

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

|                     |   |                              |
|---------------------|---|------------------------------|
| BAY MATERIALS, LLC, | ) |                              |
|                     | ) |                              |
| Plaintiff,          | ) | C.A. No. 21-1610-RGA-JLH     |
|                     | ) |                              |
| v.                  | ) | <b>DEMAND FOR JURY TRIAL</b> |
|                     | ) |                              |
| 3M COMPANY,         | ) | <b>REDACTED PUBLIC</b>       |
|                     | ) | <b>VERSION</b>               |
| Defendant.          | ) |                              |

**DECLARATION OF DR. ALAN JEFFREY GIACOMIN**

**VOLUME I (Exhibits 1 through 10)**

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Dated: March 4, 2022



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BAY MATERIALS, LLC,

Plaintiff,

v.

3M COMPANY,

Defendant.

C.A. No. 21-1610-RGA



**DECLARATION OF DR. ALAN JEFFREY GIACOMIN**

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I, Alan Jeffrey Giacomini, submit this declaration in support of Defendant 3M Company's ("3M") Opposition to Plaintiff's Motion for Preliminary Injunction, and declare as follows:

## **I. INTRODUCTION**

1. I understand that Bay Materials LLC ("Bay Materials") has sued 3M Company ("3M") for alleged patent infringement of U.S. Patent Nos. 10,946,630 ("the '630 patent" (Ex. 1)) and 10,870,263 ("the '263 patent" (Ex. 2)) associated with 3M's Clarity™ Aligners Flex.<sup>1</sup>

2. I further understand that Bay Materials has filed a "Motion for a Preliminary Injunction" alleging infringement of claims 1, 2, and 9 of the '630 patent and claims 11, 12, and 18 of the '263 patent (collectively "the Asserted Claims") (together, "the Asserted Patents") and has supported that motion with declarations from expert and fact witnesses.

3. I have been asked to offer opinions as an expert regarding non-infringement and invalidity of claims 1, 2, and 9 of the '630 patent and claims 11, 12, and 18 of the '263 patent, and to respond to allegations made by Bay Materials against 3M's Clarity™ Aligners Flex.

## **II. QUALIFICATIONS**

4. My background, qualifications, and experience relevant to the issues in this proceeding are summarized below. My *curriculum vitae* is attached as Appendix A.

5. I received a Bachelor of Science with honours in Chemical Engineering from Queen's University in 1981, a Master of Science in Chemical Engineering from Queen's University in 1983 and a Doctor of Philosophy in Chemical Engineering from McGill University

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<sup>1</sup> I understand that 3M offers a product referred to as Clarity™ Aligners Flex + Force that is a combination treatment that may include both Clarity™ Aligners Flex and Clarity™ Aligners Force orthodontic aligners. However, because the Clarity™ Aligners Force is made from a single material product that is not accused of infringement by Bay Materials, I have focused my opinions on the Clarity™ Aligners Flex product.

[REDACTED]

in 1987. I am a licensed Professional Engineer in Wisconsin (#31292-6) and Ontario (#100200622).

6. I am currently a Professor of Chemical Engineering, Mechanical and Materials Engineering and Physics, Engineering Physics and Astronomy at Queen's University at Kingston in Canada where I hold the title of Tier 1 Canada Research Chair in Physics of Fluids. I have also been serving as an Adjunct Professor at University of Nevada in Reno, Nevada since 2020. I teach three courses at Queen's University involving polymer manufacturing and rheology. Rheology is the study of flow and deformation.

7. Before joining the faculty at Queen's University, I served as the chair of the Rheology Research Center at the University of Wisconsin for nearly twenty years. I have also held visiting professorships at McGill University, the University of Sherbrooke, the Swiss Federal Institute of Technology, the Paris School of Mines, the National University of Singapore, Chung Yuan University near Taipei, Yunlin University, in southern Taiwan, Shandong University in mainland China, and the University of Nevada, Reno.

8. I am currently the immediate Past-President of the Canadian Society of Rheology and sole Editor-in-Chief of *Physics of Fluids*. I am also the former President of The Society of Rheology and former Associate Editor for Business of the *Journal of Rheology*. In addition to these roles, I am also a member of more than a dozen other professional organizations where I have held elected and appointed leadership positions.

9. My research focuses on the role played by rheology in polymer processing or in plastics manufacturing. In particular, my research has focused on experimental and theoretical investigations in plastics thermoforming and extrusion, as well as the mechanical properties, including the relation between polymer hardness and elastic modulus.

10. Over the course of my career, I have published more than 150 refereed journal publications, many of which related to polymer rheology. I have published on ASTM standards, and specifically on the hardness standard, ASTM D2240, in the *Journal of Testing and Evaluation*, the archival peer-reviewed journal of the American Society for Testing and Materials, and also in *Polymer-Plastics Technology and Engineering*. The *Journal of Testing and Evaluation* publications are incorporated by reference in the patents at issue in this case. On thermoforming, I have published in *Polymer Engineering and Science*, *Journal of Plastic Film and Sheeting*, *Journal of Polymer Engineering*, *Journal of Advanced Engineering*, *AIChE Journal*, and *Zeitschrift Kunststofftechnik (Journal of Plastics Technology)*.

11. I have served as a peer reviewer for many refereed journals including *International Polymer Processing*, *Journal of Rheology*, *Physics of Fluids*, *Polymer Engineering and Science*, and *Polymer-Plastics Technology and Engineering* among others.

12. I have presented my research at conferences and universities across the world. I have been extended the invitation to be the keynote speaker and speak at national and international conferences including the keynote for the 62<sup>nd</sup> Canadian Chemical Engineering Conference, the keynote for the Annual Meeting of the Canadian Society of Rheology, and most recently a plenary lecture for The 30<sup>th</sup> International Symposium on Transport Phenomena in Vietnam.

13. I am a named inventor of U.S. Patent No. 5,637,268 titled “Method of Extruding Plastics,” which is related to a process for minimizing flow instability of molten plastics caused by slippage of the melt at the die wall during extrusion.

14. I am qualified to testify as an expert witness with respect to the patents at issue in this matter.

**III. SUMMARY OF OPINIONS**

15. In my opinion, 3M's 5-layer Clarity™ Aligners Flex material and the aligners made therefrom cannot be found to infringe any valid Asserted Claim, as I set forth in detail below.

16. While my opinions set forth in this declaration sufficiently demonstrate the reasons and materials supporting my conclusion that the Asserted Claims are not infringed and invalid at this preliminary injunction stage of the proceedings, at this time my opinions are confined to those expressly stated within this declaration. I reserve my right to address additional grounds for invalidity and non-infringement and to address any new information or other arguments put forth in opposition to my opinions by Bay Materials or any of its witnesses.

**IV. LEGAL STANDARDS**

17. Certain legal standards have been explained to me by counsel for 3M, as follows. I have applied these standards to my opinions.

**A. The Level of Ordinary Skill in the Art**

18. I understand that patents are interpreted and their claims evaluated from the perspective of a person of ordinary skill in the art (which I will sometimes refer to as the "skilled artisan"). I understand that because the '630 and '263 patents (and each application to which they claim priority) were filed after the AIA came into effect, the '630 and '263 patents are evaluated from a skilled artisan's perspective as of each patent's effective filing date. I understand that the '630 patent was filed on December 12, 2019, and that the '263 patent was filed on December 18, 2019. I understand that it is Bay Material's burden to establish entitlement to an earlier effective filing date based on, for example, a claim of priority to an earlier-filed provisional application or an earlier-filed utility application (for a subsequent continuation-in-part). I have been informed that the earliest filed provisional application to which the '630 and '263 patents claim priority is

May 31, 2017. Unless otherwise noted, I have applied the earliest possible effective filing date of May 31, 2017 for each of the '630 and '263 patents for my analysis herein. However, even if I use a later date of December 2019 (based on when the '630 and '263 patents were actually filed), my opinions would not change.

19. I understand that Dr. Osswald has provided the following statement regarding the person of ordinary skill in the art:

In my opinion a person of ordinary skill in the art is defined as someone with at least a bachelor's degree in mechanical engineering, biomedical engineering, chemical engineering, materials science, or other similar type of engineering degree, and who would have taken courses in polymer processing or polymer materials science, combined with at least two years of experience in the field of design, manufacture, and processing of thermoformable polymer sheets for use in various applications, such as in orthodontic and dental appliances. More relevant experience could compensate for less education, and more relevant education could likewise compensate for less experience. This level of education and background provides the necessary training and understanding combined with at least two years of experience in the field of design and manufacturing of polymer orthodontic and dental appliances.

(Osswald Decl., ¶18.)

20. While I do not necessarily agree that Dr. Osswald's definition of a person of ordinary skill in the art is correct in the context of the full disclosures of the Asserted Patents, for the sole purpose of this declaration I have adopted and applied Dr. Osswald's formulation. I reserve my right to provide a more appropriate definition of a person of ordinary skill in the art, as necessary, in the future.

## **B. Claim Interpretation**

21. I have been informed that the scope of a patent claim is to be determined by the words of the claim itself, read in view of the relevant intrinsic record—i.e., the specification and file history. I have further been informed that the claims are to be interpreted in terms of their

meaning to one of ordinary skill in the art at the time of the invention, which I understand means the effective filing date of the claimed invention.

22. I understand that the person of ordinary skill in the art is deemed to read claim terms not only in the context of the particular claim in which a claim term appears, but in the context of the entire patent, including the specification. I am informed by counsel that the patent specification, under the legal principles, has been described as the single best guide to the meaning of a claim term, and is thus highly relevant to the interpretation of claim terms.

23. I further understand that claim terms are generally given their ordinary and customary meaning, which is the meaning that the term would have to a person of ordinary skill in the art as of the effective filing date of the claimed invention. However, I understand that if claim terms have no plain or established meaning to one of ordinary skill in the art, they ordinarily cannot be construed broader than the disclosure in the specification. In other words, absent such an accepted meaning in the art, I understand that the courts construe a claim term only as broadly as provided for by the patent itself.

24. I am further informed by counsel that other claims of the patent in question, both asserted and unasserted, can be valuable sources of information as to the meaning of a claim term. Because the claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.

25. In addition to informing the interpretation of claim terms, I understand the intrinsic record may show a specialized definition for a term or compel a specific interpretation of a term that departs from its standard meaning within the art, such as when a patent term is expressly defined in the specification or when the patentee has made a clear and unambiguous disclaimer

regarding the meaning of the term within the specification or during prosecution of the patent application.

26. I also understand that extrinsic sources of information may be used to inform the understanding of one of ordinary skill in the art at the time of patenting, but that such extrinsic information cannot overcome a meaning for a term in a manner that is inconsistent with that given by the intrinsic record consisting of the claims, specification, and file history.

**C. Indefiniteness**

27. I have been informed that a patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them. I understand that a patent claim is invalid for indefiniteness if the specification delineating the patent, and the prosecution history, fail to inform those skilled in the art about the scope of the invention with reasonable certainty. I further understand that indefiniteness is measured from the viewpoint of a person skilled in the art at the time of the effective filing date of the patent.

**D. Infringement**

28. I understand that an infringement analysis of a patent claim involves two steps: (1) the claim terms are first construed—i.e., interpreted to define their scope—according to the principles I have set forth above regarding claim interpretation; and (2) the properly interpreted or construed claims are compared against the accused product. I understand that to directly infringe a claim, the accused product must meet each and every limitation of the patent claim. I further understand that a dependent claim includes all limitations recited in the dependent claim as well as the independent claim from which it depends.

[REDACTED]

**E. Anticipation**

29. I have been informed that a patent claim is “anticipated” when a single patent or printed publication describes all of the elements of a claim, either expressly or by inherent disclosure. I understand that the dispositive question is whether a skilled artisan would reasonably understand or infer from a prior art reference that every claim limitation is disclosed in that single reference. I further understand that my expert testimony permissibly sheds light on what a skilled artisan would reasonably understand or infer from a prior art reference. I understand that the limitations of a patent claim are inherently disclosed in a prior art document if the prior art necessarily functions in accordance with, or includes, the claimed limitations. I have been informed that to serve as an anticipatory reference when the reference is silent about an asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence.

30. I further understand, however, that inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill need not recognize the inherent characteristics or functioning of the prior art. I understand that the legal doctrine of anticipation by inherency enforces the basic principle that the public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate.

31. I understand that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated if *one* of them is in the prior art. Further, I understand that a prima facie case of anticipation can be sufficiently established through the prior art’s disclosure of overlapping ranges. I understand that a “prima facie case of anticipation,” as that phrase is used in the patent laws, refers to the legal principle that once the patent challenger has established its prima facie case of anticipation (through the prior art’s disclosure of an

[REDACTED]

overlapping range), the burden of production then falls upon the patentee to come forward with evidence that the claimed range is *critical* to the operability of the claimed invention. I understand that a statement in the challenged patent that something is in the prior art is binding on the patentee for determinations of anticipation.

**F. Obviousness**

32. I understand that a patent claim can be invalid because it was obvious at the time of the invention to one of ordinary skill in the art in the subject matter of the claimed invention. I understand that a determination of obviousness involves consideration of (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the relevant art. In reviewing this art, I understand it is important to examine whether the art provided a motivation or reason to make the claimed invention and if there was a reasonable expectation of success in making the combination. I understand that a finding of obviousness can also be supported by some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

33. I understand that the fact that a prior art reference may anticipate a patent claim presents no obstacle to relying on that reference as a basis for invalidity based on obviousness. I have been informed that it is established law that invalidity for obviousness can be based on a reference which also happens to anticipate the claimed subject matter. I understand that even if a single reference does not contain every limitation of a patent claim, it can still invalidate that claim if it renders the claimed invention obvious when considered by a person having ordinary skill in the art in light of other prior art references or devices. If the differences between the claimed invention and the prior art are such that the claimed invention, as a whole, would have been

obvious to a person having ordinary skill in the art at the time the invention was made without the benefit of hindsight, then the claim is invalid.

34. I understand that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. In other words, when a claim simply arranges prior art elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, then such a combination is obvious. Moreover, when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination is likely to be obvious unless the combination yields an unpredictable result.

#### **G. Written Description**

35. I have been informed that the specification of the patent must contain a written description of the invention. I have been informed that a patent claim is evaluated for compliance with the written description requirement by asking whether the patent allows a person of ordinary skill in the art to recognize, as of the time of the invention, that the inventors invented what is claimed. In other words, I understand that for the written description requirement to be satisfied, one of ordinary skill in the art must recognize that the inventors were in possession of the claimed invention.

#### **H. Enablement**

36. I have been informed that to enable a claim of a patent, the specification must teach one of ordinary skill in the art how to make and use the invention without undue experimentation. I have been informed that a patent specification must enable the full scope of a claimed invention. I understand that to make this assessment, the claims are first interpreted to determine their full

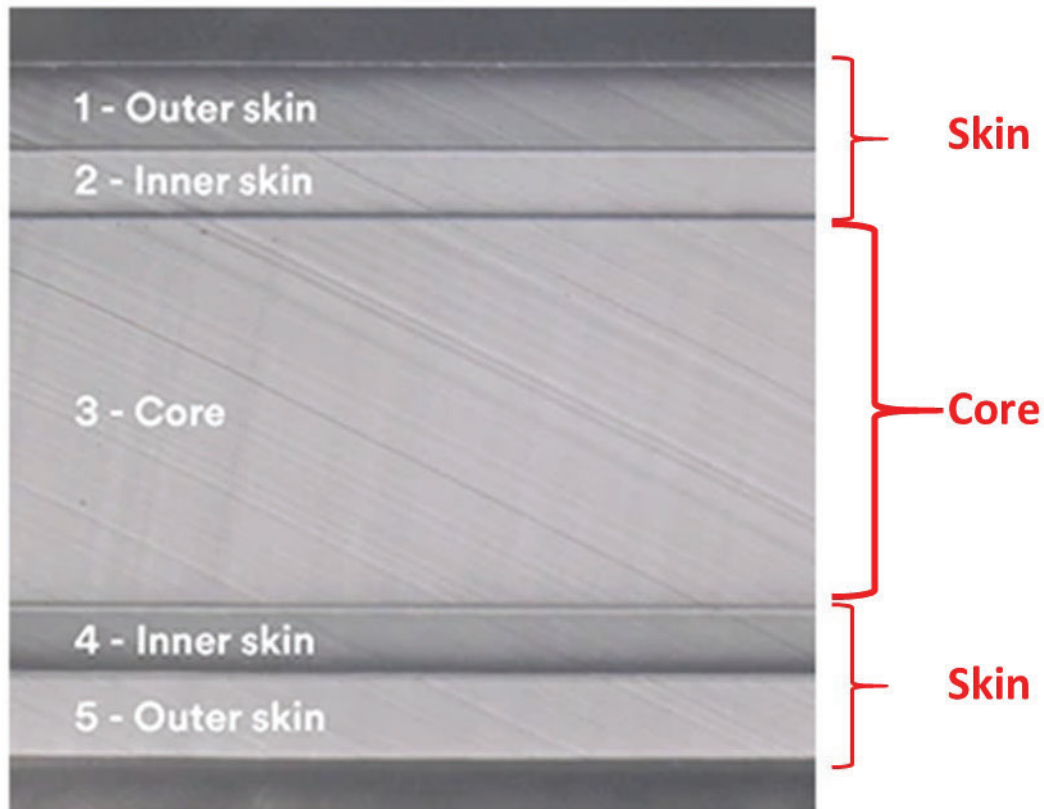
[REDACTED]

scope and then the entire scope of the claims is examined to determine whether all aspects of the entire scope of the claims can be made or used without undue experimentation.

