

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC.,
Petitioner,

v.

ALIGN TECH., INC.,
Patent Owner,

Case No. IPR2025-00820
U.S. PATENT NO. 11,648,090

DECLARATION OF DR. TIM A. OSSWALD

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I. Introduction

1. I, Dr. Tim A. Osswald, submit this declaration on behalf of Petitioner ClearCorrect Operating, LLC (“ClearCorrect”) as an expert in the fields of plastics and polymers technology. My qualifications in these areas, as well as other areas, are established below and by my curriculum vitae, which is EX1015.

A. Qualifications and Experience

2. I believe that I am qualified to serve as a technical expert in this matter based upon my qualifications, discussed in detail below.

3. I am the Kuo K. and Cindy F. Wang Professor Emeritus at the University of Wisconsin-Madison in the Department of Mechanical Engineering. I am also affiliated with the Department of Materials Science and Engineering, and I was the co-director of the Polymer Engineering Center until the summer of 2024. I have been with the Mechanical Engineering Department at the University of Wisconsin-Madison since 1989, when I joined as an Assistant Professor, and I became a Full Professor in 1999. Prior to joining the University of Wisconsin-Madison, I was a consultant for the Dynamit Nobel Research Center in Leverkusen, Germany, as well as a Humboldt Fellow at the Institute for Plastics Processing at the Technical University of Aachen, Germany, between 1987 through 1989.

4. I received a Bachelor of Science Degree in Mechanical Engineering in 1981 and a Master of Science Degree in Mechanical Engineering in 1982, both from

the South Dakota School of Mines and Technology. I also received a Ph.D. in Mechanical Engineering in 1987 from the University of Illinois at Urbana-Champaign. My Ph.D. research was in the field of polymer processing.

5. Since joining the University of Wisconsin-Madison, I have conducted research and taught classes in various areas of polymer science, including polymer and composites processing, and designing with polymers and composites. My research in polymer engineering includes modeling and simulation in polymer and composites processing, engineering design with polymers and composites, and sustainability.

6. I have extensive research and teaching experience with secondary shaping operations, including thermoforming, film blowing, and blow molding processes. I have been a consultant with industry on various thermoforming issues. In one of my required undergraduate polymer manufacturing courses, one laboratory unit was dedicated to thermoforming. I also have extensive experience with behavior and characterization of thermoplastic polymeric materials. I also have experience with polymer materials used in dental applications.

7. I have also published over 400 papers in the field of polymer engineering and have authored 11 books in the area: *Polymer Materials Science for Engineers* (Hanser Publishers, 1st Edition 1996, 2nd Edition 2003, 3rd Edition 2012), *Polymer Processing Fundamentals* (Hanser Publishers, 1998), *Injection Molding*

Handbook (Hanser Publishers, 1st Edition 2001, 2nd Edition 2006), *Compression Molding* (Hanser Publishers, 2003), *Polymer Processing – Modeling and Simulation* (Hanser Publishers, 2006), *Plastics Handbook* (Hanser Publishers 2006, 2019), *Kunststoff-Taschenbuch* (Hanser Publishers 2006, 2013, 2022), *Plastics Testing and Characterization* (Hanser Publishers 2007), *Understanding Polymer Processing* (Hanser Publishers, 1st Edition 2010, 2nd Edition 2017, 3rd Edition 2025), *Polymer Rheology* (Hanser Publishers, 2015) and *Discontinuous Fiber-Reinforced Composites-Fundamentals and Applications* (Hanser Publishers, 2020). Some of my books have been translated into Chinese, Japanese, Spanish, Italian, Farsi and Russian. I am also the series editor for the Plastics Pocket Power Series of Hanser Publishers.

8. Over the years, my research and teaching have led to the issuance of eight patents, as well as several honors and awards. For example, in 2001 I was the recipient of the VDI-K (German Engineering Society – Plastics) Dr.-Richard-Escales-Prize. In 2006, I was named Honorary Professor of the University of Erlangen-Nuremburg in Germany. In 2011, I received an Honorary Professorship at the National University of Colombia. In 2016, I was named Educator of the Year by the Society of Plastics Engineers (SPE), and in 2017, the same organization named me Educator of the Year in the Field of Composites.

9. My academic and professional background and qualifications are further elaborated in my curriculum vitae available as EX1015.

B. Compensation

10. I will be compensated for my time preparing for and testifying in this matter at my standard hourly rate of \$650/hour. I do not have any personal or financial stake or interest in the outcome of this proceeding. No part of my compensation is contingent upon the outcome of this proceeding or any issue in it.

C. Materials Considered

11. This declaration is based on my education, personal knowledge, and professional and academic experience in the areas of plastics and polymers technology, as well as the documents I have considered. My analysis is particularly focused on the state of the art in May 2012.

12. In forming my opinions, I have considered the '090 patent and other exhibits cited in my declaration, including those listed in **Appendix A**. I reserve the right to rely on documents cited in the appendices to this declaration, and to supplement my opinions in view of new materials and information that become available to me during this proceeding.

II. Level of Ordinary Skill in the Art

13. I understand that an assessment of a patent's claims should be undertaken from the perspective of a person of ordinary skill in the art ("POSITA") as of the "effective filing date" of the patent claims. In performing my analysis, I

have been asked to assume that the “effective filing date” of the ’090 patent is May 14, 2012.

14. I understand that a person of ordinary skill in the art is determined by looking at (1) the type of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field.

15. In my opinion, a person of ordinary skill in the art with respect to the ’090 patent would have had at least a four-year undergraduate degree in materials science, mechanical engineering, chemical engineering, or a closely related field and at least two years of experience in the field of polymer 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. Additional education could substitute for professional experience and vice versa. As explained above in Section I.A., I had at least these qualifications by May 2012 and am qualified based on my education and experience to provide an opinion as to what a POSITA would have known and concluded as of May 2012. *Supra* Section I.A.

III. Legal Standards

16. The opinions I express in this declaration involve the application of my technical knowledge and experience in evaluating certain prior art with respect to the '090 patent. In preparing this declaration, certain patent law concepts have been explained to me by counsel, including the legal standard for interpreting claims as well as those for assessing obviousness of a patent claim.

17. I have been informed that, in IPR proceedings such as this one, the party challenging the patent bears the burden of proving unpatentability by a preponderance of the evidence. I understand that a preponderance of the evidence means “more likely than not.”

18. I understand that patentability must be analyzed from the perspective of a POSITA in the same field as the challenged patent as of the “effective filing date” of the claims. I understand that a POSITA is a hypothetical individual presumed to know the relevant art as of the effective filing date of the claims.

19. I understand that the Patent Trial and Appeal Board interprets claims based on their ordinary meaning as understood by a POSITA at the time of the effective filing date in view of the claim language, patent specification, and prosecution history. I also understand that the specification may reveal a special definition given to a claim term by an inventor that differs from its ordinary meaning

as understood by a POSITA. In that case, I understand that the inventor's definition governs.

20. I have been informed that a dependent claim is a patent claim that refers back to another patent claim. I have been informed that a dependent claim includes all of the limitations of the claim to which it refers.

21. I understand that a patent claim is invalid if it would have been **obvious** to a person of ordinary skill in the art as of the effective filing date. I understand that assessing obviousness entails considering: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the art, and (4) any secondary considerations of non-obviousness.

22. I understand that a claim may be obvious based on a combination of multiple prior art references, as well as based on the knowledge and skill of a POSITA as of the effective filing date. I also understand that to combine prior art references, there must have been a motivation that would have prompted a POSITA to do so. In other words, obviousness requires a **motivation to combine** the features of the prior art. I further understand that a POSITA must have had a reasonable expectation that the combination would work. That is, obviousness requires a **reasonable expectation of success** in combining the prior art to achieve the claimed subject matter. I also understand that, while obviousness requires a reasonable

expectation of success, it does not require absolute predictability of success in achieving the claimed subject matter.

23. I understand that a motivation to combine prior art references may arise from a variety of sources, including, among other things, scientific literature, a need or unsolved problem in the field, or market demand.

24. I also understand that a claim may be obvious if a POSITA would have found it obvious to try combining a finite number of predictable solutions known in the art. For example, if one technique had been used to improve a method of using a device, and a POSITA would have recognized that the same technique was one of a limited number of solutions and would improve similar devices in the same way, a POSITA may have found it obvious to try that same technique on similar devices.

25. I understand that, when present, evidence of “secondary considerations” must be considered along with the other factual evidence relevant to obviousness. Such secondary considerations could include unexpected results, commercial success of products or processes using the invention, long-felt but unmet need for the invention, failure of others to make the invention, industry acceptance of the invention, or copying of the invention by others. I understand that, in order for such evidence to support nonobviousness, it must have a “nexus” to the features of the invention as claimed.

26. I understand that the question of whether a patent's claims would have been obvious to a person of ordinary skill in the art as of the effective filing date is a different inquiry from the question of whether the claims are enabled. To be enabled, the patent's written description must permit a person of ordinary skill in the art as of the effective filing date to practice the full scope of the claims without undue experimentation. I understand that a patent claim may be both invalid as obvious and, at the same time, not enabled by the patent's written description.

IV. Technological Background

A. Polymer Processing Techniques

27. Manufacturing products out of plastic can involve one or more of the following steps: shaping operations, secondary shaping operations, material removal, and joining operations. EX1036 (*Osswald* (2006)) at 111. The process usually begins with a shaping operation, which transforms polymer pellets, powder, or resin into a final product or a preform (e.g., a polymer sheet) via an extrusion or molding process. EX1036 (*Osswald* (2006)) at 111. The initial shaping operation may be followed by a secondary shaping operation, which takes a preform such as a polymer sheet and transforms it into the final product using thermoforming or blow molding. EX1036 (*Osswald* (2006)) at 111.

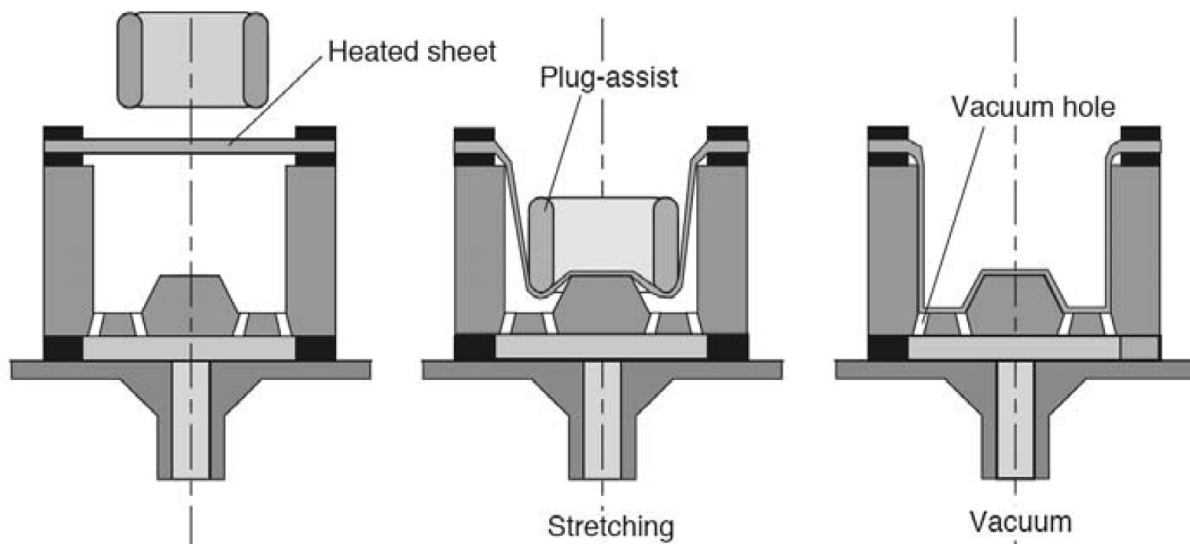
1. Thermoforming

28. Thermoforming is a secondary shaping operation used to transform a previously solidified plastic film or sheet into a final product. EX1036 (*Osswald*

(2006)) at 111, 150-51, 157-58. The thermoforming process consists of warming the plastic sheet and forming it into a cavity or over a positive model using vacuum, air pressure, mechanical means, or a combination thereof. EX1037 (*Osswald* (2006-2)) at 170. The process dates back at least to the 18th century, when tortoise shells and hooves were thermoformed into combs and other goods. EX1037 (*Osswald* (2006-2)) at 170. The process was refined over time to use various cellulose and acrylic materials and eventually plastic polymers. EX1037 (*Osswald* (2006-2)) at 170. In the 1950s, for example, thermoforming was used widely in the production of cups and blisterpacks. EX1037 (*Osswald* (2006-2)) at 170. The use of thermoforming continued to grow over time to include the manufacture of, for example, showers and bathtubs, polymer liners for refrigerators, pick-up truck cargo boxes, automotive trunks, glove compartments, and door panels. EX1037 (*Osswald* (2006-2)) at 170. In May 2012, which I understand is the earliest possible effective filing date of the '090 patent, thermoforming was commonly used to manufacture dental aligners, such as those disclosed and claimed in the '090 patent. *See, e.g.*, EX1003 (*Tadros*) at [0073], [0080], [0087]; *see also* '090 patent at 7:7-13 (noting exemplary thermoforming methods were disclosed in previous patents by Align and on Align's website).

29. Thermoforming typically involves uniformly heating a plastic sheet using a radiative heater to a temperature where it can be easily shaped but still has

enough rigidity to be held without much sagging. With amorphous polymers, the ideal forming temperature is slightly above the glass transition temperature. The thermoforming process time mainly depends on the heating and cooling times of the polymer sheet, which in turn depend on the forming temperature. EX1036 (*Osswald* (2006)) at 397; EX1038 (*Osswald* (1998)) at 119, 152, 203; EX1039 (*Osswald* (2012)) at 299. Once the sheet reaches the forming temperature, it is shaped into the desired final product, sometimes using a plug assist to push the softened sheet into a cavity over a positive model followed by vacuum suction to pull the sheet into the precise shape of the model. EX1036 (*Osswald* (2006)) at 396-97.



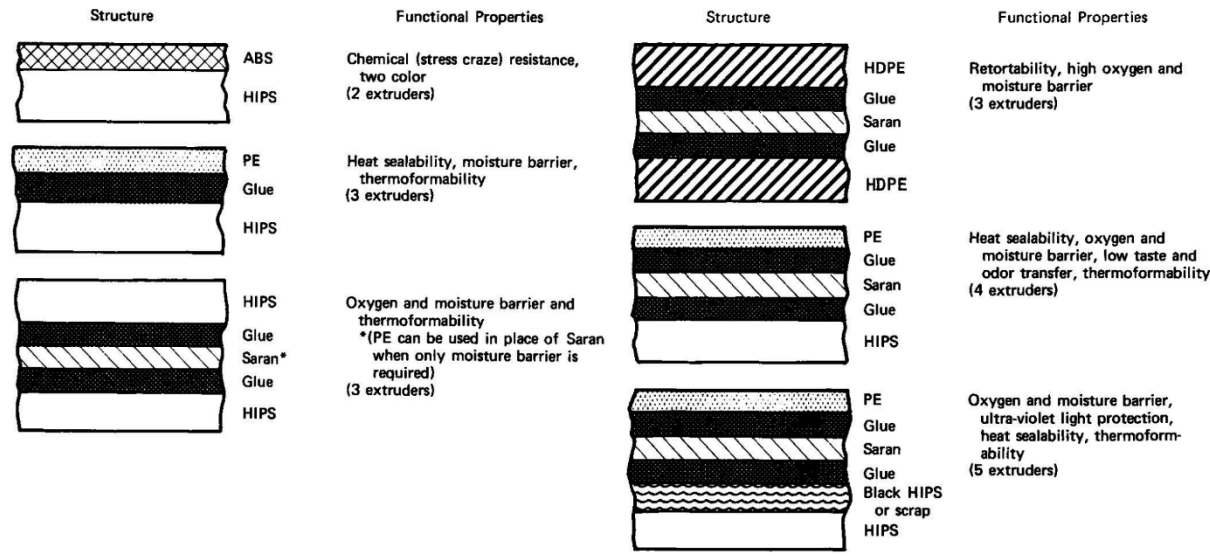
EX1036 (*Osswald* (2006)), Fig. 4.118.

The product is allowed to cool and then removed from the mold. EX1036 (*Osswald* (2006)). During cooling, the shaped product will shrink to its final shape. The amount of shrinkage depends on the temperature difference between the forming temperature and the final temperature of the shaped product. High forming

temperatures result in large shrinkage or large deviations from the mold dimensions. EX1039 (*Osswald* (2012)) at 295-99. Final processing steps can then be performed such as the removal of excess material or the assembly of a multicomponent product. EX1036 (*Osswald* (2006)) at 271.

a. Thermoforming Using Multilayer Films and Sheets

30. By the 1970s it was well known that multilayer polymer sheets could be thermoformed. Further, it was understood that when thermoformed, “[a] polymer layer in a multilayer sheet or film can exhibit different mechanical behavior from a free film of the same material,” and that “[p]articularly striking effects can be observed in laminar composites containing a ‘hard’ component and a ‘soft’ component.” EX1019 (*Schrenk*) at 154. It was understood that these changes were a result of the interaction between the hard and soft layers in a multilayer sheet. EX1019 (*Schrenk*) at 155. Accordingly, multilayer sheets were produced in industries which required good thermoformability, for example, in the food packaging industry. EX1019 (*Schrenk*) at 162.



EX1019 (*Schrenk*) Fig. 21

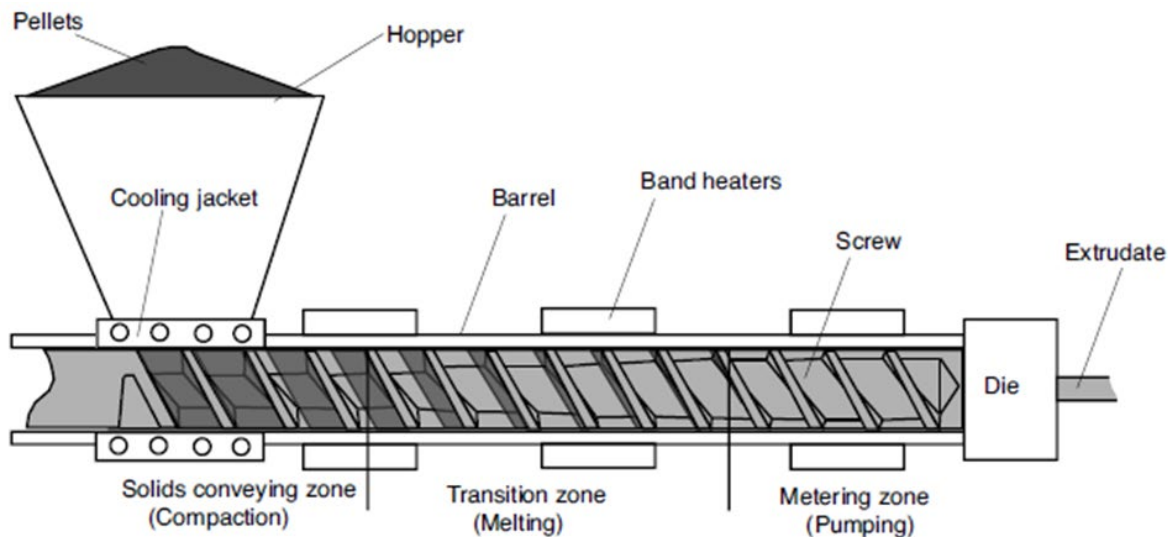
2. Multilayer Sheet Preparation Methods

31. Lamination and coextrusion are two well-known methods of preparing multilayer polymer films for thermoforming. While both manufacturing techniques can produce multilayer polymer films, they differ from each other in several ways, as detailed below. Further, the manufacturing technique chosen can have impacts on the mechanical properties of the polymers combined. For instance, certain manufacturing processes (e.g., coextrusion) may lead to molecular diffusion or mixing between the layers, as well as cross-linking, that can change the properties of the polymers within a layer, whereas the pure polymer properties are preserved when the multilayer sheet is produced using a process such as adhesive lamination, which does not lead to molecular diffusion or cross-linking between the layers. The properties of a layer in a multilayer sheet produced using coextrusion or dual

lamination therefore may differ from the properties of the pure polymer in that layer before being formed into a multilayer sheet.

a. Extrusion and Coextrusion

32. During extrusion, a polymer is melted and pumped towards an “extrusion die” that forms the melted polymer into a desired shape. EX1036 (*Osswald* (2006)) at 294, 296-313. The polymer is generally fed into the extruder as a solid, such as polymer pellets, and is melted as it is moved towards the extruder die by an extrusion screw. EX1036 (*Osswald* (2006)) at 271-72. There are numerous types of dies depending on the desired shape; a “sheeting die” is commonly used to create flat, uniform sheets of a plastic. EX1036 (*Osswald* (2006)) at 309-10. The formed polymer is then cooled to maintain this shape, and, for flat sheets, may be compressed by a “roller” as it is fed out of the die to ensure a consistent sheet thickness. EX1036 (*Osswald* (2006)) at 310, 388. A diagram of a “single screw extruder” process is shown below.



EX1036 (*Osswald* (2006)), Fig. 4.32.

33. Coextrusion is a process in which two or more extruders melt and feed multiple materials through a single die. EX1040 (*Baur*) at 212-14. The die exit can take various shapes depending on the final product's geometry. EX1040 (*Baur*) at 213. These shapes may include a simple slit, as seen in sheeting dies, an annulus for tubular products, or any other form dictated by the product's design.

34. There are multiple ways to arrange the materials in a coextrusion process, with the configuration being controlled either by the die or the extruders that melt and pump the polymers toward the die. Figure 1 below illustrates several methods for arranging multiple polymers in coextrusion processes.

