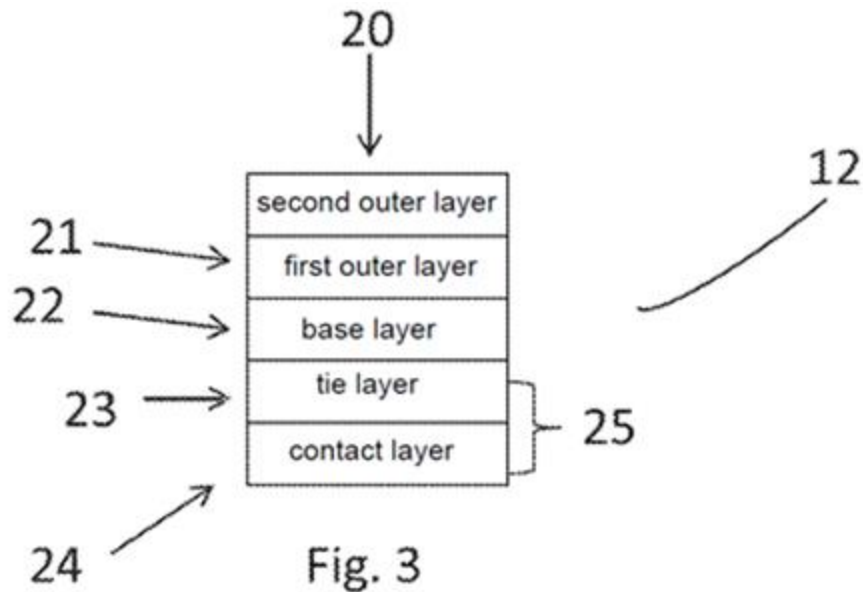
141. As recognized by the '624 patent, a laminate includes an outer layer, typically made of mechanically wear resistant material, and the aggressive chemical resistant film. EX. 1001, 7:54–63; *see also* EX. 1001, 8:8-23 (providing the laminate as including outer layers to the described film). The specification of the '624 patent defines the terms “film” and “laminate” as follows:

The term “film” according to the disclosure contemplates a product comprising a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or base layer laminated with a tie layer and a contact layer.

...

The term “laminate” according to the disclosure contemplates the film to which a further layer is laminated, such as a first outer layer.
Ex. 1001, 11:64-12:8.

142. The specification also discloses embodiments wherein a laminate comprises a film (i.e., a contact layer, tie layer, and base layer) and first and second outer layers, such as that depicted in Figure 3. EX. 1001, 7:54-8:23, 13:51-14:13, 16:17-67.

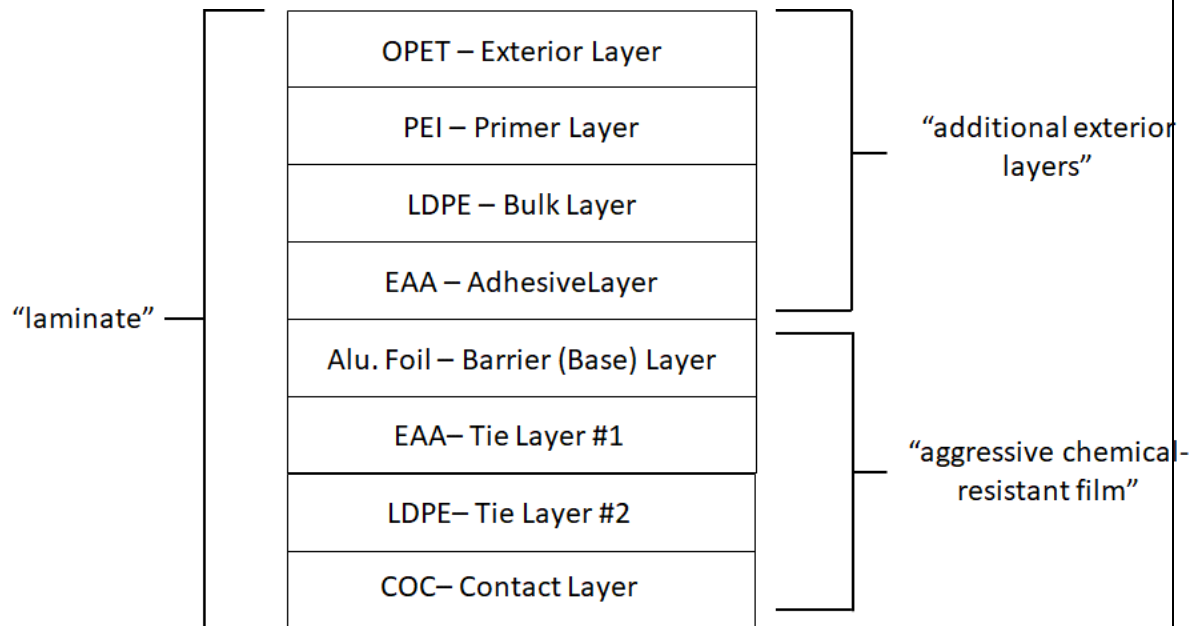


(’624 patent, Figure 3 - annotated)

143. Thus, a POSITA would understand that the term “film” is limited to the contact layer (24), tie layer (23), and base layer (22) and that the term “laminate” includes the film plus any additional layers (21, 20).

144. Riis’s Example 5 comprises a “sealant film” consisting of a product contact layer, a multi-layer tie layer, and a base layer. EX. 1004, ¶[00174]. Specifically, the “sealant film” consists of “a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface” of a “multilayer base layer.” EX. 1004, ¶[00174]. The “sealant film” of Riis’s Example 5 is part of an eight-layer laminate that, like the embodiment of Figure 3 of the ’624 patent, further includes exterior layers. EX.

1004, ¶[00174]. An illustration of the laminate of example 5, including the aggressive chemical-resistant film, is depicted below.



145. Riis teaches a “multilayer base film” of OPET/PEI/LDPE/EAA/Al foil/. EX.

1004, ¶¶[00160]-[00174]. It is noted that in Riis’s examples, (with respect to at least paragraphs [00160]-[00174]) there are inconsistencies as to the spelling of “EAA”. Based on the full disclosure of the examples, it is my opinion that any reference to “EVA” or “EAN” of the base film is a typographical error and instead, as taught in paragraph [00160], [00163], and examples 1-4, the base film includes EAA. Any reference to “EVA” or “EAN” as to these particular paragraphs and examples are understood to reference “EAA.”

146. Referring now back to the base film, a POSITA would have understood that the aluminum foil serves as a water and oxygen resistant “base layer,” as that

term is used in the '624 patent. A POSITA also would have understood that PEI, LDPE, and EAA serve as intermediate or adhesive layers arranged on the side of the aluminum base layer opposite the tie layer and COC layer. Ex. 1004, ¶¶[0068]-[0078], [00174] (noting that “adhesive layers...may also be primers,” e.g., PEI, and that “[s]uitable intermediate layers may include” LDPE and EAA). And a POSITA would have understood that the OPET serves as an abuse-resistant outer layer. Ex. 1004, ¶[0018] (defining “OPET” as “biaxially oriented polyester terephthalate”), ¶[0066]-[0067] (describing “polyester terephthalate” as a “preferred exterior child resistant layer). Accordingly, in the context of the '624 patent, Riis’s three-layer coextrusion “sealant film” along with the aluminum foil base layer forms an “aggressive chemical-resistant film.” Thus, Riis teaches this limitation.

147. I understand that “comprising” means “including the following but not excluding others.”

148. However, even if the exterior and intermediate/adhesive layers are considered part of the “base layer,” Riis’s Example 5 still meets the limitation “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.” Ex. 1001, Claim 1 and 13. The plain language of the

claims requires only “the base layer comprising the aluminum.” EX. 1001, claim 1 and 13. Thus, the composition of the base layer is therefore open-ended. Riis specifies that the three-layer coextrusion (contact layer / tie layer 1 / tie layer 2) of Example 5 “was extrusion coated onto the aluminum foil surface of the multilayer base film.” EX. 1004, ¶[00174]. That “multilayer base film”—OPET/PEI/LDPE/EVA/Al foil—comprises aluminum. EX. 1004, ¶¶[00160]-[00174]. Thus, Riis teaches this limitation even if the base layer is deemed to include the additional outer and intermediate / adhesive layers of Example 5.

viii. [1.h] “wherein the tie layer comprises one or more layers, and”

149. As discussed in limitation [1.c] above, Riis discloses a tie layer further comprising layers of EAA and LDPE as two distinct layers of a “three-layer coextrusion...which was extrusion coated onto the [base layer].” Ex. 1004, ¶[00174]. Thus, Riis teaches this limitation.

ix. [1.i] 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.”

150. To the extent loading is not indefinite, based on the high-level definition found in the '624 patent—“the amount of polymer left, in the layer when the film has dried,” EX1001, 6:38-39—a POSITA would have sought to determine loading based on the known thickness of a polymer layer and the known material densities of each polymer layer.

151. In '624 patent, thickness is expressed in “mils,” where 1 mil = 0.001 inches, which is based on the imperial, not metric, measurement system. However, the '624 patent identifies that loading is expressed in units of “g/m².” This unit of measurement is a scaled version of the SI unit kg/m² used to measure the area density of a two-dimensional object – calculated as mass per unit area. ISO 536:2019. Area density is often used in the paper and pulp industry as a US-standard paper size of pounds (lb) per a ream (500 sheets of a given basis size).
152. To obtain a value of loading as used in the '624 patent, a POSITA would need to know the thickness and mass density of the polymer comprising a specific layer. While the mass densities of polymers can either be obtained from tabulated sources, measured from established protocols or estimated from theoretical frameworks, the layer thickness must be determined from experimental conditions to achieve the desired multifunctional property set of the laminate. Once the layer thickness is known in units of “mils” (M, for the sake of illustration), it can be converted to cm by the following conversion: (M mils) x (0.001 in / 1 mil) x (2.54 cm / 1 in). Since mass densities are generally expressed in units of g/cm³, multiplying the thickness by the mass density yields the area density in g/cm², which can be converted to g/m² via multiplying by (100 cm / 1

m)². All of these calculations implicitly presume that each polymer of interest is dry so that the mass density can be used for calculational purposes.