**V. 3M's Clarity™ Aligners Flex**

37. 3M's accused Clarity™ Aligners Flex material is a next-generation 5-layer material with a skin-core-skin construction consisting of a rigid “core” surrounded on both sides by a double-layered “skin.” I have been informed that [REDACTED]

[REDACTED] which is situated between the relatively thinner skins, as follows:



(See Ex. 3 at 2.)

38. I understand that the overall thickness of the Clarity™ Aligners Flex material is 0.625 mm (or 625 microns) before it is thermoformed into an orthodontic aligner. I have been informed that the relative thickness of the skin-core-skin is designed to have a [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] I also understand that the [REDACTED]

[REDACTED]

[REDACTED]

39. I understand that it is Dr. Osswald’s opinion that in Clarity™ Aligners Flex “layers [REDACTED],” which he characterizes as a [REDACTED]” (See Osswald Decl., ¶¶81, 128.) I further understand that it is Dr. Osswald’s opinion that in Clarity™ Aligners Flex “[REDACTED].” (See Osswald Decl., ¶92.)

40. The distinctive thick rigid-core-with-skins configuration of Clarity™ Aligners Flex material when used in an orthodontic aligner, creates a synergistic affect that provides superior properties, and thereby addresses a range of different needs of material properties of an orthodontic aligner, including at least: (1) force persistence that lasts for weeks; (2) durability to resist cracking; (3) resistance to staining and discoloration; and (4) ease of use for patients regarding insertion and removal. (Ex. 3 at 2.) In doing so, the Clarity™ Aligners Flex material strikes the balance of flexibility needed for easy insertion onto the teeth and removal with the rigidity needed for force persistence, durability, and stain resistance. (*Id.* at 4.)

## **VI. THE ASSERTED PATENTS**

### **A. The ’630 Patent**

41. The ’630 patent, entitled “Dual shell dental appliance and material constructions,” was filed on December 12, 2019 as a continuation of application of No. 16/211,176 (“the ’176 application”), which was filed on December 5, 2018. (See Ex. 1 (’630 patent).)

42. The ’630 patent is directed to “polymeric sheet compositions” that “are useful for making dental appliances having outer layers comprised of a material having a modulus of from

about 1,000 MPa to 2,500 MPa ('hard') and an inner core comprised of elastomeric material or materials having a modulus of from about 50 MPa to 500 MPa ('soft')[.]” ('630 patent, abstract.) The '630 patent refers to the “hard” outer layers around a “soft” inner core as a “dual shell” construction. (E.g., '630 patent, 5:60, title.) The '630 patent explains that “[d]ental appliances may be constructed by thermoforming a dual shell material over a model of one or more teeth or may be constructed by sequentially thermoforming rigid and elastomeric precursor sheets or by sequentially dip coating a model with polymer solutions or polymer forming monomers or oligomers which may optionally cured or otherwise post processed.” ('630 patent, 5:62-6:2.)

43. The '630 patent asserts that the alleged improvement in properties derives from the hard-soft-hard configuration of the shell-core-shell structure:

The present disclosure is based on the discovery that many of the deficiencies in prior art materials, and dental appliances constructed from them can be reduced or eliminated with *a sheet or device having outer layers comprised of a material having a modulus of greater than about 1,000 MPa up to 2,500 MPa and an inner elastomeric layer or core comprised of elastomeric material or materials having a modulus of from about 50 MPa to 500 MPa*, which can be non-staining, has a lower cost than rigid urethanes, exhibits improved elastic properties, and has surprisingly greater environmental stress cracking resistance.

('630 patent, 5:26-36 (emphasis added).)

44. The '630 patent discloses alleged inventions according to an ABC layering scheme, wherein layer A, layer B, and layer C can be “a single layer or multiple layers,” wherein each layer is comprised of “one or more” materials:

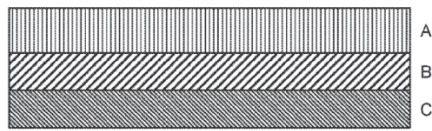


FIG. 1A

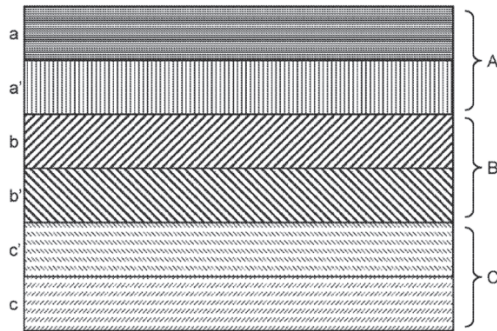


FIG. 1B

## BRIEF DESCRIPTION OF THE DRAWINGS

40

FIG. 1A is a schematic depiction of a cross sectional view of a three-layer sheet of the invention with a simple ABC construction. Layer A and layer C may be the same or different materials and each layer may be comprised of one or more materials, or blends or alloys. Layer B may be a

FIG. 1B is a schematic depiction of a cross sectional view of a multiple layer sheet. Each layer A, B and C, may be a comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials. Layer A may be comprised of more than one layer, for example, layer a and a', layer B may be comprised of more than one layer, for example, layer b and b', and layer C may be comprised of more than one layer, for example, layer c and c', as exemplified in FIG. 1B.

55

'630 patent, 3:39-55

('630 patent, FIG. 1A, FIG. 1B, 3:39-55; *see also id.*, 3:65-67 ("layers A, B and C may be comprised of one or more materials and may each individually comprise one or more layers").)

45. With respect to the ABC layering scheme wherein layer A, layer B, and layer C can be a single layer or multiple layers, the '630 patent explains that "a composition comprised of at least two outer layers A and C and a middle layer B is provided. The A and C layers individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and a glass transition temperature and/or melting point of from about 80° C. to 180° C. and the middle B layer is comprised of at least an elastomer having a modulus of from about 50 MPa to about 500 MPa and one or more of a glass transition temperature and/or melting point of from about 90° C. to about 220° C." ('630 patent, 1:51-60.)

46. The asserted claims of the '630 patent (claims 1, 2, and 9) recite claims with "layer A," "layer B," and "layer C" as follows:

|        |                                                                                                                                                                                       |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | <b>'630 patent, claims 1, 2, and 9</b>                                                                                                                                                |
| 1[pre] | 1. A polymeric sheet composition, comprising:                                                                                                                                         |
| 1[a]   | at least two outer layers A and C and an elastomeric inner layer B,                                                                                                                   |
| 1[b]   | wherein one or more of the outer layers A and C is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa,                                        |
| 1[c]   | the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75, and                                                                                |
| 1[d]   | the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa.                                                                                            |
| 2      | 2. The polymeric sheet composition of claim 1, wherein the A, B and C layers of the polymeric sheet composition have a combined thickness of from about 250 microns to 2,000 microns. |
| 9      | 9. A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 2.                                                                   |

## **B. The '263 Patent**

47. The '263 patent, also entitled "Dual shell dental appliance and material constructions," was filed on December 18, 2019 as a continuation-in-part of the '176 application. Although the '263 patent maintains all of the same disclosures as the '176 application, as a continuation-in-part, the '263 patent contains additional disclosures not found in the '176 application (which shares an identical specification as the '630 patent). (*See* Ex. 2 ('263 patent).) These new disclosures include the first recitation of polymer sheet embodiments with reference to a "layer D," and new disclosures with respect to "inner layers B and B' compris[ing] a polymeric material with a hardness of from about A 60 to D 85," which also appear in the asserted claims from the '263 patent. (*See* '263 patent, 12:25-30, 12:64-66.)

48. The asserted claims of the '263 patent (claims 11, 12, and 18) recite claims with "layer A," "layer B," "layer B'," "layer C," and "layer D" as follows:

|         |                                                                                                                                                                                                             |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         | <b>'263 patent, claims 11, 12, and 18</b>                                                                                                                                                                   |
| 11[pre] | 1. A polymeric sheet composition comprised of[:]                                                                                                                                                            |
| 11[a]   | at least two rigid or hard outer layers A and C, at least two soft inner layers B and B', and at least a rigid or hard inner layer, D,                                                                      |
| 11[b]   | wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and                                                       |
| 11[c]   | the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.                                                                                     |
| 12      | 12. The polymeric sheet composition of claim 11, wherein the polymeric sheet composition has a combined thickness of from 250 microns to 2,000 microns and a flexural modulus of from 500 MPa to 1,500 MPa. |
| 18      | 18. A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.                                                                                       |

## VII. Claim Interpretation

### A. “layer A,” “layer B,” and “layer C”

49. All of the Asserted Claims recite some permutation of the terms “layer A,” “layer B,” and “layer C.” ('630 patent, claim 1 (“at least two outer layers A and C and an elastomeric inner layer B”); '263 patent, claim 11 (“at least two rigid or hard outer layers A and C, at least two soft inner layers B and B”).) There is no plain and ordinary meaning for “layer A,” “layer B,” and “layer C” to a person of ordinary skill in the art. Rather, by reciting the layers by their identification as “layer A,” “layer B,” and “layer C,” the claims are referring to the specific teachings regarding “layer A,” “layer B,” and “layer C” according to the ABC stacking schemes for a multi-layer polymer sheet disclosed within the '630 patent. In this regard, as explained in the following paragraphs, the '630 patent expressly redefines the meaning of “layer” within the context of “layer A,” “layer B,” and “layer C” in a way that departs from the ordinary usage of the word “layer” to a person of ordinary skill in the art.

50. The '630 patent teaches “a three-layer sheet of the invention with a simple ABC construction.” ('630 patent, 3:41-46.) For a sheet including three unitary (or single) layers, the identification of “layer A,” “layer B,” and “layer C” is relatively straightforward. As taught in connection with Figure 1A, each individual layer within the three-layer sheet embodiment is identified as “layer A,” “layer B,” and “layer C.” That is, for a three-layer sheet, “layer A,” “layer B,” and “layer C” are each individually a *single* layer (i.e., there is a one-to-one mapping between the layers in the sheet and the recited A, B, and C layers).

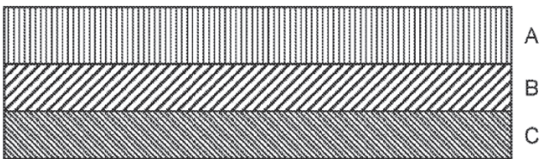


**FIG. 1A**

BRIEF DESCRIPTION OF THE DRAWINGS

40

FIG. 1A is a schematic depiction of a cross sectional view of a three-layer sheet of the invention with a simple ABC construction. Layer A and layer C may be the same or different materials and each layer may be comprised of one or more materials, or blends or alloys. Layer B may be a 45 single material, a blend of materials or alloys.

'630 patent, 3:41-46

('630 patent, Fig. 1A, 3:41-46.)

51. With respect to multi-layer sheets having more than 3 layers, however, the '630 patent maintains the same overall ABC stacking scheme. In doing so, the '630 patent defines each “layer A,” “layer B,” and “layer C” as being “comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials.” ('630 patent, 3:48-51.)

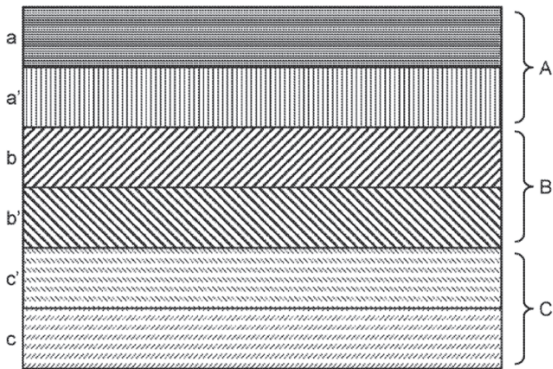


FIG. 1B

FIG. 1B is a schematic depiction of a cross sectional view of a multiple layer sheet. Each layer A, B and C, may be a comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of 50 materials. Layer A may be comprised of more than one layer, for example, layer a and a', layer B may be comprised of more than one layer, for example, layer b and b', and layer C may be comprised of more than one layer, for example, layer c and c', as exemplified in FIG. 1B. 55

'630 patent, 3:47-55

('630 patent, Fig. 1B, 3:47-55.)

52. Figure 1B depicts a stacking scheme for a six-layer embodiment within the '630 patent that shows each of the respective six single layers is identified as a, a', b, b', c', and c. (See '630 patent, Fig. 1B, 3:51-55.) As described in connection with Figure 1B, "Layer A may be comprised of more than one layer, for example, layer a and a', layer B may be comprised of more than one layer, for example, layer b and b', and layer C may be comprised of more than one layer, for example, layer c and c', as exemplified in FIG. 1B." ('630 patent, 3:51-55.) That is, in connection with Figure 1B, the '630 patent differentiates between the lower case stacking scheme (i.e., layers a, a', b, b', c', and c) that depicts a one-to-one mapping with each layer of the depicted 6-layer sheet and the upper case/capital letters stacking scheme (i.e., layers A, B, C) recited in the claims of the '630 patent. Hence, for example, Figure 1B discloses that "layer a" (small) and "layer A" (capital) have different meanings within the '630 patent. The same is true of the difference between "layer b" and "layer B," and "layer c" and "layer C."

53. Thus, it is clear from the '630 patent's specification that each of "layer A," "layer B," or "layer C" can be either a *single layer or multiple layers*. This departs from the ordinary meaning of a "layer" because the '630 patent expressly includes both a "single layer" as well as the plural "multiple layers" within the meaning of what is identified as singular "layer A," "layer

[REDACTED]

B,” or “layer C.” (’630 patent, 3:47-55 (“*Each layer A, B and C, may be a comprised of a single layer or multiple layers* and each layer may be comprised of one or more materials or a blend of materials”) (emphasis added); *see also id.*, 3:65-67 (“*layers A, B and C* may be comprised or one or more materials and *may each individually comprise one or more layers*”) (emphasis added).

54. The ’630 patent further indicates that the different layers that can make up “layer A,” “layer B,” and “layer C,” can be different materials. (’630 patent, 3:47-55 (“Each layer A, B and C, may be a comprised of a single layer or multiple layers and *each layer may be comprised of one or more materials* or a blend of materials”) (emphasis added); *see also id.*, 3:65-67 (“*layers A, B and C may be comprised or one or more materials* and may each individually comprise one or more layers”) (emphasis added).)

55. Accordingly, in my opinion, the proper construction for “layer A,” “layer B,” and “layer C” is “comprised of a single layer or multiple layers and may be comprised of one or more materials or a blend of materials.” (’630 patent, 3:47-55; *see also id.*, 3:65-67 (“layers A, B and C may be comprised or one or more materials and may each individually comprise one or more layers”); *see also supra* ¶¶51-54.) My proposed construction captures the redefinition of the word “layer” in the context of the disclosed ABC stacking scheme to reflect that each of “layer A,” “layer B,” and “layer C” may be comprised of either a *single layer or multiple layers*, and that each of “layer A,” “layer B,” and “layer C” may be comprised of one or more materials or a blend of materials. My opinion is further supported by Dr. Osswald’s deposition testimony with reference to the description provided in connection with Figure 1B: “It says *each layer, that means single cap A, cap B, cap C, could be single or it could be multiple. It’s clearly defined there.*” (Ex. 4 (“Osswald Tr.”) at 155:11-14) (emphasis added).)

**B. “inner layer B” (as recited in ’630 Patent)**

56. As with “layer B,” the term “*inner* layer B,” as recited, for example, in claim 1 of the ’630 patent, has no established ordinary and customary meaning in the art. I have been informed by counsel that where a claim term has no established meaning in the art (like “inner layer B” here), it should be construed by examining the specification and file history to obtain the meaning of the term.

57. I have not found the words “inner layer B” in the specification of the ’630 patent. Rather, all embodiments and examples disclosing “layer B” (or the “B layer”) in the ’630 patent refer to it as the “*middle* layer B” or “*middle* B layer” of a multilayer polymeric sheet. (E.g., ’630 patent, 1:51-52 (“at least two outer layers A and C and a middle layer B”), 8:17-18 (same), 10:27-28 (same), 11:60-61 (same), 12:2-3 (same), 1:56 (“middle B layer”), 1:65 (same); 2:4 (same), 2:44 (same), 3:34 (same), 4:5 (same) 4:12 (same), 8:32 (same), 8:44-45 (same), 10:43 (same), 11:61 (same), 7:48 (“middle elastomeric B layer”), 21:49-54 (“inner B layer” in the middle of a “three-layer sheet”); Figs. 1A, 1B, 2; Tables 3 and 8.)