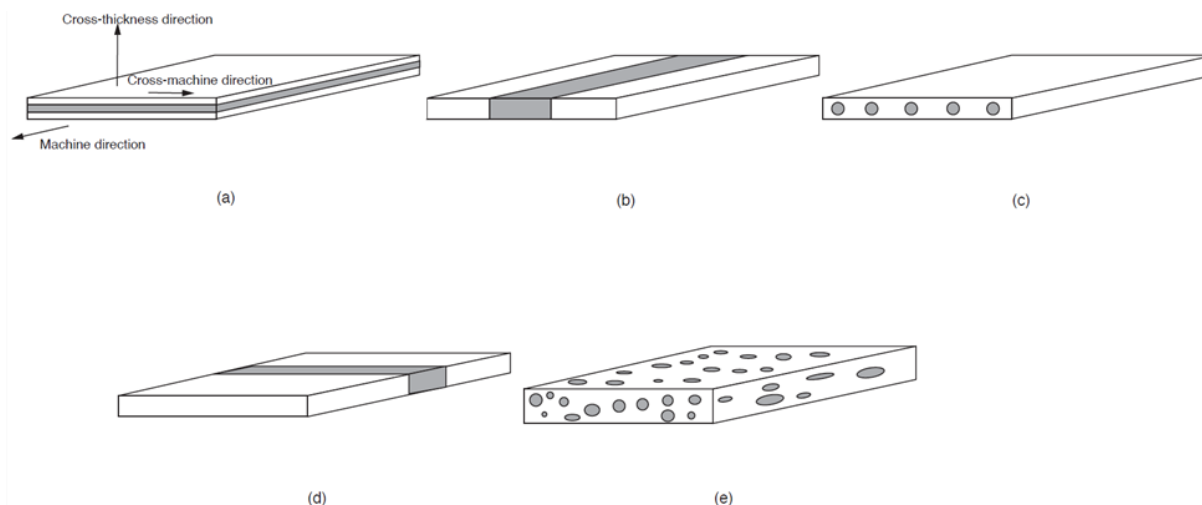
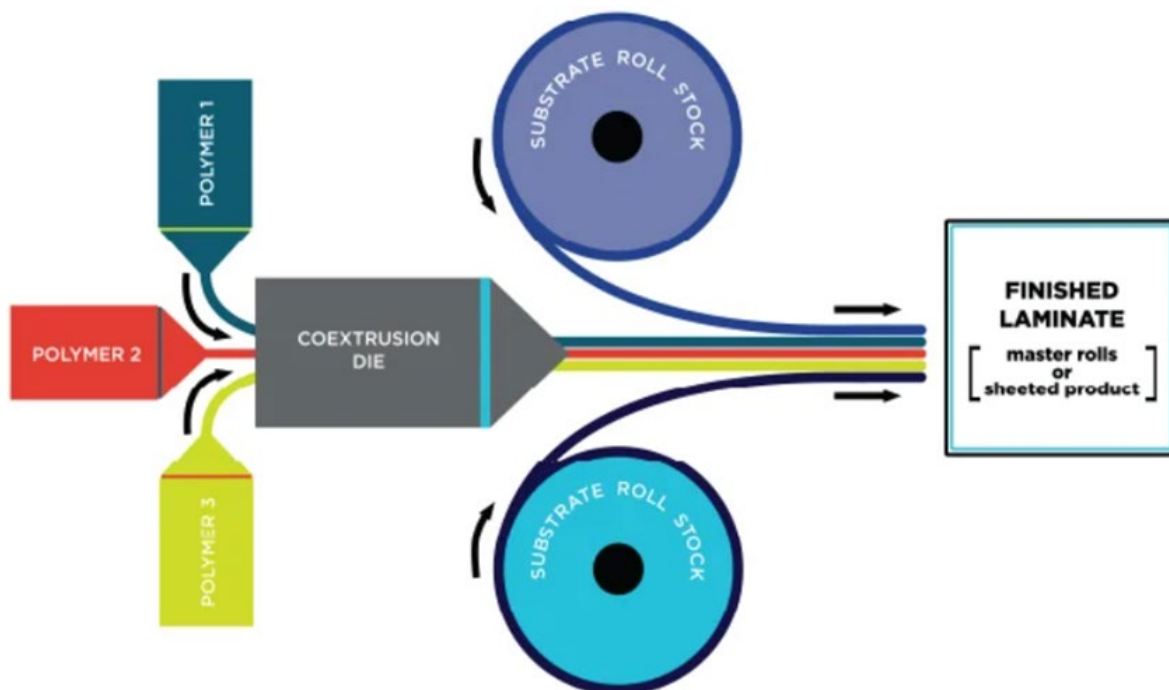


Fig. 1

35. One method of arranging multiple materials in coextrusion involves pumping two or more streams of polymer melt or additives into a die, where they are structured into layers across the thickness direction. For example, polycarbonate sheets are coated with UV-protective layers through coextrusion, making them suitable for outdoor applications. EX1040 (*Baur*) at 457-58. This type of layered arrangement is illustrated in diagram (a) in Figure 1 above. In other multilayered products, coextrusion is widely used in film casting and tubular film blowing processes to create films with multiple layers across the thickness. This is particularly beneficial in packaging applications, where low-permeability polymer layers help protect food products from oxygen exposure. EX1040 (*Baur*) at 658. The interaction between separate polymer melts at the interface, whether through crosslinking, molecular diffusion, or molecular entanglement, can influence the mechanical properties of both the polymer layers and the overall multilayer polymer

sheet. In some variations of coextrusion of multilayer sheets, additional layers outside the extrusion process may be further formed on the multilayer sheet during the rolling process as the materials cool. A diagram of such a process to create a multilayer sheet is shown below.



Coextrusion Process, BIXBY INTERNATIONAL, 2025,
<https://www.bixbyintl.com/process/extrusion-coextrusion> (EX1047).

36. Another method of arranging multiple materials in coextrusion is distributing them in the cross-machine direction, as seen in multicolored drinking straws—for instance, a white straw with a colored stripe running along its length. This type of material arrangement is illustrated in diagram (b) in Figure 1 above. Similarly, a different material can be embedded as strands oriented in the machine direction, as shown in diagram (c) in Figure 1 above. EX1038 (*Osswald* (1998) at 58-59.

37. Another type of coextrusion process occurs when extruders pump polymer melts into the die sequentially. EX1040 (*Baur*) at 221. This process, known as *sequential coextrusion*, results in a final extruded product with varying properties—such as color or stiffness—along the machine direction, as illustrated in diagram (d) in Figure 1 above. Sequential coextrusion is particularly useful for manufacturing products with rigid-flexible combinations. For example, it can be used to produce a rigid tube with soft and flexible thermoplastic elastomer sections that serve as hinges, allowing for greater flexibility. EX1040 (*Baur*) at 533.

38. Another method of arranging polymer components is by dispersing one polymer within another, such as is done with polymer blending. Polymer blending involves mixing two or more different polymers to create a material with enhanced properties through synergistic effects. EX1039 (*Osswald* (2012)) at 179-200. This dispersive mixing process results in one polymer forming a continuous phase, while the other appears as small, dispersed droplets, as illustrated in diagram (e) in Figure 1 above. Such intensive mixing can be achieved using twin-screw extruders, co-kneaders, or coextrusion processes that combine different extruders to produce a well-dispersed polymer blend.

b. Lamination

39. “Lamination,” as understood in the art, broadly refers to a means of combining thin layers of distinct materials into a thicker, layered composite. EX1045

(*Jones*) at 6-8; *see also* EX1041 (WO 2008/104371) at 4-5. Use of adhesives, pressure, and heat are common means to combine multiple layers of plastic materials into a multilayer laminate. EX1045 (*Jones*) at 8; *see also* EX1046 (*Mattox*) at 846.

40. Adhesive lamination, or adhesive bonding, is considered a “basic industrial process.” *See* EX1042 (*Ebnesajjad*) at xix; *see also* EX1042 (*Ebnesajjad*) at 410 (defining “Laminate” as “[t]o unite layers of material with adhesive.”). Adhesive lamination, as its name suggests, consists of joining materials, including plastics, by use of an adhesive material. EX1042 (*Ebnesajjad*) at 3-4. This adhesive material can be a structural part of the laminate structure, or it can be an additional nonstructural component that binds together the layers of the actual laminate structure (referred to as a “tie layer” or “glue layer”). EX1042 (*Ebnesajjad*) at 3-4; EX1019 (*Schrenk*) at 140.

41. One primary advantage of adhesives is the ability to bind both similar and dissimilar materials to one another. *See* EX1042 (*Ebnesajjad*) at 3-4; EX1043 (*Troughton*) at 147 (“[A]ny thermoplastics can be joined with adhesive bonding.”). For example, polyesters and polyurethanes are suitable materials to use in adhesive lamination processes, whether they are bonded to one another (i.e., adhering a polyester to a polyurethane layer) or bonded to themselves (i.e., adhering a polyester to another polyester layer). *See, e.g.*, EX1042 (*Ebnesajjad*) at 254 (providing suitable adhesives for polyurethanes and polyesters); EX1008 (*Wen*) at [00198],

[00201], [00208] (explaining that adhesives may be used to connect layers in a multilayer dental aligner, including connecting “hard” layers of copolyesters or polycarbonates with “softer” polyurethane layers). In certain instances, the surfaces of the adherents or layers can be treated prior to applying an adhesive to improve bonding between the layers, if necessary. *See* EX1042 (*Ebnesajjad*) at 56-77, 115, 121-22, 129 (describing adhesion treatment methods that improve bonding without altering the bulk properties of the layers, including for polyurethanes and polyesters).

42. Heat and pressure can also be used to laminate materials. The timing of heating and pressure application in lamination processes can be varied, including when used to create molded appliances. For instance, in some lamination processes at least one of the bonded materials is preheated before being placed in contact with other layers, while in other lamination processes, all materials are heated simultaneously. *Compare* EX1044 (*Covestro Lamination*) (describing preheating a single layer in “flame lamination”) *with* EX1045 (*Jones*) at 20-23 (describing methods of heating all layers simultaneously from a heat source). Pressure can be applied to the sheets through an external positive force or through negative pressure in the system (i.e., creating a vacuum). *See, e.g.,* EX1045 (*Jones*) at 21 (Fig. 1-14).

c. Simultaneous thermoforming

43. In some lamination processes, the layers are fully laminated prior to molding and thermoforming, while in other lamination processes the layers are adhered further throughout the molding process. EX1045 (*Jones*) at 20-26. That is, in certain processes the thermoforming itself may laminate layers of a material together. A diagram of such a process is shown in Figure 2 below.

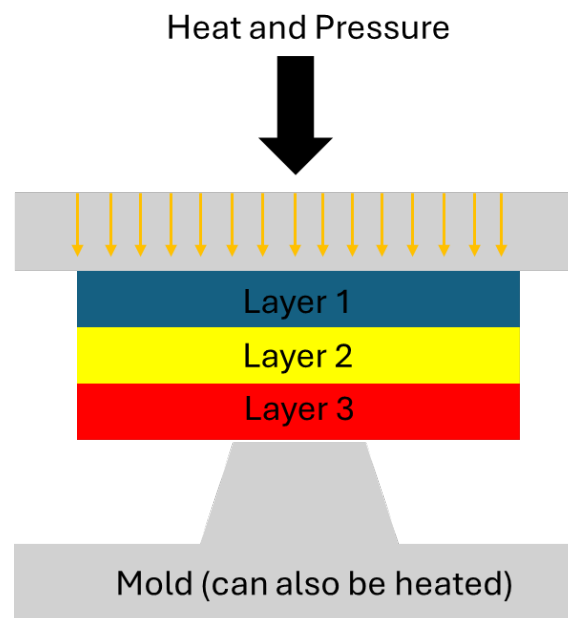


Fig. 2.

44. Figure 2 shows a process similar to that described in *Jones*, wherein the layers of a multilayer appliance are heated as pressure is applied. See EX1045 (*Jones*) at Figs. 1-13, 1-14. The combination of heat and pressure may increase the bonds between the layers, while also allowing the layers to be molded into an ideal shape. One advantage of such a process is efficiency, since the laminating and thermoforming process takes place in a single step. Similar processes have been

applied to create multilayer dental appliances, wherein separate hard and soft sheets are deep-drawn in a thermoforming process to create a laminated, formed dental appliance. *See, e.g.*, EX1008 (*Wen*) at [00205]-[00207] (disclosing “heat[ing] [a first sheet] for a specified time,” “pressing ... [the first sheet] against a patient’s physical tooth models,” using a vacuum pump to remove air and cause the first sheet to “fittingly form[] around the surface of the dental arch model,” and repeating with multiple layers). In such processes, it still may be desirable to promote lamination by the use of an adhesive agent prior to thermoforming.

d. Both Lamination and Coextrusion Processes Were Well Known Methods for Fabricating Multilayer Sheets

45. Lamination and coextrusion processes can be combined, such that a multilayer appliance may have some layers that were bonded through coextrusion while others were adhered through lamination. *See, e.g.*, EX1047, *Coextrusion Process*, BIXBY INTERNATIONAL, 2025, <https://www.bixbyintl.com/process/extrusion-coextrusion> (showing lamination of additional sheets to coextruded composite). In my opinion, both lamination and coextrusion, as well as variations or combinations thereof, are well-known fabrication methods for manufacturing multilayer sheets. *See supra* Sections IV.A.2.a-IV.A.2.c. A POSITA would consider a variety of factors (e.g., cost, time,

adhesion strength) when selecting the preferred fabrication method, but either lamination or coextrusion would be successful in creating a dental aligner.

B. Layer Configurations in Multilayer Appliances

1. Soft-Hard-Soft Layer Configurations Were Commonly Used in Prior Art Dental Aligners

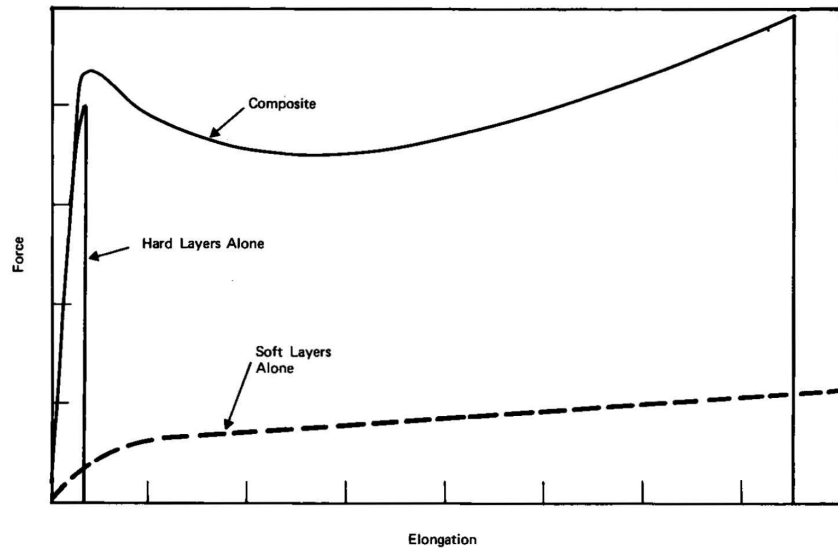
46. Early variations of modern thermoplastic dental aligners were first introduced in the 1970s and consisted of a single layer of a polymeric mixture. EX1048 (*Alfadil*) at 1 (citing EX1049 (*Ponitz*)). Although the specific polymers used and the resulting properties of the aligner (i.e., rigidity, flexibility) were varied, the general monolayer configuration of aligners remained the same through around the year 2000. *See, e.g.*, EX1020 (*Schwartz*), U.S. Patent No. 5,692,894 (patent filed in 1996 by Essix using single polyvinyl siloxane layer); EX1050, U.S. Patent No. 5,975,893 (patent filed in 1997 by Align using single “elastomeric” layer).

47. However, the monolayer structure of dental aligners often required a tradeoff between positioning force, patient comfort, and aligner fit. Specifically, aligners made out of a single “hard” layer provided strong repositioning forces needed to move teeth but were often uncomfortable when contacting a patient’s gums and did not sit down properly on patient’s teeth, causing further discomfort. *See* EX1051 U.S. Patent No. 6,077,075 (*Bedard*) at 1:4-38. Conversely, aligners made out of a single “soft” layer provided improved fit and comfort but did not provide sufficient strength and durability. *See* EX1051 (*Bedard*) at 1:59-61.

48. A solution to this problem, adopted in the early 2000s, was to use a *multilayer* structure, wherein a core hard layer provided the repositioning forces for the appliance, and a soft gum-contacting layer was used to decrease uncomfortable rubbing and rocking on a patient's gums. *See, e.g.,* EX1051 (*Bedard*); EX1003 (*Tadros*); EX1005 (*Kalili*); EX1052 (*Chen*). It was also found that patient comfort could be improved in a similar fashion by placing an additional soft layer on the outer surface of the appliance. *See* EX1008 (*Wen*) at [00198]; EX1003 (*Tadros*) at [0073].

49. The combination of hard and soft layers can also provide improved mechanical properties. “A polymer layer in a multilayer sheet or film can exhibit different mechanical behavior from a free film of the same material.” EX1019 (*Schrenk*) at 154. “Particularly striking effects can be observed in laminar composites containing a ‘hard’ component and a ‘soft’ component.” EX1019 (*Schrenk*) at 154. For example, “a laminar composite containing a layer of high-modulus, low elongation polymer sandwiched (with good adhesion) between layers of a high-elongation material” can result in a “toughening effect” sometimes referred to as “mutual interlayer reinforcement.” EX1019 (*Schrenk*) at 154-55. Specifically, “[w]hen the composite is tested to failure in tension, the adhering high-elongation layers may act to prevent transverse crack propagation in the hard layer,” resulting in the entire composite exhibiting high elongation. EX1019 (*Schrenk*) at 154-55.

This interaction between hard and soft layers in a multilayer sheet is represented schematically in the figure below.



EX1019 (*Schrenk*), Fig. 18.

50. In my opinion, based on my review of the prior art, this practice of creating a multilayer dental aligner by (1) starting with a hard layer to provide repositioning force, and (2) adding soft outer layer(s) (on the gum-contacting side and, optionally, on the other outer surface) to improve patient comfort and mechanical properties of the appliance was well known by at least the mid-2000s. Indeed, it is my understanding that Patent Owner acknowledged during prosecution of the '691 patent that multilayer dental appliances, and in particular, “soft-hard-soft” dental appliances, were known in the art before the earliest possible priority date of the '090 patent. *See, e.g.*, EX1010 ('691 File History) at 1224-1226 (acknowledging the inventors were aware of soft-hard-soft configurations in the

prior art, and alleging the invention was an improvement over prior art because of the specific materials used).

2. It Was Well Known That Using Several Thinner Layers of a Polymer Could Improve Functionality of Multilayer Appliances

51. Multilayer appliances require some method of adhering the layers to each other. As described above, lamination and coextrusion are both known methods of achieving adhesion between layers. In the context of dental aligners, it was well known that, when using lamination, using multiple thinner “sublayers” of a given polymeric material, rather than a single, thicker layer of that same material, could result in improved fabrication of a final dental appliance.

52. First, it was well known that using thinner layers improves the conformity of each layer to the tooth model. Put another way, using thinner layers results in a more detailed and precise dental aligner because the layers can more easily form into the fine contours of a model of a patient’s teeth. This concept was recognized in the art. *See, e.g.*, EX1051 (*Bedard*) at 3:55-67; EX1008 (*Wen*) at [00212]. Importantly, more precisely shaped dental aligners can more efficiently exert the appropriate repositioning forces on each individual tooth, because there are more points of contact between the tooth and the aligner that allow the aligner to engage with the teeth. *See, e.g.*, EX1008 (*Wen*) at [0021], [00198], [203].

53. Second, using thinner layers improves interlayer bonding, particularly between materials with disparate properties, lowering the degree of adhesion required to achieve mutual layer reinforcement. This concept was also recognized in the art. EX1008 (*Wen*) at [00231]; EX1019 (*Schrenk*) at 155-56.

54. Interlayer interactions such as the “mutual interlayer reinforcement” described above, “require some degree of adhesion at the interfaces.” EX1019 (*Schrenk*) at 155. However, “[s]ome pairs of polymers ... exhibit weak interfacial adhesion.” EX1019 (*Schrenk*) at 148. One solution is to replace thicker layers with a series of thinner layers. “[T]he thinner the layers, the lower will be the degree of adhesion required in order for one layer to influence the response of its neighbor. Thus, in microlayer film, with hundreds of very thin layers, interlayer interactions can be anticipated even with very poorly adhering components.” EX1019 (*Schrenk*) at 155-56.

55. Notably, these well-known improvements in fabrication of a dental aligner using thinner sublayers in a multilayer sheet would not be expected to change the other properties of the sheet or resulting dental aligner, under very particular circumstances where (1) the sublayers are the same material (i.e., each respective “hard” or “soft” section is a single composition), (2) the particular ordering of “hard” and “soft” sections of the aligner was not changed (i.e., in both a soft-hard and soft-hard-hard configuration, the soft layer is still providing patient comfort while the

hard layer provides repositioning force), and (3) the overall thickness of each respective “hard” or “soft” portion of the aligner were not changed (i.e., properties that are dependent on thickness, such as flexural modulus, will remain constant).

56. Accordingly, in my opinion, using thinner layers of a “hard” or “soft” polymer rather than a single thicker layer of that same polymer would result in a dental appliance that has superior conformity to the teeth and interlayer bonding, but is otherwise equivalent to the original configuration in terms of mechanical properties.

C. Overview of Relevant Mechanical Properties

1. Stress and Strain

57. Mechanical properties of polymeric materials, such as flexural modulus, are quantified by observing the behavior of that material when subjected to external forces. This behavior is understood and expressed through the concepts referred to as “stress” and “strain.”

58. When an external deforming force acts on a physical body, it produces stress in that body. *See* EX1053 (*Painter*) at 402-04. “Stress” is defined as the amount of force experienced by the body per unit of cross-sectional area and is typically expressed in units of newtons per square meter (N/m^2) (also referred to as a Pascal (Pa)). EX1053 (*Painter*) at 403-04. An object under stress may deform (e.g., by bending or stretching) in response to that stress, which is described as “strain.”

See EX1053 (*Painter*) at 403-04. In other words, strain is the measure of how much an object is deformed when a force is applied to the object. Strain is a unitless measurement calculated as the ratio of the change in a physical dimension of the object to its initial dimension. EX1053 (*Painter*) at 405.

59. Plotting stress and strain on an X-Y graph produces what is called a stress-strain curve. See, e.g., EX1039 (*Osswald* (2012)) at 368. Various sections of a stress-strain curve describe different behaviors of materials and provide important information on the properties of the material being tested. See EX1040 (*Baur*) at 70-71. Figure 3 below illustrates a typical stress-strain curve for a polymeric material.

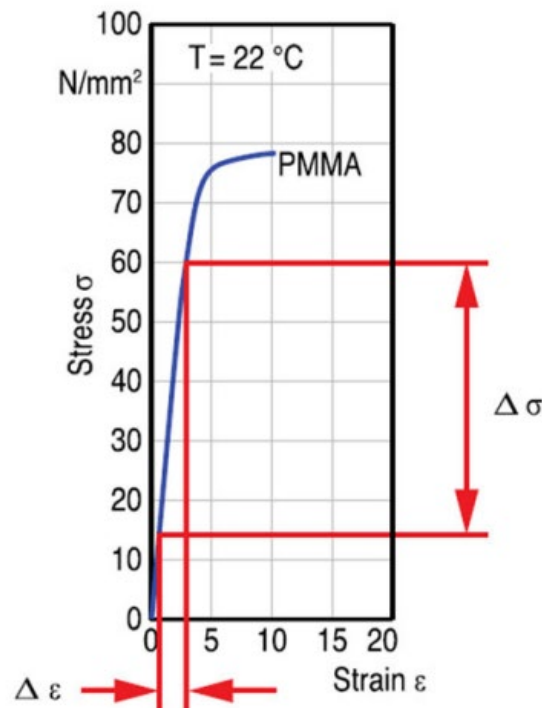


Fig. 3.

2. Flexural Modulus and Tensile Modulus (Elastic Modulus)

60. Flexural modulus refers to a material's ability to resist bending deformation under force. Tensile modulus (also called *elastic modulus*) refers to a material's ability to resist stretching deformation under force. EX1040 (*Baur*) at 69-71. Although flexural modulus and tensile modulus are measured by different experiments, they are practically identical under typical use conditions for polymeric materials. EX1054 (ISO 178:2019) at 24; *see also* EX1045 (*Jones*) at 11 (noting that an "isotropic body has material properties that are the same in every direction at a point in the body"). Indeed, the ISO 178:2019 publication states that "[d]isregarding influences by the measurement process, from a physical point of view moduli obtained in tension and in flexure should be identical." EX1054 (ISO 178:2019) at 24. The ISO publication includes a table showing similar experimental values of tensile and flexural tests, which is reproduced below.

Material	Tensile modulus MPa		Flexural modulus MPa
	Machine 1	Machine 2	Machine 3
PBT GF30 lot 1	9 749 ± 85	9 726 ± 134	9 750 ± 66
PBT GF30 lot 2	9 888 ± 129	9 745 ± 122	9 892 ± 68
ASA	2 523 ± 24	2 521 ± 31	2 705 ± 33
PBT	2 582 ± 35	2 522 ± 31	2 542 ± 27

EX1054 (ISO 178:2019), Table D.1.

61. Flexural modulus can be measured using either the ASTM D790 or ISO 178 test method. For these tests, a 3-point bending analysis is applied to a

rectangular beam sample. EX1055 (ASTM D790-17) at 1-6; EX1054 (ISO 178:2019) at 5, 16-17. This involves placing the sample on two support points at the ends of the beam and applying a force (F) downward between the two supports. EX1040 (*Baur*) at 72-73. The flexural stress creates a displacement (D) in the material, called “deflection.” EX1040 (*Baur*) at 72-73. This testing is illustrated in Figure 4 below.

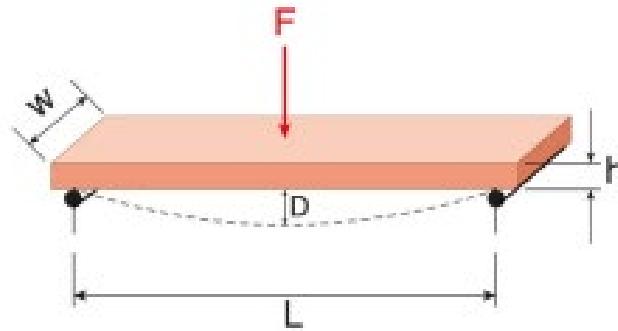


Fig. 4.

62. After the force is applied, the centerline of the bent specimen maintains the original length of the beam, while the upper surface is shortened and the lower surface is lengthened. EX1040 (*Baur*) at 72-73 In other words, the lower surface is in tension (i.e., under tensile stresses), the upper surface is in compression (i.e., under compressive stresses), and the centerline experiences neither. See EX1040 (*Baur*) at 72-73. This is illustrated in Figure 5 below.

