

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

BAY MATERIALS, LLC,

Plaintiff,

v.

3M COMPANY,

Defendant.

C.A. No. 21-1610-UNA

[REDACTED]
[REDACTED]
[REDACTED]

REDACTED PUBLIC VERSION

**DECLARATION OF DR. TIM A. OSSWALD IN SUPPORT OF PLAINTIFF'S
MOTION FOR PRELIMINARY INJUNCTION**

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I. QUALIFICATIONS

1. I, Dr. Tim A. Osswald, submit this declaration on behalf of Plaintiff Bay Materials, LLC (“Bay Materials”) 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 attached as Exhibit A.

2. I am currently the Kuo K. and Cindy F. Wang Professor at the University of Wisconsin-Madison in the Department of Engineering. I am also affiliated with the Department of Materials Science and Engineering and I am the co-director of the Polymer Engineering Center. 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.

3. 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 PhD in Mechanical Engineering in 1987 from the University of Illinois at Urbana-Champaign. My PhD research was in the field of polymer processing.

4. 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.

5. 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 is dedicated to thermoforming. I also have extensive experience with behavior and characterization of thermoplastic polymeric materials.

6. I have also published over 300 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), *Plastics Testing and Characterization* (Hanser Publishers 2007), *Understanding Polymer Processing* (Hanser Publishers, 1st Edition 2010, 2nd Edition 2017), *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, and Russian. I am also the series editor for the Plastics Pocket Power Series of Hanser Publishers.

7. Over the years, my research and teaching have led to the issuance of seven 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-Nuremberg 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.

8. My academic and professional background and qualifications are further elaborated in my curriculum vitae attached as Exhibit A.

II. DOCUMENTS AND INFORMATION CONSIDERED IN FORMING OPINIONS

9. This declaration is based on my education, personal knowledge, and experience. I have also considered the materials and items listed below:

- U.S. Patent No. 10,946,630 (“the ’630 patent”) and U.S. Patent No. 10,870,263 (“the ’263 patent”), and each patent’s file history
- Publicly available information on 3M’s Clarity™ Aligners Flex
- 3M’s WO 2020/225657 PCT Application
- Publicly available and confidential information on Bay Materials’ Zendura™ FLX
- Differential Scanning Calorimetry and Microscopy Analysis of Multilayer Film Testing Report
- McCrone Associates, Inc., Testing Report
- Baur, E., Osswald, T.A., and Rudolph, N., *Plastics Handbook - The Resource for Plastics Engineers*, Hanser Publishers, Munich, (2019)
- Beer, F., Johnston, E. and DeWolf, J., *Mechanics of Materials*. 3rd ed., Boston: Mcgraw-Hill (2001)

- Hopmann, C., and Michaeli, W., *Extrusion Dies for Plastics and Rubber*, 4th ed., Hanser Publishers (2016) ¹

10. As requested, I provide my opinions based on the knowledge and understanding of a person of ordinary skill in the art as of the May 31, 2017, which I understand is the earliest priority claimed in the '630 and '263 patents.

11. In forming my opinions, I have reviewed the '630 and '263 patents and their prosecution history. I additionally have based my opinions on my professional and academic experience in the areas of organic plastics and polymers technology. I reserve the right to testify about these materials and experience. To the extent that I am provided additional documents or information, including any declarations produced by Defendants, I may offer further opinions. In addition to these materials, I may consider additional documents and information in forming my rebuttal opinions.

III. LEGAL PRINCIPLES

12. I am not a legal expert and I offer no opinions on the law. I have, however, been informed by counsel of the legal principles relevant to my infringement and validity analysis.

13. I have been informed that a patent includes a specification containing the written description of one or more embodiments of the invention, drawings, and figures, as well as one or more claims that point out and claim the subject matter of the invention. The claims define and measure the patent's scope. Each claim defines a separate invention.

14. I have been informed that a dependent claim incorporates each and every element of the claim from which it depends.

¹ The third edition was published in 2003, the second in 1992 and the first in 1984. All editions contain a chapter on extruding multi-layer sheets. Chapter 6 in the first edition was called "Extrusion Dies for Multiple Layers of Material (Coextrusion)."

15. I have been informed that infringement occurs when a party makes, uses, sells, or offer to sell a product within the United States that falls within the scope of an asserted claim of a patent. I have been informed that a proper infringement analysis involves a two-step process. The first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. Ultimately, the claims are construed by the Court. In the absence of a formal construction by the Court, however, I have applied the claims in accordance with my belief of how a person of ordinary skill in the art at the time of the invention, reading the patent and prosecution history, would have understood the claims. For the second step in the infringement analysis, the claims, as properly construed, are compared to the accused products. Each and every element of an asserted claim must be found (either literally or equivalently) in the accused product to find infringement. A product “literally infringes” a claim if it is possible to read each and every element of the claim on a corresponding element in the accused product.