58. Furthermore, the specification discloses that the “inner elastomeric layer” is synonymous with the “core” of the multilayer polymeric sheet. (’630 patent, Abstract (“inner core comprised of elastomeric material”), 5:31 (“an inner elastomeric layer or core”); Osswald Tr. at 240:10-12 (“Q. It’s referring to the inner elastomeric layer synonymously with the core, right? A. Correct.”).) Also, I did not find any disclosures within the specification of the ’630 patent that identify any embodiments of a multilayer polymeric sheet with more than one “layer B,” and where the “layer B” is not a middle core. Indeed, the vast majority of the embodiments disclosed in the patent are to three-layer sheets, which necessarily have only a single middle core layer B. The only examples of any multilayer embodiments that have more than three layers are

in Figure 1B and Sample 8 of Table 8, which both depict a single “layer B” as the middle core layer between layers A and B.

59. Accordingly, “inner layer B,” when interpreted according to the specification of the ’630 patent and file history, refers to “the *middle core* layer B” of a polymeric sheet. When incorporating my previously set forth construction of “layer B” from paragraphs 49-55 above, in my opinion, the proper construction of “inner layer B” refers to “the middle core layer, which is comprised of a single layer or multiple layers and may be comprised of one or more materials or a blend of materials.”

60. This interpretation is further confirmed by the file history. During prosecution of the ’176 application, the patentee sought claims that recited “A polymeric sheet composition comprised of at least two outer layers A and C and an elastomeric middle layer B . . . wherein the polymeric sheet composition has *a combined thickness of the A, B, and C layers from 250 microns to 2,000 microns.*” (See, e.g., Ex. 5 (10-24-2019 Amendments) at 4 (claim 15) (emphasis added).) In characterizing this invention to the examiner, Bay Materials stated: “*the tri-layer polymer sheets of the subject invention as recited in claims 1 and 15 have a maximal thickness of 2,000 microns (2.0 mm).*” (Ex. 5 at 14 (emphasis added).)

15. (Currently amended) A polymeric sheet composition comprised of at least two outer layers A and C and an elastomeric middle layer B, wherein one or ~~both more~~ of the outer layers is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa and the ~~middle inner~~ layer B is a polyurethane elastomer having a flexural modulus of from about 50 MPa to about 500 MPa, wherein the inter layer peel strength between at least one outer layer and the middle ~~[[B]]~~ layer B is greater than about 50 N per 2.5 cm [[/inch]], wherein the polymeric sheet composition has a combined thickness of the A, B and C layers of from 250 microns to 2,000 microns and a flexural modulus of from 500 MPa to 1,500 MPa.

(Ex. 5 at 4 (claim 15).)

[REDACTED]

In contrast, the tri-layer polymer sheets of the subject invention as recited in claims 1 and 15 have a maximal thickness of 2,000 microns (2.0 mm), and also require a flexural modulus that does not exceed 1,500 mPa (equiv. 15,300 kg/cm<sup>2</sup>). Thus, the claimed materials with a maximum thickness of 2.0 mm of the claimed invention have a flexural modulus (rigidity) that is not predicted by the materials described in Takagi.

(Ex. 5 at 14.)

61. First, the patentee's characterization of "the subject invention" indicates that the claim language "at least two outer layers A and C and an elastomeric middle layer B" refers to a "tri-layer polymer sheet," and this context is no different from the present claim language "at least two outer layers A and C and an elastomeric [middle] layer B" in claim 1 of the '630 patent because the "middle layer B" and "inner layer B" are necessarily the same within an ABC tri-layer sheets. By characterizing the claimed invention as a "tri-layer" sheet, the patentee's statement to the patent office makes it clear that the patentee did not contemplate or intend for the language "at least two outer layers A and C and an elastomeric middle layer B" to refer to anything more than one "layer A," "layer B," or "layer C" (else the claims would not be directed, as clearly stated, to a "tri-layer" sheet).

62. Second, the direct correlation drawn by the patent owner between the recited "*combined thickness of the A, B, and C layers* of from 250 microns to 2,000 microns" and the "*tri-layer polymer sheets . . . maximal thickness* of 2,000 microns" demonstrates the patentee's understanding that the claim language "at least two outer layers A and C and an elastomeric middle layer B" does not contemplate or permit there to be more than one "layer A," "layer B," or "layer C" within the claimed "tri-layer sheet," and further, consistent with Figure 1B, that all of the layers within a polymeric sheet may be assigned to one of "layer A," "layer B," or "layer C." If the "subject invention" as described to the patent office by the patentee permitted other layers within a polymer sheet besides those specifically identified as being part of "layer A," "layer B," and

[REDACTED]

“layer C,” then “the tri-layer polymer sheets . . . maximal thickness” could exceed the “combined thickness of the A, B, and C layers,” which would be directly contradicted by the statements made to the patent office.

#### **VIII. INVALIDITY FOR INDEFINITENESS**

##### **A. The Asserted Claims Are Invalid for Indefiniteness Because “Layer A,” “Layer B,” and “Layer C” Have Uncertain Claim Scope**

63. I have been informed by counsel that even if a definition for a claim term is provided in the specification, claims reciting the term can still be indefinite if a person of ordinary skill in the art cannot translate the definition for the term into meaningfully precise claim scope. In my opinion, the definition provided by the patents in suit wherein each of “layer A,” “layer B,” and “layer C” is comprised of a single layer or multiple layers and may be comprised of one or more materials or a blend of materials (’630 patent, 3:48-51; ’263 patent, 3:48-51) renders the claims indefinite because a person of ordinary skill in the art would not be able to determine the scope of the claims with reasonable certainty applying this definition.

64. The Asserted Claims recite “layer A,” “layer B,” and “layer C” using capital letter “A,” “B,” and “C,” respectively. The specification, however, uses various ambiguous labels to identify the individual single layers within a multilayer polymeric sheet. For instance, the patent ambiguously uses small and capital letters as well as prime (“’”) to identify individual layers of a multi-layer sheet, such as a, a', A, and A', in connection with Figure 1B and Table 8. (See ’630 patent, Fig. 1B, Table 8; ’263 patent, (same).) This leads to a variety of alternative and ambiguous identifications for the individual physical layers of a multilayer sheet within the claims (with each individual layer being identified by the numbers in red):



TABLE 8

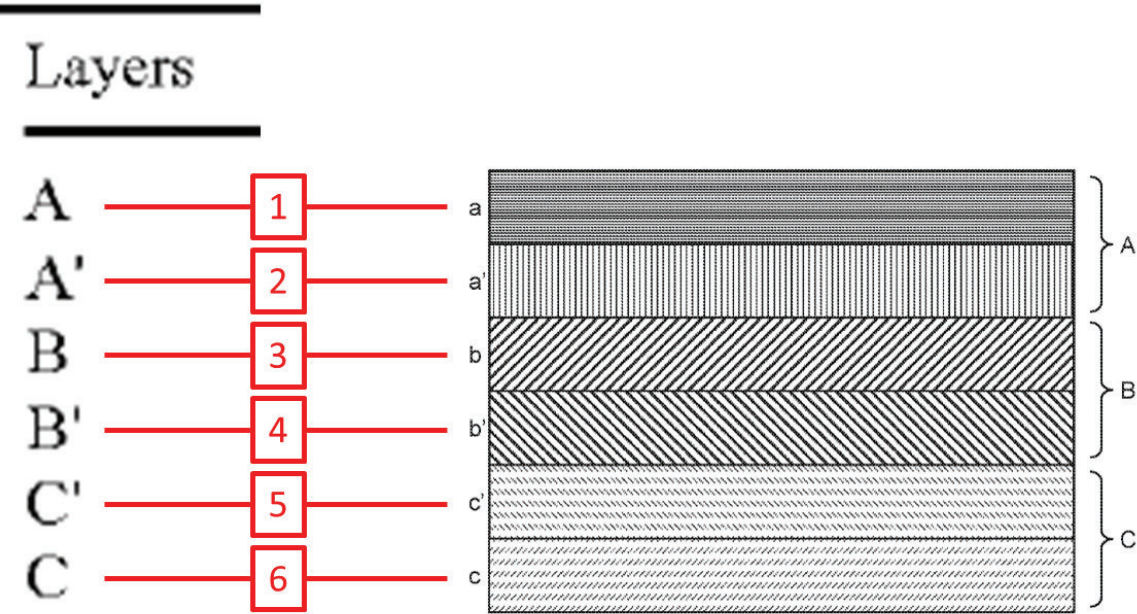


FIG. 1B

(See '630 patent, Fig. 1B; '263 patent, (same).)

65. The foregoing image depicts the indefiniteness arising with the specification’s disclosures concerning “layer A,” “layer B,” and “layer C.” For example, the patent teaches that “layer A” can be a single layer “1” when following Table 8 (on the right side of the above image) or “layer A” can be multiple layers “1” and “2” (consisting of a and a') when following Figure 1B (on the left side of the above image). The same indefiniteness arises with respect to “layer B” and “layer C,” and further is expressly permitted by the ambiguous definition of “layer A,” “layer B,” and “layer C” within the patent.

66. Thus, in my opinion, a person of ordinary skill in the art could not determine the scope of the claims with reasonable certainty because, for example, as shown in ¶65 (above), the specification expressly discloses that “layer A,” “layer B,” and “layer C” are different for the same

[REDACTED]

multilayer polymeric sheet depending on which embodiment is followed—i.e., “layer A,” “layer B,” and “layer C” each can be either a single layer (per Table 8) or multiple layers (per Fig. 1B).

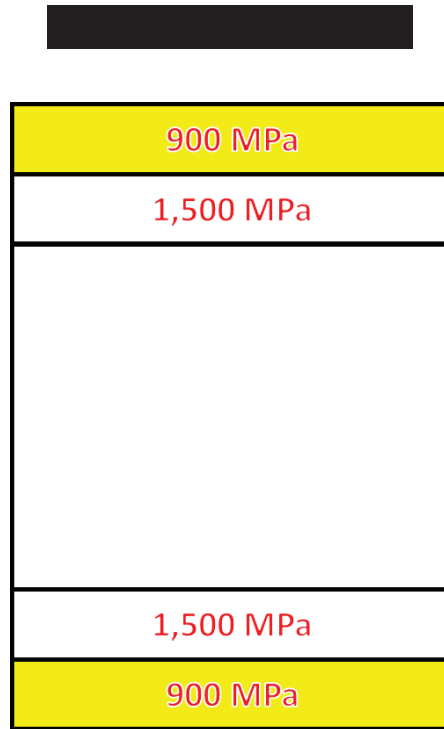
67. In my further opinion, claims 11, 12, and 18 of the '263 patent and claims 1, 2, and 9 of the '630 patent are also demonstrably indefinite based on the requirements that the “outer layers A and C” have specifically recited “flexural modulus” or “modulus” values. Claim 11 of the '263 patent recites “*the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa*” and claim 1 of the '630 patent recites “*the outer layers A and C is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa.*”

68. As one specific example of the indefiniteness of this claim language due to the ambiguous definition of “layer A,” “layer B,” and “layer C” within the Asserted Patents, a person of ordinary skill in the art seeking to design around the requirement that “layers A and C” have “a (flexural) modulus of from about 1,000 MPa to 2,500 MPa” could seek to add layers to the outside of a polymer sheet that have a relevant modulus value below “about 1,000 MPa” (*e.g.*, 900 MPa)<sup>2</sup> on top of layers that have a higher modulus value that falls within the claimed range according to the following identified modification (in yellow)<sup>3</sup>:

---

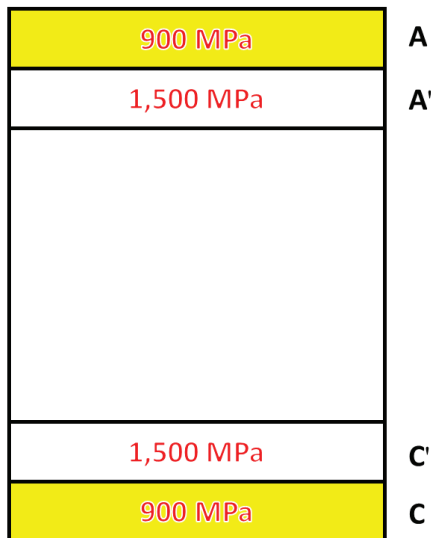
<sup>2</sup> The indefiniteness of the claims demonstrated by this example applies equally to the claims reciting a “flexural modulus” or “modulus.”

<sup>3</sup> My evaluation of indefiniteness here is the placement of layers on the outside of an otherwise infringing embodiment of the claims and with respect to the requirement of the claims regarding “layer A” and “layer C.” The recited “inner layers” are irrelevant to my demonstration of indefiniteness in this example, which applies equally to the claims of the '630 patent and the '263 patent.



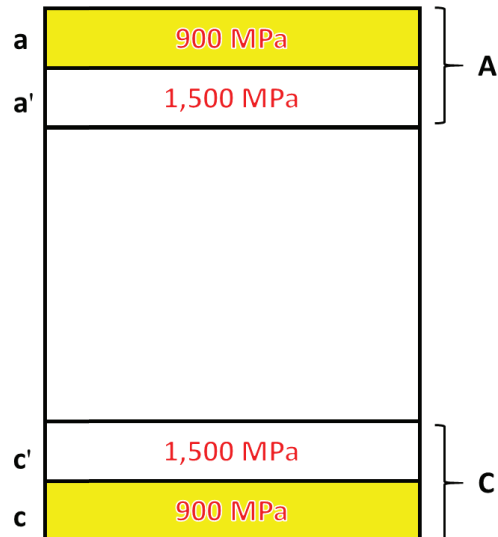
69. A person of ordinary skill in the art would not be able to determine with reasonable certainty whether adding the yellow layers to the outside of a polymer sheet would cause the resulting sheet to fall outside or inside the scope of claim 11 of the '263 patent or claim 1 of the '630 patent. As illustrated below, the indefiniteness is due to alternative outcomes based on the application of the definition and different applications of "layer A" and "layer C" in the specification of the Asserted Patents: (1) if "outer layers A and C" are each a single layer (e.g., according to the definition of "layer A" and "layer C" following Table 8) the foregoing exemplary sheet *would not satisfy the requirement that "layer A" or "layer C" has "a (flexural) modulus of from about 1,000 MPa to 2,500 MPa"* -or- (2) if "outer layers A and C" are each multiple layers (e.g., according to the definition of "layer A" and "layer C" following Fig. 1B) the foregoing exemplary sheet *could still satisfy the requirement that "layer A" or "layer C" has "a (flexural) modulus of from about 1,000 MPa to 2,500 MPa."*

“layer A” = single layer  
“layer C” = single layer



“layer A” and “layer C” do not have “a (flexural) modulus of from about 1,000 MPa to 2,500 MPa”

“layer A” = multiple layers  
“layer C” = multiple layers



“layer A” and “layer C” could have “a (flexural) modulus of from about 1,000 MPa to 2,500 MPa”

70. These different outcomes arise because the (flexural) modulus of “layer A” or “layer C” is different depending on whether each is made up of a single layer or multiple layers. When “layer A” and “layer C” are multiple layers, the (flexural) modulus of “layer A” and “layer C” will be based on the combined properties of the multiple layers that make up “layer A” and “layer C.” That is, in the example below in which the “layer A” and “layer C” are multiple layers, the (flexural) modulus will be between 900-1,500 MPa and includes values above about 1,000 MPa. Because the different alternative identifications of “layer A” and “layer C” permitted by the Asserted Patents result in a single polymer sheet that both does and does not satisfy the claims, in my opinion, this ambiguous outcome demonstrates the indefiniteness of the claims.

**B. The Recited “Flexural Modulus” Cut-Off Values Are Indefinite (Claims 1, 2, and 9 of the ’630 Patent and claims 12 and 18 of the ’263 Patent)**

71. Claim 1 of the ’630 patent recites the following limitations: “a flexural modulus of from about 1,000 MPa to 2,500 MPa” and “a flexural modulus of from about 750 MPa to 2,000 MPa.” (’630 patent, claim 1.) Claim 12 of the ’263 patent recites the following limitation: “a flexural modulus of from 500 MPa to 1,500 MPa.” (’263 patent, claim 12.) In my opinion, as explained in detail in the following paragraphs, these claim limitations are indefinite because different analytical measurements of the accepted standards for determining “flexural modulus” yield different values, the Asserted Patents do not specify a single measure or standard for determining “flexural modulus,” and, consequently, a person of ordinary skill in the art would not be able determine the scope of the claims with reasonable certainty.