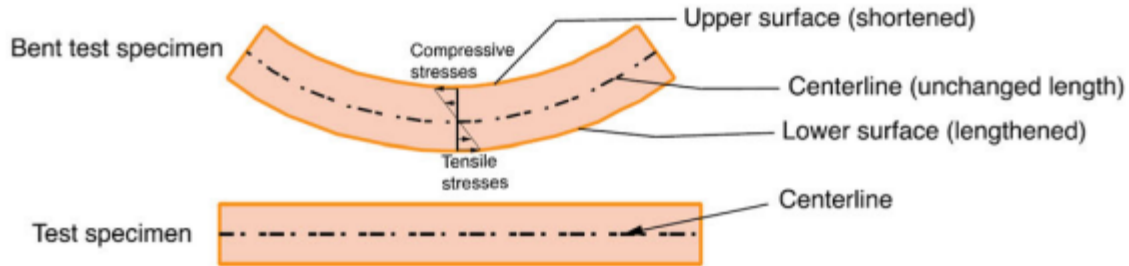


Fig. 5.

63. The reported flexural modulus value is the ratio of stress to strain, accounting for the sample dimensions, length between the supports, force applied, and displacement at the center due to the applied force. The stress and strain in the material require different calculation methods based on the location of interest. Flexural modulus measures the stress and strain values at the lower, lengthened surface.

64. Flexural strain at the lower lengthened surface in the center is computed using the following formula:

$$\varepsilon_f = \frac{6D^h}{L^2}$$

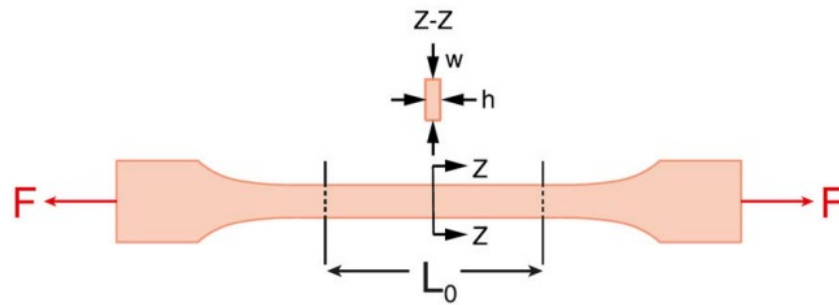
and the flexural stress is computed at the same location using:

$$\sigma_f = \frac{3FL}{2wh^2}$$

EX1055 (ASTM D790-17) at 6; EX1054 (ISO 178:2019) at 16. The ratio of these equations, flexural modulus (E_f), is thus calculated according to the following:

$$E_f = \frac{FL^3}{4wDh^3}$$

65. Tensile modulus for standard plastics can be measured, for example, using either the ASTM D638 or ISO 527-1 test method. See EX1056 (ASTM D638-14); EX1057 (ISO 527-1:2012). Rather than applying a downward force, the tensile modulus tests apply a stretching load (F) along the axis of a sample material and measure the amount of deformation. EX1040 (*Baur*) at 69-70. This test is illustrated in tFigure 3.17 from EX1040 (*Baur*), reproduced below with annotations.



EX1040 (*Baur*) at 70, Fig. 3.15 (some annotations added).

66. As with flexural modulus, the reported tensile modulus value is the ratio of stress to strain, accounting for the sample dimensions and force applied. Tensile strain compares the amount the sample stretches during testing to its initial length (L_0) at the center of the sample, as shown below in the equation:

$$\varepsilon = \frac{L - L_0}{L_0}$$

67. Tensile stress is measured as the force per unit area at the center of the sample, shown by the equation:

$$\sigma = \frac{F}{wh}$$

The ratio of these equations, tensile modulus (E), is thus:

$$E = \frac{FL_0}{wh(L - L_0)}$$

A stress-strain curve can be generated during the tensile test. This stress-strain curve can also be used to determine other mechanical properties including yield point, tensile strength at yield, and tensile strength at break. EX1040 (*Baur*) at 70-71.

3. Tensile Strength

68. Strength measures how much stress can be applied to a material before it fails. EX1053 (*Painter*) at 414, 417. “Tensile strength” therefore refers to the amount of tensile stress required to reach failure. Two modes of failure for polymers are yielding and breaking. EX1053 (*Painter*) at 408, 410.

69. Yielding refers to a material’s change from elastic to plastic behavior. In elastic behavior, a material will return to its original shape when the applied stress is removed. EX1053 (*Painter*) at 408, 410. However, there are no perfectly elastic materials, and thus there is an elastic limit for every material where it will deform permanently (referred to as plastic behavior). EX1053 (*Painter*) at 408, 410. The yield point is the point on the stress/strain curve where this transition from elastic to

plastic behavior occurs. EX1053 (*Painter*) at 410. Tensile strength at yield is thus the maximum amount of tensile stress a material can withstand before it reaches its yield point.

70. Breaking occurs when a material fractures from stress and strain. Tensile strength at break, also referred to as “ultimate tensile strength,” is thus the maximum amount of tensile stress a material can withstand before fracturing. EX1053 (*Painter*) at 408, 410, 423.

71. All real-world polymeric materials experience some form of yielding before breaking, although the degree by which a material deviates from elastic behavior before breaking may vary. EX1053 (*Painter*) at 408, 410, 430. For instance, “ductile” materials experience yielding well before fracture, while “brittle” materials continue to behave elastically until close to the breaking point. EX1053 (*Painter*) at 410. As a result, tensile strength at break is necessarily greater than tensile strength at yield for all real-world materials, even if only slightly, since more tensile stress was required for a material to reach its break point. EX1053 (*Painter*) at 408, 410, 430.

4. Elongation

72. Elongation refers to the amount a material increases in length when subjected to tensile testing. EX1053 (*Painter*) at 408, 410, 430, 446; *see supra* Section IV.C.2. Elongation can be expressed in terms of a percentage, where the

change in elongation ($L-L_0$) is compared with the initial length of the sample (L_0), as shown below.

$$\% \text{ Elongation} = \frac{(L - L_0)}{L_0} \times 100$$

73. As with tensile strength, elongation percent can be calculated at both the yield and break point, referred to as elongation at yield and elongation at break, respectively.

5. Hardness

74. Hardness quantifies the ability of a material to resist indentation. EX1058 (Q_i) at 419. Two tests used to determine hardness are the Shore hardness and Rockwell hardness tests.

75. Shore hardness tests can be conducted according to either ASTM D2240 or ISO 48-4 test methods. *See* EX1059 (ASTM D2240-15); EX1060 (ISO 48-4:2018). In both of these test methods, hardness is measured using a device called a durometer. EX1058 (Q_i) at 419. A durometer consists of an indenter, which is pressed into the material by a spring while the reaction force on the indenter and its depth of movement is measured. EX1058 (Q_i) at 419-22. The depth of penetration of the indenter into the sample is related to the hardness of the sample.

76. Figure 6 below shows a photograph of a durometer in the “zero position” with a fully extended indenter, corresponding to a Shore hardness value of zero. When the durometer is pressed against the test sample, such that the base is

flush with the surface of the test sample, the indenter pushes into the sample. The reaction force created by the sample pushes the indenter against the spring, compressing the spring. EX1040 (*Baur*) at 74. A measured Shore hardness value of 100 is the maximum hardness for a given durometer.

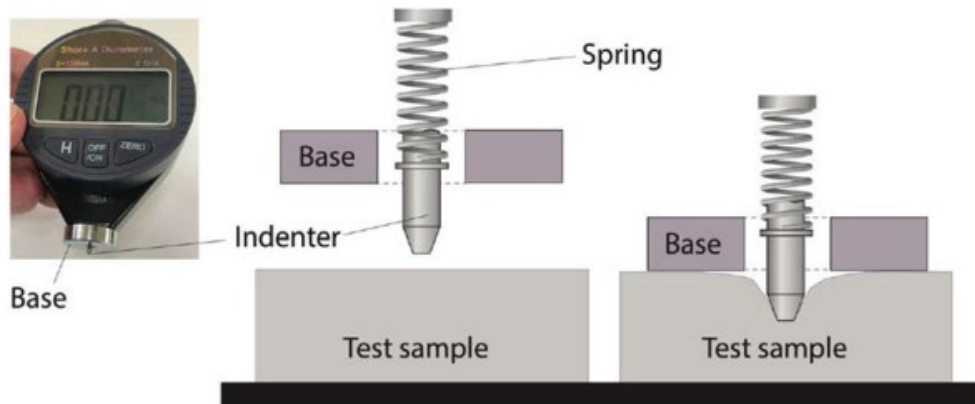


Fig. 6.

Seven different types of durometers can be used, including Shore A and Shore D durometers. The main difference between these durometers is their shape, with Shore D durometers being better suited for harder materials. EX1040 (*Baur*) at 74.

6. Compression Set

77. Compression set refers to the amount of permanent deformation of a material after it is compressed at a constant strain for a set period of time and subsequently allowed to briefly recover. EX1061 (*McKeen*) at 14-15. Compression set can be calculated using either the ASTM D395 or the ISO 815 test method. See EX1062 (ASTM D395-03); EX1063 (ISO 815:2019). Under these tests, a material is compressed to a certain percentage of its original thickness (usually 25%) for a

specified period of time (usually around 22 hours) at constant temperature. EX1061 (*McKeen*) at 14-15; *see also* EX1062 (ASTM D395-03) at 5-6; EX1063 (ISO 815:2019) at 6. The material is then allowed to recover (usually for around 30 minutes) before measuring the thickness of the sample, with compression set measured as the percentage a material fails to recover to its original thickness. EX1061 (*McKeen*) at 14-15. For instance, a compression set of 40% means that a sample only regained 60% of its original thickness. EX1061 (*McKeen*) at 14-15. Similarly, a compression set of 100% would indicate the material never recovered and remained compressed. EX1061 (*McKeen*) at 14-15. The longer a material is compressed under strain, the lower the speed of elastic recovery for a material after the strain is removed. For example, a material under strain that is released immediately after it is compressed will spring back to its original shape almost instantaneously, while a material that remains compressed for a long period of time will take longer to recover its original shape. EX1039 (*Osswald* (2012)) at 344. In other words, a material's inability to return to its original thickness, and therefore its compression set, necessarily would either be the same or increase as time under strain is increased (e.g., increasing the time under strain from 22 hours to 24 hours), assuming that the recovery period remains constant. Compression set cannot decrease with increased time under strain.

7. Stress Relaxation and Creep

78. An external force applied to a material, either in the form of stress or strain, adds energy to the material. The behavior of the material's response to this added energy can be classified as elastic or viscous. Elastic materials are able to store the added energy and perfectly oppose the deforming force without any permanent molecular rearrangement. EX1053 (*Painter*) at 408, 410. The molecules in an elastic material may stretch but are hindered in sliding past each other. EX1039 (*Osswald* (2012)) at 362. For instance, if steel were stretched to a certain length, the molecules in steel would act like a spring, opposing the tensile forces and returning to its original shape after this strain was removed.

79. In contrast to elastic materials, viscous materials dissipate the added energy from stress or strain by allowing molecules to slide past one another into a lower energy state, resulting in permanent deformation. EX1039 (*Osswald* (2012)) at 113. For instance, if honey were stretched to a certain length, the molecules in the honey would act like a dashpot, providing little to no resistance against the tensile forces. When the strain was removed, the honey would not return to its original shape, as the molecules would remain in their deformed, lower energy state.

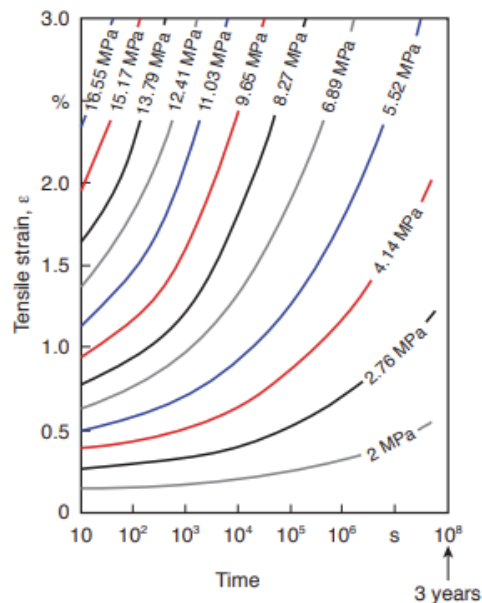
80. Polymers exhibit both viscous and elastic behavior (i.e., "viscoelastic" behavior) in responses to stress and strain. That is, a polymer exposed to a stress or strain will be neither perfectly elastic nor perfectly viscous.

81. Stress relaxation and creep are two related properties used to describe the viscoelastic behavior of materials. Stress relaxation is a measure of the decrease in stress of a material over time as it is subjected to a constant strain. EX1039 (*Osswald* (2012)) at 344. Creep is considered the inverse of stress relaxation and measures the increase in strain of a material over time as it is subjected to a constant stress. EX1039 (*Osswald* (2012)) at 375. Stress relaxation and creep are often expressed as the change in stress or strain for a given time, respectively.

82. Variables that can affect the viscoelastic behavior of a material include temperature, humidity, the amount of stress or strain applied, and the length of time this stress or strain is applied. EX1039 (*Osswald* (2012)) at 344; *see also* EX1064 (*Alemnis*); EX1038 (*Osswald* (1998)) at 25. That is, polymers will tend to display more viscous or more elastic properties depending on these variables. For this reason, tests measuring stress relaxation and creep will generally specify the particular test conditions used to ensure consistent interpretation of measured stress relaxation and creep values.

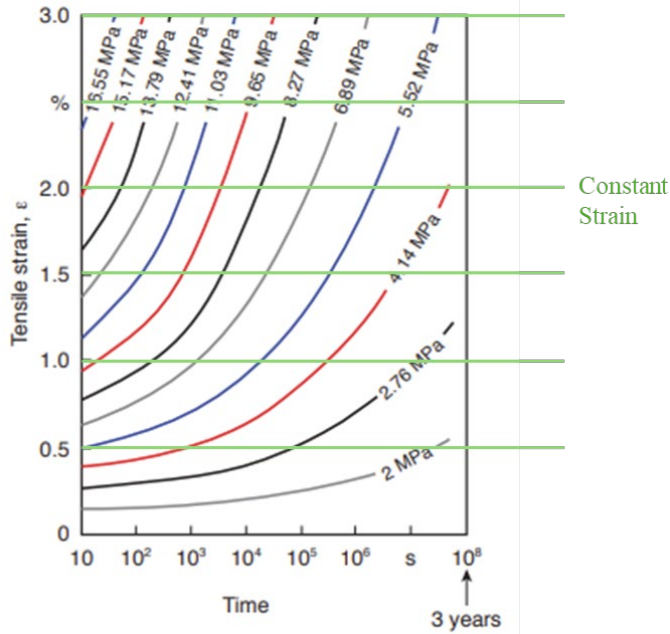
83. Although stress relaxation and creep have separate tests, the stress relaxation test is expensive and cumbersome to perform. *See* EX1039 (*Osswald* (2012)) at 344. Accordingly, it is common to derive stress relaxation curves using data from creep tests. EX1039 (*Osswald* (2012)) at 374.

84. Performing a creep test requires placing a polymer under a constant load, such as by attaching a weight to one end of a suspended material, under controlled temperature and humidity conditions. *See* EX1065 (ASTM D2990-01); *see also* EX1066 (ISO 899-1:2017). The strain, measured as the percentage change in length of the suspended material, is then plotted as a function of time. This can be repeated for a range of different stresses. An example of a creep curve is shown in the figure below for a sample propylene-ethylene copolymer at 20°C.

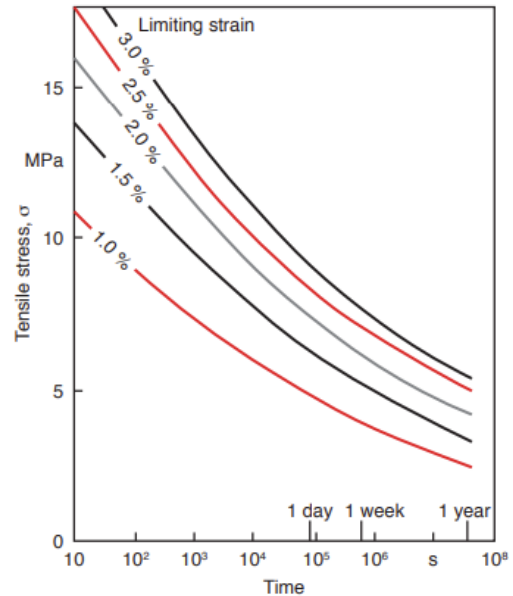


EX1039 (*Osswald* (2012)), Fig. 9.41.

85. Deriving a stress relaxation curve from the creep test is relatively straightforward and simply requires plotting data from constant strain sections of the creep curves as stress as a function of time. An example of the isometric strain lines and resulting stress relaxation curves are shown below.



EX1039 (*Osswald* (2012)), Fig. 9.41
(annotations added).



EX1039 (*Osswald* (2012)), Fig.
9.47.

86. As shown in EX1039 (*Osswald* (2012)), Figure 9.41, above, for any given constant stress curve, the resulting strain increases over time. And as shown in EX1039 (*Osswald* (2012)), Figure 9.47, above, for any given constant strain curve, the resulting stress decreases over time. Therefore, stress relaxation necessarily increases with the duration of the test. For example, the stress relaxation of a given material at 24 hours is necessarily greater than its stress relaxation at 12 hours. Further, for polymers that are sensitive to humidity, stress relaxation increases with increasing humidity due to softening, reduced stiffness, and increased molecular mobility. Therefore, the stress relaxation of a given material in a wet environment is necessarily greater than its stress relaxation in a less wet environment. For these reasons, the stress relaxation of a given polymer at 24 hours

in a wet environment, is necessarily greater than its stress relaxation after 12 hours in the same or a less wet environment. Moreover, in my experience, most polymers (including polycarbonates and copolyesters) would exhibit a stress relaxation greater than at least 10% after a timescale of 24 hours under standard laboratory conditions. EX1053 (*Painter*) at 466; EX1040 (*Baur*) at 80; EX1039 (*Osswald* (2012)) at 565-82.

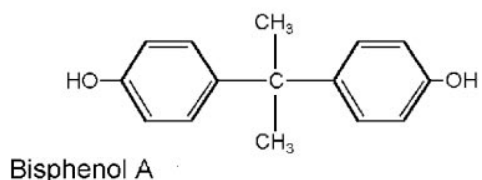
8. Light Transmission

87. When light interacts with a material, it can either be reflected, absorbed, or transmitted. EX1067 (*Fox*) at 1-2. Light transmission (sometimes referred to as light transmissivity) measures the amount of incident light that passes through a material. EX1067 (*Fox*) at 9-12; *see also* EX1067 (*Fox*) at 3 (using same coefficient to describe transmission and transmissivity). Light transmission is dependent on the wavelength of the incident light. EX1067 (*Fox*) at 3. When measured on the visible light spectrum (400 nm to 700 nm), materials that are perceived as more “transparent” will have higher light transmission values since they allow more visible light to pass through. EX1067 (*Fox*) at 3; EX1039 (*Osswald* (2012)) at 520. For example, a material like glass will have high light transmission values on the visible light spectrum, while a material like aluminum will reflect most visible light, leading to low light transmission values. EX1067 (*Fox*) at 8, 13.

D. BPAs and Tritan Copolyesters

1. The Harmful Effects of BPAs

88. Bisphenol-A (“BPA”) is a lab-made chemical first synthesized in 1891, consisting of two phenol groups (benzene rings with hydroxyl groups (-OH) attached at the para position) connected by a central carbon with two methyl groups. EX1068 (*Vandenberg*) at 76-77.



EX1068 (*Vandenberg*), Fig. 1.

89. By the 1930s, BPA had been identified as a synthetic form of the hormone estrogen because of its ability to bind to estrogen receptors in the body, but it was ultimately abandoned for pharmaceutical use in favor of a more potent diethylstilbestrol (“DES”) compound.¹ EX1068 (*Vandenberg*) at 77.

¹ DES was later banned from pharmaceutical use by the 1970s after being linked to reproductive cancers and is now known to be an endocrine-disrupting chemical linked to increased risk of numerous other cancers, birth defects, and developmental abnormalities. EX1069 (*Vogel*) at 559; EX1068 (*Vandenberg*) at 76. As explained below, similar risks were later discovered for the chemically-similar compound BPA.

90. BPA eventually found use in plastics, starting as a component in epoxy resins in the early 1950s. EX1069 (*Vogel*) at 559. In 1957, it was discovered that BPA could be polymerized to form a hard and strong plastic called polycarbonate, which was clear enough to replace glass in consumer goods. EX1069 (*Vogel*) at 559. The use of polycarbonate exploded as companies found new uses in electronics, safety equipment, automobiles, food containers, and dental appliances, with the total production of BPA in the U.S. reaching over half a billion pounds by the late 1970s. EX1069 (*Vogel*) at 559-60; EX1049 (*Ponitz*) at 266 (disclosing use of polycarbonate in invisible dental retainers). By the late 1980s, production of BPA in the United States alone had expanded to close to a billion pounds per year as the market for polycarbonates grew even further. EX1069 (*Vogel*) at 561.

91. With the growing use of polycarbonates, U.S. federal agencies began investigating potential carcinogenic effects of its BPA building blocks. EX1069 (*Vogel*) at 560-63. A 1982 final report from the National Toxicology Program (“NTP”) acknowledged that BPA “may be associated with increased cancers of the hematopoietic system,” but did not find that data available at the time met the “convincing evidence” standard required to label a chemical carcinogenic. EX1069 (*Vogel*) at 560, 563; EX1070 (*NTP 1982 Report*) at vii, xi. The Environmental Protection Agency (“EPA”) relied on this narrow “not carcinogenic” label in combination with the “lowest observed adverse effect level” from the NTP study to

set the exposure limits for BPAs in 1988. EX1069 (*Vogel*) at 560, 563-64; *see also* EX1068 (*Vandenberg*) at 78-79 (explaining nonlinear response of certain chemicals, which BPA was later discovered to exhibit, that is unsuitable for toxicity calculations based on lowest observed adverse effect level model).

92. By the early 1990s, scientists had begun to finalize a hypothesis on a class of chemicals called “endocrine disruptors” that reframed how low-dose exposure was interpreted. EX1069 (*Vogel*) at 561 (noting that the term “endocrine disruption” was officially coined in 1991 but built off of research beginning in 1979 on the carcinogenic effects of synthetic estrogenic compounds). Endocrine disruption was the hypothesis that some chemicals, such as DES and BPA, interfered with the production, processing, and transmission of hormones in the body. EX1071 (*Soto*) at 2; EX1069 (*Vogel*) at 561. Unlike carcinogens, which directly alter DNA and therefore increase cancer risk, endocrine disruptors affect hormonal processes and can lead to carcinogenesis in later life. EX1073 (*Pup*) at 603 (“With the exception of diethylstilboestrol (DES), [endocrine disruptors] cannot be considered carcinogens *per se*, but they can indirectly interfere with the endocrine and immune systems favoring true carcinogenic effects.”); *see generally* EX1071 (*Soto*). These harmful effects were especially pronounced when exposure to an endocrine disruptor occurred during early developmental stages, even at low dosages. EX1071 (*Soto*) at 7; EX1069 (*Vogel*) at 561-62.

93. Special attention was devoted to the study of BPA after a 1993 discovery that BPA, a known form of synthetic estrogen, was leaching from polycarbonate products. EX1069 (*Vogel*) at 561; *see also* EX1074 (*Suzuki*) (2000 study confirming BPA leaching from polycarbonate-based dental materials); EX1075 (*Fleisch*) (2010 study finding BPA leaching from dental materials); EX1076 (*Chung*) (2012 study linking use of BPA-containing dental appliances to increased BPA concentration in urine); EX1077 (*Kang*) (2011 study concluding “because there is some evidence of a ‘low-dose effect,’ the amount of BPA released from the resin composites used in a lingual bonded retainer should not be overlooked;” indeed, “BPA release should be minimized”). A landmark 1997 study from biologist Frederick vom Saal confirmed the harmful effects of BPA in finding that low-dose exposure to BPA led to prostate damage in mice. EX1069 (*Vogel*) at 561; *see also* EX1078 (*Nagel*) (exposing pregnant mice to 2 µg/kg/day, 25 times lower than the EPA safe exposure limit at the time, which was found to have adverse effects in male offspring). Subsequent studies in 1997 and 1998 found low-dose effects on the mammary gland and female reproductive system, and increased research on the estrogenic effects of BPA continued throughout the coming decade. EX1069 (*Vogel*) at 561; EX1079 (*vom Saal* (2005)) (noting that, as of 2004, there were 115 published in vivo studies, with 94 reporting “significant effects” from low-

dose BPA exposure); EX1071 (*Soto*) at 9 (2010 article noting that in addition to cancer, BPAs were linked to “obesity, altered behaviors and infertility”).