153. A POSITA would have understood that, by knowing the mass density of a polymer and its layer thickness (expressed in mils), one could determine a loading measurement (expressed in g/m², the units recited in the claims for defining “loading”) from a methodology generally referred to as dimensional analysis. The mass density of a material is an intensive property that relates the mass of the polymer present within a unit volume. The most common unit of measure for mass density is g/cm³. To determine the mass within a layer, the POSITA would know that the mass density would need to be multiplied by the layer thickness (preferably converted from mils to cm) so that the result would be (g/cm³) x (cm) = g/cm². The final manipulation would require the conversion from cm to m (100 cm = 1 m). This type of conversion is commonly taught in STEM courses at the middle and/or high school levels.

154. As discussed above, Riis’s Example 5 teaches a tie layer consisting of coextruded EAA and LDPE layers. EX. 1004, ¶[00174]. Riis discloses the thickness of the EAA layer—0.17 mil—and the LDPE layer—0.65 mil. EX. 1004, ¶[00174].

155. Riis further teaches that certain commercially available EAA and LDPE polymers are “exemplary.” Specifically, Riis teaches that Dupont 3990-L (tradename Nucrel) is an exemplary commercially available EAA polymer and that Dow 4012 is an exemplary commercially available LDPE polymer. EX. 1004, ¶¶[0093], [0095]. A POSITA would have found it obvious to use the polymers disclosed in Riis, as well as other commercially available resins, to create Example 5. EX. 1004, ¶ [00158].

156. Use of these polymers at the thicknesses taught for Example 5 would result in a chemical-resistant film with a tie layer having the claimed loading range. By knowing the thickness of the layer and the density of the polymer used, a skilled artisan could arrive at the unit values for loading recited in the claims— g/m^2 . Riis provides thickness in “mil” units, where 1 mil = 0.001 inch = 0.00254 cm.⁴ Thus, a POSITA could have arrived at the claimed loading unit values— g/m^2 —by (1) multiplying thickness in cm by density in g/cm^3 and (2) converting g/cm^2 to g/m^2 .

⁴ National Institute of Standards and Technology (NIST) Physical Measurement Laboratory, Special Publication 811, Appx B.8: Conversion Factors for Units List Alphabetically (2008) (<https://www.nist.gov/pml/special-publication-811/nist-guide-si-appendix-b-conversion-factors/nist-guide-si-appendix-b8>).

As taught in Riis, a 0.17 mil layer of EAA, which has a density of 0.94 g/cm^3 , has a “loading” as that term is used in the ’624 patent, of 4.06 g/m^2 . A 0.65 mil layer of Dow 4012 (LDPE), which has a density of 0.918 g/cm^3 , has a loading of 15.16 g/m^2 . These are both consistent with sources of density like those in Wypych, which provides a density of EAA as $0.92\text{-}0.96 \text{ g/cm}^3$, which with a 0.17 mil layer has a “loading,” as that term is used in the ’624 patent, of at least $3.97 \text{ g/m}^2\text{-}4.15 \text{ g/m}^2$. Further consistent with Wypych, a 0.65 mil layer of Dow 4012 (LDPE), which has a density of $0.915\text{-}0.929 \text{ g/cm}^3$, has a loading of $15.11 \text{ g/m}^2\text{-}15.34 \text{ g/m}^2$.

157. For the above calculations, Dow NUCREL™ 3990 Product Data Sheet (EX1011) provides the physical properties for Dupont 3990-L as the exemplary commercial resin of “EAA,” including Density determined by ASTM D792 and ISO 1183 test methods. EX1011. This is consistent with sources such as Wypych that provides the physical properties of “EAA,” including the density at 20°C , $0.92\text{-}0.96 \text{ g/cm}^3$. Ex. 1005, 10. It is also noted that Wypych discloses a section identifying “commercial polymers” which includes manufacturers and the tradenames of their products. For EAA, Wypych discloses DuPont Nucrel, which is also listed in Riis. Thus, one of skill in the art would understand that the

physical properties disclosed in Riis would be similar to, or the same as, the commercial polymers listed in the tables of Wypych.

158. Similar to EAA, Dow LDPE 4012 Product Data Sheet (EX1012) provides the physical properties for Dow 4012 as the exemplary commercial resin of “LDPE,” including Density determined by ASTM D792 test method. EX1012. Wypych also discloses the physical properties of “LDPE,” including the density at 20°C, 0.915-0.929 g/cm³. Ex. 1005, 21. Also, like EAA, Wypych discloses a section identifying “commercial polymers” which includes manufacturers and the tradenames of their products. For LDPE, Wypych discloses DOW LDPE, which is also listed in Riis. Thus, one of skill in the art would understand that the physical properties disclosed in Riis would be similar to, or the same as, the commercial polymers listed in the tables of Wypych.

159. Thus, a tie layer consisting of a 0.17 mil layer of EAA and a 0.65 mil layer of LDPE has a “loading” of 19.22 g/m², or as broad as from 19.08 g/m²-19.49 g/m². Example 5, as disclosed in Riis, using EAA and LDPE as the tie layer falls within the claimed range of “7 to 20 g/m².”

x. *Motivation to Combine and Reasonable Expectation of Success*

160. In view of Riis’s disclosures regarding Example 5, a skilled artisan would have been motivated to follow Riis’s disclosure to recreate the film of Example

5 and would have had a reasonable expectation of doing so to arrive at the claimed invention.

161. **Aluminum Base Layer:** All of Riis's examples, including Example 5, use aluminum foil as the base layer. EX1004, ¶¶[00159]-[00174]. Furthermore, Riis teaches that aluminum foil is suitable for use both as an oxygen barrier layer and a moisture barrier layer and therefore advantageously serves as a barrier to both oxygen and moisture. EX1004, ¶¶[0062]-[0063], [0086]-[0087]. Merial teaches that aluminum foil has the advantage of reducing packaging costs by allowing for the use of a thinner and, therefore, less expensive material. Ex. 1013, 4:53-63. Rivers, a patent directed to providing minimally scalping plastic films, teaches that various meta foils, including aluminum, can be used as an oxygen barrier layer. Ex. 1021, ¶¶[0002], [0082], [0088]. Additionally, Liu is directed to films and packages formed for oxygen-sensitive pharmaceutical products that uses aluminum foil as a gas barrier layer since the material is well known in the art for such purpose. Ex. 1015, ¶¶[0001], [0063]. Accordingly, a POSITA would have been motivated to use aluminum foil as the base layer because (1) Riis taught success in doing so, (2) aluminum foil provides suitable oxygen and moisture barrier properties with a single material, and (3) aluminum foil provides costs savings over other barrier materials.

162. **Coextruding an LDPE/EAA Tie Layer:** All of Riis’s examples, including Example 5, coextrude an LDPE layer and EAA layer onto an aluminum base layer. EX1004, ¶¶[00159]-[00174]. Riis further teaches that LDPE can also impede moisture vapor permeation. EX1004, ¶¶[0087]. Furthermore, Merical teaches an embodiment of its film wherein “a tie or adhesive layer may be a coextrusion of low density polyethylene (LDPE) and ethylene acrylic acid copolymer (EAA). Ex. 1013, 9:22-28, 9:59-63. Indeed, Examples 1, 2, 7, 8, 9, and 15 of Merical include an LDPE/EAA coextrusion, referred to as a “tie or adhesive layer” onto foil. Ex. 1013, 18:1-10 (Example 1, Table 1), 18:20-26 (Example 2, Table 2), 19:14-24 (Example 7, Table 4), 19:31-43 (Example 8, Table 5), 19:51-62 (Example 9, Table 6), 20:1-14 (Example 15, Table 8).] Liu also provides an exemplary film structure for packaging pharmaceutical products such as transdermal patches where an outer protective layer was laminated to an aluminum foil barrier layer using a coextrusion of LDPE and EAA. Ex. 1015, ¶¶[0098]-[0103]. Accordingly, a POSITA would have been motivated to coextrude an LDPE layer and EAA layer onto an aluminum base layer because Riis, Merical, and Liu taught success in doing so.

163. **COC:** In view of Riis’s suggestion that Topas COCs—and specifically Topas 8007F-400—for the product contacting layers of its films, a POSITA would have

been motivated to do exactly that when creating Example 5. EX. 1004, ¶¶ [0007], [0054], [0097], [00158]. A POSITA would have been further motivated to use Topas COCs by Topas's own suggestion in its press releases that COC is a suitable replacement for Barex® and its indication that Bemis, the assignee of Riis, was already utilizing Topas COCs in Barex® replacement products. Ex. 1017. For example, knowing that Barex® would no longer be available leaving an opening in the market for replacement materials, a POSITA would have been motivated to try the COCs being touted by Topas for use in Barex® replacement products, just as the artisans at Bemis did. As shown in the March 2006 Topas brochure discussed by Riis⁵, Topas offered five COCs suitable for such uses, designated as 8007, 6013, 6015, 5013, and 6017. Ex. 1019. Given this finite number of identified, predictable solutions, a POSITA would have found it obvious to try those COCs in the contact layer of Example 5. Furthermore, even if they chose to use COCs other than those from TOPAS, a POSITA would have been motivated to use commercially available COCs, like those characterized in Wypych, based on Merial's teaching of the use of COC for the product contacting layer of films used for packaging pharmaceuticals. This is because a

⁵ Riis incorporates by reference the entirety of the March 2006 brochure, "Topas® Cyclic Olefin Copolymers." Ex. 1004, ¶[0054].

POSITA would want to ensure that, upon producing a successful film, the COC used in the contact layer would be available for scaling up film production for commercial purposes.