72. The claims of the Asserted Patents themselves do not identify a specific method or standard to be used for determining whether the claimed “flexural modulus” values are or are not met. The specification of the Asserted Patents have a “Definitions” section. (*E.g.*, ’630 patent, 6:8-8:11.) Within the “Definitions” section, the Asserted Patents define “flexural modulus” without reference to any specific method or standard for measuring it, as follows:

The term “flexural modulus” is used herein with reference to the rigidity of a material and/or resistance of the material to deformation in bending. The higher the flexural modulus of the material, the more resistant to bending it is. For an isotropic material the elastic modulus measured in any direction are the same.

(’630 patent, 6:54-56.)

73. I did not find anything within the specification or file histories of the Asserted Patents that would otherwise require the use of a single specific method or standard that must be used to determine the value of “flexural modulus” to assess whether a recited value for “flexural modulus” is (or is not) met by claims. Rather, the only reference within the specification to any standard that *may* be used to determine a flexural modulus is permissive and does not state that it

[REDACTED]

is the only measure that can be used. (See '630 patent, 7:14-15 (“Flexural modulus *may be measured* by the test listed in ASTM D790, and uses units of force per area.”) (emphasis added).) This permissive and non-exclusive description with respect to the methods for measuring “flexural modulus” based on the “may be measured” description in the context of the Asserted Patents is contrasted against other measurement methods disclosed for other defined properties in the specification that expressly state a specific singular method or standard by specifying that such property “is measured” according to a single method or standard as part of the definition of the property. (E.g., '630 patent, 6:49-53 (“The term ‘compression set’ is used herein with reference to the permanent deformation of a material when a force is applied and removed. Unless specified otherwise, compression set *is measured* according to ASTM D 305-B at specified time and temperature, for example 22 hrs at 23° C.”) (emphasis added), 6:60-62 (“The term “hardness” is used herein with reference to a Shore hardness scale, and unless otherwise stated *is measured* according to ASTM D 2240.”) (emphasis added).) The contrast between the permissive “may be measured” with respect to the “flexural modulus” and the “is measured” language used within the specification demonstrates that the Asserted Patents in some instances did not require a specific method of measurement and in other instances did require a specific method of measurement, respectively.

74. A person of ordinary skill in the art would understand that there are multiple different methods that can be used to determine the flexural modulus of a material, and that any of those methods could be used to determine the “flexural modulus” for comparison against the asserted claims. (See Osswald Tr. at 215:10-20 (“Q. How many other accepted methods are there for determining a flexural modulus of a material? . . . A. Well, I mean, in the ASTM standards the D790 is the method to measure it, and in the ISO norms the 178 is the way to measure it. Those

[REDACTED]

are the standard methods of doing it. Then there is likely one more, the DIN, the German industrial norms, which also will measure the flexural modulus, but the most accepted ones today are the ISO and the ASTM.”.) The Asserted Patents expressly indicate that data values reported by “vendors” can be used when evaluating their disclosures and claimed inventions. (*See, e.g.*, ’630 patent, 15:14 (“Modulus from vendor literature”).) Included within the different methods reported by vendors that would be known to a person of ordinary skill in the art for determining a “flexural modulus” are the standards set forth in ISO 178 and ASTM D790. In fact, the different values for “flexural modulus” under the ISO 178 and ASTM D790 standards are regularly reported within the datasheets provided by vendors of polymers, including specifically the polymers identified in the Asserted Patents. (*See, e.g.*, Osswald Decl., Ex. M (Eastman Tritan Copolyester MX710 datasheet identifying the flexural modulus (ISO 178) = 1,495 MPa and flexural modulus (D790) = 1,550 MPa); Ex. 6 (Eastman Eastar™ Copolyester 6763 datasheet identifying the flexural modulus (ISO 178) = 2,000 MPa and flexural modulus (D790) = 2,100 MPa).)

75. The use of either the ISO or ASTM standard for determining “flexural modulus” within the asserted claims is reflected in the fact that Dr. Osswald himself refers to the ISO 178 value, and not ASTM D790 value, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*See* Osswald Decl., ¶¶55, 53.) Dr.

Osswald’s citation to Exhibit M shows that the referenced [REDACTED] has two different values for flexural modulus: [REDACTED]

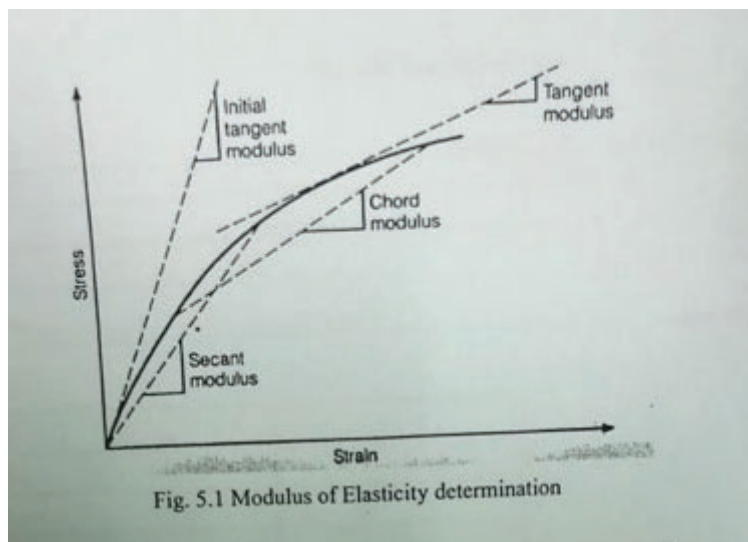
[REDACTED]

[REDACTED]

(See Osswald Decl., Ex. M.)

76. The fact that the values of “flexural modulus” vary between ISO 178 and ASTM D790, as exemplified in the above datasheet [REDACTED] arises because the different standards use different analytical methods for calculating the flexural modulus. As such, even for the same material with identically measured stress-strain data, the values of flexural modulus calculated by each method will differ. With respect to ISO-178, “[t]he reported flexural modulus is a chord modulus determined by drawing a straight line that connects the stress at 0.05% strain and the stress at 0.25% strain” (hereinafter referred to as “FM<sub>ISO-178-chord</sub>”); whereas in ASTM D790, the flexural modulus may be calculated based on a

“tangent” modulus<sup>4</sup> determined by drawing a tangent to the steepest initial straight line portion of the load-deflection curve and then dividing the difference in stress on any section of this line by the corresponding difference in the strain” (hereinafter referred to as “ $FM_{ASTM-D790-tangent}$ ”). (See Ex. 20, Modern Plastics Handbook, Table 11.22; Ex. 21 (ISO-178); Ex. 22 (ASTM D790).) The following image generally depicts how different flexural moduli can be calculated from a single stress-strain data set on a given material, with the calculation of  $FM_{ISO-178-chord}$  akin to the depicted “Chord modulus” and  $FM_{ASTM-D790-tangent}$  akin to the depicted “Initial tangent modulus”:



77. In my opinion, the recited limitation of “a flexural modulus of from about 1,000 MPa to 2,500 MPa” and “a flexural modulus of from about 750 MPa to 2,000 MPa” in claim 1 of the '630 patent and “a flexural modulus of from 500 MPa to 1,500 MPa” in claim 12 of the '263 patent do not have reasonably certain scope because a given polymer or “polymer sheet” can simultaneously satisfy and not satisfy the claim limitations depending upon which measure of “flexural modulus” is used to determine claim scope.

<sup>4</sup> Other methods of calculating the flexural modulus under ASTM D790 include a “secant” modulus. (See, e.g., Ex. 20, Modern Plastics Handbook at Table 11.22.) For purposes of my analysis herein, I focus on the “tangent” flexural modulus.

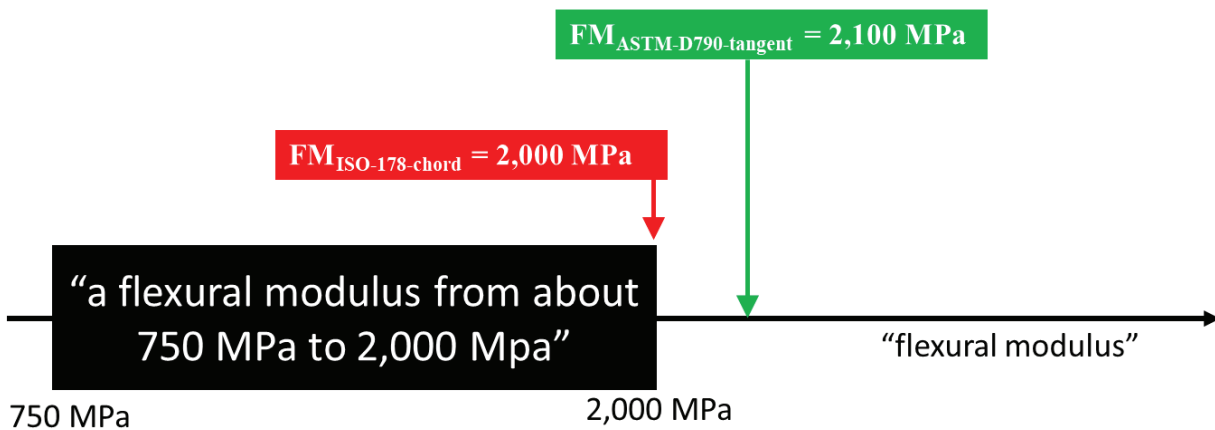
[REDACTED]

78. By way of example, Dr. Osswald has identified the flexural modulus for [REDACTED] according to ISO-178 as having a value of [REDACTED] ( $FM_{\text{ISO-178-chord}} = \text{[REDACTED]}$ ) and the datasheet for [REDACTED] also indicates a flexural modulus according to ASTM D790 of [REDACTED] ( $FM_{\text{ASTM-D790-tangent}} = \text{[REDACTED]}$ ). (See Osswald Decl., ¶¶55, 53, Ex. M.) Although the different values for flexural modulus in the datasheet are in the context of single materials, the differences between  $FM_{\text{ISO-178-chord}}$  and  $FM_{\text{ASTM-D790-tangent}}$  are indicative of the same differences that would be demonstrated using the different measures for multi-layer polymer sheets. Accordingly, for example, the exemplary differences in the flexural modulus between  $FM_{\text{ISO-178-chord}}$  and  $FM_{\text{ASTM-D790-tangent}}$  when compared against the claim language “a flexural modulus of from 500 MPa to 1,500 MPa” in claim 12 of the '263 patent highlights the situation that underlies my opinion of indefiniteness because the ISO 178 method ([REDACTED]) would satisfy the claim language and the ASTM D790 method ([REDACTED]) would not:

[REDACTED]

79. By way of further example, Table 1 of the '630 patent identifies the material “Estar 6763” supplied by Eastman Chemical. ('630 patent, column 14 (Table 1).) Table 1 identifies Estar 6763 as having a “modulus range” of 2,000 to 2,100 MPa. (*Id.*) The data sheet for Estar 6763 identifies that  $FM_{\text{ISO-178-chord}} = 2,000$  MPa and  $FM_{\text{ASTM-D790-tangent}} = 2,100$  MPa. Again, although the different values for flexural modulus in the datasheet are in the context of single

materials, the differences between  $FM_{\text{ISO-178-chord}}$  and  $FM_{\text{ASTM-D790-tangent}}$  are indicative of the same differences that would be demonstrated using the different measures for multi-layer polymer sheets. Accordingly, for example, the exemplary differences in the flexural modulus between  $FM_{\text{ISO-178-chord}}$  and  $FM_{\text{ASTM-D790-tangent}}$  when compared against the claim language “a flexural modulus of from about 750 MPa to 2,000 MPa” in claim 1 of the '630 patent highlights the situation that underlies my opinion of indefiniteness because the ISO 178 method ( $FM_{\text{ISO-178-chord}} = 2,000 \text{ MPa}$ ) would satisfy the claim language and the ASTM D790 method ( $FM_{\text{ASTM-D790-tangent}} = 2,100 \text{ MPa}$ ) would not:



80. The foregoing examples in paragraphs 78-79 highlight the differences in values of “flexural modulus” between the ISO 178 “chord” method of calculating the flexural modulus and the ASTM D790 “tangent” method of calculating the flexural modulus, and that the differences in those test methods are outcome-determinative regarding the scope of the claims. Regardless of any particular value recited for a flexural modulus cutoff within the claims, the different methods can yield different results regarding the scope of the claims because there will be instances where a given polymer or polymer sheet will fall both within and outside the recited value depending on whether the ISO 178 “chord” method or the ASTM D790 “tangent” method is used. Hence, although my examples above are specific, they demonstrate the indefiniteness of the specific

recited claim language of “a flexural modulus of from about 1,000 MPa to 2,500 MPa” and “a flexural modulus of from about 750 MPa to 2,000 MPa” in claim 1 of the ’630 patent and “a flexural modulus of from 500 MPa to 1,500 MPa” in claim 12 of the ’263 patent.

81. Furthermore, it is well known that a single polymer can have at least two differently calculated values for the generic “molecular weight” in the form of one calculation based on the number-average molecular weight (referred to as “ $M_n$ ”) and another calculation based on the weight-average molecular weight (referred to as “ $M_w$ ”). I have been informed that a numerical cutoff for a polymer that generically refers to a “molecular weight” cutoff value(s) without specifying whether the molecular weight refers to  $M_n$  or  $M_w$  (e.g., “a *molecular weight* of about 5 to 9 kilodaltons” or “a *molecular weight* of 2000 or less”) has been found by the courts to be indefinite.<sup>5</sup> In my opinion, the same reasoning applies to the claimed “flexural modulus” in that the  $FM_{ISO-178-chord}$  and  $FM_{ASTM-D790-tangent}$  are calculated in different ways and yield different outcome-determinative results as shown above in paragraphs 78-79. That is, in my opinion, the indefiniteness that arises from the different calculated values of flexural modulus for a given material is directly analogous to the indefiniteness that arises when the measure of the molecular weight of a polymer is not specified, and this further supports my opinion of indefiniteness here.

| Recited claim limitation(s)                                                                                                                                        | Different possible measures for calculating the recited limitation | Conclusion/Opinion                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• “a <i>molecular weight</i> of about 5 to 9 kilodaltons”</li> <li>• “a <i>molecular weight</i> of 2000 or less”</li> </ul> | $M_n$<br>-or-<br>$M_w$                                             | I understand such limitations have been found indefinite in judicial decisions because different ways of calculating <i>molecular weight</i> (either $M_n$ |

<sup>5</sup> My opinion herein is based on the analogy arising from the specific information on which I have been made aware regarding indefiniteness determinations by the courts arising from patent claims that recite “molecular weight” cutoffs without specifying a single method of calculating the molecular weight.

| Recited claim limitation(s)                                                                                                                                                                                                                                                                                                                | Different possible measures for calculating the recited limitation     | Conclusion/Opinion                                                                                                                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                            |                                                                        | and Mw) would yield different results for a given sample depending on the method used to determine “molecular weight”                                                                                                                                                                                 |
| <ul style="list-style-type: none"> <li>• “a <b>flexural modulus</b> of from about 1,000 MPa to 2,500 MPa” (’630 patent, claim 1)</li> <li>• “a <b>flexural modulus</b> of from about 750 MPa to 2,000 MPa.” (’630 patent, claim 1)</li> <li>• “a <b>flexural modulus</b> of from 500 MPa to 1,500 MPa.” (’263 patent, claim 12)</li> </ul> | FM <sub>ISO-178-chord</sub><br>-or-<br>FM <sub>ASTM-D790-tangent</sub> | In my opinion, these limitations are indefinite because different ways of calculating <b>flexural modulus</b> (either FM <sub>ISO-178-chord</sub> and FM <sub>ASTM-D790-tangent</sub> ) would yield different results for a given sample depending on the method used to determine “flexural modulus” |

**IX. INVALIDITY FOR LACK OF ENABLEMENT OF “AT LEAST TWO (RIGID OR HARD) OUTER LAYERS A AND C” IN ALL ASSERTED CLAIMS**

82. Claim 1 of the ’630 patent recites “at least two outer layers A and C” and claim 11 of the ’263 patent recites “at least two rigid or hard outer layers A and C.” The plain meaning of “at least two” means two *or more*. Thus, by reciting “at least two,” the full claim scope includes, for example, three or more outer layers A and C.

83. In my opinion, the full scope of the claims is not enabled because there is no description or teaching in the patent as to how to make a polymeric sheet with more than two “outer layers A and C.” Rather, a person of ordinary skill in the art would understand that a polymer sheet has only two opposing “outer” sides or surfaces and that the single layer or multiple layers that comprise “layer A” and “layer C” will have only one exterior outer surface. Accordingly, I do not believe that a person of ordinary skill in the art would be able to make a polymeric sheet that has a third “layer A” or “Layer C.”