94. The increasing evidence showing low-dose toxicity of BPA spurred renewed governmental involvement in evaluating the safety of BPAs in the early and mid-2000s. EX1069 (*Vogel*) at 561-62. In 2001, the NTP released a report on endocrine disruptors acknowledging “[s]everal studies provide[d] credible evidence for low-dose effects of bisphenol A” and, although ultimately concluding additional research on BPAs was needed, admitted standard testing procedures for toxicity should be “revisited” to properly account for low-dose, nonlinear responses commonly found in endocrine disruptors. EX1072 (*NTP 2001 Report*) at iii-vii; EX1069 (*Vogel*) at 563. In 2006, the National Institutes of Health funded a comprehensive review of current knowledge of BPA health risks to be conducted by 38 independent scientists. EX1069 (*Vogel*) at 562. In a 2007 consensus statement of its findings, the panel concluded there was “great cause for concern” with the potential for adverse effects of low-dose BPA exposure in humans given the “very long latency” for effects to be observed and the “chronic, low level exposure [to BPA] of virtually everyone in developed countries.” EX1080 (*vom Saal* (2007)) at 12; EX1069 (*Vogel*) at 563.

95. Starting around 2008, legislatures in the U.S. and abroad began enacting concrete reforms to minimize the use of BPAs. In April 2008, for instance,

Canada released a statement on its intent to ban importation of baby bottles containing BPAs, and implemented this ban in March of 2010. *See* Government of Canada Takes Action (2008). Numerous U.S. states and municipalities followed suit, passing bans on various BPA-containing products. *See, e.g.*, EX1082 (Suffolk County, New York, 2009); EX1083 (Minnesota, 2009); EX1084 (Chicago, Illinois, 2009); EX1085 (Connecticut, 2009); EX1086 (Washington, 2009); EX1087 (Wisconsin, 2010); EX1088 (Maryland, 2010); EX1089 (Vermont, 2010); EX1090 (New York, 2010); EX1091 (Massachusetts, 2010); EX1092 (Delaware, 2011); EX1093 (Maine, 2011); *see also* EX1094 (Congressional Hearing (2008)) at 2 (hearing of the U.S. House of Representatives Committee on Energy and Commerce with regards to a federal ban on BPA-containing products). The European Union and China joined in banning certain BPA-containing products around 2011. *See* EX1095 (EU Ban (2011)); EX1096 China Ban (2011).

96. During this same period of legislative action, many companies in industries relating to food-and water-contacting consumer goods began to self-regulate by removing BPA-based products. For instance, baby bottle manufacturers Avent, Disney First Years, Gerber, Dr. Brown, Playtex, and Evenflow all agreed to discontinue use of BPA in 2009. *See generally* EX1097 (*Trager*). Sports bottle manufacturers such as Nalgene, CamelBak, and Pacific Market International switched to BPA-free products in 2008. EX1098 (*Bailin*) at 7. Food container

manufacturers such as Tupperware and Carlisle Food Service Products replaced BPA-products in 2010 and 2007, respectively. *See generally* EX1099 (*Tupperware*); EX1098 (*Bailin*) at 26. Retailers also took action to limit the use of BPA, including Walmart, Whole Foods, and Toys “R” Us, as did raw material suppliers such as Sunoco. EX1098 (*Bailin*) at 6, 20 (explaining that distributors phased-out polycarbonate-based baby products as early as 2006); EX1100 (*Rust*) (2009 report noting that Sunoco, a chemical supplier of BPA, would require buyers to guarantee BPA would not be used in children’s food products). Indeed, in July 2012, the U.S. Food and Drug Administration completely removed regulations relating to certain BPA-based products after finding the use of BPA in these industries had “been permanently and completely abandoned” and therefore found regulation “unnecessary.” *See* EX1101 (*FDA Guidelines*) at 2 (removing regulations for baby bottles, sippy cups, and infant formula packaging).

97. Related industries such as the dental and orthodontics fields also began to transition to BPA-free alternatives because, as in the food packaging industry, BPA leaching had been shown to occur in dental appliances. *See* EX1074 (*Suzuki*) (2000 study confirming BPA leaching from polycarbonate-based dental materials); EX1075 (*Fleisch*) (2010 study finding BPA leaching from dental materials); EX1076 (*Chung*) (2012 study linking use of BPA-containing dental appliances to increased BPA concentration in urine); EX1077 (*Kang*) (2011 study concluding

“because there is some evidence of a ‘low-dose effect,’ the amount of BPA released from the resin composites used in a lingual bonded retainer should not be overlooked;” indeed, “BPA release should be minimized”). For example, at least by 2010, dental manufacturer 3M had reformulated all of its products to be BPA-free in response to consumer concerns. EX1102 (*3M Press Release* (2010)); EX1103 (*3M Press Release* (2023)) (2023 3M statement confirming products were BPA-free). New innovations in these fields also sought to use BPA-free materials out of concern for the known health risks associated with BPA. *See* EX1104 (U.S. Patent No. 9,022,903 (*Rafih*)), Abstract, 5:55-64 (patent filed Mar. 11, 2011 directed towards oral appliance with a hard frame comprising a material “that does not include bisphenol-A (BPA)”); EX1106 (U.S. Patent Pub. No. 2012/0136089), [0004], [0015] (patent application filed Dec. 21, 2011 directed towards “BPA-free” dental resins and polymers “[d]ue to potential health concerns” with BPA); EX1107 (U.S. Patent No. 8,979,410), Abstract, 4:9-13 (patent filed Jun. 14, 2011 directed towards toothbrush with materials that were “[p]referably ... BPA-free”); EX1108 (U.S. Patent Pub. No. 2012/0021151), Abstract, [0003], [0006]-[0007] (patent application filed Sept. 29, 2011 directed towards “transparent, flexible” medical container made of BPA-free product to avoid harm from “estrogenic activity”); EX1109 (U.S. Patent Pub. 2013/0085530), Abstract, [0017], claim 4 (patent application filed Sept. 27, 2012, claiming priority to provisional filed Sept. 30, 2011,

directed towards “teething and gum soothing device” made of a BPA-free material); EX1110 (U.S. Patent No. 9,060,918), Abstract, 6:54-58 (patent filed May 31, 2012, claiming priority to provisional filed May 31, 2011, directed towards an attachable mouthpiece spout preferably “made from a pliable plastic material free of BPA ... to reduce any potential health risks associated with such materials.”). Both dental manufacturers and dentists advertised the “BPA-free” nature of their products and services. Ex 1111 (*Ultradent Press Release* (2012)); *see also* EX1112 (*Goszkowski*) (April 3, 2012, advertising BPA-free dental bridge); EX1113 (*First Choice*) (March 23, 2011, article touting Invisalign brand products as BPA-free).

2. The Rise of Tritan as a Leading BPA-Free Replacement to Polycarbonate

98. Tritan copolyesters from Eastman Chemical Company were formally introduced in October 2007 and marketed as a BPA-free replacement to polycarbonate. EX1098 (*Bailin*) at 7. As one of the first polycarbonate replacements marketed as “BPA-free,” Tritan quickly gained large market acceptance among companies phasing-out polycarbonate. *See, e.g.,* EX1098 (*Bailin*) at 7 (describing how Pacific Market International had been “phoning pretty much every chemical company in the world” in 2006 and had ultimately determined “Eastman was the only company with a viable product in development”); EX1098 (*Bailin*) at 8, 17-18, 23 (describing large market acceptance of Tritan as the “leading BPA-free alternative to polycarbonate products”). Indeed, demand for Tritan was so high that

in May 2010, less than three years after its release, Eastman Chemical expanded its production plants with the intent to produce 60,000 tons/year of Tritan—roughly 8% of the entire polycarbonate market. EX1114 (*Deligio*) at 2-3 (noting “Tritan’s set of properties [allowed] it to target PC: a market that has a global annual volume of 700,000 tonnes by Eastman’s estimation.”); *see also* EX1115 (*Yahoo*) (discussing further expansion in 2013); EX1116 (*Eastman Press Release 2014*) (increased revenue of Eastman Chemical in 2013 “attributed to increased demand for specialty plastics products, especially for Eastman Tritan(TM) copolyester”).

99. Tritan’s wide acceptance as a BPA-free alternative to polycarbonate also included uses in the dental industry. For instance, *Rafih* describes an oral appliance with “a channel adapted to accept teeth from one of a lower jaw and an upper jaw of the mouth” made of a “softenable material” which is formed over a frame made of a Tritan copolyester. EX1104 (*Rafih*) at 5:4-29, claims 2, 9, 10. According to *Rafih*’s disclosure, the purpose of the frame is to “provide[] rigidity” to the over-molded thermoplastic channel by “having sufficient stiffness to resist excessively and/or permanently deforming when placed in the mouth of the user.” EX1104 (*Rafih*) at 5:30-64. Although the patent allows for the use of any Tritan copolyester (*see, e.g.*, claim 10) because Tritan copolyesters are BPA-free, *Rafih* specifically discloses Tritan EX401 as an exemplary material, with a stiffness of 1500 MPa. EX1104 (*Rafih*) at 5:52-64.

100. As highlighted by the disclosure in *Rafih*, in addition to being BPA-free, Tritan also had desirable performance qualities. Tritan was “unique in that it combine[d] the best traits of polycarbonate and conventional copolyesters, mitigating the drawbacks of each.” EX1098 (*Bailin*) at 21.

101. For instance, one particular shortcoming of polycarbonate recognized in the art was that it had a high glass transition temperature and, accordingly, a higher required thermoforming temperature. *See, e.g.*, EX1003 (*Tadros*) at [0100]. This higher thermoforming temperature could lead to inefficiencies such as longer thermoforming times, improper fit of polycarbonate sheets to a mold, and potential degradation of the polymer. EX1003 (*Tadros*) at [0089], [0100], [0113]; EX1042 (*Ebnesajjad*) at 251. Furthermore, a lower thermoforming temperature results in less shrinkage, and consequently in a more accurate dental appliance, that more closely reflects the dental mold dimensions. Tritan set itself apart from both polycarbonate and other BPA-free substitutes by offering a clear, durable, chemical resistant polymer that was versatile enough to be used in a variety of manufacturing processes. EX1098 (*Bailin*) at 21-22. Notably, Tritan could “be thermoformed faster and at lower temperatures than polycarbonate sheet[s].” EX1006 (*Porter*) at 62.

102. Additionally, products molded from polycarbonate were known to be “at greater risk of [environmental stress cracking], particularly in more intricate shapes,” such as dental aligners. EX1006 (*Porter*) at 62; EX1098 (*Bailin*) at 20. This

was a result of high residual stress levels in molded polycarbonate. EX1006 (*Porter*) at 62. Tritan was advertised as possessing lower levels of residual stress, and “thereby improving the [environmental stress cracking] performance of Tritan” as compared to polycarbonate. EX1006 (*Porter*) at 62.

103. Below, I describe the specific material properties of Tritan copolyesters disclosed by Eastman Chemical.

104. As of February 2009, Eastman Chemical had nine specific Tritan brand copolyesters available. EX1105 (*Wayback - Tritan Availability* (Feb. 18, 2009)). A summary of certain disclosed material properties for these stand-alone copolyesters is shown below in Table 1.

Table 1					
Tritan Copolyester	Flexural Modulus	Tensile Modulus	Elongation at Yield	Elongation at Break	Tensile Strength at Yield
Tritan MX710	225,000 psi	225,000 psi	6%	210%	6,200 psi
Tritan EX401	228,000 psi	228,000 psi	7%	140%	6,400 psi
Tritan MX711	225,000 psi	225,000 psi	6%	210%	6,200 psi
Tritan TX1000	225,000 psi	225,000 psi	6%	210%	6,200 psi
Tritan TX1001	225,000 psi	225,000 psi	6%	210%	6,200 psi

Tritan TX1500HF	228,000 psi	228,000 psi	7%	210%	6,200 psi
Tritan TX1501HF	228,000 psi	228,000 psi	7%	210%	6,200 psi
Tritan TX2000	228,000 psi	228,000 psi	7%	140%	6,400 psi
Tritan TX2001	228,000 psi	228,000 psi	7%	140%	6,400 psi

See EX1118 (*Tritan Datasheets*).²

105. As shown above, there were only slight differences between the modulus properties of the available Tritan copolyesters. In my opinion, all of these Tritan copolyesters display modulus properties that would make them suitable for use as a rigid layer in a dental or orthodontic appliance.

106. To start, the Tritan copolyesters all displayed flexural modulus values no lower than around 225,000 psi (~1550 MPa). In my opinion, such flexural

² As I explain elsewhere, these reported properties can change when the polymers are processed and combined with other polymers in certain manufacturing processes (e.g., coextrusion or dual lamination), such that the values reported in a datasheet are not preserved when the polymer is incorporated in a layer of a multilayer sheet. *See supra* Section IV.A.2. This is in contrast to other methods, such as adhesive lamination, which a POSITA would have understood would preserve the reported properties.

modulus values are indicative of relatively rigid materials that are resistant to bending. This resistance to bending would be useful in a dental appliance to exert a strong force on teeth. This force is what ultimately repositions teeth to a target position.

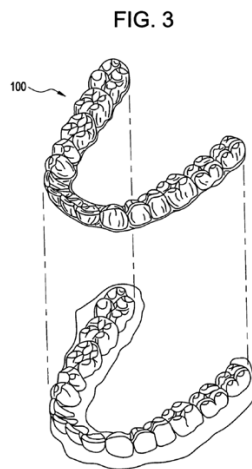
107. In a dental aligner for repositioning teeth, this force must act on the teeth in all directions. That is, the dental aligner is not only experiencing forces perpendicular to the aligner interface (along an x axis); it is also being stretched horizontally (along a y axis) and vertically (along a z axis). *See, e.g.,* EX1117 (*Gao*) at 536. For this reason, in my opinion, the high tensile modulus values of Tritan copolyesters would similarly be useful as a rigid layer exerting forces in the y and z dimensions. All of the Tritan copolyesters in the above table exhibit tensile modulus values no lower than around 225,000 psi (~1550 MPa).

108. Additionally, in my opinion, the elongation at yield, elongation at break, and ultimate tensile strength values for Tritan copolyesters are relatively high given its flexural and tensile modulus values. This indicates that Tritan copolyesters were flexible enough to withstand the counterforces from teeth without permanently deforming or breaking. This is important for a dental aligner, which must *continuously* apply appropriate force until the teeth reach a target position. If the dental aligner deforms or breaks, it will not be able to resiliently maintain its initial force, as well as pose a potential risk.

V. Summary of the Prior Art

A. *Tadros*

109. U.S. Patent Pub. No. 2005/0100853 A1 (“*Tadros*,” EX1003) discloses a dental appliance for repositioning teeth comprising a hard polymeric mixture with a “tensile strength and modulus effective to reposition ... teeth” positioned between outer layers of a “softer” material. EX1003 (*Tadros*) at [0068]. *Tadros* discloses that the dental appliance “displays properties of optical clarity, stain resistance, and transparency, which makes the appliance invisible when used in the oral cavity.” EX1003 (*Tadros*) at [0015]. These appliances are disclosed as being “easy to install” and “display[] properties of toughness and creep resistance.” EX1003 (*Tadros*) at [0015].



EX1003 (*Tadros*) at Fig. 3.

110. *Tadros* discloses that the hard layer should ideally “display[] properties of toughness and creep resistance” and “have a tensile strength and modulus effective to reposition ... teeth.” EX1003 (*Tadros*) at [0015], [0068]. *Tadros* uses a

sheet of pure polycarbonate as an example of a hard layer with ideal repositioning properties. EX1003 (*Tadros*) at [0097], Tables 2, 4 & 5. However, *Tadros* seeks to create a material that maintains these properties but is easier to thermoform and mold than polycarbonate, noting the hard layer should have a lower glass transition temperature and thermoforming temperature than polycarbonate. EX1003 (*Tadros*) at [0100], [0113]. Specifically, *Tadros* explains that “a lower glass transition temperature and a lower thermoforming temperature generally facilitate an easier deformation of the sheet over dental mold material” by “reduc[ing] fitting corrections due the difference in the coefficient of thermal expansion of the material of the appliance and the mold material.” EX1003 (*Tadros*) at [0100], [0113]. *Tadros* notes that these improved molding characteristics ultimately “improve[] dimensional stability and insure[] a good and easy fit to patient’s teeth” in the final dental appliance. EX1003 (*Tadros*) at [0100], [0113].

111. In order to achieve a polymer with the modulus properties of polycarbonate and the molding characteristics of copolyesters, *Tadros* creates mixtures of these materials wherein some of the polycarbonate is replaced with a copolyester. *Tadros* notes that the hard polymeric mixture is preferably “derived from mixing polycarbonate and polyesters,” and lists exemplary combinations such as “PC—PCCD, PC—PETG, PC—PET, PC—PBT, PC—PCT, PC—PCTG, PC—

PPC, PC—PCCD-PETG, PC—PCCD-PCT, PC—PPC—PCTG, PC—PCTG—PETG.” EX1003 (*Tadros*) at [0023].

112. *Tadros* discloses that the purpose of the soft outer layers in the disclosed sheets and appliances is “to alleviate pain, discomfort[,] and bleeding gums.” EX1003 (*Tadros*) at [0073]. *Tadros* discloses that elastomers, including polyurethanes are suitable for the soft outer layers. EX1003 (*Tadros*) at [0073].

113. In my view, a POSITA would have understood *Tadros* to disclose a soft-hard-soft configuration, wherein the “soft” layers are a lower modulus, elastomeric material designed to enhance patient comfort, while the polymeric mixture acts as a “hard” layer with a higher modulus to provide the necessary repositioning forces. *See* EX1003 (*Tadros*) at [0073]. This is consistent with other similar multilayer appliances disclosed in the prior art, which also used soft layers to improve patient comfort and distribute repositioning forces on teeth. *See supra* Section IV.B.1. In my opinion, a POSITA would have understood that *Tadros* allowed for the use of any of the listed suitable elastomers for the soft layer, including polyurethanes, and did not further limit the material that could be used for the soft outer layers.

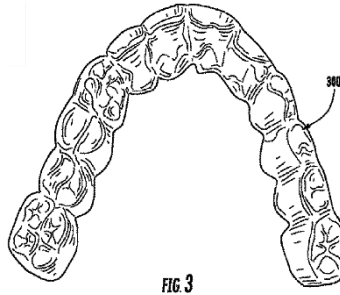
114. *Tadros* discloses that its dental appliances can be formed from the multilayer sheets by “processes such as thermoforming” or “vacuum forming” over “positive tooth models.” EX1003 (*Tadros*) at [0080], [0085]-[0090]. *Tadros*

provides exemplary process conditions for thermoforming, such as temperature and time of thermoforming. EX1003 (*Tadros*) at [0088]-[0089]. Regarding temperature, *Tadros* discloses that “a lower thermoforming temperature generally facilitate[s] easier deformation of the sheet over the dental mold material” and notes it is possible to thermoform appliances at temperatures “less than or equal to about 130° C.” EX1003 (*Tadros*) at [0113], [0120]. *Tadros* explains that the improved sheet deformation from lower thermoforming temperatures ultimately “improves dimensional stability” of the dental appliance and “insures a good and easy fit to patient’s teeth.” EX1003 (*Tadros*) at [0100].

B. *Kalili*

115. U.S. Patent Pub. No. 2011/0020761 A1 (“*Kalili*,” EX1024) discloses an “invisible[,] removable orthodontic repositioning appliance” formed from a multilayer polymer sheet “for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement.” See EX1005 (*Kalili*) at Abstract. *Kalili*’s clear, two-layer dental appliance has an inner tooth-contacting layer with a lower elastic modulus than the outer layer. See EX1005 (*Kalili*) at Abstract, [0002], [0012], [0063], claims 1, 12. *Kalili* also discloses methods of manufacturing such an appliance. See, e.g., EX1005 (*Kalili*) at [0053], [0063]. *Kalili* discloses fabricating dental appliances by “heat[ing]” and “vacuum[ing]” laminate sheets over printed teeth models. EX1005 (*Kalili*) at [0015]. *Kalili* discloses that a series of such

appliances can be created from “incrementally modif[ied]” tooth models and used sequentially to incrementally reposition a patient’s teeth. EX1005 (*Kalili*) at Abstract, [0011], [0055].



EX1005 (*Kalili*) at Fig. 3.

116. *Kalili* identifies several advantages of using a material with a lower elastic modulus for the inner layer (i.e., the layer that contacts the teeth and gums) as compared to a higher elastic modulus material, noting that materials with a higher elastic modulus can result in “damage to patient’s teeth, dental roots, and periodontum.” EX1005 (*Kalili*) at [0005]. *Kalili* discloses that using a lower elastic modulus inner layer minimizes this damage by distributing forces from the repositioning appliance more efficiently, which further results in greater patient comfort and allows for a longer duration of tooth movement. EX1005 (*Kalili*) at [0009], [0072]. Specifically, *Kalili* states that the lower elastic modulus of the inner layer “may allow for greater patient comfort, less tooth, bone, and root damage, and longer duration of tooth movement by the repositioning appliance thereby requiring less number of appliances to achieve the same or similar orthodontic alignment.” EX1005 (*Kalili*) at [0009]. *Kalili* also discloses that “there may be greater accuracy

using laminated aligners with soft inner lining than un-laminated aligners as the repositioning appliance” because the laminated aligner with soft liners demonstrates “less stress in the supporting bone” than single-layer aligners. EX1005 (*Kalili*) at [0056].

117. In my view, a POSITA would have understood *Kalili* to disclose a soft-hard configuration, wherein the inner “soft” layer is a lower modulus material designed to enhance patient comfort and decrease localized stress on teeth, while the outer “hard” layer with a higher modulus provides the necessary repositioning forces. This is consistent with other similar multilayer appliances disclosed in the prior art, which also used a soft tooth-contacting layer to improve patient comfort and distribute repositioning forces on teeth. *See supra* Section IV.B.1.

118. *Kalili* specifically discloses an embodiment wherein the hard outer layer is polycarbonate, and the soft inner layer is the commercially available thermoplastic polyurethane TEXIN 990R, which *Kalili* notes has a shore hardness of 90A. EX1005 (*Kalili*) at [0069]. *Kalili* notes that, in addition to benefits such as improving patient comfort, TEXIN 990R offers “outstanding abrasive resistance, impact strength, toughness, structural memory, and flexibility.” EX1005 (*Kalili*) at [0060]. TEXIN 990R is the only commercially available polymer specifically disclosed in *Kalili* for use in the two-layer appliance. *See generally* EX1005 (*Kalili*).

119. In my view, a POSITA would have understood that *Kalili* specifically discloses TEXIN 990R as a preferred “soft” polymer for use in other similar multilayer dental appliance wherein the POSITA was motivated to improve patient comfort and reduce tooth, bone, and root damage through use of a soft inner layer. In my opinion, a POSITA would have further been motivated and had a reasonable expectation of effectively incorporating TEXIN 990R into other dental appliances that call for a soft, lower modulus, elastomeric layer given TEXIN 990R’s “outstanding abrasive resistance, impact strength, toughness, structural memory and flexibility,” as well as “good hydrolytic stability, microbial resistance, teeth whitening, oral freshness, varied color materials, and exceptional mold release characteristics,” as disclosed in *Kalili*. See EX1005 (*Kalili*) at [0069].

120. *Kalili* discloses how the soft and hard layers can be combined to form a multilayer polymer sheet by laminating the layers to one another. See EX1005 (*Kalili*) at [0056], [0063], [0074]-[0076], [0088], claim 20. *Kalili* discloses that these laminated sheets are intended to adapt into indentations and grooves in tooth models. EX1005 (*Kalili*) at [0056], [0063], [0074]-[0076], [0088], claim 20. In my opinion, a POSITA would have understood that adhesive lamination could be used to produce the appliances disclosed in *Kalili*.