164. In view of Riis's teachings of how to produce the film of Example 5 and its experimental data demonstrating the successful anti-scalping properties of the film of Example 5, a POSITA would have had a reasonable expectation of success of arriving at the claimed invention. EX1004, ¶¶[00159]-[00197]. This expectation of success would have been further reinforced by Merical's teaching that similar film structures that use COC for the product contacting layer may be used with pharmaceutical products and Jester's discussion of prior-art films employing COC being "suitable or packaging food and drugs." Ex. 1013, 12:3-17 Ex. 1014, ¶¶[0004], [0008].

165. Accordingly, a POSITA would have found claim 1 obvious.

2. Claim 2

i. *"The method according to claim 1, wherein a melting point of the tie layer differs from a melting point of COC by 30° C or less."*

166. This limitation would have been obvious based on Riis's teachings regarding example 5 and exemplary polymers identified in Riis's specification. As discussed above, Riis's example 5 teaches coextruding a tie layer consisting of EAA and LDPE layers with a contact layer consisting of COC. Ex. 1004,

¶[00174]. Riis does not disclose the melting point of the tie layer or COC but does disclose exemplary polymers that are suitable for coextrusion onto a base film. *Id.*, ¶¶[0093]-[0097]. A POSITA would have found it obvious to use the exemplary polymers that Riis discloses to create example 5, and thereby render the claimed invention obvious.

167. Use of EAA, LDPE, and ethylene norbornene copolymer (COC) would result in a chemical-resistant film wherein the melting point of the tie layer differs from the melting point of the COC by 30°C or less. As noted above for the “loading” limitations, Wypych (Ex. 1005) discloses various physical properties for polymers, including EAA and LDPE. Wypych discloses the melting point of EAA is 75°C-112°C (Ex. 1005, 10), and the melting point of LDPE is 105°C-115°C (Ex. 1005, 21). The melting point of ethylene norbornene copolymer (COC) is 60°C-125°C, as disclosed in Tatarka. EX1008, 4:43-47, 13:60-63 (disclosing a melting point of 84°C for E-140), 15:11-13 (teaching that preferred COC polymers have melting temperatures of less than 90°C and more than 60°C). Similarly, the Topas 2006 product brochure teaches that Topas COCs have a glass transition temperature “from about 80°C to 180°C.” EX1019, 8.

Polymer	Melting Point
EAA	75-112°C
LDPE	105-115°C
Ethylene norbornene copolymer (COC)	60-125°C

168. As summarized in the table above, the melting points for each of EAA, LDPE, and COC all overlap. And even an alternative interpretation of the melting point of COC as a glass transition temperature (T_g) overlaps with the melting point ranges of EAA and LDPE. Furthermore, the '624 patent fails to identify any reason that the selection of polymers to obtain the claimed difference in melting points is critical to the claimed invention. Therefore, the melting point of the tie layer differs from the melting point of COC by 30°C or less. Accordingly, for the reasons discussed for claim 1 and because the melting temperature ranges for the relevant polymer polymers overlap, claim 2 is obvious. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018).

3. Claim 3

i. “The method according to claim 2, wherein a melting point of the tie layer differs from the melting point of COC by 5 to 15 °C.”

169. A POSITA would have found claim 3 obvious for the same reasons discussed above for claims 1 and 2. Riis’s example 5 includes a tie layer formed from a layer of EAA, LDPE, and ethylene norbornene copolymer (COC), of which have overlapping melting points at least in the range of 5°C to 15°C.

4. Claim 4

- i. *“The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m². ”*

170. As discussed in limitation [1.i] above, the term “loading” does not have an ordinary and customary meaning in the art. However, a POSITA would understand how to arrive at the unit measurement recited in the claims for the loading range—g/m²—of a polymer based on the mil thickness for each polymer layer taught by Riis and the known density ranges for the polymers taught by Riis.

171. As discussed above, Riis’s Example 5 teaches a contact layer consisting of COC. EX. 1004, ¶¶ [0052], [0055] (providing the article contact layer “consisting of” COC), [0174]. Riis does not disclose a loading range but does disclose the thickness of the COC layer as 0.43 mil. EX. 1004, ¶[00174]. Riis further teaches that the density of the product contacting layers of the films described have a density of 1.02 g/cm³. EX. 1004, ¶[0054]. This is consistent with Riis’s teaching of Topas 8007F-400, which has a density of 1.02 g/cm³, as an exemplary commercially available COC resin for use in the present invention. EX. 1004, ¶[0097]; Topas 2006 brochure, pg. 7⁶. This is also consistent with Wypych’s

⁶ The March 2006 brochure lists a density of 1.02 g/cm³ for all Topas COCs discussed, which includes those designated 8007, 6013, 6015, 5013, 6017.

teaching that the densities of commercially available COCs, including “Topas COC,” range from 1.00-1.08 g/cm³. Ex. 1005, 7.

172. Use of Topas 8007F-400, or indeed any of the Topas polymers listed in the 2006 brochure, at the thicknesses taught for Example 5 would result in a chemical-resistant film with a contact layer falling within the claimed loading range. By knowing the mil thickness of a polymer layer and the known material densities of each polymer layer, loading in g/m² can be calculated. Riis provides thickness in “mil” units, where 1 mil = 0.001 inch = 0.00254 cm.⁷ Thus, g/m² can be determined by (1) multiplying thickness in cm by density in g/cm³ and (2) converting g/cm² to g/m². Here, a 0.43 mil layer of Topas 8007F-400, which had a density of 1.02 g/cm³, would have had a loading of 11.14 g/m². And even if a POSITA chose to use other commercially available COCs, a 0.43 mil layer of commercially available COC, which, in view of Wypych, would have had a density of 1.00-1.08 g/cm³, would have had a loading of 10.92-11.80 g/m². EX1005, 7. Accordingly, practice of Riis’s example 5 would have resulted in a

⁷ National Institute of Standards and Technology (NIST) Physical Measurement Laboratory, Special Publication 811, Appx B.8: Conversion Factors for Units List Alphabetically (2008) (<https://www.nist.gov/pml/special-publication-811/nist-guide-si-appendix-b-conversion-factors/nist-guide-si-appendix-b8>).

loading of the COC contact layer falling within the claimed range of “4 to 20 g/m².”

173. Accordingly, for the reasons discussed above and for claim 1, a POSITA would have found claim 4 obvious.

5. Claim 5

i. “The method according to claim 1, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².”

174. The language of claim 5 is nearly identical to the limitation [1.i] recited in claim 1. Claim 5 additionally requires a loading of the “entirety” of the tie layer to be in a range of 7 to 20 g/m².

175. A POSITA would understand a loading of an “entirety” of a tie layer as disclosed in the ’624 patent to denote including the loading of all of the component layers that make up the tie layer. EX. 1001, 6:33-37 (disclosing “tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m²”); 13:34-46 (providing an example of a tie layer comprising two layers).

176. Similarly, Riis’s Example 5 teaches a tie layer consisting of coextruded EAA and LDPE layers. EX. 1004, ¶¶[0071]-[0072] (providing the inventive film can comprise any suitable number of tie or adhesive layers), [00174].

177. Riis further teaches that Dupont 3990-L (tradename Nucrel) is an exemplary commercially available EAA polymer and that Dow 4012 is an exemplary commercially available LDPE polymer. EX. 1004, ¶¶[0093], [0095]. A POSITA would have found it obvious to use the polymers disclosed in Riis, as well as other commercially available resins, to create Example 5. EX. 1004, ¶ [00158].
178. As discussed in limitation [1.i] above, the '624 patent does not specify how to determine loading of a tie layer comprising two resin layers. However, a POSITA would have understood that loading, i.e., “the amount of polymer left, in the layer when the film has dried,” of a tie layer comprising two resin layers is represented by the sum of the loading of the two layers.
179. Thus, a tie layer consisting of a 0.17 mil layer of EAA and a 0.65 mil layer of LDPE has a “loading” of 19.22 g/m^2 , or as broad as from 19.08 g/m^2 - 19.49 g/m^2 . Example 5, as disclosed in Riis, using EAA and LDPE as the tie layer falls within the claimed range of “7 to 20 g/m^2 .”
180. Because a POSITA would have found it obvious to use the exemplary polymers taught by Riis to create Riis’s Example 5, Riis teaches this limitation.

6. Claim 6

- i. *“The method according to claim 1, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².”*

181. The language of claim 6 is nearly identical to the limitation [1.i] recited in claim 1. Claim 6 additionally requires a loading of “at least a portion of” the tie layer to be in a range of 7 to 20 g/m².

182. A POSITA would understand a loading of “at least a portion of” a tie layer as disclosed in the '624 patent to denote including the loading of one, a portion of one, all, or a portion of all of the component layers that make up the tie layer. EX. 1001, 6:33-37 (disclosing “tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m²”); 13:34-46 (providing an example of a tie layer comprising two layers).

183. Similarly, Riis’s Example 5 teaches a tie layer consisting of coextruded EAA and LDPE layers. EX. 1004, ¶¶[0071]-[0072] (providing the inventive film can comprise any suitable number of tie or adhesive layers), [00174]. Riis does not disclose a loading range but does disclose the thickness of the EAA layer—0.17 mil—and the LDPE layer—0.65 mil. EX. 1004, ¶[00174].

184. Riis further teaches that Dupont 3990-L (tradename Nucrel) is an exemplary commercially available EAA polymer and that Dow 4012 is an exemplary commercially available LDPE polymer. EX. 1004, ¶¶[0093], [0095]. A POSITA

would have found it obvious to use the polymers disclosed in Riis, as well as other commercially available resins, to create Example 5. EX. 1004, ¶ [00158].

185. As discussed in limitation [1.i] above, a 0.65 mil layer of LDPE, which has a density of 0.918 g/cm^3 , or as broad as from $0.915\text{-}0.929 \text{ g/cm}^3$, and thus has a loading of 15.16 g/m^2 , or as broad as from $15.11 \text{ g/m}^2\text{-}15.34 \text{ g/m}^2$. A POSITA would understand that the loading of the 0.65 mil LDPE layer as a portion of the tie layer falls within the claimed range of “7 to 20 g/m^2 .”