16. I have been informed that even where no literal infringement exists, a product may nevertheless infringe a patent under the doctrine of equivalents. The doctrine of equivalents was judicially created to prevent pirating of another’s invention while avoiding literal infringement of the claim language. The doctrine of equivalents permits the effective scope of patent protection to be extended beyond the claim’s literal wording. The doctrine of equivalents applies when a product is insubstantially different from the invention as claimed.

17. I have also been informed that, when all of the claimed features are present in the accused product (literally or equivalently), the use of additional features in an accused product does not avoid infringement. It is not required that a claim read on the entirety of an accused product to infringe. If a claim reads on a part of an accused product, that is enough for infringement.

IV. A PERSON OF ORDINARY SKILL IN THE ART

18. I have been asked to consider these questions as of May 31, 2017, from the perspective of a person of ordinary skill in the art. In my opinion a person of ordinary skill in the art is defined as someone with at least a bachelor's degree in mechanical engineering, biomedical engineering, chemical engineering, materials science, or other similar type of engineering degree, and who would have taken courses in polymer processing or polymer materials science, combined with at least two years of experience in the field of design, manufacture, and processing of thermoformable polymer sheets for use in various applications, such as in orthodontic and dental appliances. More relevant experience could compensate for less education, and more relevant education could likewise compensate for less experience. This level of education and background provides the necessary training and understanding combined with at least two years of experience in the field of design and manufacturing of polymer orthodontic and dental appliances.

V. BACKGROUND

A. The Patents-at-Issue

1. Patent Disclosures

19. The '630 patent (Ex. B) was filed December 12, 2019, as U.S. Pat. App. No. 16/712,536 ("the '536 application) and is a continuation of U.S. Patent No. 10,549,511, filed December 5, 2018, which claims benefit to U.S. Provisional Application No. 62/512,789, filed May 31, 2017, and U.S. Provisional Application No. 62/590,627, filed November 26, 2017. The '263 patent was filed December 22, 2020, as U.S. Pat. App. No. 16/719,256 ("the '256 application), and it is a continuation-in-part application of U.S. Patent No. 10,549,511. I have been asked to consider the understanding of one of ordinary skill in the art as of May 31, 2017, which I understand is the earliest priority claimed in the '630 and '263 patents. My opinions also

would not change if I considered the understanding of one of ordinary skill in the art as of the filing dates of the applications for the '630 and '263 patents. The '263 patent (Ex. C) includes the same specification as the '630 patent, with some additional material included. For purposes of my discussion below, I have referred to the '630 patent specification unless otherwise indicated.

20. The '630 and '263 patents generally disclose multilayer polymeric sheet compositions for use in dental appliances. '630 patent at Abstract. The patents explained that polymeric materials used for orthodontic and dental appliances were constructed from single layer, bi-layer, or tri-layer materials, all of which exhibit limited functionality and performance deficiencies. *Id.* at 1:31-34. One such issue is that existing aligners have a very limited elastic range, typically between 4% to 7%, and when deformed these aligners can exhibit a rapid decay of recovery force. *Id.* at 4:57-59. Recovery force refers to the polymer's ability to relax the stresses within the sheet after application of a force or formation. It is an important property for orthodontic aligners because it affects the force the aligner can exert on a patient's teeth and the aligner's ability to continue exerting force over time. Attempts at improving aligners by using a thin outer elastomer layer resulted in aligners with reduced tooth movement accuracy and higher likelihood of staining. *Id.* at 4:63-5:2. Other issues with existing aligner technologies include: manufacturing difficulties, poor chemical resistance, low impact and tear strength, user discomfort, and potential damage to tooth roots. *Id.* at 5:4-25.

21. The '630 and '263 patent inventors solved the existing issues by creating aligners using inventive multilayer polymeric sheet compositions having hard or rigid outer layers made for contact with a user's teeth and softer inner layers comprised of an elastomeric material. *Id.* at 5:26-36. The "rigidity" of a material is described by the material's flexural modulus. *Id.* at 6:54-

59. That is, a material with a greater flexural modulus will be “more resistant to bending” and thus more rigid. *Id.* The outer layers of the inventive multilayer polymeric sheet compositions contain a thermoplastic polymer having a flexural modulus of between 1,000 MPa to 2,500 MPa, and the inner elastomeric layers contain elastomeric materials having a flexural modulus of between 50 MPa to 500 MPa. *Id.* at 5:26-36. The inventors discovered the claimed multilayer polymeric compositions are non-staining, have lower costs than traditional polymeric materials, exhibit improved elastic properties, and have greater environmental stress cracking resistance. *Id.*

22. The patent specifications describe multiple embodiments of the invention, including a three-layer sheet having two rigid outer layers and an elastomeric inner layer. *Id.* at 3:56-60. In another embodiment, the specifications explain that the polymeric sheet can, for example, have five layers: three rigid layers and two elastomeric layers. *Id.* at 5:37-39. In these embodiments, the multilayer polymeric sheet has two rigid outer layers, two elastomeric inner layers, and one inner rigid layer at the center, situated between the two elastomeric inner layers. *Id.* The different embodiments all contain rigid outer layer that, when formed into an orthodontic appliance, are in contact with the user’s teeth. *Id.* at 5:42-46. The inventive multilayer polymer construction significantly reduces stress cracking, thus expanding the range of materials that can be used in the sheet compositions or aligners. *Id.* at 6:2-6.