C. *Wen*

121. International Patent Pub. No. 2006/096558 A2 (“*Wen*,” EX1008) discloses multilayer dental aligners consisting of two or more layers, wherein the layers have “different properties, (e.g., such as stiffness, elasticity, hardness, surface friction, hydrophobicity, etc.).” EX1008 (*Wen*) at [0042]-[0043], [00189]. *Wen* notes that a softer material may be used as an inner (gum-contacting) layer “to make the multilayer dental aligner more comfortable for the patient to wear” and “allow wider contact area to the patient’s teeth.” EX1008 (*Wen*) at [00198], [00200], [00203]. Additionally, *Wen* notes that a softer material may be used as an outer (non-gum-contacting) layer to “help the fitting between the teeth of the patient’s upper arch and the lower arch.” EX1008 (*Wen*) at [00198], [00200], [00203]. *Wen* discloses that suitable materials for layers of the dental aligners are “polyurethane[s]” and “polyesters.” EX1008 (*Wen*) at [0043], [00198]. *Wen* discloses that a series of these multilayered dental aligners can be used to gradually reposition teeth. EX1008 (*Wen*) at [00109]-[00111].

122. *Wen* discloses various methods of fabricating multilayer sheets and dental aligners, including laminating layers to adhere them to each other. In a first method, *Wen* discloses separately drawing individual layers over a physical tooth model. EX1008 (*Wen*) at [00205]. Specifically, *Wen* discloses “heat[ing] [a first sheet] for a specified time,” “pressing ... [the first sheet] against a patient’s physical

tooth models,” using a vacuum pump to remove air and cause the first sheet to “fittingly form[] around the surface of the dental arch model,” and allowing the material to cool down. EX1008 (*Wen*) at [00205]. *Wen* then discloses subsequently repeating this process for additional layers. EX1008 (*Wen*) at [00206]. This drawing process is a form of lamination.

123. In a second method, *Wen* discloses combining a first layer and additional layers “prior to forming over the tooth model.” EX1008 (*Wen*) at [00207]. *Wen* discloses that the layers may optionally be attached to one another by “an adhesive” or by “laminat[ion].” EX1008 (*Wen*) at [00208], [00210]. The multilayer sheet is then “heated and vacuum-formed over the arch models to provide multilayer dental aligners.” EX1008 (*Wen*) at [00210]. *Wen* discloses that the degree of heating and vacuum forming can be adjusted based on the properties of the polymer used in each layer. EX1008 (*Wen*) at [00214].

124. *Wen* discloses advantages of using thinner sublayers of a material rather than a thicker layer of the same material when fabricating a multilayer dental appliance, and *Wen* discloses at least two benefits of using such thinner sublayers. First, *Wen* explains that “thinner layers can be more easily conformed to the physical tooth models than a single thick layer.” EX1008 (*Wen*) at [00212]. Second, *Wen* explains that “[t]hinner films allow more intimate contact between polymer sheets and therefore help bond the films to one another.” EX1008 (*Wen*) at [00213]. *Wen*

discloses that this is particularly useful when polymers with disparate properties are used, since “[p]olymers of disparate properties may delaminate from one another where thicker films are used.” EX1008 (*Wen*) at [00213].

D. *Porter*

125. David S. Porter and Randy S. Beavers, Dishwasher Safe, *Plastics Technology*, December 2007 (“*Porter*,” EX1006) discloses benefits of a hard copolyester polymer called “Tritan” that was developed by Eastman Chemical Company and marketed as an improvement over polycarbonate. *Porter* discloses that Tritan is “similar to polycarbonate in many important respects,” such as having “high heat resistance and toughness” and exhibiting a high modulus. EX1006 (*Porter*) at 61, 63. *Porter* discloses that Tritan is a durable material able to withstand high heat, hydrolytic, and chemical attack with no visible crazing or cracking, which *Porter* describes as “a vast improvement over polycarbonate.” EX1006 (*Porter*) at 61. *Porter* notes other benefits of Tritan, such as being BPA-free, having high light transmission, and having low residual stress values. EX1006 (*Porter*) at 61-62. *Porter* includes a datasheet listing the mechanical and optical properties of Tritan. EX1006 (*Porter*) at 63.

126. *Porter* discloses that Tritan can be used in a variety of fabrication methods, including “extruded sheet applications,” “molded products,” “deep draw[ing],” and “thermoforming.” EX1006 (*Porter*) at 62. *Porter* further notes that

Tritan can be “thermoformed faster and at lower temperatures than polycarbonate sheet[s].” EX1006 (*Porter*) at 62. *Porter* discloses that, given its similarities to polycarbonate, it is not necessary to change molds when switching from polycarbonate to Tritan. EX1006 (*Porter*) at 62.

127. *Porter* discloses that Tritan can be used in a variety of applications, including kitchen appliances, reusable food containers, sports bottles, mugs, and pitchers. EX1006 (*Porter*) at 61. *Porter* provides examples of companies that have switched from polycarbonate to Tritan, such as CamelBak, a reusable water bottle manufacturer that switched to Tritan after “requests from consumers for ... a product free of bisphenol-A (BPA).” EX1006 (*Porter*) at 63, 76. *Porter* explains that “Tritan was the answer, providing a BPA-free material that also has greater durability to withstand rugged use and dishwasher cleaning.” EX1006 (*Porter*) at 63. In my view, a POSITA would have understood that *Porter* specifically discloses Tritan copolyester as a preferred substitute for polycarbonate.

E. *Texin 990R*

128. The manufacturer’s product information sheet for TEXIN 990R (“*Texin 990R*,” EX1009) discloses mechanical properties of the thermoplastic polyurethane polymer disclosed in *Kalili* (prior to any processing to form a multilayer sheet), including a Shore hardness of 90A, an ultimate elongation (i.e., elongation at break) of 450%, a flexural modulus of 6,000 psi (41.4 MPa), a

compression set of 75% after 22 hours at 70°C, and a tensile strength (i.e., ultimate tensile strength) of 5,000 psi (34.5 MPa). EX1009 (*Texin 990R*) at 3. Manufacturers customarily make this kind of product information sheet available for their commercial polymer products to inform potential purchasers about the chemical and physical properties of the polymers.

VI. The '090 Patent

A. Disclosure of the '090 Patent

129. The '090 patent specification discloses “multilayer polymer sheets” and “related methods, systems, and appliances.” '090 patent at Abstract.

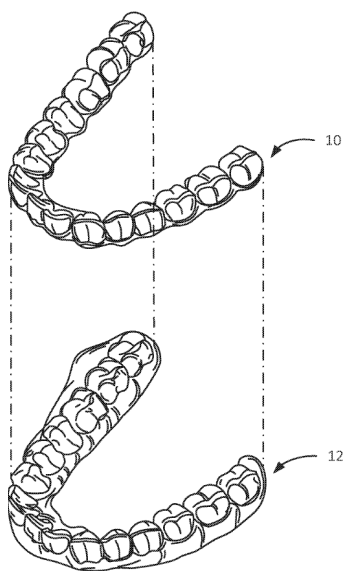


FIG. 1

'090 patent, Fig. 1.

130. The '090 patent discloses that such appliances are “multilayer” appliances, specifically a hard polymer layer disposed between two soft polymer layers (i.e., a soft-hard-soft appliance). '090 patent at 1:19-20.

131. The '090 patent describes a “hard” polymer layer as having, in some embodiments, at least one of a tensile strength at yield of 4,000-6,500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus of greater than about 150,000 psi, a stress relaxation at 24 hours testing in a wet environment of greater than 10%, and a light transmission between 400 nm to 800 nm of greater than about 75%. '090 patent at 5:60-6:10.

132. The patent additionally describes a “soft” polymer layer as having, in some embodiments, at least one of a hardness of about 60A to 85D, an ultimate tensile strength of greater than 5,000 psi, an elongation at break of greater than about 200%, a compression set at about 70° C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%. '090 patent at 6:23-36.

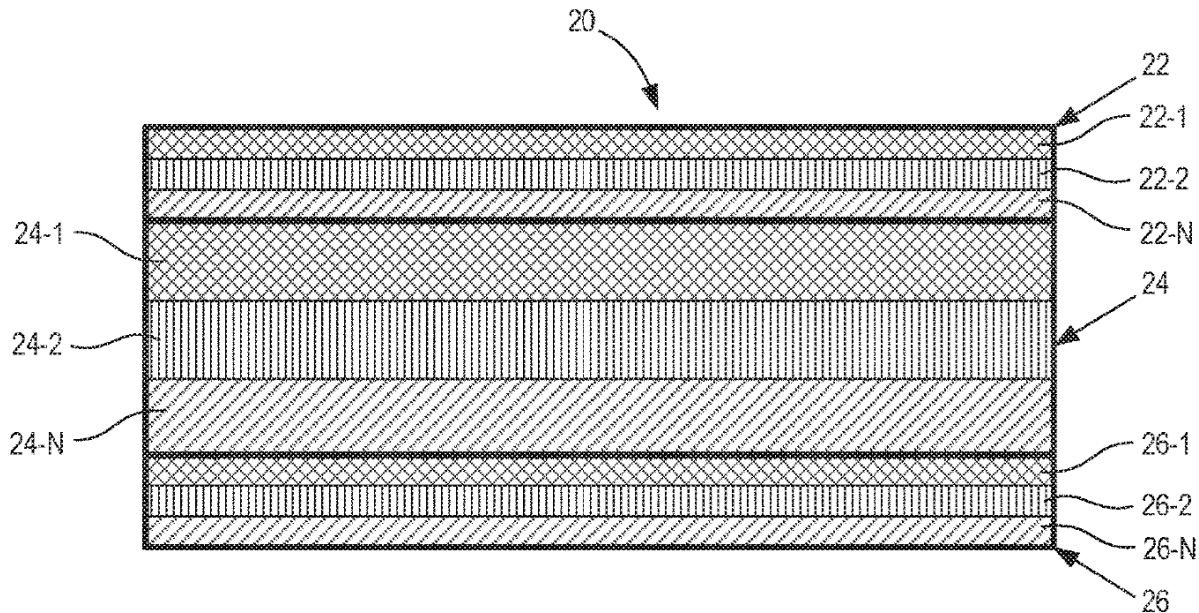
133. The '090 patent specification exclusively describes a three-layer configuration with a hard layer disposed between two soft layers (i.e., a *soft-hard-soft* configuration). *See* '090 patent at 2:5-7. The '090 patent specification does not describe or enable a POSITA to make any other configuration of layers for a

multilayer sheet or dental appliance for positioning a patient's teeth. Accordingly, the '090 patent specification does not address the significant effect that layer configuration and composition can have on the efficacy of dental aligners. Specifically, the efficacy of repositioning teeth using dental aligners can change significantly based on changes to the relative placement of the hard and soft layers; substitution of one polymer for another without guidance to do so; or manufacturing techniques that alter the polymers' properties when they are formed into a multilayer sheet. The '090 patent specification does not provide a POSITA with any guidance regarding these considerations or how to implement any such alternative aligners to the single embodiment disclosed. Nonetheless, I understand that Patent Owner is asserting the '090 patent against a configuration that was not disclosed in the specification—a *hard-soft-hard* layer configuration—in co-pending district court litigation. Because the '090 patent does not disclose or enable any layer configuration besides “soft-hard-soft,” Patent Owner's infringement arguments incorrectly assume that a skilled artisan would have known how to modify the sole disclosed configuration (“soft-hard-soft”) to create a dental aligner with the exact opposite configuration (“hard-soft-hard”), ignoring the layer configuration's impact on a dental aligner's properties and efficacy. Those issues, however, do not affect my analysis here because the claims would have been obvious under both the

disclosed “soft-hard-soft” configuration and under Patent Owner’s broader application of the claims to other configurations (e.g., “soft-hard-hard”).

134. Meanwhile, as described above, the use of multilayer appliances consisting of soft outer layers and a hard inner layer (as disclosed in the specification) was well known before the priority date of the ’090 patent. *See supra* Section IV.B.1. The ’090 patent does not describe the multilayer sheet or the specific disclosed soft-hard-soft configuration of the sheet as a novel feature of the invention. *See generally* ’090 patent.

135. The ’090 patent specification discloses that the “soft” and “hard” layers of the multilayer dental appliances can be made up of multiple layers of polymer material. ’090 patent, at 5:56-59, 6:59-7:2. Figure 2 of the ’090 patent demonstrates this concept by showing a multilayer appliance consisting of soft outer sections and a hard inner section, with each section composed of multiple thinner sublayers of material.



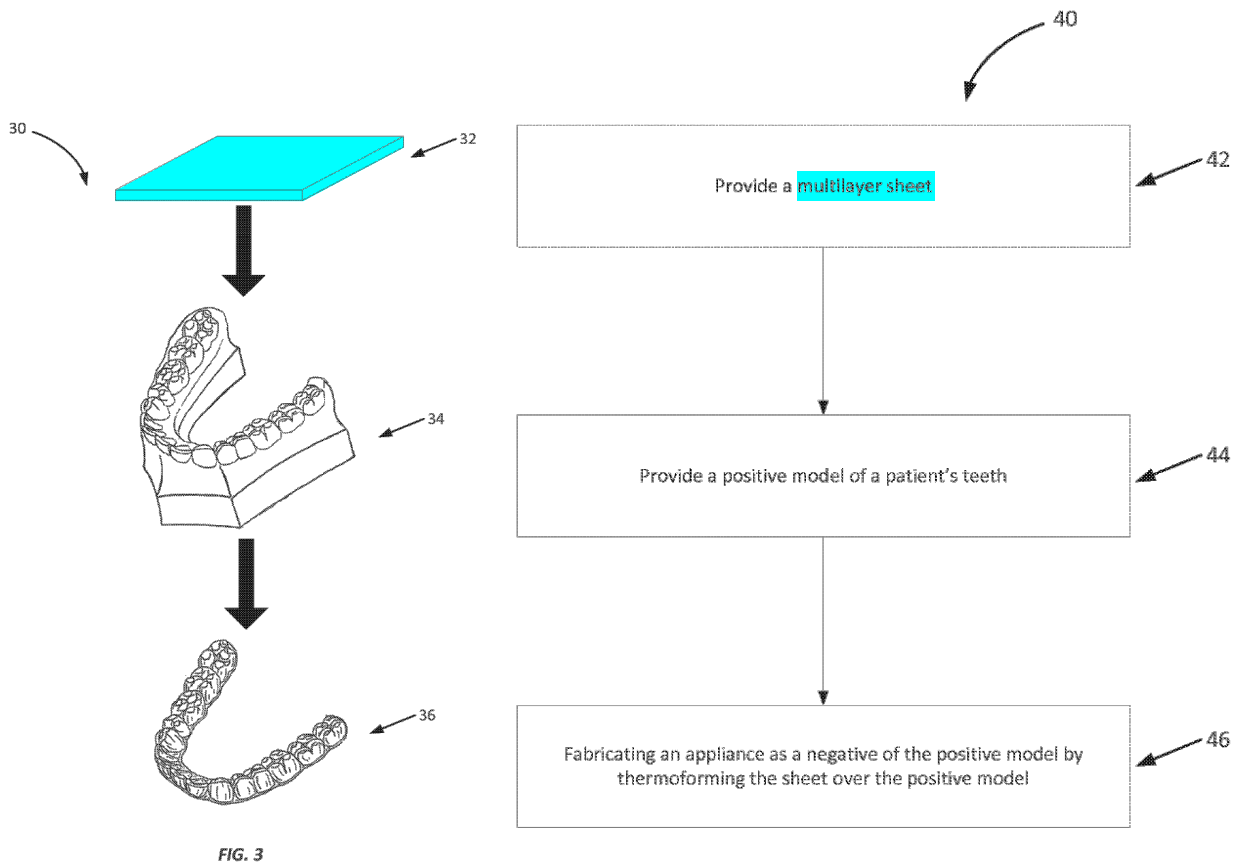
'090 patent, Fig. 2.

136. As described above, the use of thinner sublayers of materials was well known in the art. *See supra* Section IV.B.2. The '090 patent does not describe the use of sublayers as a novel feature of the invention. *See generally* '090 patent.

137. The '090 patent specification identifies characteristics and mechanical properties of the hard and soft polymer layers, including: the thickness of the layers; the material used for the layers; the tensile strength, elongation, tensile modulus, flexural modulus, stress relaxation, and light transmission of the hard layer; and the hardness, tensile strength, elongation, compression set, flexural modulus, and light transmission of soft layers. '090 patent, 5:34-37, 5:37-41, 5:44-56, 5:67-6:10, 6:11-22, 6:28-36. The specification does not describe any of these materials or properties as novel. As described above, materials such as TEXIN 990R and Tritan

copolyesters were examples of polymers that were well known before the priority date of the '090 patent and displayed these disclosed properties and characteristics.

138. The '090 patent specification discloses that the dental appliances can be formed by thermoforming a multilayer sheet over a positive tooth model. '090 patent, at 7:4-7:7.



'090 patent, Fig. 3.

'090 patent, Fig. 4.

139. As described above, thermoforming of multilayer sheets was well known before the priority date of the '090 patent. The '090 patent does not describe thermoforming as a novel feature of the invention and acknowledges that exemplary methods were previously disclosed. *See* '090 patent, at 7:7-13 (citing U.S. Application No. 13/186,374 and invisalign.com and noting “[e]xemplary methods for fabricating the appliances ... are described in numerous patents and patent applications ... as well as on [Align Technology]’s website.”). Although the specification seems to imply that thermoforming a soft-hard-soft sheet is a novel manufacturing process, as described above, this was disclosed in the prior art. *See, e.g.,* EX1003 (*Tadros*) at [0073], [0080], [0087].

140. Despite the '090 patent’s disclosures regarding the dental appliances of the invention being formed from a multilayer sheet, the '090 patent provides little to no disclosure on how individual polymer layers can be combined to form this multilayer sheet. Instead, the only disclosure on methods of creating a multilayer sheet is in discussions of sublayers, where the specification notes that the hard layer can be composed of sublayers that are “co-extruded to form one hard layer” and likewise, that the hard and soft polymer layers “can include several polymer layers laminated together.” *See* '090 patent at 5:56-59, 6:46-48. Even here, the specification does not provide any further detail on the specific types of lamination and coextrusion methods used. *See* '090 patent at 5:56-59, 6:46-48. As described

above, there are a variety of methods of forming multilayer sheets, including lamination and co-extrusion, which were well known in the art. *See supra* Section IV.A.2.d. In my view, the '090 patent's limited disclosure on methods of creating a multilayer sheet reaffirms that (1) the patent is not holding out the method of combining the layers of the multilayer sheet as a purportedly novel aspect of the invention, and thus did not require a detailed disclosure of that method and (2) any known method of combining individual layers, including variations of lamination, would be suitable in creating a dental aligner of the alleged invention.³

B. Claims of the '090 Patent

141. The '090 patent's independent claim recites “a method of making multilayer dental aligner” by “providing a multilayer sheet comprising three polymer layers”: a first copolyester layer, a second TPU layer, and a third layer. (EX1001, claim 1.) The claim further specifies numerical ranges for certain mechanical properties of either the hard or soft polymer layer(s) used in making the appliance, such as flexural modulus, elongation at break, and hardness. (EX1001, claim 1.) The dependent claims further limit the mechanical properties and layer configuration,

³ As noted above, lamination methods such as adhesive lamination would preserve the properties of the polymer. *See supra* Section V.A.2.d.

with certain dependent claims adding a fourth layer to the multilayer appliance. (*See, e.g.,* EX1001, claims 6, 7.)

142. As I explained above, multilayer sheets and dental appliances consisting of hard and soft polymer layers were known in the art before the priority date of the '090 patent. Similarly, polymer materials with the properties claimed in the '090 patent for the “hard” and “soft” layers were known in art. For these reasons, and as I explain further below, the '090 patent claims would have been obvious to a POSITA.

C. Claim Construction

143. I have read all claim terms as having their ordinary meaning as understood by a POSITA.

VII. The '090 Patent Claims Would Have Been Obvious

A. A POSITA Would Have Been Motivated to Combine the Cited Prior Art with a Reasonable Expectation of Success in Achieving the Claimed Subject Matter

144. Grounds 1 and 2 rely on a combination of *Tadros*, *Kalili*, and *Texin 990R*, wherein the soft TEXIN 990R layer disclosed in *Kalili* is used as the soft outer polyurethane layers disclosed in *Tadros* and wherein the polycarbonate layer in *Tadros* is modified to use the improved, BPA-free Tritan co-polyester, which as disclosed in *Porter*, was a desirable replacement for polycarbonate for several reasons. Ground 1 discloses every element of claims 1-2, 4-5, and 8-11. Ground 2

further applies *Wen*'s teaching of the benefits of using sublayers to improve interlayer bonding and discloses every limitation of claims 1-11.

145. Ground 3 relies on a combination of *Kalili*, *Porter*, *Wen*, and *Texin 990R*, wherein the polycarbonate layer in *Kalili* is modified to use the improved, BPA-free Tritan co-polyester disclosed in *Porter* as a replacement for polycarbonate. That combination is further modified in view of *Wen*'s teaching of the benefits of using sublayers to improve interlayer bonding. This combination discloses every limitation of claims 1-6 and 8-11. As explained below, a POSITA would have been motivated to combine *Kalili*, *Porter*, *Texin 990R*, and *Wen* to arrive at the claimed subject matter and would have had a reasonable expectation of success in doing so.

146. While the efficacy of repositioning teeth using dental aligners that either alter the relative placement of the hard and soft layers or replace layers with other polymers without guidance to do so is unpredictable, the use of Tritan and TEXIN 990R to reposition teeth would have been obvious to a POSITA based on the disclosures of the cited prior art. For example, *Kalili* instructs a POSITA to use TEXIN 990R as the "soft" or elastomeric layer in a multilayer dental aligner based on its "outstanding" properties in that specific application. *Porter* instructs a POSITA to substitute Tritan for polycarbonate based on the improved properties and elimination of harmful BPAs, while *Rafih* would inform a POSITA that *Porter*'s

guidance regarding replacing polycarbonate with Tritan applies to dental appliances where Tritan is used in combination with a soft inner layer. *See supra* Sections V.B, V.D, IV.D.2. The asserted grounds thus rely on the express disclosures of the cited prior art, which would have given a POSITA specific motivation to make multilayer sheets and dental aligners exactly as claimed in the '090 patent.

1. It Would Have Been Obvious to Replace the Polycarbonate in the Appliance of *Kalili* or the Polycarbonate-Polyester Coextrusion in the Appliance of *Tadros* with Tritan Copolyester (Grounds 1-3)

147. In my opinion, a POSITA would have been motivated to modify the appliances disclosed in *Tadros* and *Kalili* to use BPA-free Tritan, as disclosed in *Porter*, instead of polycarbonate or a polycarbonate mixture. At the time of the invention, there were at least three interrelated motivations to combine the disclosures of *Porter* with either *Tadros* and *Kalili* related to the BPA-free nature of Tritan. There is also the additional motivation disclosed in *Porter* that Tritan was not simply a “replacement” for polycarbonate, but it was actually an improvement on shortcomings of polycarbonate.

a. *Kalili*

148. It would have been obvious to replace the hard layer of polycarbonate in *Kalili* with Tritan, as disclosed in *Porter*.

149. First, a POSITA would have been motivated to create a safe dental aligner. As described above, decades of research prior to the priority date of the '090

patent in 2012 suggested that BPA was an endocrine disruptor that was toxic when ingested, even at low doses, and that could lead to increased cancer risk. *See supra* Section IV.D.1. Further, it had been demonstrated that BPA leached out of polycarbonate products, including dental appliances, when exposed to high-heat and chemically abrasive environments. *See supra* Section IV.D.1. A POSITA would have been aware of these risks in using polycarbonate in an intraoral appliance and would have sought to replace polycarbonate with a BPA-free alternative. As disclosed in *Porter*, Tritan brand products were specifically marketed as a BPA-free replacement to polycarbonate that maintained many of the same properties. *See* EX1006 (*Porter*) at 63, 76; *see supra* Section IV.D.2. Accordingly, a POSITA would have been particularly motivated to modify the polycarbonate layer in *Kalili* to use Tritan in order to avoid toxic BPA leeching while maintaining a functional dental aligner.

150. Second, a POSITA would have been motivated to create a dental aligner that consumers would be willing to buy. As described above, consumer demand for BPA-free products led many industries, including the dental industry, to begin phasing out polycarbonate-containing products prior to 2012. *See supra* Section IV.D.2. A POSITA would have recognized that there would be improved market demand for a dental aligner that did not contain BPA-containing materials such as polycarbonate. *See supra* Section IV.D.2. Further, as disclosed in *Porter*, a

POSITA would have recognized that BPA-free Tritan would be accepted by consumers. *See* EX1006 (*Porter*) at 63, 76 (disclosing switch in other industries to Tritan was in response to “requests from consumer.”). A POSITA would therefore have been motivated to modify the polycarbonate layer in *Kalili* with Tritan in response to this market demand.