186. As discussed in limitation [1.i] above, the '624 patent does not specify how to determine loading of a tie layer comprising two resin layers. However, a POSITA would have understood that loading, i.e., “the amount of polymer left, in the layer when the film has dried,” of a tie layer comprising two resin layers is represented by the sum of the loading of the two layers. Thus, a tie layer consisting of a 0.17 mil layer of EAA and a 0.65 mil layer of LDPE has a “loading” of 19.22 g/m^2 , or as broad as from $19.08 \text{ g/m}^2\text{-}19.49 \text{ g/m}^2$ Example 5, as disclosed in Riis, using EAA and LDPE as the tie layer falls within the claimed range of “7 to 20 g/m^2 .”

187. Because a POSITA would have found it obvious to use the exemplary polymers taught by Riis to create Riis's Example 5, Riis teaches this limitation.

7. Claim 7

- i. *“The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers is in the range of 7 to 20 g/m².”*

188. The language of claim 7 is nearly identical to the limitation [1.i] recited in claim 1. Claim 7 additionally requires “wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers” to be in a range of 7 to 20 g/m².

189. A POSITA would understand a loading of a plurality of the layers of a tie layer as disclosed in the '624 patent to denote including the loading of all of the component layers that make up the tie layer. EX. 1001, 6:33-37 (disclosing “tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m²”); 13:34-46 (providing an example of a tie layer comprising two layers).

190. Similarly, Riis’s Example 5 teaches a tie layer consisting of coextruded EAA and LDPE layers. EX. 1004, ¶¶[0071]-[0072] (providing the inventive film can comprise any suitable number of tie or adhesive layers), [00174]. Riis does not disclose a loading range but does disclose the thickness of the EAA layer—0.17 mil—and the LDPE layer—0.65 mil. EX. 1004, ¶[00174]. Riis further teaches that Dupont 3990-L (tradename Nucrel) is an exemplary commercially available

EAA polymer and that Dow 4012 is an exemplary commercially available LDPE polymer. EX. 1004, ¶¶[0093], [0095]. A POSITA would have found it obvious to use the polymers disclosed in Riis, as well as other commercially available polymers, to create Example 5. EX. 1004, ¶ [00158] (providing that processing parameters “for commercially available resins . . . are provided in technical bulletins made available by resin manufacturers).

191. As discussed in limitation [1.i] above, a POSITA would have understood to calculate loading by (1) multiplying thickness in cm by density in g/cm^3 and (2) converting g/cm^2 to g/m^2 . Here, a 0.17 mil layer of EAA, which has a density of 0.94 g/cm^3 , or as broad as from $0.92\text{-}0.96 \text{ g/cm}^3$, has a “loading,” as that term is used in the ’624 patent, of 4.06 g/m^2 , or as broad as from $3.97 \text{ g/m}^2\text{-}4.15 \text{ g/m}^2$. A 0.65 mil layer of LDPE, which has a density of 0.918 g/cm^3 , or as broad as from $0.915\text{-}0.929 \text{ g/cm}^3$, has a loading of 15.16 g/m^2 , or as broad as from $15.11 \text{ g/m}^2\text{-}15.34 \text{ g/m}^2$.

192. As discussed in limitation [1.i] above, the ’624 patent does not specify how to determine loading of a tie layer comprising two resin layers. However, a POSITA would have understood that loading, i.e., “the amount of polymer left, in the layer when the film has dried,” of a tie layer comprising two resin layers is represented by the sum of the loading of the two layers. Thus, a POSITA would understand

that a tie layer consisting of a 0.17 mil layer of EAA with a loading of at least 4.06 g/m², or as broad as from 3.97 g/m²-4.15 g/m², and a 0.65 mil layer of LDPE with a loading of 15.16 g/m², or as broad as from 15.11 g/m²-15.34 g/m², has a total “loading” of 19.22 g/m², or as broad as from 19.08 g/m²-19.49 g/m². Example 5, as disclosed in Riis, using EAA and LDPE as the tie layer falls within the claimed range of “7 to 20 g/m².”

193. Because a POSITA would have found it obvious to use the commercially available resins taught by Riis to create Riis’s Example 5, Riis teaches this limitation.

8. Claim 8

i. “The method according to claim 1, wherein the one or more layers of the tie layer consists of two layers.”

194. As discussed in limitations [1.c] and [1.h] above, Riis discloses a tie layer further comprising layers of EAA and LDPE as two distinct layers of a “three-layer coextrusion...which was extrusion coated onto the [base layer].” Ex. 1004, ¶[00174]. Example 5 of Riis does not disclose any additional layers between the aluminum foil surface of the base film and the COC contact layer. Thus, the EAA and LDPE layers are the only two layers that make up the tie layer disclosed by Riis’s Example 5. Accordingly, the tie layer of Example 5 consists of two layers—one EAA layer and one LDPE layer. Ex. 1004, ¶[00174].

9. Claim 9

- i. “The method according to claim 1, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.”*

195. As discussed in limitation [1.c] above, the example sealant films (coextrusion layer) of Riis “were either extrusion coated or adhesively laminated” to the base film to form the overall film structure. EX. 1004, ¶ [0160]. Riis also provides that the layers of the example films “may be formed by any suitable method including coextrusion.” EX. 1004, ¶ [0157].

196. Regarding Example 5 of the inventive film, the sealant film is a “three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene copolymer (COC)” extrusion coated onto the base film. EX. 1004, ¶ [0174] (emphasis added). A POSITA would understand the sealant film three-layer coextrusion being extrusion coated onto the base film to be “coating the coextrusion layer to the base layer [by] a coextrusion coating.”

10.Claim 10

- i. “The method according to claim 1, wherein at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer.”*

197. As discussed in limitation [1.c] above, a POSITA would understand that EAA and LDPE as provided in the sealant layer three-layer coextrusion of Example 5 constitute a tie layer selected to act as intermediate adhesive layers.

198. Riis identifies EAA as “ethylene acrylic acid copolymer” and LDPE as “low density polyethylene.” EX. 1004, ¶¶[0018], [0027] (identifying LDPE as a “broad grouping of polyethylene”), [0085], [0093] (identifying Dupont 3990-L (tradename Nucrel) as a commercially available EAA resin), [0095] (identifying Dow 4012 as a commercially available LDPE resin); *see also* EX. 1005, 10 (“commercial polymers” section identifies DuPont Nucrel as a poly(ethylene-co-acrylic acid)(EAA)); EX. 1005, 21 (“commercial polymers” section identifies Dow LDPE as a “low density polyethylene” (LDPE)). A POSITA would understand ethylene acrylic acid copolymer as an acrylic acid layer and would further understand low density polyethylene, as a broad grouping of polyethylene, to be a polyethylene layer.

11.Claim 11

- i. “The method according to claim 1, wherein the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer.”*

199. The language of claim 11 is nearly identical to the language of claim 10, except that claim 11 requires the tie layer to comprise “an acrylic acid layer and a polyethylene layer.” As discussed in limitation [1.c] and in claim 10 above, the tie layer of Riis Example 5 includes EAA (an acrylic acid layer) and LDPE (a polyethylene layer). Accordingly, a POSITA would have found Example 5 of Riis renders this claim obvious.

12.Claim 12

- i. “The method according to claim 11, wherein the acrylic acid layer comprises ethylene acrylic acid.”*

200. Claims 12 depends from claim 11 and further requires that the acrylic acid layer includes an ethylene acrylic acid layer. As discussed in limitation [1.c] and claims 10 and 11 above, the tie layer of Riis Example 5 includes EAA and LDPE. As also discussed in claim 10 above, Riis identifies EAA as “ethylene acrylic acid copolymer,” with Dupont 3990-L (tradename Nucrel) as a commercially available EAA resin described as “a copolymer of ethylene and acrylic acid.” EX. 1004, ¶¶[0085], [0093] (identifying Dupont 3990-L as a commercially available EAA resin); *see also* EX. 1005, 10 (“commercial polymers” section identifies DuPont Nucrel as a poly(ethylene-co-acrylic acid)(EAA)). A POSITA would understand that the ethylene acrylic acid copolymer used in Example 5 of Riis renders this claim obvious.

13.Claim 13

201. The language of independent claim 13 is similar to the language of independent claim 1 but differs in at least two aspects. First, claim 13 requires “[a] method for providing a laminate, wherein the laminate comprises an aggressive chemical-resistant film,” whereas claim 1 merely requires the aggressive chemical-resistant film. Second, the specific chemical resistance to

nicotine, fentanyl, rivastigimine, or lidocaine recited in the preamble of claim 1 has been moved to the body of claim 13.

202. Claim 13 requires all of the method steps of claim 1 for providing an aggressive chemical-resistant film. As discussed in limitation [1.g] above, a POSITA would understand that a laminate according to the '624 patent includes the film, limited to the contact layer, tie layer, and base layer, and further includes any additional layers adhered or laminated to the film. EX. 1001, 11:64-12:8 (defining the terms “film” and “laminate”); *see also* EX. 1001, 7:54-63 (providing that a laminate includes an outer layer and an aggressive chemical resistant film).

203. As discussed in claim 1 above, Riis teaches an aggressive chemical resistant film of independent claim 1.

204. Regarding the laminate of claim 13, Example 5 of Riis teaches an eight-layer laminate comprising an aggressive chemical-resistant film. As depicted below, the film has the following layers (from exterior to product-contacting interior): OPET (abuse-resistant outer layer) / PEI (intermediate / primer layer) / LDPE (intermediate / adhesive layer) / EAA (intermediate / adhesive layer) / Al foil (base layer) / EAA (first tie layer) / LDPE (second tie layer) / COC (contact layer). Ex. 1004, ¶¶[00161]-[00168], [00173]-[00174]. The Al foil / EAA / LDPE

/ COC layers constitute the claimed “film,” and, in combination with the remaining layers, make up the claimed “laminate.”