[REDACTED]

84. My opinion is further supported by the fact that there is no embodiment in the patent of a polymeric sheet that has more than “two outer layers A and C.” Every disclosed embodiment has only two outer layers. Figure 1A discloses a three-layer polymer sheet with just two “outer layers A and C.” (’630 patent, Fig. 1A.) With respect to multiple layer polymer sheets with more than three layers, the specification likewise only discloses two “outer layers A and C.” The 6-layer sheet depicted in Figure 1B discloses only two “outer layers A and C,” wherein “layer A” is made up of layers a and a' and “layer C” is made up of layers c' and c. (’630 patent, Fig. 1B.) Similarly, the 5-layer sheet depicted in Sample #8 of Table 8 also only discloses two “outer layers A and C” and distinguishes between the recited “layer A” and “layer C” from the identified layer A' and layer C'. (’630 patent, column 21 (Table 8).)

85. Accordingly, because the full scope of the claims include more than “two outer layers A and C” and because a person of ordinary skill in the art would not be able to make a polymeric sheet with more than “two outer layers A and C,” it is my opinion that the claims are invalid for a lack of enablement.

**X. NON-INFRINGEMENT OF CLARITY™ ALIGNERS FLEX**

86. In my opinion, Dr. Osswald’s opinions of infringement are flawed. I understand that the first step in an infringement analysis is to determine the meaning and scope of the claim language in accordance with the intrinsic record and the legal principles explained to me and set forth above. In this regard, Dr. Osswald has not set forth any specific interpretation of any of the claim language and during deposition admitted that he “did not do an analysis on the meaning of words in the claim.” (Osswald Tr. at 10:16-17.)

87. Dr. Osswald asserts that “[i]n the absence of a formal construction by the Court, however, I have applied the claims in accordance with *my belief* of how a person of ordinary skill

[REDACTED]

in the art at the time of the invention, reading the patent and prosecution history, would have understood the claims.” (Osswald Decl., ¶15 (emphasis added).) Yet, Dr. Osswald never articulates how he is interpreting any specific claim language based on his “belief.” At best, he seems to imply that claim terms are to be interpreted according to their plain meaning in the absence of a formal construction by the Court. (Osswald Decl., ¶15.) In my opinion, Dr. Osswald has not properly interpreted and applied the claim language.

88. For instance, claim 1 of the ’630 patent recites “layers A and C” and “layer B.” (’630 patent, claim 1.) As I explain above in paragraphs 49-62, the specification of the ’630 patent departs from the ordinary usage of “layer” when describing the recited “layer A,” “layer B,” and “layer C,” which Dr. Osswald has not accounted for in his opinions. Likewise, as I explain above in paragraphs 56-62, the term “inner layer B” in the ’630 patent has no established meaning within the art, and the proper construction of this term based on the teachings of the specification is that “inner layer B” refers to “the middle or core layer of a multilayer polymeric sheet, which is comprised of a single layer or multiple layers and may be comprised of one or more materials or a blend of materials.”

89. According to Dr. Osswald, the terms “layer A,” “layer B,” and “layer C” are “just labels” within the claims. (Osswald Tr. at 178:8-10 (“I say ‘At least two outer layers A and C and elastomeric inner layer B.’ To me A and B, they’re just labels, right.”).) I disagree with Dr. Osswald’s presumption that the recited claim terms “layer A,” “layer B,” and “layer C” are “just labels” because the specification’s express description for the terms provides them with specific meaning, which have no established plain meaning outside of the context of the intrinsic record.

90. Furthermore, the conclusion that “layer A,” “layer B,” and “layer C” have meaning distinctly different from the plain meaning of “layer” is further reflected in the differences between

[REDACTED]

the two independent claims of the '630 patent. In contrast to independent claim 1, independent claim 15 recites a “polymeric sheet composition” that recites at least five different layers (“more than two rigid layers” plus “two or more elastomeric layers”), and uses the plural term “layers” without identifying the layers according to any of “layer A,” “layer B” or “layer C.” In my opinion, the contrast between these two claims further demonstrates that reciting “layer A,” “layer B,” and “layer C” within claim 1 is different from a generically recited “layer” and that the “A,” “B,” and “C” language chose by the patentee are not “just labels,” but rather that they must be interpreted and applied based on the disclosures in the intrinsic record.

91. The only disclosures in the '630 patent showing the stacking of a 5-layer or 6-layer polymeric sheet in the context of “layer A,” “layer B,” and “layer C,” is in Table 8 and Figure 1B, respectively. Dr. Osswald, however, has not set forth how he interpreted these portions of the specification as part of his opinions of infringement. To the contrary, his opinions are inconsistent with these relevant disclosures in the specification of the '630 patent. In fact, with respect to the disclosure of a 5-layer sheet in Table 8, Dr. Osswald admitted that he “did not do an analysis on that particular example.” (Osswald Tr. at 9:16-25, 100:17-101:20.) In my opinion, Dr. Osswald’s failure to follow the express example in Table 8 of the '630 patent indicates that he is not properly applying the specification’s teaching to the claimed inventions within his analysis.

92. In my opinion, following the express teachings of the specification regarding the disclosures of a 5-layer polymeric sheet, the accused Clarity™ Aligners Flex material does not infringe any of the Asserted Claims.

**A. Claims 1, 2, and 9 of the '630 Patent**

**1. Non-infringement of claims 1, 2, and 9 of the '630 patent**

93. Independent claim 1 of the '630 patent recites “an elastomeric inner layer B” wherein “the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75.” ('630 patent, claim 1.) As noted above in paragraphs 56-62, I have interpreted the term “inner layer B” from the specification and file history as referring to the middle core layer, which is comprised of a single layer or multiple layers and may be comprised of one or more materials or a blend of materials. I further understand that the core layer (3) of the Clarity™ Aligners Flex material has been identified by Dr. Osswald as comprising the [REDACTED] and has identified it as having tensile modulus of [REDACTED] (See, e.g., Osswald Decl., ¶132.) In my opinion, Clarity™ Aligners Flex does not infringe claims 1, 2, and 9 of the '630 patent because its material's middle core layer is not comprised of an elastomeric material having a hardness from about A80 to D75.

94. My opinion is also supported by the sole example of a 5-layer polymeric sheet in the '630 patent Sample 8 of Table 8, which I have annotated below:

TABLE 8

---

**Exemplary Multilayer Sheet Materials**

---

|        | Sample #6         |           | Sample #7                                   |           | Sample #8             |           |          |           |
|--------|-------------------|-----------|---------------------------------------------|-----------|-----------------------|-----------|----------|-----------|
| Layers | Material          | Thickness | Material                                    | Thickness | Material              | Thickness |          |           |
| A      | Trogamide CX 7323 | 0.125 mm  | Trogamide CX 7323/Polyamide 614 Blend 90:10 | 0.2 mm    | Altuglas Luctor CR 13 | 0.125 mm  | <b>1</b> | <b>A</b>  |
| A'     |                   |           |                                             |           | Altuglas SG10         | 0.125 mm  | <b>2</b> | <b>A'</b> |
| B      | Pebax Clear 300   | 0.5 mm    | Pellethane 2373 55D                         | 0.3 mm    | Kurararity LA4285     | 0.25 mm   | <b>3</b> | <b>B</b>  |
| B'     |                   |           |                                             |           |                       |           |          |           |
| C'     | Trogamide CX 7323 | 0.125 mm  | Trogamide CX 7323/Polyamide 614 Blend 90:10 | 0.2 mm    | Altuglas SG10         | 0.125 mm  | <b>4</b> | <b>C'</b> |
| C      |                   |           |                                             |           | Altuglas Luctor CR 13 | 0.125 mm  | <b>5</b> | <b>C</b>  |

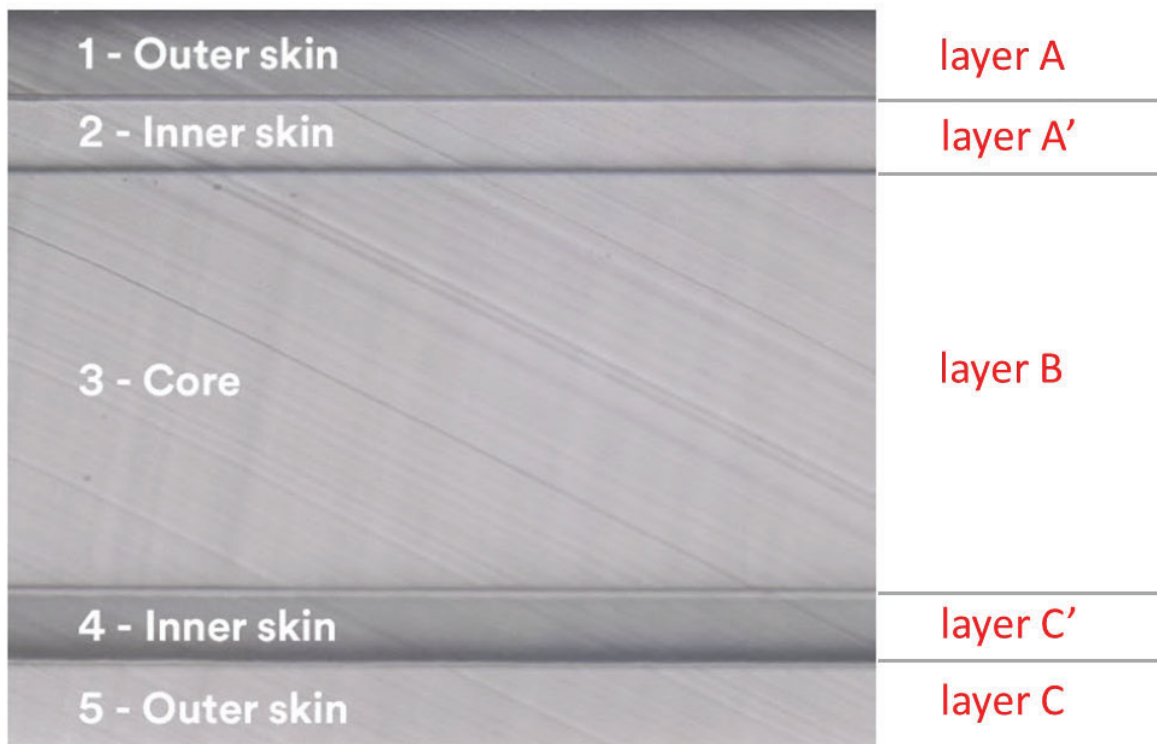
} 5-layers

Altuglas SG10 is a transparent impact modified polymethyl methacrylate sold by Arkema  
Altuglas Luctor CR13 is a transparent impact modified polymethyl methacrylate sold by Arkema  
Kurararity LA4285 is an acrylic ABA block co-polymer of methyl methacrylate and butyl methacrylate

('630 patent, column 21 (Table 8).)

95. With respect to the 5-layer construct of Sample 8, the middle core layer (i.e., “3”) is identified as “layer B,” and the overall layers 1-2-3-4-5 are identified as having an A-A'-B-C'-C stacking configuration. Here, layer A, layer A', layer B, layer C', and layer C are *single* layers and all 5 layers are assigned a letter within the stacking configuration (i.e., no layers within Sample 8 are skipped with reference to their stacking configuration), and the “inner layer B” is plainly middle core layer 3.

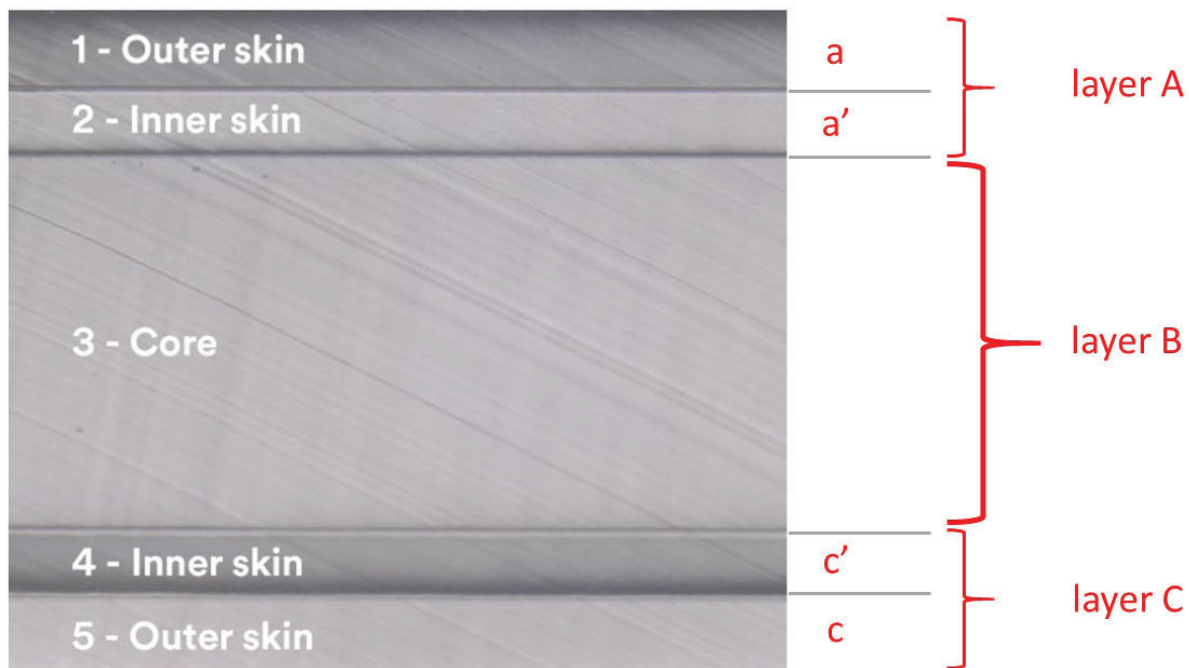
96. Applying the same stacking sequence of the 5-layer polymeric sheet of Sample 8 in Table 8 to the Clarity™ Aligners Flex yields the following configuration, wherein the core of the Clarity™ Aligners Flex is “inner layer B” and the skins are layers A and A' and layers C and C', respectively:



97. Based on my understanding that the core layer (3) of the Clarity™ Aligners Flex material has been identified by Dr. Osswald as comprising the [REDACTED]

██████████ and has identified it as having tensile modulus of ██████████ it is not an elastomeric material and it does not have a hardness “from about A80 to D75.”

98. Furthermore, as noted above in ¶52, the '630 patent expressly teaches that “[l]ayer A may be comprised of more than one layer, for example, layer a and a’” and “layer C may be comprised of more than one layer, for example, layer c and c’[.]” ('630 patent, 3:47-55.) Thus, according to the definition for “layer A” and “layer C” provided in connection with Figure 1B, the “outer layers A and C” can each be comprised of multiple layers and each can be comprised of more than one material, which leads to the following ABC tri-layer stacking configuration when compared against the 5-layer Clarity™ Aligners Flex:



99. In my further opinion, Dr. Osswald’s interpretation of the claims is inconsistent with the intrinsic record in ways that fails to justify or explain. First, Dr. Osswald fails to acknowledge that the claimed ABC layering scheme used to describe and claim the purported inventions in the '630 patent—i.e., “at least two outer layers A and C and an elastomeric inner

layer B”—has no plain meaning in the art. To the contrary, in my opinion, the ABC stacking scheme of the '630 patent claims must follow the intrinsic record. Dr. Osswald has not done so.

100. Second, Dr. Osswald improperly contends that the “‘Inner skin’ 2 and 4 correspond to inner layer B.” (Osswald Decl., ¶100.) The intrinsic record lacks any teaching, however, where more than one “inner layer B” exists in any of the disclosed polymer sheets of the '630 patent.

101. Third, Dr. Osswald incorrectly ignores the inner core of the Clarity™ Aligners Flex material in his identification of the claimed “layer A,” “layer B,” and “layer C” within the claims. As I note above in paragraphs 56-62 regarding the proper construction of “inner layer B” from the specification and relevant file history, “inner layer B” expressly refers to the middle core layer of a polymeric sheet.

102. Fourth, as I have explained above in paragraphs 63-66, the Asserted Claims of the '630 patent are, in my opinion, invalid for indefiniteness. Dr. Osswald appears to rely on the indefiniteness of the claim language regarding “layer A,” “layer B,” and “layer C” because he interprets what constitutes “layer B” different in different portions of his infringement opinions as demonstrated below. (*Compare* Osswald Decl., ¶100 *with* Osswald Decl., ¶126.) That is, in one instance Dr. Osswald states that for the Clarity™ Aligners Flex the “‘Inner Skin’ 2 and 4 correspond to inner layer B” and in another instance he contends that “‘Inner Skin’ layers 2 and 4 correspond to inner layers B and B'.” Dr. Osswald provides no justification from the intrinsic record for why or how he is interpreting the same layers in the Clarity™ Aligners Flex as different “layer B” in his analysis.