151. Third, a POSITA would have been motivated to create a dental aligner that complied with governmental regulations. As described above, by 2008 legislation was being proposed in the United States and abroad to regulate products containing BPAs such as polycarbonate. *See supra* Section IV.D.1. A POSITA would have recognized that these regulations could potentially encompass dental aligners containing polycarbonate, preventing sales of such aligners, and the POSITA would therefore feel regulatory pressure to replace polycarbonate with a BPA-free material. A POSITA would have thus been motivated to modify the polycarbonate layer in *Kalili* with Tritan, which as disclosed in *Porter* was BPA-free and complied with government regulations. *See* EX1006 (*Porter*) at 63, 76; EX1098 (*Bailin*) at 7 (noting Tritan was BPA-free and approved for food and contact uses).

152. Additionally, as noted above, Tritan was advertised as maintaining the modulus properties of polycarbonate while providing improved molding capabilities. *See supra* Section IV.D.2. Specific disclosed capabilities of Tritan

included being better in thermoforming applications and being more resistant to environmental stress cracking than polycarbonate. *See* EX1006 (*Porter*) at 62 (“[Tritan] [p]roducts can be thermoformed faster and at lower temperatures than polycarbonate sheet.”); EX1006 (*Porter*) at 63 (“Products molded in polycarbonate are at a greater risk of [environmental stress cracking], particularly in more intricate shapes.”). These improvements are particularly relevant to manufacturing dental aligners, since the manufacturing process typically requires thermoforming a sheet over a mold to create a detailed positive model of a patient’s teeth. *See supra* Section IV.A.1. These intricate shaped aligners would then need to be able to withstand the harsh heat, chemical, and hydrolytic attack of intraoral conditions. In other words, a POSITA would understand that the shortcomings of polycarbonate related to thermoforming and cracking would be especially pronounced in dental applications, and the POSITA would thus be motivated to modify the polycarbonate layer in *Kalili* with Tritan based on Tritan’s improved properties.

153. Moreover, in my opinion, a POSITA would have had a reasonable expectation of success in utilizing Tritan copolyesters instead of polycarbonate in dental aligners such as those disclosed in *Kalili*.

154. To start, Tritan is disclosed as having similar modulus properties to polycarbonate. *See* EX1006 (*Porter*) at 63; *see also supra* Section IV.D.2. Therefore, a POSITA would have expected Tritan to be able to provide the resilient

repositioning forces needed for a hard layer in a multilayer dental appliance. *See supra* Section IV.D.2.

155. Additionally, Tritan is disclosed as being suitable for extruded sheet applications, molded products, and thermoforming, which are the same processes used to create the layered appliance in *Kalili*. *See* EX1006 (*Porter*) at 61; EX1005 (*Kalili*) at [0053], [0069], [0074] (disclosing combining a soft layer with a hard layer and vacuum forming this sheet over a tooth model). In fact, *Porter* discloses that Tritan is superior to polycarbonate in certain fabrication processes, providing a further basis for a reasonable expectation of success. *See* EX1006 (*Porter*) at 62-63; *see also* EX1098 (*Bailin*) at 21-22. Further, for multilayer applications, polycarbonate and copolyesters, such as Tritan, would be expected to have similar bonding processes, including when adhered or laminated to a polyurethane. EX1008 (*Wen*) at [00198], [00201], [00208] (explaining that adhesives may be used to connect layers in a multilayer dental aligner, including connecting “hard” layers of copolyesters or polycarbonates with “softer” polyurethane layers). Any minor bonding differences between polycarbonate and copolyesters could be resolved by optimizing adhesion of Tritan through, for example, surface treatment methods prior to adhesive lamination. *See* EX1042 (*Ebnesajjad*) at xix (discussing adhesive lamination as “basic” process); *supra* Section IV.A.2.b. Thus, while substituting one polymer for another in a dental aligner for repositioning teeth is unpredictable unless

a POSITA has guidance that making that substitution would be suitable, and while using unsuitable polymers could lead to undesirable properties, here, a POSITA would have understood that *Porter* expressly discloses that Tritan was advertised as a direct replacement to polycarbonate and would perform at least equivalently to polycarbonate in manufacturing the layered appliance of *Kalili* with lamination. A POSITA also would have understood from *Porter* that Tritan would provide several advantages over polycarbonate in terms of longevity and safety.

156. Finally, Tritan is disclosed as showing excellent chemical resistance when exposed to heat, chemical, and hydrolytic attack, and being less susceptible to environmental stress cracking compared to polycarbonate. *See* EX1006 (*Porter*) at 61-62, 76; EX1098 (*Bailin*) at 21-22. A POSITA therefore would have expected Tritan to be durable enough, and superior to polycarbonate, to withstand intraoral conditions, as needed for a dental aligner such as *Kalili*.

157. This evidence demonstrates that a POSITA would have had a reasonable expectation of success in modifying *Kalili* based on the teachings of *Porter*. That reasonable expectation is further supported by the fact that Tritan had already been incorporated into layered dental appliances prior the priority date of the '090 patent. As described above, *Rafih* discloses using Tritan as a “BPA-free” rigid layer combined with a soft inner layer. *See supra* Section IV.D.2. A POSITA would have understood that Tritan was appropriate for use in dental appliances and thus

would have similarly expected Tritan to work effectively as a BPA-free rigid layer when combined with a soft layer of TEXIN 990R, as disclosed in *Kalili*.

b. *Tadros*

158. It would have been obvious to replace the polycarbonate-containing layer in *Tadros* with Tritan. In particular, Tritan was designed as an improved polycarbonate material, just like the material in *Tadros*, but was able to achieve these properties without the use of BPA-containing polycarbonate.

159. The disclosed purpose of *Tadros*'s central hard layer is to provide a tough, creep-resistant material with "a tensile strength and modulus effective to reposition teeth" that can also be easily thermoformed into a clear dental appliance. EX1003 (*Tadros*) at [0015], [0068], [0089], [0100]. *Tadros* highlights pure polycarbonate as a comparative example of a material with ideal modulus properties but insufficient thermoforming capabilities, noting that "[i]t is generally desirable for the glass transition temperature of the [hard layer] to be less than that of polycarbonate" because "a lower glass transition temperature and a lower thermoforming temperature generally facilitate an easier deformation of the sheet over the dental mold material." EX1003 (*Tadros*) at [0097], [0113]. Further, *Tadros* highlights comparative copolyesters (specifically, PCCD variations) as materials with better thermoforming capabilities than polycarbonate but insufficient modulus properties. EX1003 (*Tadros*) at [0097], [0113]. *Tadros* sought to improve upon the

pure polycarbonate or pure copolyesters commonly used in the art as the hard repositioning layer in multilayer dental appliances by creating a material that combined the best features of each.

160. *Tadros* discloses that, to effectively reposition teeth in a manner comparable to pure polycarbonate, the hard layer should have a tensile modulus of about 1,500 N/mm² to about 2,500 N/mm². EX1003 (*Tadros*) at [0068], Table 2. To improve thermoforming compared to pure polycarbonate, *Tadros* discloses that the hard layer should have a glass transition temperature of about 120°C or less, which is “at least about 25°C less” than a comparative pure polycarbonate sample. EX1003 (*Tadros*) at Table 3, [0113]; *see also* EX1003 (*Tadros*) at [0054] (“In general, it is desirable for the [hard layer] to have a glass transition temperature of less than or equal to about 205° C., preferably less than or equal to about 175° C., and more preferably less than or equal to about 150° C., and most preferably less than or equal to about 95° C.”).) *Tadros* also discloses the ideal thermoforming temperature as about 180°C or less, which is 23°C lower than that of polycarbonate. EX1003 (*Tadros*) at [0100].

161. In order to create a hard layer with polycarbonate’s modulus properties and copolyester’s thermoforming properties, *Tadros* used polycarbonate-copolyester mixtures. EX1003 (*Tadros*) at [0022]-[0023]. *Tadros* discloses that its polymer mixtures were an improvement over pure polycarbonate because they had

comparable tensile properties to polycarbonate and lower thermoforming temperatures. A POSITA would have known, however, that polycarbonate contains harmful BPAs that would be released from polycarbonate-based dental aligners, including those disclosed in *Tadros* containing polycarbonate-copolyester mixtures. EX1006 (*Porter*) at 63, 76. A POSITA thus would have sought to replace *Tadros*'s hard mixture with a BPA-free alternative that still achieved *Tadros*'s goal of providing a hard layer with high tensile modulus values and improved thermoforming capabilities. EX1003 (*Tadros*) at [0015], [0068], [0089], [0100].

162. A POSITA therefore would have been motivated to substitute Tritan copolyester, as disclosed in *Porter*, for the polycarbonate-containing hard layer in the soft-hard-soft polymer sheet in *Tadros* to improve product safety. *See supra* Section IV.D.2. *Porter* discloses that Tritan copolyesters were a BPA-free product with similar modulus properties to polycarbonate that could “be thermoformed faster and at lower temperatures than polycarbonate sheet[s].” EX1006 (*Porter*) at 63, 76. This aligns with the stated purpose of the hard layer in *Tadros*. EX1003 (*Tadros*) at [0015], [0068], [0089], [0100].) *Porter* also discloses specific properties of Tritan that satisfy *Tadros*'s ideal benchmarks for the hard layer, including a tensile modulus of 1,551 N/mm² (about 1,500 N/mm² to about 2,500 N/mm²), a glass transition temperature of 108°C (about 120°C or less). EX1006 (*Porter*) at 63. Further, a POSITA would have thermoformed Tritan at a temperature only slightly higher than

108°C, the glass transition temperature, well within the ideal range of about 180°C or less disclosed in *Tadros*. EX1003 (*Tadros*) at [0100].

163. A POSITA would have had a reasonable expectation of success in replacing *Tadros*'s hard layer with the Tritan copolyester disclosed in *Porter* based on Tritan's proven use in thermoforming processes and extruded-sheet applications, its durability in the "harsh" environments of "heat, hydrolytic and chemical attack, and applied stress" required for dental aligners, and past industry success in replacing polycarbonate-based materials with Tritan copolyester. EX1006 (*Porter*) at 61-62, 63, 76.

164. This evidence demonstrating a reasonable expectation of success in modifying *Tadros* based on the teachings of *Porter* is further supported by the fact that Tritan had already been incorporated into layered dental appliances prior to the priority date of the '090 patent. As described above, *Rafih* discloses using Tritan as a "BPA-free" rigid layer combined with a soft inner layer. *See supra* Section IV.D.2. A POSITA would have understood that Tritan was appropriate for use in dental appliances and thus would have similarly expected Tritan to work effectively as a BPA-free rigid layer when combined with a soft TPU layer, as disclosed in *Tadros*. A POSITA therefore would have been motivated to replace the polycarbonate mixture in *Tadros* with Tritan copolyester based on the express disclosures in *Porter* encouraging that precise substitution.

2. It Would Have Been Obvious to Use TEXIN 990R For the Soft Elastomeric Layers in *Tadros* (Grounds 1 and 2)

165. In my opinion, a POSITA would have been motivated to make *Tadros*'s soft-hard-soft appliance for repositioning teeth using TEXIN 990R polyurethane elastomer, as disclosed in *Kalili*, for the soft outer layers.

166. *Tadros* discloses that “[s]uitable examples of elastomers” for the soft, lower modulus layers may include “polyurethanes.” EX1003 (*Tadros*) at [0073]. TEXIN 990R is disclosed in *Kalili* as a polyurethane used as the soft, lower modulus layer of a multilayer dental appliance. EX1005 (*Kalili*) at [0069]. *Kalili* further teaches that TEXIN 990R exhibits many desirable properties for use in a dental appliance. *See supra* Section V.B. *Kalili* notes, for example, that using TEXIN 990R offers benefits including improving patient comfort, “outstanding abrasive resistance, impact strength, toughness, structural memory, and flexibility.” EX1005 (*Kalili*) at [0069]. In my opinion, a POSITA would have understood based on this disclosure alone that TEXIN 990R was a preferred material for use in combination with *Tadros* and thus would have been motivated to combine these known elements.

167. A POSITA would have been further motivated to combine *Texin 990R* with *Tadros* because the soft layers in both *Tadros* and *Kalili* serve the same purpose—to improve patient comfort. Specifically, *Tadros* discloses that the soft layer “contacts the gums of the patient” to “alleviate pain, discomfort and bleeding gums.” EX1003 (*Tadros*) at [0073]. Likewise, *Kalili* discloses that the soft gum-

contacting layer (in particular, TEXIN 990R) “allow[s] for greater patient comfort [and] less tooth bone and root damage.” EX1005 (*Kalili*) at [0009], [0069]. Therefore, a POSITA would have understood that TEXIN 990R would not only be “suitable” as the soft layer in *Tadros*, but that it would also specifically achieve the disclosed purpose of patient comfort disclosed in *Tadros*.

168. In my opinion, a POSITA would have been motivated to use TEXIN 990R for both the gum-contacting and non-gum-contacting outer layer in *Tadros*. As noted above, *Tadros* discloses that a polyurethane elastomer is suitable for both soft outer layers. EX1003 (*Tadros*) at [0073]. After electing to use TEXIN 990R for the gum-contacting layer, in my opinion, a POSITA would naturally look to use TEXIN 990R for the non-gum contacting outer layer, again based on its “outstanding” properties. Thus, a POSITA would have been motivated to dispose the hard polymeric mixture in *Tadros* between two soft layers of TEXIN 990R.

169. Moreover, in my opinion, a POSITA would have had a reasonable expectation of success in using TEXIN 990R for the soft outer layers in the dental appliance disclosed in *Tadros*. Both *Tadros* and *Kalili* disclose multilayered dental sheets wherein a soft, lower elastic modulus elastomer is combined with a hard layer and wherein a soft layer is in contact with the teeth and gums. See EX1003 (*Tadros*) at [0023], [0073] (combining soft elastomers with polycarbonate and co-polyester mixtures); EX1005 (*Kalili*) at [0069] (combining TEXIN 990R with polycarbonate).

Likewise, both *Tadros* and *Kalili* disclose thermoforming (vacuum forming or thermo vacuum-forming) these sheets into multilayer dental appliances. *See* EX1003 (*Tadros*) at [0080], [0088]-[0089]; EX1005 (*Kalili*) at [0053]. Although the mechanical properties of a polymer can change during certain manufacturing processes to make a multilayer sheet, such as coextrusion or dual lamination, a POSITA would have been aware of manufacturing techniques such as adhesive lamination, which would preserve the properties of a polymer when it is joined to another layer. Therefore, in my opinion, a POSITA would have had a reasonable expectation of success in using TEXIN 990R as the soft layers in *Tadros*, given the material's demonstrated success as a soft layer in combination with polycarbonate in a thermoformable multilayer sheet used to create a dental appliance.

3. It Would Have Been Obvious to Use Multiple Thinner Sublayers Rather than a Single Thicker Layer of the Same Material in the Appliances in *Tadros* and *Kalili* (Grounds 2 and 3)

170. In my opinion, a POSITA would have been motivated to modify the appliances disclosed in *Kalili* and *Tadros* to use multiple thinner sublayers rather than a single thicker layer of the same material. As disclosed in *Wen*, a POSITA would have understood at least two advantages of using multiple thinner sublayers.

171. First, *Wen* teaches that thinner sublayers conform better to tooth models, allowing for more effective tooth repositioning. *See supra* Section IV.B.2. In my view, effective tooth repositioning would be one of the primary variables a

POSITA would have sought to improve when designing a dental aligner. Indeed, it is my understanding that during prosecution the Patent Owner attempted to distinguish the parent of the '090 patent from prior art by citing to clinical trials showing alleged improved tooth repositioning of its "SmartTrack material (ST30), which is a product according to the instant claims." EX1010 ('691 File History) at 1239-1242. The Li Declaration goes on to state that the alleged "improved performance" had been the focus of Patent Owner's seven years of experimentation. EX1010 ('691 File History) at 1237-1238. In other words, the actions of the '090 patent's own inventors demonstrate a motivation to improve tooth repositioning for dental appliances, which according to *Wen* could be achieved using thinner sublayers.

172. Second, *Wen* teaches that using thinner sublayers improves bonding between layers, particularly between layers having disparate properties. *See supra* Section IV.B.2. In my view, a POSITA would have been motivated to optimize bonding between layers to ensure the fabricated dental appliance would not delaminate, and therefore lose its functionality, when used in intraoral applications. *See, e.g.*, EX1008 (*Wen*) at [00213]. The '090 patent specification acknowledges this motivation, noting that "bonding strength between the layers further improves the durability of the aligners, for example, by withstanding teeth grinding by a patient." '090 patent at 5:19-22. In my opinion, a POSITA would have been

particularly motivated to optimize inter-layer bonding in the appliances disclosed in *Tadros* and *Kalili* since these appliances use “soft” and “hard” layers with different mechanical properties. *See* EX1008 (*Wen*) at [00213] (noting delamination is particularly common at the interface of polymers with disparate properties); *see also* EX1019 (*Schrenk*) at 150. A POSITA would have recognized that using thinner layers, as disclosed in *Wen*, would be desirable when bonding a rigid polymer such as co-polyester or polycarbonate to a soft, elastomeric layer made from polyurethane.

173. Thus, given the strong motivation in the industry for improved tooth repositioning and improved bonding between layers, and in view of my understanding that Patent Owner did not dispute that the use of sublayers was known in the art (*see supra* Section IV.B.2), in my opinion, it would have been obvious for a POSITA to modify the appliances in *Tadros* and *Kalili* to use thinner sublayers, as taught in *Wen*. The resulting appliance would still have the same relative position of hard and soft layers, the same overall thickness, and the same thickness of the hard and soft portions of the aligner.

174. Moreover, in my opinion, a POSITA would have had a reasonable expectation of success in combining the teachings of *Wen* regarding use of thinner sublayers with the dental aligners disclosed in *Tadros* and *Kalili*. To start, *Wen*, *Tadros*, and *Kalili* all disclose multilayer dental appliances utilizing hard and soft

polymer layers. *See* EX1008 (*Wen*) at [00198], [00201], [00211], [00225] (disclosing a multilayer aligner consisting of sections of soft layers, including polyurethane, and hard layers, including polyesters); EX1003 (*Tadros*) at [0023], [0073] (same); EX1005 (*Kalili*) at [0069] (same). Additionally, the disclosed fabrication methods for these multilayer appliances similarly consist of bonding layers together into a sheet and thermoforming this sheet over a positive tooth model. *See* EX1008 (*Wen*) at [00210], [00214] (disclosing laminating two or more polymer layers to form a sheet that is subsequently heated and vacuum-formed over positive tooth models); EX1003 (*Tadros*) at [0080], [0088]-[0090] (same); EX1005 (*Kalili*) at [0053], [0074] (same). In my opinion, given these similarities with *Wen*, it would have been straightforward for a POSITA to utilize the same fabrication methods disclosed in *Tadros* and *Kalili* (i.e., lamination), but using thinner sublayers of the same material in place of a single, thicker layer.

175. Further, as noted above, a POSITA would have understood that the flexural modulus and other relevant properties of the aligners (and thus, the repositioning force) would not be expected to change if thinner sublayers were used, so long as the total thickness of a section remained unchanged. *See supra* Section IV.B.2. Thus, a POSITA would have had a reasonable expectation that the appliances of *Tadros* and *Kalili*, as modified by the teaching of *Wen* to substitute multiple thinner layers for a single thicker layer of the same material, would still

successfully reposition a patient's teeth. In my opinion, a POSITA therefore would have had a reasonable expectation that using thinner layers as disclosed in *Wen* in a multilayer dental appliance as in the combination of *Tadros* and *Kalili* would improve the dental aligner and would not result in any disadvantages that would impair the aligner's functioning to reposition teeth.

B. Ground 1: Claims 1-2, 4-5, and 8-11 Would Have Been Obvious Over *Tadros* in View of *Porter*, *Kalili* and *Texin 990R*.

1. Independent Claim 1

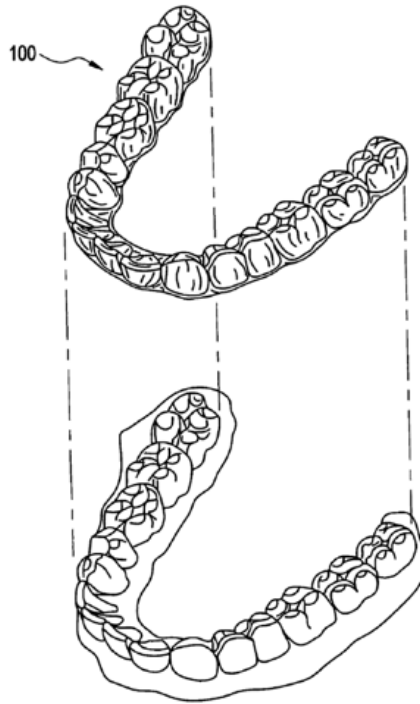
Claim 1[pre]

“A method of making a multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the method comprising:”

176. *Tadros* discloses a dental appliance for repositioning teeth, and discusses using a series of these appliances to incrementally reposition teeth. *See* EX1003 (*Tadros*) at [0015] (discussing “incremental repositioning of individual teeth”), claim 19 (“[M]ethod for maintaining or repositioning teeth in the oral cavity comprising: placing an appliance in a patient's mouth...”); *see also* EX1003 (*Tadros*) at [0006]-[0007], [0021].)⁴

⁴ *Tadros*'s disclosures (and *Kalili*'s disclosures, Ground 3) provide at least as much detail as the '090 patent's disclosure that its method provides a tooth-positioning

FIG. 3



EX1003 (*Tadros*) at Fig. 3.

177. *Tadros* teaches that the appliance can consist of at least three layers—a central hard layer disposed between two soft layers (i.e., a soft-hard-soft configuration). EX1003 (*Tadros*) at [0073].

appliance. *See, e.g.*, '090 patent at 3:65-67. To the extent a POSITA would have understood the '090 patent's disclosure as enabling a tooth positioning appliance, a POSITA would also have been able to practice *Tadros*'s method of repositioning teeth, in my opinion.

178. *Tadros* also discloses manufacturing this appliance by providing a multilayer sheet and using thermoforming to mold the sheet into a multilayer dental appliance. EX1003 (*Tadros*) at claim 21; *see also* EX1003 (*Tadros*) at [0080], [0088]-[0089], [0069]. For forming the multilayer sheet, a POSITA would have been aware of suitable techniques for adhering multiple polymer layers together. For example, the layers could be joined by adhesive lamination involving using a glue layer or tie layer of material between the structural layers of the appliance. EX1019 (*Schrenk*) at 150; *see supra* Section IV.A.2 (discussing use of lamination techniques). *Tadros* discloses that the formed aligner has “cavities designed to receive teeth.” EX1003 (*Tadros*) at Abstract, [0006]-[0008]. Therefore, in my opinion, *Tadros* discloses this limitation.

179. *Kalili* also discloses a repositioning appliance and thus discloses this limitation. For example, *Kalili*’s Figure 3 shows a “repositioning appliance” that that can “move the patient’s teeth from misalignment to alignment on an incremental basis.” EX1005 (*Kalili*) at [0053]; *see also* EX1005 (*Kalili*) at [0054]-[0056], [0063] (describing forming the repositioning appliance by forming a sheet over a model of an impression of a patient’s teeth).

Claim 1[a]

“providing a multilayer sheet comprising three polymer layers, the three polymer layers comprising:”

180. *Tadros* discloses “formable sheets” that can be utilized in the production of dental appliances. EX1003 (*Tadros*) at [0001], [0067], [0073]. *Tadros* specifies that these sheets can consist of at least three layers, with a central hard layer positioned between two soft layers. EX1003 (*Tadros*) at [0073]. The *soft-hard-soft* sheet configuration disclosed in *Tadros* is analogous to the three-layer sheet structure detailed in the ’090 specification, which also has a *soft-hard-soft* configuration. *See supra* Section VI.A; *see also* EX1005 (*Kalili*) at [0053], [0069] (disclosing multilayer sheet of higher modulus and lower modulus layers).

Claim 1[b]

“a first layer consisting of a co-polyester, the co-polyester having a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and”

181. As I detailed above, a POSITA would have been motivated and had a reasonable expectation of success in using hard Tritan copolyester, as disclosed in *Porter*, for the central hard layer due to its advantageous properties. *See supra* Section VII.A.1.b.