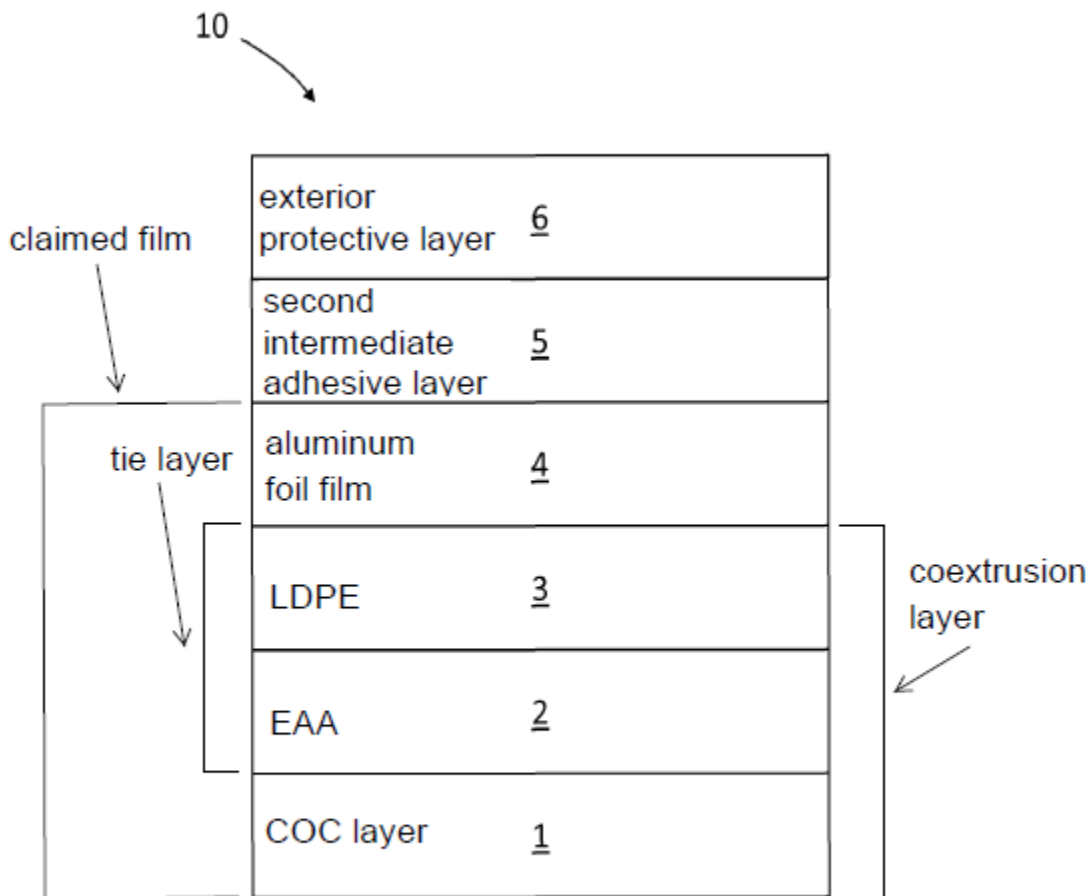


FIG. 1

(EX. 1004, Figure 1 (annotated))

205. A POSITA also would have understood that PEI, LDPE, and EAA serve as intermediate or adhesive layers arranged on the side of the aluminum base layer opposite the tie layer and COC layer. Ex. 1004, ¶¶[0068]-[0078], [00174] (noting that “adhesive layers...may also be primers,” e.g., PEI, and that “[s]uitable

intermediate layers may include” LDPE and EAA). And a POSITA would have understood that the OPET serves as an abuse-resistant outer layer. Ex. 1004, ¶[0018] (defining “OPET” as “biaxially oriented polyester terephthalate”), ¶[0066]-[0067] (describing “polyester terephthalate” as a “preferred exterior child resistant layer). Accordingly, in the context of the ’624 patent, Riis’s outer protective OPET layer serves as an additional layer adhered or laminated to the aggressive chemical-resistant film that is limited to the base layer, tie layer, and contact layer. Thus, Riis teaches this claim.

i. Motivation to Combine and Reasonable Expectation of Success

206. In view of Riis’s disclosures regarding Example 5, a skilled artisan would have been motivated to follow Riis’s disclosure to recreate the eight-layer laminate comprising an aggressive chemical-resistant film of Example 5 and would have had a reasonable expectation of doing so to arrive at the claimed invention.

207. For at least all of the reasons discussed with respect to claim 1 above, a POSITA would have been motivated to use an aluminum foil as the base layer, coextrude an LDPE layer and an EAA layer onto the aluminum base layer, and use a commercially available COC polymer for the product contacting layer of the aggressive chemical-resistant film. *Supra* ¶¶ 159-62. Further for at least the

reasons discussed with respect to claim 1 above, a POSITA would have had a reasonable expectation of success in arriving at the claimed method of providing an aggressive chemical-resistant film in light of Riis's teachings of how to produce the film of Example 5 and its experimental data demonstrating successful anti-scalping properties. *Supra* ¶ 163.

208. A POSITA would have further been motivated to follow Riis's disclosure to recreate the laminate of Example 5 because chemically resistant films disclosed in the art are implemented in a practical end-product packaging by laminated exterior layers to the film. Riis discloses that "[s]ince [the film] is seen by the user/consumer . . . the exterior surface of the film preferably has desirable optical properties," and also "preferably withstands contact with sharp object and provides abrasion resistance." Ex. 1004, ¶[0067]. Riis terms the outer layer an exterior abuse-resistant layer that is most often "the exterior layer of any package, bag, pouch or other container made from the inventive film." *Id.* In addition to provide abuse resistance to external abrasive forces, the outer layers "may be touch to impart resistance to opening by children," thus making the film safe for distribution to consumers in the form of a laminate package containing the film. *Id.*

209. A POSITA would have also been motivated to follow Riis's disclosure of Example 5 to create a laminate including the chemically resistant film since it was known that film forming steps like coextrusion could be coupled with lamination to exterior protective layers to form final packaging. For example, Jester teaches preparing multilayer films containing COC within the contact layer by suitable methods, including co-extrusion and lamination. Ex. 1014, ¶[0043]-[0044]. As an example, Jester teaches utilizing coextrusion to form a film comprising COC and polyethylene, then subsequently laminating onto a paperboard layer. *Id.*, ¶[0044]. Merical additionally teaches the use of a formed chemically resistant film to be laminated to other film layers, such as optional printed layers and an outer abuse layer, in order to form suitable packaging. Ex. 1013, 9:63-10:12. Rivers also teaches the use of "one or more structural or abuse layers that can serve to resist abrasion, puncture, and/or other potential causes of reduction of package integrity," and that such abuse layer can be provided with "graphic elements such as printing and embossing to provide information for the consumer and/or a pleasing appearance to the package." Ex. 1021, ¶¶[0089], [0090]. Accordingly, a POSITA would have been motivated to form the example laminate of Riis's Example 5 by incorporating the aggressive chemical resistant

film into an end-user package, such as a pouch, by further adding an abuse resistant outer layer to the film to form a laminate packaging.

210. In view of Riis's teachings of how to produce the laminate of Example 5, as further reinforced by at least Jester's, Merical's, and Rivers's teachings of similar multilayer films laminated with outer abuse resistant layers, a POSITA would have had a reasonable expectation of success in forming a laminate comprising an aggressive chemical resistant film. Ex. 1013, 9:63-10:12; Ex. 1014, ¶¶[0043]-[0044]; Ex. 1021, ¶¶[0089]-[0090].

Ground 3: The Combination of Riis, Wypych, and Tatarka Renders Claims 1–13 Obvious

211. Ground 3 relies on the teachings of Riis, Wypych, and Tatarka to render claims 1–13 unpatentable as obvious. Riis provides specific polymers used in the manufacture of an aggressive chemical-resistant film except for specific materials properties, such as the loading ranges and relative melting points of the component tie layer and contact layer. A POSITA would have found it obvious to look to references such as Wypych and Tatarka to determine these missing materials properties. Both Wypych and Tatarka show that the materials properties of the types of polymers taught by Riis exhibit ranges overlapping with those of the challenged claims, thereby rendering them obvious. In general, materials design requires examination of material properties to ensure that the properties

will satisfy the application requirements. The materials selection process is based on rational and thorough determination of material properties and is not at all random. The onus is on the designer to ensure that due diligence is exercised with regard to prior publications, patents and other reference sources (such as property or data handbooks or electronic databases) prior to selection of a material for a specific application. This selection process is particularly important with regard to polymers due to the property variations available. A POSITA involved in packaging manufacture would have examine all available literature regarding the use of COCs in multilayer packaging prior to developing a particular design.

1. Claim 1

- i. [1.a] “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:”**

212. Riis teaches this same limitation for the same reasons discussed in Ground 2, limitation [1.a] above.

- ii. [1.b] “providing a base layer, wherein the base layer comprises aluminum and is resistant to one or more of water or oxygen;”**

213. Riis teaches a multilayer base film that includes a barrier layer to serve as both a gas and moisture barrier layer. EX. 1004, ¶¶[0058]-[0059], [00159]-[00163]. Riis’s barrier layer “provide[s] an oxygen permeability sufficiently diminished to protect the packaged article from undesirable deterioration or oxidative

processes.” EX. 1004, ¶[0060]. Riis’s barrier layer also “provide[s] a moisture permeability sufficiently diminished to protect the packaged article from undesirable deterioration.” EX. 1004, ¶[0061]. To accomplish the disclosed function of acting as both a gas and moisture barrier layer, Riis provides that its barrier layer “can comprise any suitable material,” specifically identifying aluminum foil. EX. 1004, ¶¶[0062]-[0063]. Furthermore, as discussed for Ground 2, limitation [1.b], Riis’s example 5 includes an aluminum foil base layer. Thus, Riis teaches this limitation.

iii. [1.c] “coextruding a tie layer and a contact layer to provide a coextrusion layer,”

214. Riis teaches a multilayer laminate that includes a tie layer and contact layer.

Riis’s Figure 1 depicts a cross-section of a six-layer laminate, wherein the layers are (from interior contact layer to exterior): (1) product contacting layer, (2) polyolefin bulk layer, (3) intermediate adhesive layer, (4) oxygen barrier layer, (5) second intermediate adhesive layer, (6) exterior protective layers. Ex. 1004, ¶[00135].