103. Finally, in my opinion, Dr. Osswald’s opinions regarding claim 9 of the '630 patent are clearly incorrect because his opinions do not properly interpret the claim language. Claim 9 recites: “9. A dental appliance conformal to one or more teeth comprising a polymeric sheet

[REDACTED]

composition according to claim 2.” Claim 9 recites a “dental appliance” that has all of the limitations of dependent claim 2: “2. The polymeric sheet composition of claim 1, wherein the A, B and C layers of the polymeric sheet composition have a combined thickness of from about 250 microns to 2,000 microns.” In my interpretation of claim 9, it requires that the combined thickness of “the A, B, and C layers” in the “dental appliance” be at least about 250 microns. In Dr. Osswald’s identification of his interpretation of the claimed layers “A, B, and C,” which I do not agree with, he has identified the combined thickness of the layers as 218 microns. (Osswald Decl., ¶116 (“those layers have *a combined thickness of 218 microns* after thermoforming”) (emphasis added).) Because the claim is specifically directed to the features of the “dental appliance,” in my opinion Dr. Osswald cannot show infringement under his (improper) interpretation of the claims.

104. According to Dr. Osswald, the “dental appliance” limitation of claim 9 can be satisfied by a thermoformed aligner and the dependent limitations of combined thickness of the A, B, and C layers of claim 2 (i.e., “the A, B and C layers of the polymeric sheet composition have a combined thickness of from about 250 microns to 2,000 microns”) can be satisfied by the pre-thermoformed Clarity™ Aligners Flex material. (Osswald Tr. at 212:19-213:2 (“Q. Right. So you were -- you were relying on for claim 9 the thermoformed Clarity™ Aligner Flex dental appliance to satisfy the “dental appliance conformal to one or more teeth” requirement, and then for the thickness portion of claim 2 you’re relying on the pre-thermoformed thickness of the Clarity™ Aligner sheet, right? A. Correct.”).) I see nothing in the claim that would permit such an interpretation.

105. To the contrary, claim 9 is plainly directed to a polymeric sheet composition in the form of the “dental appliance” because the claim recites that it is to a “dental appliance . . . *comprising* a polymeric sheet composition according to claim 2.” The claim does not recite a

[REDACTED]

“dental appliance . . . *made from* a polymeric sheet composition according to claim 2,” which I have been informed by counsel would referred to as a product-by-process claim. Accordingly, in my opinion, Dr. Osswald’s opinions regarding claim 9 of the ’630 patent cannot support a finding of infringement because they misinterpret the claim language.

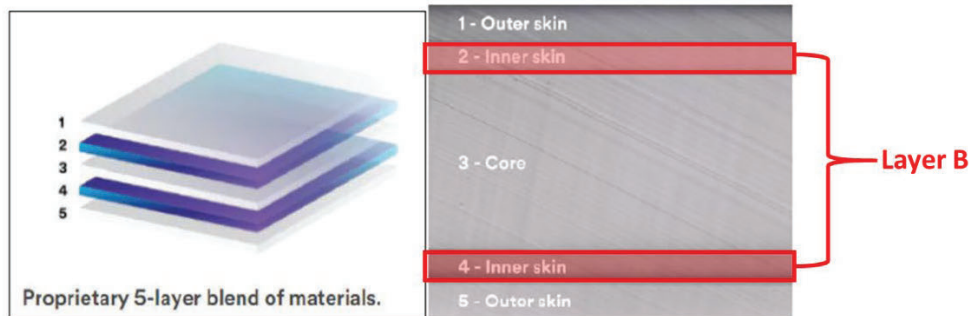
**2. Non-infringement of claims 11, 12, and 18 of the ’263 patent**

106. Claim 11 of the ’263 patent recites a polymeric sheet with “layer A,” “layer B,” “layer B’,” “layer C,” and “layer D.” Although the claim recite additional layers beyond “layer A,” “layer B,” and “layer C,” in my opinion, because the ’263 patent shares the same disclosures as the ’630 patent, the same conclusions regarding non-infringement of the ’630 patent apply here as well. That is, the 5-layer Sample 8 in Table 8 of the ’263 patent is the same as in the ’630 patent and according to this embodiment, which is identically contained in the ’630 patent, the 5-layer Clarity™ Aligners Flex material has an A-A'-B-C'-C layer configuration and therefore does not infringe the asserted claims of the ’263 patent.

107. While the ’263 patent contains new matter that discloses a polymeric sheet that includes a “layer D” and “layer B’,” by maintaining the same disclosures with respect to “layer A,” “layer B,” and “layer C” and reciting those same layers within the claims of the ’263 patent, the same layering configuration with respect to ABC must still apply: layer B is the inner core of the polymeric sheet. For instance, claim 1 of the ’263 patent recites “at least two outer layers A and C and an elastomeric inner layer B,” which is identical to the same language in claim 1 of the ’630 patent. This indicates that the ’263 patent maintains the same meaning for “layer A,” “layer B,” and “layer C” as associated with the ABC configuration disclosed within the ’263 patent and the ’630 patent.

108. I see no principled reason why the identification of, for example, “layer B” should be different between different claims of the same patent. In this regard, Dr. Osswald contends that there is no “layer B” within the 5-layer Clarity™ Aligners Flex material in the context of claim 1 of the ’630 patent, which would apply equally to the interpretation of what constitutes “layer B” in the claims of the ’263 patent:

Dr. Osswald’s identification of “layer B” in the Accused Product



100. According to the above images, “Outer skin” 1 and 5 correspond to outer layers A and C. In my opinion, “Inner skin” 2 and 4 correspond to inner layer B.

(Osswald Decl., ¶100.)

109. Thus, following this opinion from Dr. Osswald, the 5-layer Clarity™ Aligners Flex material does not have a B' layer and therefore does not infringe the claims of the ’263 patent. Dr. Osswald has provided no indication or justification for how he is supporting different interpretations of the identical language “layer B” as between his different opinions.

## **XI. INVALIDITY BASED ON THE PRIOR ART**

110. In my opinion, the asserted claims of the ’630 patent and ’263 patent are invalid over the disclosures and teachings of the prior art.

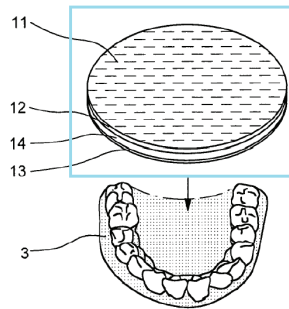
### **A. Prior Art Invalidity of Claims 1, 2 and 9 of the ’630 Patent**

#### **1. Claims 1, 2, and 9 of the ’630 patent are anticipated by Hinz**

a. **Independent Claim 1**

i **“A polymeric sheet composition, comprising:” ([1pre])**

111. To the extent the preamble of claim 1 recites a claim limitation, Hinz discloses a **“polymeric sheet composition,”** as shown in Figure 3:



(Ex. 7, (“Hinz”), Fig. 3.)<sup>6</sup>

112. A skilled artisan would recognize that Hinz’s “deep-drawing film 11” (Hinz, 8:241), as shown in Figure 3 above, discloses a **“polymeric sheet composition”** as claimed.

ii **“at least two outer layers A and C and an elastomeric inner layer B,” ([1a])**

113. As described in Hinz: “Figure 3 shows that a three-layer dental splint according to the invention can also be obtained in a single step deep-drawing process by deep drawing a deep-drawing film 11 which has a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Hinz, 8:240-243.)

114. Hinz accordingly discloses **“at least two outer layers A and C,”** as claimed, in the form of “two outer hard layers 12, 13 made of polycarbonate.” (Hinz, 8:242.)<sup>7</sup>

<sup>6</sup> All emphasis and color annotation have been added to the cited text and figures, unless otherwise noted.

<sup>7</sup> The ’630 specification also describes embodiments in which “the A and C layers are comprised of... a polycarbonate....” (’630 patent, 1:61-62.)

115. Hinz also discloses “**an elastomeric inner layer B**” in the form of “a soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Hinz, 8:242-243.) Hinz describes this “internal soft layer” as “having higher elasticity” than the two hard outer layers. (Hinz, 3:73-76.) Hinz also refers to the polyurethane used for the “soft layer” as a “thermoplastic polyurethane (TPU),” and explains that use of this material “result[s] in a sufficiently high elasticity of the dental splint according to the invention....” (Hinz, 3:89-91; *see also* Hinz, 9:278, 10:323.) A skilled artisan would reasonably understand<sup>8</sup> Hinz’s “soft layer 14 made of polyurethane” to disclose an “**elastomeric**” inner layer. (*See* Osswald Tr. at 265:3-5 (TPUs fall under elastomeric materials).)

iii      **“wherein one or more of the outer layers A and C is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa,” ([1b])**

116. As explained, the “**outer layers A and C**” correspond in Hinz to the “two outer hard layers 12, 13 made of polycarbonate.” (Hinz, 8:242.) A skilled artisan would recognize that “polycarbonate” as used in Hinz is a “**polyester**,” and accordingly, would recognize that Hinz discloses “**wherein one or more of the outer layers A and C is a polyester or co-polyester.**”<sup>9</sup>

117. Moreover, “polycarbonate,” as used in Hinz, discloses and anticipates a “**polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa.**” This is because a skilled artisan would recognize Hinz’s polycarbonate to be one of the several compositions covered by claim 1’s recitation of “**polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa.**” I have been informed that under the legal

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<sup>8</sup> In an anticipation analysis, under the legal principles of anticipation as I have been informed by counsel, the dispositive question is whether a skilled artisan would reasonably understand or infer from a prior art reference that every claim limitation is disclosed in that single reference. I further understand that my expert testimony permissibly sheds light on what a skilled artisan would reasonably understand or infer from a prior art reference.

<sup>9</sup> *See, e.g.*, Osswald Decl., Ex. E at p.xvii (identifying subchapter “5.9.1 Polycarbonates (PC)” as a section within chapter “5.9 Aromatic (Saturated) Polyesters.”)

principles, when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated if *one* of them is in the prior art.

118. As discussed, a skilled artisan would recognize Hinz's polycarbonate to be a **"polyester."** A skilled artisan would further recognize that Hinz's polycarbonate has a **"flexural modulus"** that is higher than 1,000 MPa and lower than 2,500 MPa, i.e., a flexural modulus *within* the claimed range of **"about 1,000 MPa to 2,500 MPa."** As confirmed by one of the textbooks cited by Dr. Osswald, non-reinforced polycarbonate has an elastic modulus of about 2,350-2,400 MPa. (See Ex. 8 (Baur, *Plastics Handbook*), p.459 (identifying "[t]ensile modulus of elasticity" as "2350-2400" MPa).) As further explained by Dr. Osswald, "[f]lexural modulus is fundamentally equivalent to the elastic modulus of a material...." (Osswald Decl., ¶30; *see also* Osswald Tr. at 234:5-12 (testifying that flexural modulus and elastic modulus are "relatively the same for single materials").) Consistent with Dr. Osswald's explanation, a skilled artisan would therefore recognize Hinz's polycarbonate to be *one specific example* of the range of compositions covered by claim 1's recitation of a **"polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa."** A skilled artisan would also recognize Hinz's specific use of polycarbonate to disclose the claimed modulus range of **"about 1,000 MPa to 2,500 MPa"** with sufficient specificity.<sup>10</sup> I understand that, when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated if *one* of them is in the prior art.

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<sup>10</sup> Although **reinforced** polycarbonate and polycarbonate-based **blends** can have a different elastic (and flexural) modulus, Hinz nowhere discloses (or even implies) that the polycarbonate it uses would be a **reinforced** polycarbonate or a polycarbonate-based **blend**. Even if Bay Materials or Dr. Osswald were to argue it is possible for polycarbonate to have a flexural modulus higher than 2,500 MPa, it would still have been natural and obvious, for purposes of my obviousness theory (discussed at **Part XI.A.2** below), to use polycarbonate having a flexural modulus that falls within the claimed range of **"about 1,000 MPa to 2,500 MPa."** This is because Hinz suggests that one should not use polycarbonate that is "very hard" or "superficially reinforced." (Hinz, 2:36-38 ("The known splints made of polycarbonate have the disadvantage, however, that they are very

119. To the extent Bay Materials or Dr. Osswald argues that it is possible for Hinz's polycarbonate to have a ***broader range*** of values for its flexural modulus (e.g., a broader range of values than 2,350-2,400 MPa as evidenced by the Baur textbook), any such alleged broader range would still necessarily ***overlap*** with the claimed range of “**about 1,000 MPa to 2,500 MPa**,” and a skilled artisan would recognize this overlap. I have been informed that under the legal principles, a prima facie case of anticipation can be sufficiently established through the prior art's disclosure of ***overlapping*** ranges.<sup>11</sup>

iv      **“the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75, and”  
([1c])**

120. As explained for claim 1a (*see Part XI.A.1.a.ii* above), the “**elastomeric**,” “**inner layer B**” corresponds to Hinz's “soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Hinz, 8:242-243.) Hinz describes the “internal soft layer” as “having higher elasticity.” (Hinz, 3:76.) Hinz also refers to the polyurethane used for the “soft layer” as a “thermoplastic polyurethane (TPU),” and explains that use of this material “result[s] in a sufficiently high elasticity of the dental splint....” (Hinz, 3:89-91; *see also id.*, 9:278, 10:323.)

121. Based on these descriptions, a skilled artisan would reasonably understand Hinz to disclose, with sufficient specificity, an elastomeric material having a “hardness” that *overlaps* with

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hard, particularly because they are superficially reinforced with acrylic....”).) A skilled artisan would also understand that using polycarbonate with relatively lower stiffness (i.e., within the claimed range of “**about 1,000 MPa to 2,500 MPa**”) allows Hinz's dental device to be “inserted into and removed from patients easily,” which Hinz describes as a desirable characteristic of his invention. (Hinz, 2:56-57, 2:58-59.)

<sup>11</sup> I understand from counsel that a “prima facie case of anticipation,” as that phrase is used in the patent laws, refers to the legal principle that once the patent challenger has established its prima facie case of anticipation (through the prior art's disclosure of an overlapping range), the burden of production then falls upon the patentee to come forward with evidence that the claimed range is ***critical*** to the operability of the claimed invention.

the claimed range of “**about A80 to D75.**” A skilled artisan would recognize that a “thermoplastic polyurethane (TPU),” as used for Hinz’s soft layer (Hinz, 3:89-91, 8:242-243), is a material with a hardness range that overlaps with “**about A80 to D75,**” as claimed. (See, e.g., Ex. 9 (Campo, *Selection of Polymeric Materials* (2008)), p.51 (Table 2.3 listing TPUs with individual hardnesses of A90, D51, and D62); Ex. 10 (Drobny, *Handbook of Thermoplastic Elastomers* (2014)), pp.398-399 (identifying “Desmopan 445” TPU with hardness of D45, “Desmopan 453” TPU with hardness of D53).)<sup>12</sup> As mentioned, I understand that a prima facie case of anticipation can be sufficiently established through the prior art’s disclosure of overlapping ranges.<sup>13</sup>

**v “the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa.” ([1d])**

122. As explained (see **Part XI.A.1.a.i** above), the “polymeric sheet composition” corresponds in Hinz to the “deep-drawing film 11” shown in Figure 3, “which has a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Hinz, 8:240-243; see also Hinz, Fig. 3.) A skilled artisan would recognize and understand that Hinz’s film 11 has a “**flexural modulus**” that *necessarily overlaps* with the claimed range of “**about 750 MPa to 2,000 MPa.**” In other words,

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<sup>12</sup> The ’630 patent specification confirms a number of “polyurethanes” that each have a hardness within the claimed range were known and commercially available in the prior art, including Elastollan 1195A, Texin RxT50D, Elastollan 1185A, and Texin 985. (’630 patent, column 14 (Table 2); see also Osswald Tr. at 250:22-251:2.) I have been informed that under the legal principles, a statement in the patent that something is in the prior art is binding on patentee for determinations of anticipation and obviousness.

<sup>13</sup> Even if Bay Materials or Dr. Osswald were to argue it is possible for a TPU to have a hardness lower than A80, it would still have been natural and obvious, for purposes of my obviousness theory (discussed at **Part XI.A.2** below), to use a TPU having a hardness that falls within the claimed range of “**about A80 to D75.**” This is because several *commercially available* TPUs have a hardness from “**about A80 to D75**” as claimed, and a skilled artisan would have known this. (See Ex. 10 (Drobny, *Handbook of Thermoplastic Elastomers* (2014)), pp.398-399; ’630 patent, column 14 (Table 2).)

[REDACTED]

a skilled artisan would understand Hinz to disclose a “**flexural modulus**” range, for film 11, that necessarily overlaps with the claimed range of “**about 750 MPa to 2,000 MPa.**”

123. Dr. Osswald has testified, and I agree, that the flexural modulus of a multilayer polymeric sheet composition (in the direction perpendicular to the flat surface of the sheet) can be “calculated based on the modulus and thickness of each individual layer.” (Osswald Decl., ¶38.) This calculation method was well-known to skilled artisans, and I have provided a detailed discussion of it in **Part VIII.B** above. (See Osswald Decl., ¶¶38-47; Osswald Tr. at 228:3 (testifying that the equations he cites are “just basic mechanics”).) Because Hinz discloses the modulus and thickness of each individual layer of film 11, a skilled artisan would recognize that the flexural modulus of film 11 necessarily overlaps with the claimed range of “**about 750 MPa to 2,000 MPa,**” as explained further below.