182. *Tadros* reports the objective of the central hard layer as providing a tough, creep-resistant material with “a tensile strength and modulus effective to

reposition teeth” that can also be easily thermoformed into a clear dental appliance. EX1003 (*Tadros*) at [0015], [0068], [0089], [0100]. *Tadros* highlights pure polycarbonate as a comparative example of a material with ideal modulus properties but insufficient thermoforming capabilities, noting that “[i]t is generally desirable for the glass transition temperature of the [hard layer] to be less than that of polycarbonate” because “a lower glass transition temperature and a lower thermoforming temperature generally facilitate an easier deformation of the sheet over the dental mold material.” EX1003 (*Tadros*) at [0097], [0113]. Further, *Tadros* highlights comparative copolyesters (specifically, PCCD variations) as materials with better thermoforming capabilities than polycarbonate but insufficient modulus properties. EX1003 (*Tadros*) at [0097], [0113]. *Tadros* sought to improve upon the pure polycarbonate or pure copolyesters commonly used in the art as the hard repositioning layer in multilayer dental appliances, and create a material that combined the best features of each. *See supra* Section IV.D.2 (discussing known shortcomings of polycarbonate).

183. *Tadros* specifies that that, to effectively reposition teeth in a manner comparable to pure polycarbonate, the hard layer should have a tensile modulus of about 1,500 N/mm² to about 2,500 N/mm². EX1003 (*Tadros*) at [0068], Table 2. To improve thermoforming compared to pure polycarbonate, *Tadros* discloses that the hard layer should have a glass transition temperature of about 120°C or less, which

is “at least about 25°C less” than a comparative pure polycarbonate sample. EX1003 (*Tadros*) at Table 3, [0113]; *see also* EX1003 (*Tadros*) at [0054] (“In general, it is desirable for the [hard layer] to have a glass transition temperature of less than or equal to about 205° C., preferably less than or equal to about 175° C., and more preferably less than or equal to about 150° C., and most preferably less than or equal to about 95° C.”). *Tadros* also discloses the ideal thermoforming temperature as about 180°C or less, which is 23°C lower than that of polycarbonate. EX1003 (*Tadros*) at [0100].

184. In order to create a hard layer with polycarbonate’s modulus properties and copolyester’s thermoforming properties, *Tadros* used polycarbonate-copolyester mixtures. EX1003 (*Tadros*) at [0022]-[0023]. A POSITA would have known, however, that polycarbonate contains harmful BPAs that would be released from polycarbonate-based dental aligners, including those disclosed in *Tadros*. EX1006 (*Porter*) at 63, 76; *supra* Section IV.D.1 (discussing known dangers of BPAs). A POSITA thus would have sought to replace *Tadros*’s hard mixture with a BPA-free alternative that still achieved *Tadros*’s goal of providing a hard layer with high tensile modulus values and improved thermoforming capabilities. EX1003 (*Tadros*) at [0015], [0068], [0089], [0100]; *supra* Section VII.A.1.b.

185. *Porter* discloses that Tritan copolyesters were developed and marketed as a BPA-free product with high hardness and comparable modulus properties to

polycarbonate that could “be thermoformed faster and at lower temperatures than polycarbonate sheet[s].” EX1006 (*Porter*) at 62-63, 76. This aligns with the stated purpose of the hard layer in *Tadros*. EX1003 (*Tadros*) at [0015], [0068], [0089], [0100]. *Porter* also discloses specific properties of Tritan that satisfy *Tadros*’s ideal benchmarks for the hard layer, including a tensile modulus of 1,551 N/mm² (about 1,500 N/mm² to about 2,500 N/mm²), a glass transition temperature of 108°C (about 120°C or less). EX1006 (*Porter*) at 63. Further, a POSITA would have thermoformed Tritan at a temperature only slightly higher than 108°C, the glass transition temperature, well within the ideal range of about 180°C or less disclosed in *Tadros*. EX1003 (*Tadros*) at [0100]. A POSITA therefore would have been motivated to substitute Tritan copolyester, as disclosed in *Porter*, for the polycarbonate-containing hard layer in the *soft-hard-soft* polymer sheet in *Tadros* to improve product safety. *See supra* Section VII.A.1.b.

186. A POSITA additionally would have had a reasonable expectation of success in using Tritan copolyester, as disclosed in *Porter*, in place of *Tadros*’s hard layer. The prior art specifically instructed a POSITA to use Tritan (*see Porter* and *Rafih*). *See supra* Section VII.A.1. Tritan was recognized as effective in thermoforming processes and extruded-sheet applications and durable in the “harsh” environments of “heat, hydrolytic and chemical attack, and applied stress” required for dental aligners, and past industry successes demonstrated the ability to replace

polycarbonate-based materials with Tritan copolyester. EX1006 (*Porter*) at 61-62, 63, 76; *See supra* Section VII.A.1.b.

187. A POSITA would have understood that methods like adhesive lamination would avoid inter-layer mixing and thereby preserve the properties of the single polymer within the first layer. *See supra* Section IV.A.2. Accordingly, the first layer would “consist[] of” pure Tritan copolyester, as required by the claim.

188. *Porter* discloses properties for Tritan copolyester such as a flexural modulus of 225,000 psi (“greater than 150,000 psi”); elongation at yield of 6% (“greater than 4%”); tensile modulus of 225,000 psi (“greater than 150,000 psi”); tensile strength at yield of 6,200 psi (between “4000-6500 psi”); and elongation at break of 210% (“greater than 70%”).⁵ *Porter* thus discloses “a first layer” as recited in claim 1[b]. EX1006 (*Porter*) at 63.

⁵ As stated previously, the mechanical properties of a polymer can significantly change depending on the manufacturing method used to combine and fabricate the multi-layer sheet. Processes such as adhesive lamination (as disclosed in the cited art), however, would preserve the polymers’ properties after processing. Further, I understand that Patent Owner has taken the position that reported properties of a stand-alone polymer provide sufficient evidence that a multi-layer material containing that polymer has the claimed properties.

Claim 1[c]

“a second layer consisting of a thermoplastic polyurethane elastomer, the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and”

189. *Tadros* discloses using soft outer layers to “alleviate pain, discomfort and bleeding gums,” and that those soft layers are preferably “elastomers” such as “polyurethanes.” EX1003 (*Tadros*) at [0073].

190. In my opinion, a POSITA would have been motivated to use the specific polyurethane elastomer disclosed in *Kalili* (TEXIN 990R) in the soft-hard-soft aligner of *Tadros* with a reasonable expectation of success for several reasons. First, both are directed to dental aligners for repositioning teeth. *Kalili*, similar to *Tadros*, discloses “[a]n invisible, removable orthodontic repositioning appliance ... for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement.” EX1005 (*Kalili*) at Abstract, [0015].

191. Second, both references disclose multilayer polymer sheets using soft layers as a tooth contacting layer. The appliance of *Kalili*, like in *Tadros*, is a multilayer aligner with a “higher modulus outer layer” (i.e., non-tooth contacting layer) and “a lower modulus inner layer” (i.e., tooth-contacting layer). EX1005 (*Kalili*) at [0069]. Like *Tadros*, *Kalili* notes that the purpose of this soft layer is to

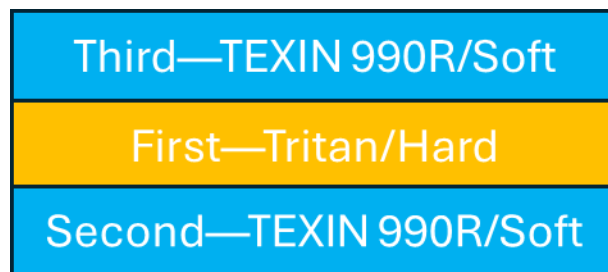
provide patient comfort, explaining that “[t]he lower elastic modulus on the inner [i.e., tooth-contacting] layer may allow for greater patient comfort, [and] less tooth, bone and root damage.” EX1005 (*Kalili*) at [0009].

192. In my opinion, a POSITA would have been further motivated to combine *Kalili* with *Tadros* based on *Kalili*’s disclosure of numerous advantages of using TEXIN 990R as the soft layer. EX1005 (*Kalili*) at [0069]. *Kalili* lists notes that TEXIN 990R is a suitable TPU for the soft layer and lists many desirable qualities of TEXIN 990R for use in a multilayer dental aligner including “outstanding abrasive resistance, impact strength, toughness, structural memory and flexibility” and “good hydrolytic stability, microbial resistance, teeth whitening, oral freshness, varied color materials, and exceptional mold release characteristics.” EX1005 (*Kalili*) at [0069]. In my opinion, a POSITA would have understood that TEXIN 990R’s advantages disclosed in *Kalili* would be equally desirable for the soft layers in *Tadros*.

193. Although it was known that the mechanical properties of a polymer (or free film) can change when the polymer is combined into a multilayer sheet (e.g., during coextrusion) (*see supra* Section IV.A.2), as I have explained above, a POSITA also would have been aware of manufacturing processes such as adhesive lamination that preserve the desirable mechanical properties reported for the TEXIN® 990R polymer even after such combination. For example, a POSITA

would have been aware that adhesive lamination techniques (*see supra* Section IV.A.2.b) to bond TEXIN® 990R to the other layers would preserve the reported mechanical properties for TEXIN® 990R during processing. In my opinion, a POSITA therefore would have expected that, by laminating a TEXIN 990R layer in a multilayer sheet, the resulting soft layer would have the properties disclosed in *Texin 990R*.

194. Thus, based on *Kalili*'s disclosures regarding the beneficial properties of the commercially available TEXIN 990R polymer in dental applications, in my opinion, a POSITA would have been motivated to use TEXIN 990R as the soft layers in *Tadros*'s multilayer aligner. Indeed, the prior art specifically instructed a POSITA to use TEXIN 990R (*see Kalili*). *See supra* Section VII.A.2. This configuration is shown below.



195. A POSITA would have had a reasonable expectation of success in doing so. *Kalili* discloses using TEXIN 990R for the same application and purpose as the lining layers of *Tadros*, namely, to enhance patient comfort. EX1003 (*Tadros*) at [0073]. Additionally, I understand that according to Patent Owner's assertions in

its Preliminary Infringement Contentions, properties of the soft polymer recited in a manufacturer's datasheet are evidence of its properties *after* being combined with other polymers in a multilayer sheet. Moreover, as I explained above, a POSITA would have been aware that adhesive lamination, in contrast to coextrusion, would preserve the polymer's properties when formed into a multilayer sheet. *See* Section IV.A.2.

196. A POSITA would have understood that manufacturing processes such as adhesive lamination would avoid inter-layer mixing and thereby preserve the properties of the single polymer within the second layer. *See supra* Section IV.A.2. Accordingly, the second layer would “consist[] of” pure TEXIN 990R TPU, as required by the claim.

197. *Texin 990R* datasheet discloses properties including ultimate tensile strength of 5,000 psi (“greater than 5000 psi”), an elongation at break of 450% (“greater than 200%”), and a hardness of 90A (from “60A to 85D”), as recited in the claim. EX1009 (*Texin 990R*) at 3.

198. In my opinion, a POSITA would interpret *Texin 990R* as disclosing an ultimate tensile strength of greater than 5,000 psi. To start, a POSITA would understand that there is a margin of error when measuring mechanical properties and, accordingly, *Texin 990R* appears to have rounded measurements in increments of 50 psi. *See, e.g.,* EX1009 (*Texin 990R*) at 3. A POSITA would also have

understood that strength values are typically rounded down rather than up. In other words, the measured tensile strength for the reported value of 5,000 psi in *Texin 990R* could vary, and it is possible that separate tensile strength tests of the same TEXIN 990R sample could yield separate values around 5,000 psi. Importantly, there would be no appreciable difference between the performance of a material with a tensile strength within 50 psi of the reported value of 5,000 psi, and a POSITA would have understood that a material with a tensile strength slightly above 5,000 psi would perform nearly identically to material with a tensile strength of exactly 5,000 psi. Additionally, in my view, a POSITA would have understood the term “tensile strength” as reported to refer to ultimate tensile strength or tensile strength at break. However, as described above, even if the “tensile strength” reported in *Texin 990R* were interpreted to be the tensile strength at yield, TEXIN 990R’s ultimate tensile strength would necessarily be greater than or equal to the reported tensile strength at yield. *See supra* Section IV.C.3. For all of these reasons, it is my view that a POSITA would have understood the disclosed ultimate tensile strength of TEXIN 990R to be greater than 5,000 psi.

Claim 1[d]

“a third layer;”

199. As described above, *Tadros* discloses a soft-hard-**soft** configuration. This additional soft layer is “a third layer” as recited in claim 1. *See* claim 1[pre]; EX1003 (*Tadros*) at [0073].

Claim 1[e]

“wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer;”

200. As detailed above, *Tadros* in combination with *Porter*, *Kalili*, and *Texin 990R* results in a soft-hard-soft sheet wherein the “first layer” is Tritan and a second layer is TEXIN 990R. Tritan has an elastic modulus of 225,000 psi, which is greater than 6,000 psi, the flexural modulus of the TEXIN 990R, as recited in this claim. *See* claim 1[pre]-1[d]. As I explained above, the tensile modulus (or elastic modulus) of a polymeric material is the same as its flexural modulus under typical use conditions. *See supra* Section IV.C.2. Moreover, a POSITA would have been aware that certain manufacturing processes such as adhesive lamination preserve the desirable mechanical properties reported for the Tritan and TEXIN® 990R polymers even after such combination, such that the layer modulus is equivalent to the polymer’s modulus. *See supra* Section IV.A.2. The asserted prior art therefore meets this element.

Claim 1[f]

“providing a mold;”

201. *Tadros* discloses thermoforming the multilayer sheet over a positive model in order to create the dental aligner. *See supra* 1[pre]; EX1003 (*Tadros*) at claim 21; *see also* EX1003 (*Tadros*) at [0081], [0085]-[0087] (using “molds, which are, in effect, positive tooth models...of each successive stage of the treatment” to produce the dental appliance). Likewise, *Kalili* discloses making a dental aligner by printing a “model of the digital file [of the patient’s teeth]...using rapid prototype 3D printers” and then heating and vacuuming the sheet over the positive model. EX1005 (*Kalili*) at [0015]; *see also* EX1005 (*Kalili*) at [0089]. *Tadros* thus discloses this limitation.

Claim 1[g]

“thermoforming the multilayer sheet over the mold to form a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement; and”

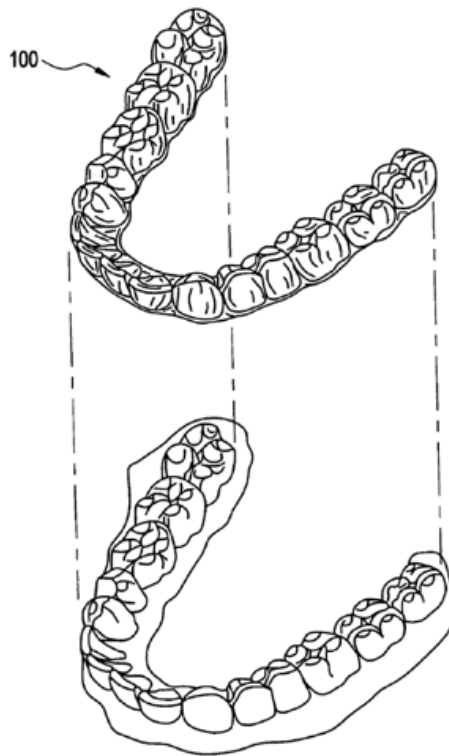
202. As I explained above for claim 1[pre] and 1[f], *Tadros* and *Kalili* describe thermoforming multilayer sheets over dental repositioning appliances, and these appliances have cavities designed to receive patient’s teeth. *See* claim 1[pre], 1[d]; *see also* EX1003 (*Tadros*) at [0087]-[0089]; EX1005 (*Kalili*) at [0053]-[0056], [0063]. This limitation is therefore disclosed.

Claim 1[h]

“trimming excess material from the thermoformed multilayer sheet to form the multilayer dental aligner.”

203. *Tadros* discloses the multilayer sheets are thermoformed over a positive mold to create the dental aligners. *See* claim 1[pre]. In my opinion, a POSITA would have understood that such a process results in excess material that must be removed in order for the aligner to properly fit over patient’s teeth. In my opinion, the dental aligner disclosed in *Tadros*, including the appliance depicted in Figure 3, has had excess material trimmed so the aligned properly fits over teeth, and a POSITA would have understood this.

FIG. 3



EX1003 (*Tadros*) at Fig. 3.

204. *Tadros* thus discloses this limitation.

205. Accordingly, in my opinion, the multilayer dental aligner of claim 1 would have been obvious to a POSITA in 2012 over *Tadros* in view of *Kalili*, *Porter*, and *Texin 990R*.

2. Dependent Claims 2, 4-5, and 8-11

206. Dependent Claims 2, 4-5, and 8-11 ultimately depend from claim 1 and would have been obvious for the reasons described above (*see supra* claim 1) and the additional reasons detailed below.

Claim 2

“The method of claim 1, wherein the co-polyester has a light transmission between 400 nm and 800 nm of greater than about 75%.”

207. *Porter* discloses that Tritan (the “first layer”) has a total light transmittance of 90%. In my opinion, a POSITA would understand that this discloses a material that has a light transmission between 400 nm and 800 nm (the visible light spectrum) of greater than about 75%, as claimed. EX1006 (*Porter*) at 63.

Claim 4

“The method of claim 1, wherein the first layer is disposed adjacent to the third layer.”

208. The hard “first layer” is disposed adjacent to additional soft “third” layer in the soft-hard-**soft** configuration of *Tadros*, as claimed. *See* claim 1. The asserted combination thus renders claim 4 obvious.

Claim 5

“The method of claim 1, wherein the first layer is coextruded with or laminated to the third layer.”

209. As I detailed above, a POSITA would have been aware of manufacturing processes such as adhesive lamination that preserve the desirable mechanical properties reported for the Tritan and TEXIN® 990R polymers even after such combination. *See supra* Section IV.A.2. A POSITA therefore would have been motivated and would have had a reasonable expectation of success in creating a laminated dental appliance, where in the first hard layer of Tritan is laminated to an outer soft layer of TEXIN 990R, the third layer. *See supra* Section VII.A.3. The cited prior art thus discloses this limitation.

210. Accordingly, in my opinion, the multilayer sheet of claim 5 would have been obvious to a POSITA in 2012 in view of *Tadros*, *Kalili*, *Porter*, and *Texin 990R*.

Claim 8

“The method of claim 1, wherein the thermoplastic polyurethane elastomer comprises a compression set at about 70° C. of greater than 40% after 24 hours.”

211. TEXIN 990R, which is the TPU in the “second” layer, has a compression set of 75% at 70°C after 22 hours. EX1009 (*Texin 990R*) at 3. As I explained above, compression set after 24 hours would be greater than or equal to compression set after 22 hours, and thus the cited art discloses this element. *See supra* Section V.C.6. The asserted combination thus renders claim 8 obvious.

Claim 9

“The method of claim 1, wherein the thermoplastic polyurethane elastomer comprises a light transmission between 400 nm and 800 nm of greater than about 75%.”

212. *Texin 990R* describes the TEXIN 990R TPU as having a “natural color.” EX1009 (*Texin 990R*) at 1. TEXIN 990R is also used as a layer in *Kalili*’s “invisible” repositioning appliance, and notes that the materials used are provided in “clear forms.” EX1005 (*Kalili*) at abstr., [0007], [0053], [0063], [0069]. Given these disclosures, in my opinion, a POSITA would have understood TEXIN 990R to have a light transmission between 400 nm and 800 nm of greater than about 75%. The asserted combination thus renders claim 9 obvious.

Claim 10

“The method of claim 1, wherein the co-polyester has a stress relaxation at 24 hours in a wet environment of between 90-100% humidity of greater than 10%.”

213. As I detailed above, a POSITA would have been motivated to use the Tritan copolyester disclosed in *Porter* in place of the hard layer in *Tadros* to avoid BPAs and to improve longevity and performance. *See supra* Section VII.A.1.b. Additionally, as I explained, most polymers (including polycarbonates and copolyesters) would exhibit a stress relaxation greater than at least 10% after a timescale of 24 hours under standard laboratory conditions. *See supra* Section IV.C.7. As an example, the copolyester-polycarbonate blends disclosed in *Tadros* had stress relaxation values of 33% and 27% after 12 hours (i.e., three times greater than the amount the claims require and in half the amount of time). EX1003 (*Tadros*) at Tables 2, 4, 5. In my opinion, a POSITA therefore would have expected Tritan copolyester to have a stress relaxation meet this limitation.

Claim 11

“The method of claim 1, wherein the first layer is thicker than the second layer.”

214. *Tadros* discloses that the multilayer sheets are “of a variable thickness” and can be in the range of “about 125...to about 1,250...micrometers.” EX1003 (*Tadros*) at [0067]. In my opinion, a POSITA would have understood that the appliance could be created with layers of varying thicknesses so long as the total thickness was within this range, and the POSITA therefore would have understood

that a suitable appliance could have a first hard layer that is thicker than the soft layer(s).

215. This understanding is also supported by *Kalili*'s disclosure of using a hard layer with an "inner lining" of soft material (specifically, TEXIN 990R) suggesting a soft layer that is comparatively thinner than the hard layer. EX1005 (*Kalili*) at [0053], [0063], [0069]. In my view, a POSITA would have understood this disclosure in *Kalili* applicable to *Tadros*, given that the initial motivation to use the elastomer TEXIN 990R was based on *Kalili*'s disclosure. *See* claim 1[c]; *See supra* Section VII.A.2.

216. For these reasons, in my opinion, it would have been obvious for the hard "first" layer in the soft-hard-soft appliance to be thicker than the soft "second" layer, as recited in claim 11.

C. Ground 2: Claims 1-11 Would Have Been Obvious Over *Tadros* in View of *Porter*, *Kalili* and *Texin 990R* and Further in View of *Wen*.

217. Dependent Claims 3, 6, and 7 ultimately depend from claim 1 and would have been obvious for the reasons described above (*see supra* claim 1) and the additional reasons detailed below.

1. Claim 3

"The method of claim 1, wherein the third layer comprises a same or different co-polyester."

218. As I explained above, *Tadros* discloses a soft-hard-soft layer configuration and. Moreover, in view of *Porter* and *Kalili*, a POSITA would have used Tritan as the hard rigid layer in *Tadros*'s soft-hard-soft appliance and TEXIN 990R as soft outer layers. *See supra* Section VII.A.1.b.

219. As disclosed in *Wen*, it was known before the priority date that there are several advantages of replacing a single polymer layer with multiple thinner layers of the same polymer, wherein these thinner layers collectively having the same overall thickness as the initial layer. EX1008 (*Wen*) at [00210], [00212] (discussing “plurality of thinner layers”); *See supra* Section IV.B.2. Specifically, *Wen* gives two advantages noting: (1) “thinner layers can be more easily conformed to the physical tooth models” and (2) thinner films “help bond the films to one another,” especially for “polymers of disparate properties,” which are more likely to “delaminate from one another.” EX1008 (*Wen*) at [00212]-[00213]. A POSITA would have known that sufficient adhesion between layers of disparate properties was necessary to achieve the desired interlayer interactions and that thinner layers would lower the degree of adhesion required. EX1019 (*Schrenk*) at 150.

220. Based on these teachings, a POSITA would have two thinner layers of the hard Tritan layer (totaling the same overall thickness as the single layer) to achieve the advantages disclosed in *Wen*—improved tooth conformity and inter-layer bonding, especially between the layers with disparate properties. *See supra*

Section IV.B.2. A POSITA would also have been motivated to combine *Wen* with *Tadros* because both references are directed to improved dental aligners for positioning teeth, including the composition and configuration of those layers. Further, both *Tadros* and *Wen* teach the use of multilayer polymer sheets comprising layers of different hardness, thermoformed into dental aligners over a positive model of a patient's teeth. *See supra* claim 1; EX1008 (*Wen*) at [00189], [00197]-[00198], [00207], [00210]; *supra* Section VII.A.3.

221. In my opinion, a POSITA would have had a reasonable expectation of success in combining *Wen*, *Tadros*, and *Porter*. The POSITA would have understood that the hard layer in *Tadros*'s soft-hard-soft configuration could be modified to comprise two thinner layers of the same material based on *Wen*'s disclosures and industry practice of thermoforming polymer sheets with many layers. EX1019 (*Schrenk*) at 160-162; *see supra* Section VII.A.3. Further, a POSITA would have understood that *Wen*'s teaching applies to Tritan copolyester given *Wen*'s statement that its teachings apply to hard layers of "polyesters." EX1008 (*Wen*) at [00201].