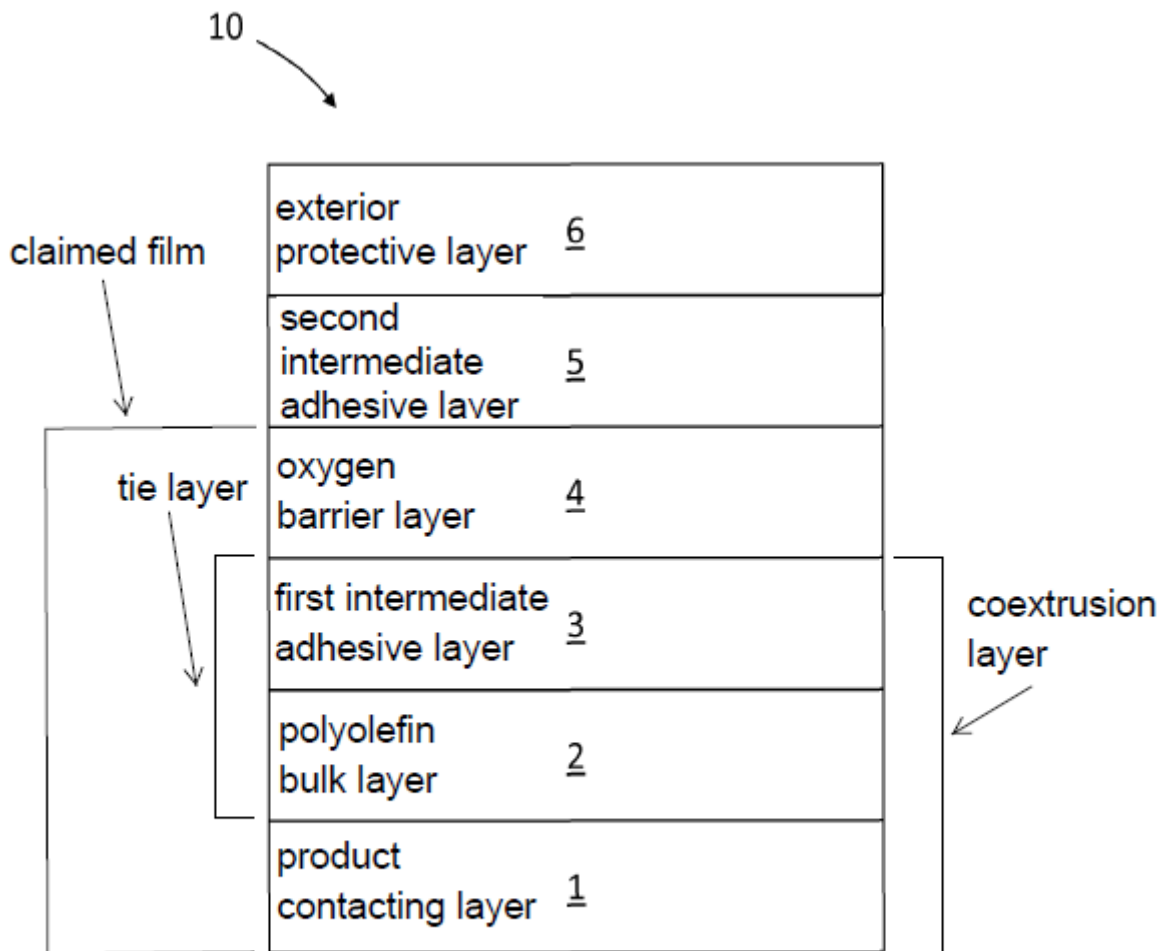


FIG. 1

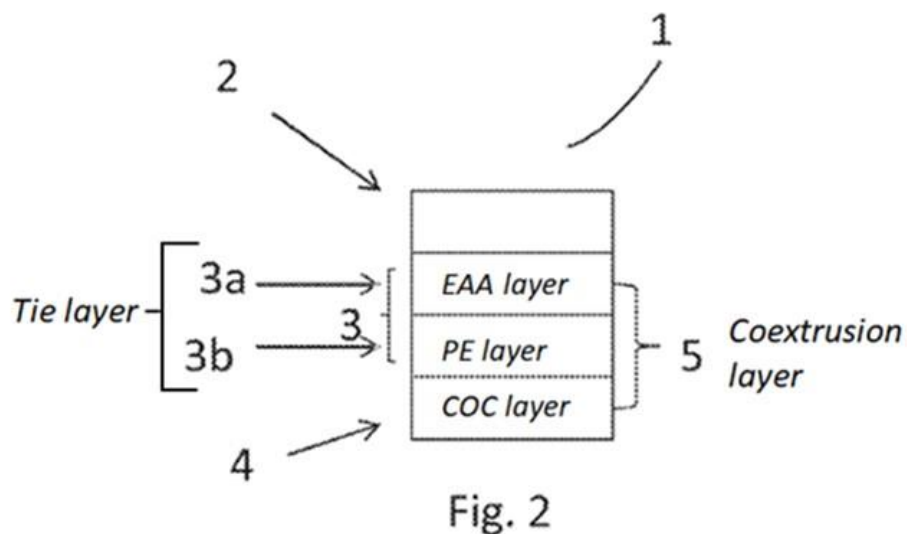
(EX. 1004, Figure 1 (annotated))

215. Regarding layer (1), Riis provides that “[t]he article contact layer comprises at least 90 wt.% of ethylene norbornene COC, more preferably at least 95 wt.%, and most preferably 100 wt.%.” EX. 1004, ¶ [0055].

216. Regarding layer (2), Riis provides that “a polyolefin bulk layer can serve as an adhesive or tie layer” and that “[p]referred bulk layers comprise one or more polyolefins such as polyethylene.” EX. 1004, ¶¶ [0065], [00135].
217. Regarding layer (3), Riis equates “tie layers” to “adhesive layers” and further explains that “[a]dhesives useful in the present invention include...acrylic and anhydride modified polymers,” such as EAA. EX. 1004, ¶¶[0071], [0085], [0088]. A POSITA would understand that EAA, as ethylene acrylic acid, is a copolymer of ethylene and acrylic acid monomers and is produced by reacting ethylene with acrylic acid. *See e.g., Rünzi et al., J. Am. Chem. Soc.* **2010**, 132, 17690-17691. Thus, a POSITA would understand that EAA is an acrylic modified polymer within the disclosure of Riis.
218. Regarding layer (4), Riis teaches that “[a] barrier layer can comprise any suitable material” and specifies that both moisture and oxygen barrier layers may comprise aluminum foil.” Ex. 1004, ¶[0062]. Riis also teaches that such multilayer films “may be formed by any suitable method including coextrusion, extrusion coating and lamination,” noting that “extruder and die temperatures...for commercially available resins are generally known in the art, or are provided in technical bulletins made available by resin manufacturers.” EX. 1004, ¶¶[00157]-[00158]. Furthermore, as discussed for Ground 2,

limitations [1.b] and [1.c], Riis's example 5 was manufactured by "three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene copolymer (COC) which was extrusion coated onto the aluminum foil surface of the multilayer based film." EX. 1004, ¶[00174].

219. Riis's teachings mirror the disclosure of the '624 patent. For example, Figure 2 of the '624 patent depicts an aggressive chemical-resistant film where "tie layer, 3, comprises two layers" where first layer 3a is EAA and second layer 3b is polyethylene (PE). EX. 1001, 13:42-46.



(Ex. 1001, Figure 2 (annotated))

220. As discussed in Ground 2, limitation [1.c] above, the '624 patent confirms that EAA and LDPE, as taught by Riis, are a "tie layer" when coextruded with a COC layer onto aluminum foil. *Supra* ¶ 129; EX. 1004, ¶¶ [0068]-[0069] (discussing

that an intermediate layer may include a tie layer and may include adhesive, adhesive polymers, and suitable polyolefins, such as polyethylene and polymeric olefin resins like LDPE and EAA); [0071]-[0072] (providing the configuration of any suitable number of tie layers “between and in direct contact with the barrier layer and the interior [contact] layer”). This is consistent with Riis’s teaching that the “tie layers may be formed of any suitable thermoplastic materials . . . in particular members of the polyethylene family such as LLDPE, VLDPE, HOPE, LDPE, ethylene vinyl ester copolymer or ethylene alkyl acrylate copolymer.” Ex. 1004, ¶[0074] (emphasis added). Thus, Riis teaches this limitation.

iv. [1.d] “wherein the contact layer consists of cycloolefin copolymer (COC);”

221. Riis teaches this same limitation for the same reasons discussed in Ground 2, limitations [1.c]-[1.d] and Ground 3, limitation [1.c] above.

v. [1.e] “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”

222. Riis teaches this same limitation for the same reasons discussed in Ground 2, limitations [1.c], [1.e] and Ground 3, limitation [1.c] above.

vi. [1.f] “allowing the coextrusion layer coated to the base layer to adhere to form the aggressive chemical-resistant film,”

223. Riis teaches this same limitation for the same reasons discussed in Ground 2, limitation [1.f] above.

vii. [1.g] “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;”

224. Riis teaches this same limitation for the same reasons discussed in Ground 2, limitation [1.g] and Ground 3, limitation [1.c] above.

viii. [1.h] “wherein the tie layer comprises one or more layers, and”

225. Riis teaches this same limitation for the same reasons discussed in Ground 2, limitation [1.h] and Ground 3, limitation [1.c] above.

ix. [1.i] 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.”