124. **Disclosed thickness for each layer of film 11:** Hinz discloses that “a three-layer dental splint” can be “obtained in a single step deep-drawing process by deep drawing a deep-drawing film 11....” (Hinz, 8:240-241.) After the film 11 has been deep drawn into a dental splint, the hard layer 13 can have a thickness of “less than 0.2 mm” (Hinz, 11:328), the hard layer 12 can have a thickness of “less than 0.8 mm” (Hinz, 11:330), and the soft layer 14 can have a thickness of “less than 1.0 mm” (Hinz, 11:333). Because Hinz further discloses that “the layer thickness of the deep-drawing film is reduced upon deep drawing” (Hinz, 4:116-117), a skilled artisan would reasonably understand from Hinz’s disclosures that the original film 11, *before it is deep drawn*, has a hard layer 13 about 0.2 mm thick (Hinz, 11:328), a hard layer 12 about 0.8 mm thick (Hinz, 11:330), and a soft layer 14 about 1.0 mm thick (Hinz, 11:333).

125. **Disclosed elastic modulus for each layer of film 11:** As discussed, the “two outer hard layers 12, 13 [are] made of polycarbonate” (Hinz, 8:240-243), which was known to have an

[REDACTED]

elastic modulus of about 2,350-2,400 MPa. (See Ex. 8 (Baur, *Plastics Handbook*), p.459 (identifying “[t]ensile modulus of elasticity” as “2350-2400” MPa).) Moreover, the “thermoplastic polyurethane (TPU)” used for the soft layer 14 (Hinz, 3:89-91, 8:242-243) was known to have an elastic modulus ranging from 5-2,000 MPa. (See Ex. 10 (Drobny, *Handbook of Thermoplastic Elastomers* (2014)), p.237 (“With Young moduli values ranging from 5 to 2000 MPa, TPUs are virtually bridging the gap between elastomers and plastics.”) (internal citations omitted).)

126. Based on the disclosed thickness and modulus properties of each of the three layers of the multilayer film 11, a skilled artisan would recognize, using the same calculation method cited by Dr. Osswald (see Osswald Decl., ¶¶38-47), that the original film 11 would have a flexural modulus that necessarily overlaps with “**about 750 MPa to 2,000 MPa**.”<sup>14</sup> To demonstrate this overlap, I have performed one exemplary calculation (attached hereto as Appendix B) using 2,350 MPa for the polycarbonate layers 12 and 13 (see Ex. 11 (Olabisi, *Handbook of Thermoplastics* (2016)), p.353 (disclosing modulus of 2350 for exemplary commercial polycarbonate “Makrolon 3208”)), and 103 MPa for the TPU layer 14 (see Ex. 10 (Drobny, *Handbook of Thermoplastic Elastomers* (2014)), p.399 (disclosing modulus of 15,000 psi = 103 MPa for exemplary commercial TPU “Desmopan 453”)).<sup>15</sup> In this particular example, Hinz’s film 11 would have a flexural modulus of about 1,488 MPa, which falls squarely within the range of “**about 750 MPa**

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<sup>14</sup> As explained in **Part X.II** of my declaration below, the calculation method cited by Dr. Osswald at ¶¶38-47 of his declaration contains one error, which appears in the equation he provides for the “neutral axis” at ¶42 of his declaration. Other than this error at ¶42 of his declaration, his calculation method for the flexural modulus is correct, and it supports Hinz’s inherent disclosure of the “**flexural modulus**” limitation of claim 1, as would be recognized and understood by skilled artisans.

<sup>15</sup> For purposes of my obviousness theory (discussed at **Part XI.A.2** below), it would have been natural and obvious to use polycarbonate and TPU with these modulus properties. These modulus properties were inherent in *commercially available* “Makrolon 3208” polycarbonate and “Desmopan 453” TPU as demonstrated by the reference texts cited above, and a skilled artisan would have known this.

[REDACTED]

to 2,000 MPa,” as claimed. While it is possible to derive both higher and lower values for the flexural modulus using different modulus values for the individual polycarbonate (12, 13) and (14) TPU layers, my example demonstrates (as a skilled artisan would recognize based on Hinz’s disclosures) that the *range* of flexural modulus values achieved based on the disclosed properties of film 11 *necessarily overlaps* with the claimed range. I understand that under the legal principles, a prima facie case of anticipation can be sufficiently established through the prior art’s disclosure of overlapping ranges.

**b. Dependent Claim 2**

127. As just explained, a skilled artisan would reasonably understand from Hinz’s disclosures that the original film 11, before it is deep drawn, has a hard layer 13 about 0.2 mm thick (Hinz, 11:328), a hard layer 12 about 0.8 mm thick (Hinz, 11:330), and a soft layer 14 about 1.0 mm thick (Hinz, 11:333). The “combined thickness” of these three layers is therefore about 2 mm (or 2,000 microns), which falls within the claimed range of “about 250 microns to 2,000 microns.” I understand that under the legal principles, when a patent claims a range, that range is anticipated by a prior art reference if the reference discloses a point within the range.

**c. Dependent Claim 9**

128. As discussed, Hinz discloses that “a three-layer dental splint... can also be obtained in a single step deep-drawing process by deep drawing a deep-drawing film 11...” (Hinz, 8:240-241.) This “three-layer dental splint” corresponds to the claimed “**dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 2.**”<sup>16</sup>

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<sup>16</sup> During his deposition, Dr. Osswald testified that the dental appliance in the context of claim 9 is “a product that is formed from a sheet for conform to the teeth.” (Osswald Tr. at 115:9-21.)

**2. Claims 1, 2 and 9 of the '630 Patent are Obvious over Hinz and Sun**

129. To the extent Bay Materials or Dr. Osswald dispute that a skilled artisan would reasonably understand Hinz's film 11 to have a "**flexural modulus**" that overlaps with the claimed range of "**about 750 MPa to 2,000 MPa**," an overlapping range is explicitly disclosed in Sun (Ex. 12). As explained in Sun: "For any particular shape (or geometry), flexural modulus is representative of the force required to deform (or deflect) a material." (Sun, [0098].) Sun explicitly discloses that a dental guard can have "a flexural modulus of less than 300,000 psi at 37° C." (Sun, [0057].) Expressed in MPa units, "less than 300,000 psi" is equivalent to less than 2068 MPa, which overlaps with the claimed range of "**about 750 MPa to 2,000 MPa**."

130. A skilled artisan would have combined Hinz and Sun for several reasons. Both describe inventions that can be used as a dental guard. (Hinz, 1:20-22; Sun, Abstract.) A skilled artisan starting with Hinz would have been led to Sun, for example, because Sun provides express motivations to implement Hinz so as to arrive within the claimed flexural modulus range:

[T]here is a need for night guards having improved comfort, stability, and fit. The night guard should be flexible so that it conforms easily to a patient's teeth and is comfortable to wear. The patient should be able to insert and remove the night guard easily. At the same time, the night guard should be made from a material having good mechanical integrity and wear-resistance.

(Sun, [0015]; *see also id.*, [0055], [0057]; *compare* Hinz, 2:55-59.)

131. A skilled artisan starting with Sun would also have been led to Hinz, at least because Hinz improves upon the type of two-layer structure used in Sun by adding a third hard outer layer. This hard outer layer, in turn, provides (as one exemplary benefit) protection against "discoloration of the soft polyurethane layer." (Hinz, 2:43-47; *compare* Sun, [0034], [0041] (expressly contemplating use of polyurethane for its night guard).)

132. Finally, to the extent any other limitations of claims 1, 2, and 9 are argued to be inadequately disclosed by Hinz alone, any such limitation would at least have been obvious over

[REDACTED]

the combined teachings of Hinz and Sun, particularly when considered in light of the background knowledge, ordinary creativity, and common sense a skilled artisan would have had.

**B. Prior Art Invalidity of Claims 11, 12 and 18 of the '263 Patent**

**1. Claims 11, 12 and 18 of the '263 Patent are Anticipated by Yu**

**a. Yu is entitled to a May 3, 2019 effective filing date based on the Yu Provisional, and thus qualifies as prior art to claims 11, 12, and 18 of the '263 patent**

133. As explained below in ¶¶160-166, claims 11, 12, and 18 of the '263 patent are entitled to an effective filing date no earlier than the filing date of the application that issued as the '263 patent, which is December 18, 2019.

134. Therefore, as I have been informed by counsel, a patent application publication can qualify as prior art to claims 11, 12, and 18 of the '263 patent if that patent application publication was effectively filed before December 18, 2019 (i.e., before the effective filing date of claims 11, 12, and 18 of the '263 patent).

135. I understand that patent application publication WO 2020/225657 A1 ("Yu," Ex. 13), which I analyze below, has a filing date of April 29, 2020. However, I understand that Yu also claims priority to an earlier-filed provisional application, Provisional 62/843,171 ("Yu Provisional," Ex. 14), which was filed on May 3, 2019. May 3, 2019 predates the December 18, 2019 effective filing date of claims 11, 12, and 18 of the '263 patent. Therefore, as I have been informed by counsel, Yu can qualify as prior art to claims 11, 12, and 18 of the '263 patent, with respect to any subject matter that is described in *both* Yu and the Yu Provisional,<sup>17</sup> if Yu is entitled to claim a right of priority to the Yu Provisional.

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<sup>17</sup> For each and every portion of the subject matter described in Yu that I cite to demonstrate anticipation of claims 11, 12, and 18 below, I have included parallel citations to where that subject matter appears in both Yu and the Yu Provisional.

[REDACTED]

136. I have been informed that Yu will have the priority date of the Yu Provisional (i.e., May 3, 2019) for prior art purposes if the information contained in the Yu Provisional adequately supports the written description of the claims of Yu.<sup>18</sup> Further, counsel has asked me to form an opinion as to whether the written description of the Yu Provisional adequately demonstrates that the inventors were in possession of the inventions in the claims of Yu within Yu Provisional.

137. I have analyzed the written description of the Yu Provisional and the claims of Yu, and in my opinion, Yu's claims are adequately supported by the written description of the Yu Provisional to demonstrate that the effective filing date of Yu is the date of the May 3, 2019 date of the Yu Provisional. To demonstrate this, I have prepared a chart (attached hereto as Appendix C) showing how each of Yu's claims is supported by disclosures from the Yu Provisional. The cited disclosures from the Yu Provisional, as set forth in the chart (attached hereto as Appendix C), would reasonably convey to those skilled in the art that the inventor of the Yu Provisional had possession of the subject matter later claimed in Yu.

**b. Independent Claim 11 is Anticipated by Yu**

138. In my opinion, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>18</sup> I understand from counsel that this formulation of the law is based on the Federal Circuit's opinions in *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015) and *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017). I understand that both of these opinions dealt specifically with *pre-AIA* § 102(e), and that it is presently unsettled as to whether the legal requirements articulated in these opinions also apply to *AIA* § 102, which governs this proceeding. However, counsel has asked me to assume that the legal standard for establishing Yu's effective filing date for prior art purposes, as set forth above in the text based on *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015) and *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017), applies to this case.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

139. Example 1 of Yu is a 5-layer polymeric film with an overall thickness of 760 microns and the following configuration: Tritan(TX1000)/Neostar(FN007)/Tritan(TX1000)/Neostar(FN007)/Tritan(TX1000). (See Yu Provisional [0088], [0075] (Materials: “TRITAN: copolyester from Eastman Chemicals, grade: TX1000” and “NEOSTAR: copolyester ether elastomer: from Eastman Chemicals, grade: FN007”); Yu [0092], [0078] (Materials: “TX1000: copolyester from Eastman Chemicals, brand: TRITANMX710” and “NEOSTAR: copolyester ether elastomer from Eastman Chemicals, grade: FN007”).) I understand that [REDACTED]

[REDACTED] (See, e.g., Osswald Decl., ¶65)

140. The Tritan TX1000 of Yu Example 1 and Tritan MX710 are identified by Eastman Chemical as having identical Tensile Modulus values: Tensile Modulus of 1548 MPa (ISO 527) and 1550 MPa (ASTM-D638). (See Exs. 16-17.) The Neostar(FN007) elastomer of Yu Example 1 and Ecdel(9967) have identical vendor-reported hardness values: A 95 and D 55. (See Exs. 18-19.) The Neostar(FN007) elastomer of Yu Example 1 and Ecdel(9967) also have identical vendor-reported Tensile Modulus values: 170 MPa (ASTM-D638) and 197 MPa or 221 MPa (ASTM D

882).<sup>19</sup> (See Exs. 18-19.) Thus, with respect to the “modulus” of the “rigid or hard” materials or the “hardness” of the “elastomeric material” recited in claim 11, [REDACTED]

[REDACTED] and, in my opinion, Example 1 of Yu necessarily anticipates claim 11 under Dr. Osswald’s analysis of the claim.

141. In the following paragraphs, I apply Dr. Osswald’s interpretation of claim 11 of the ’263 patent against a 5-layer polymeric sheet, which as I note above, is inconsistent with the interpretation of “layer A,” “layer B,” and “layer C” as set forth in Table 8 and in Figure 1B, but is nonetheless instructive for demonstrating earlier possession of the alleged inventions claimed in the ’263 patent by Yu.

**i “A polymeric sheet composition comprised of:” ([11pre])**

142. In my opinion, claim 11 is anticipated by Yu’s disclosures associated with “Example 1” following Dr. Osswald’s analysis of infringement. (See, e.g., Yu, [0092]; Yu Provisional, [0088].) To the extent the preamble’s recitation of a **“polymeric sheet composition”** provides a claim limitation, it is disclosed by the 5-layer film described with respect to Yu’s Example 1. (Yu, [0092] (“A 5-layer CBABC (TX1000/NEOSTAR/TX1000/NEOSTAR/TX1000) film was extruded....”); Yu Provisional, [0088] (“A 5-layer ABABA (Tritan/Neotsar/Tritan/Neostar/Tritan) film was extruded....”).)

143. A skilled artisan would recognize that the “TX1000” material referenced in Yu is the same as the “Tritan” material referenced in the Yu Provisional. (Yu, [0078] (“TX1000: copolyester from Eastman Chemicals....”); Yu Provisional, [0075] (“TRITAN: copolyester from

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<sup>19</sup> The Tensile Modulus values reported for Ecdel(9967) are in units of PSI. When converted to MPa using the value of 1 MPa = 145.04 PSI, the values in the units of MPa are the same (i.e., 24,700 PSI = 170 MPa; 28,600 PSI = 197 MPa; 32,100 PSI = 221 MPa).

Eastman Chemicals, grade: TXI000....”).) Moreover, though Yu uses the acronym “CBABC” to refer to the arrangement of the individual layers, and the Yu Provisional uses the acronym “ABABA,” a skilled artisan would understand and recognize that both Yu and the Yu Provisional describe the same 5-layer arrangement with respect to Example 1. Specifically, a skilled artisan would understand Example 1 of Yu and the Yu Provisional to disclose the following arrangement of individual layers for a 5-layer film:

| Layer # | Yu/Yu Provisional | Claimed layer per Dr. Osswald’s analysis |
|---------|-------------------|------------------------------------------|
| 1       | Tritan(TX1000)    | A                                        |
| 2       | Neostar(FN007)    | B                                        |
| 3       | Tritan(TX1000)    | D                                        |
| 4       | Neostar(FN007)    | B’                                       |
| 5       | Tritan(TX1000)    | C                                        |

(See Yu, [0092], [0078] (Materials); Yu Provisional, [0088], [0075] (Materials).)

144. In my analysis of the claim limitations below, I will use the phrases “Layer 1: TX1000”, “Layer 2: Neostar”, “Layer 3: TX1000”, “Layer 4: Neostar”, and “Layer 5: TX1000” as a shorthand to facilitate my demonstration of the correspondence between each of the individual layers described in Yu (and the Yu Provisional), and each of the individual layers recited in claim 11 according to the analysis performed by Dr. Osswald for infringement.

ii “at least two rigid or hard outer layers A and C, at least two soft inner layers B and B’, and at least a rigid or hard inner layer, D,” ([11a])

145. In my opinion, claim element 11a is disclosed by Example 1 of Yu and the Yu Provisional according to Dr. Osswald’s infringement analysis as I set forth below.

146. **Rigid or hard outer layer A:** This layer corresponds to Yu’s “Layer 1: TX1000”. (Yu, [0092] (“5-layer CBABC (**TX1000**/NEOSTAR/TX1000/NEOSTAR/TX1000) film....”); Yu

Provisional, [0088] (“5-layer ABABA (Tritan/Neotsar/Tritan/Neostar/Tritan) film....”). A skilled artisan would understand this to be a “**rigid or hard outer layer[]**,” as claimed.