222. The resulting configuration is a soft-hard-hard-soft aligner, wherein the first and third layer are the same Tritan copolyesters as disclosed in *Porter*, disposed between second and fourth layers of TEXIN 990R disclosed in *Kalili*, which meets the limitations of claim 3. This configuration is shown below. The asserted combination thus renders claim 3 obvious.



2. Claim 6

“The method of claim 1, wherein the multilayer sheet further comprises a fourth layer comprising a same or different thermoplastic polyurethane elastomer.”

223. As I explained for claim 3, a POSITA would be motivated to and had a reasonable expectation of success in applying the teachings of *Wen* to *Tadros* to result in a soft-hard-hard-**soft** configuration wherein the “fourth layer” is the TPU TEXIN 990R, and thus discloses this limitation. *See* claim 3. The asserted combination thus renders claim 6 obvious.

3. Claim 7

“The method of claim 6, wherein the first layer and the third layer are disposed between the second layer and the fourth layer.”

224. As detailed above for claim 3, the resulting configuration is a soft-hard-hard-soft configuration with first and third layer of Tritan disposed between a first

and fourth layer of TEXIN 990R. The asserted combination thus renders claim 7 obvious. *See* claim 3.

4. Claims 1-2, 4-5, 8-11

225. These claims, which as detailed above would have been obvious under the Ground 1 prior-art combination of *Tadros*, *Porter*, *Kalili*, and *Texin 990R*, are equally obvious under Ground 2, which merely adds *Wen*'s disclosures regarding using multiple thinner layers.

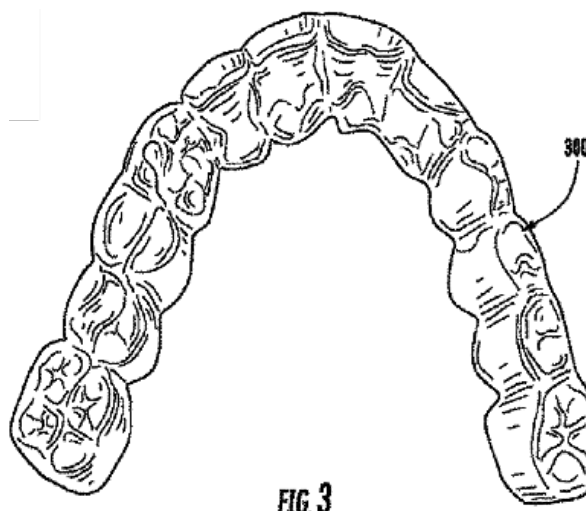
D. Ground 3: Claims 1-6 and 8-11 Would Have Been Obvious Over *Kalili* in View of *Porter*, *Wen*, *Texin 990R*.

1. Independent Claim 1

Claim 1[pre]

“A method of making a multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the method comprising:”

226. *Kalili* discloses “[a]n invisible, removable orthodontic repositioning appliance ... for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement.” EX1005 (*Kalili*) at Abstract, [0015], [0069]. *Kalili*'s appliance “position[s] a patient's teeth.” EX1005 (*Kalili*) at p.1 (57), claim 12. *Kalili* discloses that this appliance is multilayer and is formed from a multilayer sheet. EX1005 (*Kalili*) at Abstract, [0015], [0069].



EX1005 (*Kalili*) at Fig. 3.

227. *Kalili* also discloses methods of making the disclosed appliance. EX1005 (*Kalili*) at [0015]. First, “a model of the digital file [of the patient’s teeth] is printed using rapid prototype 3D printers.” EX1005 (*Kalili*) at [0015]. Then, “[a] polymer sheet is heated and vacuumed over the printed model.” EX1005 (*Kalili*) at [0015].

228. *Kalili* discloses that new impressions of patient’s teeth can be taken, allowing for such appliances to move teeth on an “incremental basis” for a treatment period. EX1005 (*Kalili*) at [0053]. After the treatment period, new impressions of teeth are taken and new appliances can be formed. EX1005 (*Kalili*) at [0053]. *Kalili* thus meets these claim limitations.

Claim 1[a]

“providing a multilayer sheet comprising three polymer layers, the three polymer layers comprising:”

229. The multilayer sheet of *Kalili* includes a higher modulus outer layer that doesn't contact the patients teeth laminated to a lower modulus tooth contacting layer. EX1005 (*Kalili*) at [0069], Abstract. *Kalili* discloses the outer, higher modulus layer, can be made from polycarbonate. EX1005 (*Kalili*) at [0053]. *Kalili* discloses the lower modulus layer can be a TPU (specifically, TEXIN 990R) and notes that this tooth contacting layer “may allow for greater patient comfort, [and] less tooth, bone and root damage.” EX1005 (*Kalili*) at [0009], [0069].

230. The layers in *Kalili*'s multilayer sheet are laminated, and discloses the outer layer as being “laminated” to the inner layer. EX1005 (*Kalili*) at [0063], [0082]. As I explained above, a POSITA would have been aware of suitable techniques for laminating the first layer (the hard layer) and second layers (softer layers) as described above. For example, the layers could be laminated by “introducing a thin layer of a third polymer that shows good adhesion to both of the materials.” EX1019 (*Schrenk*) at 150; *see supra* Section VII.A.3.

231. *Wen*, similar to *Kalili*, teaches that using layers with certain properties can be used to avoid “discomfort to the patient.” EX1008 (*Wen*) at [00199]. *Wen* also similarly teaches that “two or more polymer sheets may be laminated to one another to form a single sheet that is heated and vacuum-formed ... to provide multi-

layer dental aligners.” EX1008 (*Wen*) at [00210]. To improve the fabrication of such a multi-layer dental aligner, *Wen* adds that, “rather than forming a dental aligner by a thick layer of the same aligner-making material, the aligner is formed by a plurality of thinner layers of the aligner-making material using vacuum forming.” EX1008 (*Wen*) at [00212]. *Wen* explains that (1) “thinner layers can be more easily conformed to the physical tooth models than a single thick layer” and that (2) “[t]hinner films allow more intimate contact between sheets and therefore help bond the films to one another,” especially where “polymers of disparate properties” are used, which are more likely to “delaminate from one another.” EX1008 (*Wen*) at [00212]-[00213].

232. As described above, a POSITA would have been motivated to modify the single, higher-modulus hard layer in *Kalili* to use two or more thinner layers of the same material that totaled the same overall thickness as the single layer. *See supra* Section IV.B.2; VII.A.3. A POSITA would have understood that doing so would improve tooth conformity and inter-layer bonding—especially between the layers with disparate properties—as taught in *Wen* (e.g., resulting in a soft-hard-hard layer configuration). *see supra* Section IV.B.2; VII.A.3. A POSITA also would have understood that sufficient adhesion between layers of disparate properties was necessary to achieve the desired interlayer interactions and that thinner layers would

lower the degree of adhesion required. EX1019 (*Schrenk*) at 150; *see supra* Section IV.A.2.

233. Further, in my opinion, a POSITA would have had a reasonable expectation of success in producing and thermoforming a polymer sheet with three polymer layers based on the explicit teachings of *Wen* and industry practice of thermoforming polymer sheets with up to seven layers. EX1019 (*Schrenk*) at 160-162; *see supra* Section IV.A.1. Additionally, both *Kalili* and *Wen* teach the use of multilayer polymer sheets comprising layers of different hardness, thermoformed into dental aligners over a positive model of a patient's teeth. EX1008 (*Wen*) at [00189], [00197]-[00198], [00207], [00210].

234. Thus, the additional hard layer in the resulting soft-hard-**hard** configuration resulting from combining *Kalili* with *Wen* is a “third” layer. “[A] multilayer sheet comprising three polymer layers” thus would have been obvious to a POSITA in 2012 in view of *Kalili* and *Wen*.

Claim 1[b]

“a first layer consisting of a co-polyester, the co-polyester having a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and”

235. *Kalili* discloses using a polycarbonate as the higher-modulus layer material. EX1005 (*Kalili*) at [0053]. As noted above, a POSITA would have been motivated to replace *Kalili*'s polycarbonate layer with Tritan copolyester (disclosed in *Porter*) to eliminate BPAs, improve longevity, and benefit from Tritan's proven and desirable mechanical properties, such as its high hardness and modulus, that are similar to polycarbonate. *See supra* Section VII.A.1.a. The prior art specifically instructed a POSITA to use Tritan (*see Porter* and *Rafih*). *See supra* Section VII.A.1.

236. *Porter* describes Tritan copolyester as having a flexural modulus of 225,000 psi ("greater than 150,000 psi"); elongation at yield of 6% ("greater than 4%"); tensile modulus of 225,000 psi ("greater than 150,000 psi"); tensile strength at yield of 6,200 psi (between "4000-6500 psi"); and elongation at break of 210% ("greater than 70%"). *Porter* thus discloses "a first layer" as recited in claim 1[b]. EX1006 (*Porter*) at 7.

237. A POSITA would have understood that manufacturing processes such as adhesive lamination would avoid inter-layer mixing and thereby preserve the properties of the single polymer within the first layer. *See supra* Section IV.B.2. Accordingly, the first layer would "consist[] of" pure Tritan copolyester, as described in the claim.

Claim 1[c]

“a second layer consisting of a thermoplastic polyurethane elastomer, the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and”

238. *Kalili* discloses the use of TEXIN 990R as the lower modulus soft layer. The lower-modulus inner layer in *Kalili*’s exemplary appliance is “a polyurethane.” EX1005 (*Kalili*) at [0074]. *Kalili* discloses that “the liner may be a polymer such as Thermoplastic Polyurethane that is an aromatic polyether based grade, such as TEXIN® 990R resin with a shore hardness of approximately 90A.” EX1005 (*Kalili*) at [0069]. *Kalili* describes TEXIN 990R’s desirable qualities for use in a layered dental aligner, including “outstanding abrasive resistance, impact strength, toughness, structural memory and flexibility” and “good hydrolytic stability, microbial resistance, teeth whitening, oral freshness, varied color materials, and exceptional mold release characteristics.” EX1005 (*Kalili*) at [0069].

239. *Texin 990R* datasheet discloses that TEXIN 990R has ultimate tensile strength of 5,000 psi (“greater than 5000 psi”), an elongation at break of 450% (“greater than 200%”), and a hardness of 90A (from “60A to 85D”). TEXIN 990R at 3. As I explained above, even if the “tensile strength” reported in *Texin 990R* were interpreted to be the tensile strength at yield, TEXIN 990R’s ultimate tensile strength would necessarily be greater than or equal to the reported tensile strength at yield.

see supra Section IV.C.3. These meet the properties of the second layer in claim 1[c].

240. In my opinion, a POSITA would interpret *Texin 990R* as disclosing an ultimate tensile strength of greater than 5,000 psi. To start, a POSITA would understand that there is a margin of error when measuring mechanical properties and, accordingly, *Texin 990R* appears to have rounded measurements in increments of 50 psi. *See, e.g., EX1009 (Texin 990R)* at 3. A POSITA would also have understood that strength values are typically rounded down rather than up. In other words, the measured tensile strength for the reported value of 5,000 psi in *Texin 990R* could vary, and it is possible that separate tensile strength tests of the same TEXIN 990R sample could yield separate values around 5,000 psi. Importantly, there would be no appreciable difference between the performance of a material with a tensile strength within 50 psi of the reported value of 5,000 psi, and a POSITA would have understood that a material with a tensile strength slightly above 5,000 psi would perform nearly identically to material with a tensile strength of exactly 5,000 psi. Additionally, in my view, a POSITA would have understood the term “tensile strength” as reported to refer to ultimate tensile strength or tensile strength at break. However, as described above, even if the “tensile strength” reported in *Texin 990R* were interpreted to be the tensile strength at yield, TEXIN 990R’s ultimate tensile strength would necessarily be greater than or equal to the reported

tensile strength at yield. *See supra* Section IV.C.3. For all of these reasons, it is my view that a POSITA would have understood the disclosed ultimate tensile strength of TEXIN 990R to be greater than 5,000 psi.

241. A POSITA would have understood that manufacturing processes such as adhesive lamination would preserve the properties of the single polymer within the layer and would not cause mixing of layers. *See supra* Section IV.A.2. Accordingly, the first layer would “consist[] of” pure TEXIN 990R, as required by the claim.

Claim 1[d]

“a third layer;”

242. The additional hard layer in the resulting soft-hard-**hard** configuration is a “third” layer as required by claim 1[d]. *See* claim 1[a]. This configuration is shown below.



Claim 1[e]

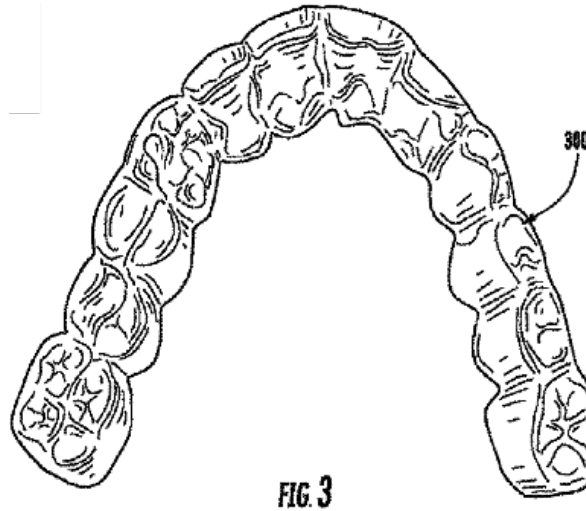
“wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer;”

243. As detailed above, *Kalili* in combination with *Porter*, *Wen*, and *Texin 990R* results in a soft-hard-hard configuration wherein the copolyester (Tritan, disclosed in *Porter*) has an elastic modulus of 225,000 psi, which is greater than 6,000 psi, the flexural modulus of the TPU (TEXIN 990R, disclosed in *Kalili* and *Texin 990R*). The cited prior art thus discloses this limitation. See claim 1[pre]-1[d]. As I explained above, the tensile modulus (or elastic modulus) of a polymeric material is the same as its flexural modulus under typical use conditions. See *supra* Section IV.C.2.

Claim 1[f]

“providing a mold;”

244. *Kalili* also discloses methods of making the disclosed appliance. EX1005 (*Kalili*) at [0015]. First, “a model [(i.e., mold)] of the digital file [of the patient’s teeth] is printed using rapid prototype 3D printers.” EX1005 (*Kalili*) at [0015]. Then, “[a] polymer sheet is heated and vacuumed over the printed model.” EX1005 (*Kalili*) at [0015]. This thermoforming process results in “[a]n invisible, removable orthodontic repositioning appliance ... for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement.” EX1005 (*Kalili*) at Abstract, [0015]. The appliance has numerous “indentations” configured to receive and reposition teeth. EX1005 (*Kalili*) at p.1 (57), [0015], [0053], [0088], claims 1, 12.



EX1005 (*Kalili*) at Fig. 3.

Claim 1[g]

“thermoforming the multilayer sheet over the mold to form a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement; and”

245. As detailed above for claim 1[pre] and 1[f], *Kalili* discloses this limitation. *See* claim 1[pre], 1[f]. Thermoforming processes were well known in the art. *See supra* Section IV.A.1.

Claim 1[h]

“trimming excess material from the thermoformed multilayer sheet to form the multilayer dental aligner.”

246. *Kalili* discloses the multilayer sheets are thermoformed over a positive mold to create the dental aligners. *See* claim 1[pre], 1[f]. In my opinion, a POSITA would have understood that such a process results in excess material that must be removed so the aligner fits properly over a patient's teeth. Indeed, a POSITA would have understood that aligner disclosed in *Kalili*, as depicted in *Kalili*'s Figure 3, has had excess material trimmed so the aligner properly fits over teeth.



EX1005 (*Kalili*) at Fig. 3.

247. *Wen* provides further support for this, noting that after thermoforming such multilayer appliances, the excess material can be cut from the aligner. EX1008 (*Wen*) at [0046], [0049], claim 45. As noted above, *Kalili* and *Wen* disclose similar laminated multilayer appliances, and a POSITA therefore would have been motivated to apply *Wen*'s teachings to manufacturing the dental aligner of *Kalili*

with a reasonable expectation of success. *See* claim 1[a]. Accordingly, this limitation is met by *Kalili* alone, or alternatively, *Kalili* in combination with *Wen*.

2. Dependent Claims 2-6 and 8-11

248. Dependent Claims 2-6 and 8-11 ultimately depend from claim 1 and would have been obvious for the reasons described above (*see supra* claim 1) and the additional reasons detailed below.

Claim 2

“The method of claim 1, wherein the co-polyester has a light transmission between 400 nm and 800 nm of greater than about 75%.”

249. *Porter* discloses that Tritan (the “first layer”) has a total light transmittance of 90%. EX1006 (*Porter*) at 7. In my opinion, this discloses a material that has a light transmission between 400 nm and 800 nm of greater than about 75%, as claimed. The asserted combination thus renders claim 2 obvious.

Claim 3

“The method of claim 1, wherein the third layer comprises a same or different co-polyester.”

250. As detailed above for claim 1, in the soft-hard-**hard** configuration described above, the third hard layer is comprised of Tritan copolyester, therefore disclosing this limitation. *See* claim 1. The asserted combination thus renders claim 3 obvious.

Claim 4

“The method of claim 1, wherein the first layer is disposed adjacent to the third layer.”

251. As detailed above for claim 1, in the soft-hard-hard configuration described above, the first and third hard layers comprised of Tritan copolyester are disposed adjacent to one another, therefore disclosing this limitation. *See* claim 1. The asserted combination thus renders claim 4 obvious.

Claim 5

“The method of claim 1, wherein the first layer is coextruded with or laminated to the third layer.”

252. *Kalili*’s multilayer sheet is laminated, and a POSITA would have been motivated to laminate all layers of the disclosed soft-hard-hard appliance and would have had a reasonable expectation of success. *See* claim 1[a]; *supra* Section IV.A.2.d. The first and third layer thus would be laminated to one another, and the asserted combination thus renders claim 5 obvious.

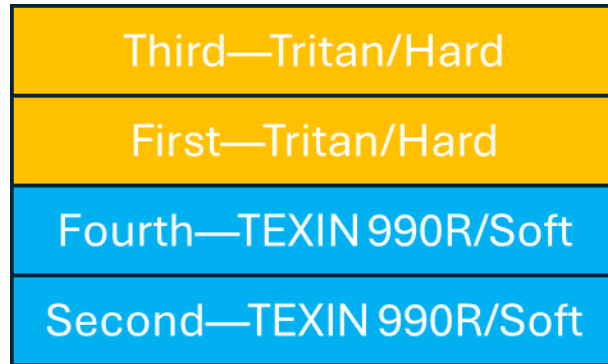
Claim 6

“The method of claim 1, wherein the multilayer sheet further comprises a fourth layer comprising a same or different thermoplastic polyurethane elastomer.”

253. In my opinion, a POSITA would have been motivated to modify *Kalili* based on the teachings of *Wen* to use thinner sublayers of TEXIN 990R, in addition

to those of Tritan, resulting in a soft-*soft*-hard-hard configuration, wherein the “second” and “fourth” layer are both the TPU TEXIN 990R. *See* claim 1[a], 1[c].

This configuration is shown below.



Based on *Wen*’s disclosures, a POSITA would have understood that using thinner layers of both the TEXIN 990R and Tritan polymers would improve adhesion between the layers and improve thermoforming. *See supra* Section IV.B.2; VII.A.3.

The asserted combination thus renders claim 6 obvious.

Claim 8

“The method of claim 1, wherein the thermoplastic polyurethane elastomer comprises a compression set at about 70° C. of greater than 40% after 24 hours.”

254. TEXIN 990R, the TPU of the second layer, has compression set of 75% at 70°C after 22 hours. EX1009 (*Texin 990R*) at 3. As I explained above, a compression set after 24 hours would be greater than or equal to compression set after 22 hours, and thus the asserted combination renders claim 8 obvious.. *See supra* Section IV.C.6.

Claim 9

“The method of claim 1, wherein the thermoplastic polyurethane elastomer comprises a light transmission between 400 nm and 800 nm of greater than about 75%.”

255. *Texin 990R* described the TEXIN 990R TPU as having a “natural color.” EX1009 (*Texin 990R*) at 1. Further, *Kalili* employs TEXIN 990R as a layer in an “invisible” repositioning appliance, and notes that the materials used are provided in “clear forms.” EX1005 (*Kalili*) at abstr., [0007], [0053], [0063], [0069]. Given these disclosures, in my opinion, a POSITA would expect TEXIN 990R to have light transmission between 400 nm and 800 nm of greater than about 75%. The asserted combination thus renders claim 9 obvious.

Claim 10

“The method of claim 1, wherein the co-polyester has a stress relaxation at 24 hours in a wet environment of between 90-100% humidity of greater than 10%.”

256. As detailed above, a POSITA would have been motivated to use the Tritan copolyester disclosed in *Porter* in place of the hard layer in *Tadros* to avoid BPAs and to improve longevity and performance. As I explained, most polymers (including polycarbonates and copolyesters) would exhibit a stress relaxation greater than at least 10% after a timescale of 24 hours under standard laboratory conditions. *See supra* Section IV.C.7. For example, the copolyester-polycarbonate blends

disclosed in *Tadros* had stress relaxation values of 33% and 27% after 12 hours. EX1003 (*Tadros*) at Tables 2, 4, 5. Therefore, in my opinion, a POSITA would have expected Tritan copolyester to have a stress relaxation meet this limitation. The asserted combination thus renders claim 10 obvious.

Claim 11

“The method of claim 1, wherein the first layer is thicker than the second layer.”

257. *Kalili* discloses that this dental appliance may range in thickness from 0.020-0.20 inches. A POSITA would have understood that the appliance could be created with layers of varying thicknesses so long as the total thickness of the appliance was within this range. EX1005 (*Kalili*) at [0053]. *Kalili* gives an exemplary thickness of the hard layer of 0.030 inches, which a POSITA would have understood could be laminated to a soft layer of, for instance, 0.010 inches thick (less than that of a single thick hard layer of 0.030 inches or two equal thickness thinner hard layers of 0.015 inches) and still fall within *Kalili*’s acceptable total thickness range. EX1005 (*Kalili*) at [0053].

258. *Kalili* further describes using a hard layer with an “inner lining” of soft material (specifically, TEXIN 990R), suggesting that the soft layer is comparatively thinner than the hard layer. EX1005 (*Kalili*) at [0053], [0063], [0069]. Additionally, as I noted above, a POSITA would be motivated to use thinner sublayers of the soft

layer, thereby decreasing the thickness of the second layer further as compared with the first hard layer. *See* claim 6; *See supra* Section IV.B.2; VII.A.3.

259. For these reasons, it would have been obvious over the cited combination for the hard “first” layer to be thicker than the soft “second” layer, as recited in claim 11.

VIII. Conclusion

260. For the reasons set forth above, it is my opinion that claims 1-11 of the ’090 patent would have been obvious to a person of ordinary skill in the art as of the patent’s earliest possible priority date.

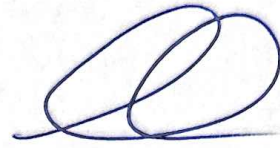
261. I reserve the right to offer opinions relevant to the invalidity of the ’090 patent claims at issue or offer testimony in support of this declaration.

262. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in this case, and that any cross-examination will take place in the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

263. I declare under penalty of perjury under the laws of the United States that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further, that these

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Date: 4-13-2025

A handwritten signature in blue ink, consisting of a stylized, overlapping loop structure.

Dr. Tim A. Osswald

Appendix A

- EX1001: U.S. Patent No. 11,648,090 B2 (issued May 16, 2023)
- EX1002: U.S. Patent No. 9,655,691 B2 (issued May 23, 2017)
- EX1003: U.S. Patent Application Publication No. 2005/0100853 A1 (published May 12, 2005)
- EX1004: U.S. Patent No. 10,973,613 B2 (issued Apr. 13, 2021)
- EX1005: U.S. Patent Application Publication No. 2011/0020761 A1 (published Jan. 27, 2011)
- EX1006: D.S. Porter and R.S. Beavers, Dishwasher Safe, Plastics Technology (Dec. 2007) [Appendix 1 to Declaration of Lauren Gluckman]
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