226. This limitation would have been obvious over Riis in view of Wypych.

227. To the extent loading is not indefinite, based on the high-level definition found in the '624 patent—“the amount of polymer left, in the layer when the film has dried,” EX1001, 6:38-39—a POSITA would have sought to determine loading based on the known mil thickness of a polymer layer and the known material densities of each polymer layer.

228. The '624 patent identifies that loading is measured in units “g/m².” This unit of measurement is a scaled version of the SI unit kg/m² used to measure area density of a two-dimensional object – calculated as mass per unit area. ISO 536:2019. Area density is often used in the paper and pulp industry as a US-standard paper size of pounds (lb) per a ream (500 sheets of a given basis size).

229. As discussed above, Riis's Example 5 teaches a tie layer consisting of coextruded EAA and LDPE layers. EX. 1004, ¶[00174]. Riis discloses the thickness of the EAA layer—0.17 mil—and the LDPE layer—0.65 mil. EX. 1004, ¶[00174].
230. A POSITA reading Riis would have understood that Riis teaches a variety of polymers—including LDPE and EAA, among others—suitable for use as a tie layer, including identifying exemplary polymers. *See generally* EX. 1004, ¶¶[0070]-[0080]. However, a POSITA would also have understood that different commercial applications require optimization of various properties.
231. Riis provides several examples of modifying polymer layer properties to meet the commercial desired commercial application. In one example, Riis teaches that “[v]arious adhesive layers are formulated and positioned to provide a desired level of adhesive between specific layers of the film.” EX. 1004, ¶[0072]. In another example, Riis teaches that “[p]referred films may also provide a beneficial combination of one or more of all of the properties including low haze, high gloss, good machinability, good mechanical strength and good barrier properties including high barriers to oxygen and water permeability.” EX. 1004, ¶[0080]. In yet another example, Riis teaches that it is desirable to “modify various properties of the desired film such as heat sealability, interlayer adhesion,

wrinkle resistance, puncture resistance, printability, toughness, gas and/or water barrier properties, abrasion resistance, printability, and optical properties such as gloss, haze, freedom from lines, streaks or gels.” EX. 1004, ¶[00157]. Riis further teaches various tests that may be used to determine the suitability of particular polymers and layer structures as aggressive chemical-resistant films. *See, e.g.*, EX. 1004, ¶¶[00175]-[00195] (providing for a Nicotine Direct Contact Test and a Nicotine Vapor Test). Accordingly, a POSITA would have been motivated to look to Wypych to determine materials properties of exemplary resins discussed in Riis and to identify other commercial purveyors of such resins.

232. As discussed above, Wypych provides that data included in the Handbook of Polymers come from literature available from manufacturers or various grades of polymers, plastics, and finished products among other sources. EX. 1005, 4. Wypych notes that “[f]requently, data from different sources vary in a broad range” and must be reconciled by selecting “values closest to their average and values based on testing of the most current grades of materials” in order to provide information characteristic of currently available products. EX. 1005, 4.

233. As discussed in Ground 2, limitation [1.i] above, by knowing the thickness of the layer and the density of the polymer used, a skilled artisan could arrive at the unit values for loading recited in the claims—g/m². Riis teaches that “any single

layer of a multilayer film can have any suitable thicknesses, including 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 mils, or any increment of 0.1 or 0.01 mil therebetween.” EX. 1004, ¶[0091]. Riis teaches that the polyolefin bulk layer, which may be a tie layer, “may be of any suitable thickness from 0.1 to 7 mils.” EX. 1004, ¶[0065]. Riis further teaches that example 5 has an EAA layer of 0.17 mil and an LDPE layer 0.65 mil. EX. 1004, ¶[00174]. Wypych teaches that EAA has a density range of 0.92-0.96 g/cm³ and that LDPE has a density of 0.915-0.929 g/cm³. Ex. 1005, 10. Thus, based on the loading ranges of Riis’s example 5, in view of Wypych, Riis teaches loading ranges for the EAA layer of at least 3.97 g/m²-4.15 g/m² and for the LDPE layer of at least 15.11 g/m²-15.34 g/m². The sum of those ranges provides the loading range of the “tie layer”—19.08 g/m²-19.49 g/m²—which falls within the claimed loading range of 7 g/m² to 20 g/m².

234. This limitation would have been obvious over Riis in view of Wypych because the loading ranges resulting from the use of commercially available EAA and LDPE at the thicknesses taught by Riis fall within the claimed loading ranges. Specifically, a POSITA would have been motivated to use resins, such as EAA and LDPE taught by Riis, that were commercially available at the time of the invention. Wypych taught the density ranges for such commercially available resins, as well as identifying the manufacturers of such resins. Using EAA and

LDPE resins having the density ranges taught by Wypych results in loading ranges that fall within those of claim 1. Accordingly, the claimed loading range is obvious in view of the prior art references.

x. *Motivation to Combine and Reasonable Expectation of Success*

235. In view of Riis's disclosures regarding exemplary polymers used in Example 5, a skilled artisan would have been motivated to look to Wypych and Tatarka in order to learn more about the properties and characteristics of exemplary polymers and to find suitable commercial sources to obtain polymers for a desired film attribute.

236. Similarly, for at least the reasons discussed with respect to Ground II above, a POSITA would have been motivated to follow Riis's Example 5 to arrive at the claimed inventive film and would have had a reasonable expectation of success in doing so.

237. As discussed above, Riis discloses a number of desirable properties and attributes of an aggressive chemical resistant film and also provides a number of suitable polymers utilized to form the film. Thus, a POSITA would have known that different polymers have different properties and characteristics and that those characteristics affect the end attributes of a multilayer film formed from those component polymers. For example, Riis discloses that some example adhesive

layer components, such as EMAC SP 1330, have physical properties including density, melt index, a melting point, and others; other disclosed polymers will have their own physical properties lending to different processing conditions and film attributes. Ex. 1004, ¶[0073]. Riis also provides that particular polymers used in the processing of forming the film can inform selection of processing parameters, such as by looking to manufacturer provided technical bulletins or other sources of knowledge for used polymers. *Id.*, ¶[00158]. A POSITA would have known that polymers disclosed by Riis have known properties and processing parameters and such polymers come from commercial suppliers. However, such properties and processing parameters are not included in Riis.

238. A POSITA would have known to look to relevant materials to ascertain the properties and processing parameters of polymers disclosed by Riis. A POSITA would have also recognized that Wypych, as a Handbook of Polymers, provides relevant polymer data for use in practical problem solving. Ex. 1005, 5. A POSITA would have known that such a Handbook contains relevant information not only from manufacturers, but also from other sources including open literature and patent literature in order to provide the most up to date information relating to polymers. *Id.* at 5. Wypych also contains relevant data for disclosed polymers, such as “commercial polymers” indicating commercially sources for

polymers, “physical properties,” and “processing.” *Id.* at 4. Accordingly, a POSITA would have known to look to resources such as Wypych to supply relevant properties, processing parameters, and commercial sources of availability for polymers disclosed in Riis.

239. As similarly as a POSITA would have known to look to Wypych as a Handbook of Polymers to provide additional property and processing information related to polymers disclosed by Riis, so too a POSITA would have been motivated to look to patent literature, such as Tatarka, related to polymers disclosed by Riis. Tatarka teaches physical and chemical properties related to COCs used in coextrusion processes with other polymers in flexible packaging applications. Ex. 1008, 3:55-60. Accordingly, a POSITA would have known to look to resources such as Tatarka to supply relevant properties, processing parameters, and commercial sources of availability for polymers disclosed in Riis.

240. In view of Riis’s disclosure of polymers used to make the film of Example 5 and Wypych’s and Tatarka’s teachings of relevant polymer properties, commercial sources, and processing parameters, a POSITA would have had a reasonable expectation of success of arriving at the claimed invention. For example, Riis discloses the use of polymers such as EAA, LDPE, and COC

within the scope of being used for forming film packaging and further discloses exemplary commercial suppliers of each polymer, including Dupont, Dow, and Topas. Ex. 1004, ¶¶[0093], [0095], [0097]. Wypych similarly discloses “commercial polymers” for each polymer that aligns with the disclosure of Riis, including Dupont for EAA, Dow for LDPE, and Topas for COC. EX. 1005, 7 (listing Topas and Topas COC), 10 (listing DuPont Nucrel for EAA), 21 (listing Dow LDPE).

241. Accordingly, a POSITA would have found claim 1 obvious over Riis and Wypych.

2. Claim 2

- i. “The method according to claim 1, wherein a melting point of the tie layer differs from a melting point of COC by 30° C or less.”*

242. This limitation would have been obvious based on Riis’s teachings regarding example 5 and exemplary polymers identified in Riis’s specification. As discussed above, Riis’s example 5 teaches coextruding a tie layer consisting of EAA and LDPE layers with a contact layer consisting of COC. Ex. 1004, ¶[00174]. Riis does not disclose the melting point of the tie layer or COC but does disclose exemplary polymers that are suitable for coextrusion onto a base film. *Id.*, ¶¶[0093]-[0097]. A POSITA would have found it obvious to use the

exemplary polymers that Riis discloses to create example 5, and thereby render the claimed invention obvious.

243. Use of EAA, LDPE, and ethylene norbornene copolymer (COC) would result in a chemical-resistant film wherein the melting point of the tie layer differs from the melting point of the COC by 30°C or less. As noted above for the “loading” limitations, Wypych (Ex. 1005) discloses various physical properties for polymers, including EAA and LDPE. Wypych discloses the melting point of EAA is 75°C-112°C (Ex. 1005, 10), and the melting point of LDPE is 105°C-115°C (Ex. 1005, 21). The melting point of ethylene norbornene copolymer (COC) is 60°C-125°C, as disclosed in Tatarka. EX1008, 4:43-47, 13:60-63 (disclosing a melting point of 84°C for E-140), 15:11-13 (teaching that preferred COC polymers have melting temperatures of less than 90°C and more than 60°C); EX1003 ¶[]. Similarly, the 2006 brochure teaches that Topas COCs have a glass transition temperature “from about 80°C to 180°C.” EX1019, 8.