147. This is also confirmed by Dr. Osswald’s repeated characterization of the Tritan TX1000 as a “hard” layer or a “hard” polymer. (Osswald Decl., ¶66, ¶128 & n.8, ¶132 & n.9.) Yu describes “TX1000” as having a flexural modulus of 1.55 GPa. (Yu, [0079] (Table 1); Yu Provisional, [0076] (Table 1).)

148. **Rigid or hard outer layer C:** This layer corresponds to Yu’s “Layer 5: TX1000”. (Yu, [0092] (“5-layer CBABC (TX1000/NEOSTAR/TX1000/NEOSTAR/TX1000) film....”); Yu Provisional, [0088] (“5-layer ABABA (Tritan/Neotsar/Tritan/Neostar/Tritan) film....”).) A skilled artisan would understand this to be a “**rigid or hard outer layer[]**,” as claimed.

149. **Rigid or hard inner layer D:** This layer corresponds to Yu’s “Layer 3: TX1000”. (Yu, [0092] (“5-layer CBABC (TX1000/NEOSTAR/TX1000/NEOSTAR/TX1000) film....”); Yu Provisional, [0088] (“5-layer ABABA (Tritan/Neotsar/Tritan/Neostar/Tritan) film....”).) A skilled artisan would understand this to be a “**rigid or hard inner layer[]**,” as claimed.

150. **Soft inner layer B:** This layer corresponds to Yu’s “Layer 2: Neostar”. (Yu, [0092] (“5-layer CBABC (TX1000/NEOSTAR/TX1000/NEOSTAR/TX1000) film....”); Yu Provisional, [0088] (“5-layer ABABA (Tritan/Neotsar/Tritan/Neostar/Tritan) film....”).) A skilled artisan would understand this to be a “**soft inner layer[]**,” as claimed. Yu describes “Neostar” as having a flexural modulus of about 0.2 GPa. (Yu, [0079] (Table 1); Yu Provisional, [0076] (Table 1).)<sup>20</sup>

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<sup>20</sup> While the Yu Provisional identifies Neostar as having a flexural modulus of “0.15” GPa and Yu identifies “0.2” GPa, a skilled artisan would understand and recognize this to simply be a function of Yu using one less significant digit than the Yu Provisional, which results in 0.15 being rounded up to 0.2. Both Yu and the Yu Provisional make clear that they are referring to the same material, and a skilled artisan would understand this. (Yu, [0078] (“NEOSTAR: copolyester ether elastomer

151. **Soft inner layer B'**: This layer corresponds to Yu's "Layer 4: Neostar". (Yu, [0092] ("5-layer CBABC (TX1000/NEOSTAR/TX1000/NEOSTAR/TX1000) film..."); Yu Provisional, [0088] ("5-layer ABABA (Tritan/Neotsar/Tritan/Neostar/Tritan) film...").) A skilled artisan would understand this to be a "**soft inner layer**[]," as claimed.

iii **"wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and" ([11b])**

152. As just explained, the "**rigid or hard layers, A, C and D**" in Example 1 of Yu are each made from Tritan's "TX1000" material. A skilled artisan would understand Tritan's "TX1000" to be a "**thermoplastic polymer**," as claimed. This is confirmed by Dr. Osswald's testimony that, for purposes his infringement opinion, "[t]o the extent layers '1,' '3,' and '5' are comprised of TX1000," they would still meet claim 11b. (Osswald Decl., ¶132 n.9.)

153. Tritan's "TX1000" material also has a "**modulus of from about 1,000 MPa to 2,500 MPa.**" The datasheet for TX1000 discloses that it has a modulus of 1548 MPa (ISO 527) and 1550 MPa (ASTM-D638), which falls within the claimed range. (See Ex. 16.) This is confirmed by Dr. Osswald's testimony that, for purposes his infringement opinion, "[t]o the extent layers '1,' '3,' and '5' are comprised of TX1000," they would still meet claim 11b. (Osswald Decl., ¶132 n.9.)

iv **"the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85." ([11c])**

154. As explained with respect to claim 11a above, the "**soft inner layers B and B'**" in Example 1 of Yu are each made from "Neostar" material. A skilled artisan would understand

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from Eastman Chemicals, grade: FN007"); Yu Provisional, [0075] ("NEOSTAR: copolyester ether elastomer: from Eastman Chemicals, grade: FN007").)

[REDACTED]

“Neostar” to be an “**elastomeric material**,” as claimed. (Yu, [0078] (“NEOSTAR: copolyester ether elastomer from Eastman Chemicals, grade: FN007”); Yu Provisional, [0075] (“NEOSTAR: copolyester ether elastomer: from Eastman Chemicals, grade: FN007”); *see also* Ex. 18.)

155. Further, “Neostar” is disclosed as having grade “FN007.” (Yu, [0078]; Yu Provisional, [0075].) This material has a hardness of A95 or D55, and a skilled artisan would recognize this. (*See* Ex. 18.) Thus, the use of “Neostar” grade FN007 in Example 1 discloses a “**hardness**” within the claimed range of “**from about A 60 to D 85.**” I understand that under the legal principles, when a patent claims a range, that range is anticipated by a prior art reference if the reference discloses a point within the range.

**c. Dependent Claim 12**

156. **Combined thickness of from 250 microns to 2,000 microns:** Yu discloses that the 5-layer film of Example 1 has a combined thickness of **0.76 mm, i.e., 760 microns**. (Yu, [0092] (“The overall sheet thickness was controlled at 30 mils (0.76 mm).”); Yu Provisional, [0088] (same).)

157. **Overall flexural modulus of from 500 MPa to 1,500 MPa:** Yu discloses a “Summary of Test Procedures” and notes that “[t]he following test procedures were used in the examples below.” (Yu, [0080]; Yu Provisional, [0077].) For each of its described examples (including Example 1), Yu discloses that “[t]he flexural modulus was tested according to ASTM D790-17.” (Yu, [0081]; Yu Provisional, [0078].) As I previously noted, the ASTM standard for “flexural modulus” is a tangent modulus, and this flexural modulus is identified for Example 1 to be **1.23 GPa, i.e., 1,230 MPa**, which falls within the recited range of “500 MPa to 1,500 MPa.” (Yu, [0108] (Table 2); Yu Provisional, [0103] (Table 2).)

**d. Dependent Claim 18**

158. As explained for the preamble of claim 11 (*see Part XI.B.1.b.i* above), the claimed “polymeric sheet composition” corresponds to the 5-layer film described with respect to Yu’s Example 1. (Yu, [0092] (“A 5-layer CBABC (TX1000/NEOSTAR/TX1000/NEOSTAR/TX1000) film was extruded...”); Yu Provisional, [0088] (“A 5-layer ABABA (Tritan/Neotsar/Tritan/Neostar/Tritan) film was extruded...”).) Yu discloses that such a multilayer film, after it is extruded, can be used to make a dental appliance. (Yu, [0013] ([T]he present disclosure is directed to a method of making a dental appliance by forming a plurality of tooth-retaining cavities in a multilayered polymeric film.”); Yu Provisional, [0013] (same).)

159. Therefore, a skilled artisan would understand Yu to disclose the claimed “**dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.**”<sup>21</sup>

**e. Claims 11, 12, and 18 of the ’263 patent have an effective filing date no earlier than December 18, 2019**

160. I understand that the ’263 patent, as stated on its face, is a “*continuation-in-part* application of U.S. application Ser. No. 16/211,176, filed Dec. 5, 2018....” (’263 patent, 1:7-8.) I understand that Application 16/211,176 issued as U.S. Patent No. 10,549,511 and shares an identical specification with the ’630 patent (the ’630 patent being a *continuation* of Application 16/211,176).

161. I have been informed by counsel that for the claimed inventions recited in claims 11, 12, and 18 of the ’263 patent to be entitled to the benefit of the earlier December 5, 2018 filing

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<sup>21</sup> During his deposition, Dr. Osswald testified that the dental appliance in the context of claim 9 of the ’630 patent, which resembles claim 18 of the ’263 patent discussed above, is “a product that is formed from a sheet for conform to the teeth.” (Osswald Tr. at 115:9-21.)

[REDACTED]

date of Application 16/211,176, the disclosure of this earlier application must provide adequate written description support for claims 11, 12, and 18 of the '263 patent. I understand that the test for adequate written description is whether the disclosure of the application relied upon (here, Application 16/211,176) reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. I understand this requires the specification of the earlier application (here, Application 16/211,176) to indicate with some clarity what claims 11, 12, and 18 of the '263 patent recite. Further, I understand that in the case of a claimed range, a skilled artisan must be able to reasonably discern a disclosure of that range.

162. I have been asked by counsel to form an opinion as to whether the disclosure of Application 16/211,176 reasonably conveys to those skilled in the art that the inventor had possession of the subject matter of claims 11, 12, and 18 of the '263 patent, so as to entitle these claims to the benefit of the earlier December 5, 2018 filing date.

163. In my opinion, the claims 11, 12, and 18 of the '263 patent cannot claim priority to any date prior to the December 18, 2019 filing date of the '263 patent. First, I have not found any mention of a claimed invention reciting a "layer D" anywhere other than within the new matter added to the '263 patent. I have provided a version of the '263 patent that highlights the new matter that was added to the '263 application when it was filed on December 18, 2019 which clearly shows the first recitation of any embodiment or alleged invention described as having a "layer D." In my opinion, the fact that "layer D" only first appears within the '263 patent demonstrates that the inventions reciting a "layer D" cannot find written description support in an earlier application.

164. Additionally, in my opinion, there is no written description support for the full range of the claimed hardness range for layers B and B' in claims 11, 12, and 18 of the '263 patent.

[REDACTED]

Claim 11 recites that the “layers B and B’ individually comprise an elastomeric material having a hardness from about A 60 to D 85.” (’263 patent, claim 11.) In my review of the disclosures of the ’630 patent, which I understand are identical to the ’263 patent’s parent ’176 application, there is no basis from which to conclude that the inventors were in possession of any inventions wherein the elastomeric layers have such a broad hardness range prior to the ’263 patent.

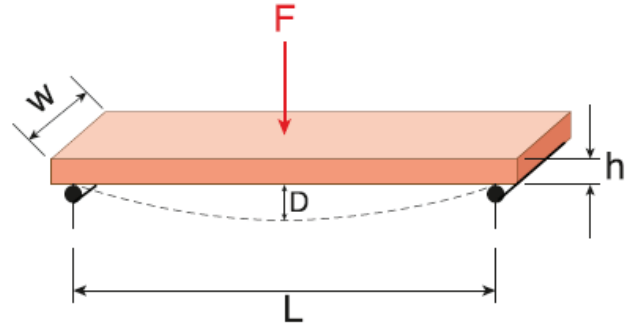
165. By way of comparison, the claims of the ’630 patent recite a narrower hardness range from A 80 to D 75, which is consistent with the scope of disclosures in the specification of the ’630 patent—none of which identify a hardness down to A 60 or as high as D 85. Indeed, by extending the hardness range within the claims of the ’263 patent up to D 85, the ’263 patent results in claim scope wherein the “soft inner layers B and B’” are actually harder than the claimed “rigid or hard” layers.

166. For instance, the patent states that “Shore hardness and modulus are generally correlated and can be converted by approximation if only one value is known by methods described in the art.” (’263 patent, 6:67-7:2.) The equivalent modulus for a hardness of D 85 can be calculated according to methods I developed and established within the art and, when doing so, indicates that a hardness of D 85 equates to a modulus of 1,180 MPa. That is, within the claims of the ’263 patent, the hardness range of A 60 to D 85 is broad enough such that the claims include multilayer materials wherein the modulus of the “soft inner layers B and B’” (up to 1,180 MPa (D 85)) is greater than the modulus of the “rigid or hard layers A, C, and D” (when they are between 1,000-1,180 MPa as allowed by the claims). Accordingly, the claims broad recitation of a hardness range of A 60 to D 85 represents a fundamental extension beyond the allegedly inventive “hard-soft-hard” structures disclosed in the ’630 patent and, in my opinion, there is no demonstration

that the inventors were in possession of such claimed inventions within the disclosure of the '630 patent (or, equally, the '176 application).

## XII. RESPONSE TO DR. OSSWALD REGARDING “FLEXURAL MODULUS”

167. Dr. Osswald’s declaration includes a “Technological Background” section in which he describes a calculation method, involving several mathematical equations, that can be used together to



compute the *flexural modulus* of a multilayer polymeric sheet composition. (Osswald Decl., ¶¶38-47; Osswald Decl., ¶39 (“The flexural modulus of a multilayer polymeric sheet composition... can be computed using the thickness ( $h_i$ ) and elastic modulus ( $E_i$ ) of each layer  $i$ ,...”).) In this section of his declaration, Dr. Osswald explains, and I agree, that the flexural modulus of a multilayer polymeric sheet composition (in the direction perpendicular to the flat surface of the sheet) can be “calculated based on the modulus and thickness of each individual layer.” (Osswald Decl., ¶38.) This calculation would be a “tangent” flexural modulus as it is based on the elastic modulus of the component layers.

168. As Dr. Osswald confirmed at his deposition, his calculation method for flexural modulus is based on “just basic mechanics.” (Osswald Tr. at 228:3 (testifying that the equations he cites are “just basic mechanics”).) Specifically, as Dr. Osswald confirmed at his deposition, his calculation method involves “an elastic bending analysis of a beam,” and relies on the well-known “parallel axis theorem.” (Osswald Tr. at 252:13-14, 253:3-5.)

169. While I generally agree with the calculation method for flexural modulus as provided by Dr. Osswald at ¶¶38-47 of his declaration, one of the equations he provides contains

a key error, which is easily shown. At ¶42 of his declaration, he provides an equation for the “location of the neutral axis” as the following:

$$\bar{Y} = \frac{\sum n_i A_i \bar{y}_i}{\sum A_i} = \frac{w \sum n_i h_i \bar{y}_i}{w \sum h_i}$$

170. This equation, for deriving the “neutral axis,” is incorrect. Specifically, the denominator is missing a key term,  $n_i$ . The correct equation, therefore, should instead be:

$$\bar{Y} = \frac{\sum n_i A_i \bar{y}_i}{\sum n_i A_i} = \frac{w \sum n_i h_i \bar{y}_i}{w \sum n_i h_i}$$

(See Ex. 15 (Beer, *Mechanics of Materials* (2001)), p.231 (“[T]he resistance to bending of the bar would remain the same if both portions were made of the first material, provided that the width of each element of the lower portion were multiplied by the factor  $n$ .”).)<sup>22</sup>

171. The error in Dr. Osswald’s equation for “neutral axis,” from ¶42 of this declaration, is easily shown. As he correctly observes: “In a symmetric multi-layer system and in a single layer system, the neutral axis is at the center of the sheet.” (Osswald Decl., ¶42.) However, without the term  $n_i$  in the denominator, his equation would not provide a neutral axis “at the center of the sheet” for symmetric multilayer systems.

172. To illustrate using a simple 3-layer system, in which each layer is 0.1 mm thick, and in which the modulus of the middle layer is half of that of the outer layers, such that:

- $h_1 = 0.1$ ;  $n_1 = 1$ .
- $h_2 = 0.1$ ;  $n_2 = 0.5$ .

<sup>22</sup> Beer is the same textbook cited by Dr. Osswald as Exhibit E of his declaration.

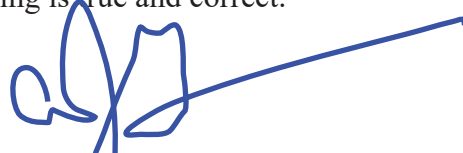
- $h_3 = 0.1$ ;  $n_3 = 1$ .

173. The neutral axis for this system, as would be intuitive, is “at the center of the sheet,” i.e.,  $\bar{Y} = 0.15$  mm for a symmetrical 3-layer sheet with a total thickness of 0.3 mm. But if one were to use Dr. Osswald’s equation, one would get  $\bar{Y} = 0.125$  mm. This is clearly an incorrect result, because 0.125 mm from the bottom of the sheet is not “the center of the sheet.” (Osswald Decl., ¶42.)

174. Aside from this error with respect to the equation for “neutral axis” at ¶42 of Dr. Osswald’s declaration, the remainder of Dr. Osswald’s calculation method (*see* Osswald Decl., ¶¶38-47) is correct, assuming that the application of his calculation method is limited to the flexural modulus of a *flat* multiplayer polymeric sheet. (*See* Osswald Decl., ¶35 (showing a figure of the “[f]lexural test” as being performed on a flat sheet).)

I declare under penalty of perjury that the foregoing is true and correct.

Dated: March 4, 2022



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Dr. Alan Jeffrey Giacomini