Polymer	Melting Point
EAA	75-112°C
LDPE	105-115°C
Ethylene norbornene copolymer (COC)	60-125°C

244. As summarized in the table above, the melting points for each of EAA, LDPE, and COC all overlap. And even an alternative interpretation of the melting point of COC as a glass transition temperature overlaps with the melting point ranges of EAA and LDPE. Furthermore, the '624 patent fails to identify any reason that the selection of polymers to obtain the claimed difference in melting points is critical to the claimed invention. Therefore, the melting point of the tie layer differs from the melting point of COC by 30°C or less. Accordingly, for the reasons discussed for claim 1 and because the melting temperature ranges for the relevant polymer polymers overlap, claim 2 is obvious. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018).

3. Claim 3

- i. “The method according to claim 2, wherein a melting point of the tie layer differs from the melting point of COC by 5 to 15 °C.”***

245. A POSITA would have found claim 3 obvious for the same reasons discussed above for Ground 3, claim 2. Riis’s example 5 includes a tie layer formed from a layer of EAA, LDPE, and ethylene norbornene copolymer (COC), of which have overlapping melting points at least in the range of 5°C to 15°C.

4. Claim 4

- i. *“The method according to claim 1, wherein the contact layer has a loading in the range of 4 to 20 g/m². ”*

246. As discussed in limitation [1.i] above, the term “loading” does not have an ordinary and customary meaning in the art. However, a POSITA would understand how to arrive at the unit measurement recited in the claims for the loading range—g/m²—of a polymer based on the mil thickness for each polymer layer taught by Riis and the known density ranges for the polymers taught by Riis.

247. This limitation would have been obvious based on Riis’s teaching that COC should be used as the product contacting layer. Ex. 1004, ¶[0052]. Riis teaches that “any single layer of a multilayer film can have any suitable thicknesses, including 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 mils, or any increment of 0.1 or 0.01 mil therebetween.” EX. 1004, ¶[0091]. Riis provides thickness in “mil” units, where 1 mil = 0.001 inch = 0.00254 cm.⁸ Thus, g/m² can be determined by (1) multiplying thickness in cm by density in g/cm³ and (2) converting g/cm² to g/m². Riis further teaches that example 5 has a COC layer of 0.43 mil. EX. 1004,

⁸ National Institute of Standards and Technology (NIST) Physical Measurement Laboratory, Special Publication 811, Appx B.8: Conversion Factors for Units List Alphabetically (2008) (<https://www.nist.gov/pml/special-publication-811/nist-guide-si-appendix-b-conversion-factors/nist-guide-si-appendix-b8>).

¶[00174]. Wypych teaches that COCs have a density of 1.00-1.08 g/cm³. Ex. 1005 at 7. This is consistent with Riis's teaching of Topas 8007F-400, which has a density of 1.02 g/cm³, as an exemplary commercially available COC resin for use in the present invention." Ex. 1004, ¶[0054]; Topas 2006 brochure, pg. 7⁹. Thus, Riis, in view of Wypych, teaches loading ranges for the contact layer of at least 10.92 g/m²-11.80 g/m².

248. This limitation would have been obvious over Riis in view of Wypych because the loading ranges resulting from the use of commercially available COCs at the thicknesses taught by Riis fall within the claimed loading ranges. Specifically, a POSITA would have been motivated to use polymers, such as the COC Topas 8007F-400 taught by Riis, or indeed any of the Topas polymers listed in the 2006 brochure that were commercially available at the time of the invention. Wypych teaches the density ranges for such commercially available resins, as well as identifies the manufacturers of such resins. Using COC resins having the density ranges taught by Wypych results in loading ranges that overlap with those of claim 4.

⁹ The March 2006 brochure lists a density of 1.02 g/cm³ for all Topas COCs discussed, which includes those designated 8007, 6013, 6015, 5013, 6017.

249. Accordingly, for the reasons discussed above and for claim 1, a POSITA would have found claim 4 obvious.

5. Claim 5

- i. ***“The method according to claim 1, wherein a loading of an entirety of the tie layer is in the range of 7 to 20 g/m².”***

250. A POSITA would have found claim 5 obvious for the same reasons discussed above for Ground 2, claim 5 and Ground 3, limitation [1.i].

6. Claim 6

- i. ***“The method according to claim 1, wherein a loading of at least a portion of the tie layer is in the range of 7 to 20 g/m².”***

251. A POSITA would have found claim 6 obvious for the same reasons discussed above for Ground 2, claim 6 and Ground 3, limitation [1.i]. For example, based on the loading ranges of Riis’s example 5, in view of Wypych, Riis teaches loading ranges for the EAA layer of at least 3.97 g/m²-4.15 g/m², which overlaps with the claimed loading range. And, based on the loading ranges of Riis’s example 5, in view of Wypych, Riis teaches loading ranges for the for the LDPE layer of at least 15.11 g/m²-15.34 g/m², which falls within the claimed loading range.

7. Claim 7

- i. “The method according to claim 1, wherein the one or more layers of the tie layer comprises a plurality of layers, and wherein a loading of the plurality of layers is in the range of 7 to 20 g/m².”*

252. A POSITA would have found claim 7 obvious for the same reasons discussed above for Ground 2, claim 7 and Ground 3, limitation [1.i].

8. Claim 8

- i. “The method according to claim 1, wherein the one or more layers of the tie layer consists of two layers.”*

253. A POSITA would have found claim 8 obvious for the same reasons discussed above for Ground 2, claim 8 and Ground 3, limitations [1.c] and [1.h]. For example, the tie layer of example 5 consists of two layers—one EAA layer and one LDPE layer. Ex. 1004, ¶[00174].

9. Claim 9

- i. “The method according to claim 1, wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating.”*

254. A POSITA would have found claim 9 obvious for the same reasons discussed above for Ground 2, claim 9 and Ground 3, limitation [1.c].

10. Claim 10

- i. “The method according to claim 1, wherein at least one of the one or more layers of the tie layer comprises an acrylic acid layer or a polyethylene layer.”*

255. A POSITA would have found claim 10 obvious for the same reasons discussed above for Ground 2, claim 10 and Ground 3, limitation [1.c]. For example, a

POSITA would understand that EAA and LDPE as provided in the sealant layer three-layer coextrusion of Example 5 constitute a tie layer selected to act as intermediate adhesive layers.

256. Riis identifies EAA as “ethylene acrylic acid copolymer” and LDPE as “low density polyethylene.” EX. 1004, ¶¶[0018], [0027] (identifying LDPE as a “broad grouping of polyethylene”), [0085], [0093] (identifying Dupont 3990-L (tradename Nucrel) as a commercially available EAA resin), [0095] (identifying Dow 4012 as a commercially available LDPE resin); *see also* EX. 1005, 10 (“commercial polymers” section identifies DuPont Nucrel as a poly(ethylene-co-acrylic acid)(EAA)), 21 (“commercial polymers” section identifies Dow LDPE as a “low density polyethylene” (LDPE)). A POSITA would understand ethylene acrylic acid copolymer as an acrylic acid layer and would further understand low density polyethylene, as a broad grouping of polyethylene, to be a polyethylene layer.

11.Claim 11

- i. “The method according to claim 1, wherein the one or more layers of the tie layer comprises an acrylic acid layer and a polyethylene layer.”*

257. A POSITA would have found claim 11 obvious for the same reasons discussed above for Ground 2, claim 11 and Ground 3, limitation [1.c] and claim 10.

12.Claim 12

- i. “The method according to claim 11, wherein the acrylic acid layer comprises ethylene acrylic acid.”*

258. A POSITA would have found claim 12 obvious for the same reasons discussed above for Ground 2, claim 12 and Ground 3, limitation [1.c], claim 10, and claim 11.

13.Claim 13

259. A POSITA would have found claim 11 obvious for the same reasons discussed above for Ground 2, claim 13 and Ground 3, limitation [1.g].

- i. Motivation to Combine and Reasonable Expectation of Success*

260. In view of Riis’s disclosures regarding exemplary polymers used in Example 5, a skilled artisan would have been motivated to look to Wypych and Tatarka in order to learn more about the properties and characteristics of exemplary polymers and to find suitable commercial sources to obtain polymers for a desired film attribute.

261. For at least the reasons discussed with respect to Ground 2, claim 13 and Ground 3, limitation [1.g] above, a POSITA would have been motivated to form an aggressive chemical resistant film according to the claimed invention by recognizing the specific polymers disclosed for use by Riis and looking to sources such as Wypych and Tatarka to discern pertinent polymer properties, processing parameters, and commercial sources of availability. *Supra* ¶¶ 200-09, 223. Due

to Tatarka and Wypych teaching applicable properties regarding commercial polymer resins as disclosed in Riis and as discussed with respect to Ground 3, limitation [1.g] above, a POSITA would have had a reasonable likelihood of success in employing the known properties and parameters in Wypych and Tatarka to the same commercial polymer resins disclosed in Riis.

262. For the at least the reasons discussed with respect to Ground 2, claim 13 a POSITA would have been motivated to form the example laminate of Riis's Example 5 by incorporating the aggressive chemical resistant film into an end-user package, such as a pouch, by further adding an abuse resistant outer layer to the film to form a laminate packaging, and a POSITA would have had a reasonable likelihood of success in doing so as further reinforced by at least Jester's, Merical's, and Rivers's teachings of similar multilayer films laminated with outer abuse resistant layers. Ex. 1013, 9:63-10:12; Ex. 1014, ¶¶[0043]-[0044]; Ex. 1021, ¶¶[0089]-[0090].

CONCLUSION

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

United States. If cross-examination is required, I will appear for cross-examination within the United States during the time allotted.

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

Executed on this 30th day of November 2022.



Richard J. Spontak, Ph.D.