23. The patent specifications contain numerous examples demonstrating the surprising benefits of the claimed multilayer polymeric compositions. *See, e.g., id.* at 12:64-22:5. Example 1 describes the process for making the multilayer polymeric sheet compositions and the mechanical and optical properties of said multilayer polymeric sheets. *Id.* at 15:34-17:56. Three prior art materials—P1, P2, and P3—were included as comparative samples. *Id.* P1 is described as a commercial thermoformable aligner material supplied by Bay Materials, P2 is described as

an Eastman polyester sold under the trade name Eastar 6763, and P3 is described as Align's soft-hard-soft multilayer polymeric aligner material. *Id.* at 17:16-24. When comparing tear strength in Example 1, the patent specifications show that the inventive multilayer polymeric compositions "have significantly greater tear strength than comparable monolayer structures or prior art multilayer structured." *Id.* at 17:39-56. And when comparing durability in Example 4, the inventors discovered that an inventive multilayered composition recovered its shape from a stress cracking experiment more rapidly and completely than prior art materials P1, P2, and P3. *Id.*

24. Example 5 compared the mechanical properties and environmental stress cracking of various samples. *Id.* at 19:37-20:30. The inventors discovered that, despite the prior art teaching "that thermoplastic non-crystalline co-polyesters (PETGs and PCTGs) have poor environmental stress cracking resistance and are prone to rapid degradation when used as dental appliances," the inventive samples with hard polyester outer layers actually exhibited improved environmental resistance compared to prior art aligner materials. *Id.* at 19:40-20:23. This improvement is thought to be from the harder outer layer transferring strain induced stress to the elastomeric inner layer. *Id.* at 19:57-62. Having soft layers disposed between two hard polyester layers, the inventors created a multilayer polymeric sheet composition with unexpectedly beneficial properties for use in an aligner. *Id.* at 20:10-22.

2. Claims of the '630 and '263 Patents

25. The '630 patent (Ex. B) has 18 claims. I have focused my analysis on claims 1, 2, and 9. Claim 9 depends on claim 2, which in turn depends on claim 1. Claims 1, 2, and 9 of the '630 patent read as follows:

1. A polymeric sheet composition, comprising:
at least two outer layers A and C and an elastic inner layer B,
wherein one or more of the outer layers A and C is a polyester or
co-polyester having a flexural modulus of from about 1,000 MPa
to 2,500 MPa, the inner layer B is comprised of an elastomeric

material having a hardness from about A80 to D75, and the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa.

2. The polymeric sheet composition of claim 1, wherein the A, B and C layers of the polymeric sheet composition have a combined thickness of from about 250 microns to 2,000 microns.

9. A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 2.

26. The '263 patent (Ex. C) has 34 claims. I have focused my analysis below on claims 11, 12, and 18. Claim 18 depends on claim 12, which in turn depends on independent claim 11. Claims 11, 12, and 18 of the '263 patent read as follows:

11. A polymeric sheet composition, comprised of at least two rigid or hard outer layers A and C, at least two soft inner layers B and B', and at least a rigid or hard inner layer, D, wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.

12. The polymeric sheet composition of claim 11, wherein the polymeric sheet composition has a combined thickness of from about 250 microns to 2,000 microns and a flexural modulus of from about 500 MPa to 1,500 MPa.

18. A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.

27. The relevant claims of the '630 and '263 patents share many of the same polymer mechanical property limitations; however, claim 1 of the '630 patent recites polymeric sheet compositions with at least three layers, whereas claim 11 of the '263 patent recites polymeric sheet compositions with at least five layers.

B. Technological Background

28. As discussed above, the '630 and '263 patents relate to multilayer polymeric sheet compositions for use in dental aligners. My infringement analysis below requires an

understanding of polymer mechanical properties claimed in the patents, as well as an understanding of certain concepts in the field of polymer science.

29. The claims I have focused on recite flexural modulus of both the individual polymer sheet layers and the polymeric sheet composition as a whole. In my opinion, therefore, understanding the claims requires an understanding of both the difference between flexural modulus and elastic modulus and the effects of multiple polymer layers on the overall flexural modulus of the polymeric sheet composition.

30. The flexural modulus of a material refers to the ability of that material to bend and, in mechanical terms, is the ratio of stress to strain during flexural deformation. *See* Ex. D at 72-73. The elastic modulus of a material refers to the measure of stiffness of a material and is the ratio of stress to strain during deformation. *Id.* at 69-71. Flexural modulus is fundamentally equivalent to the elastic modulus of a material, but the two properties can, and often do, hold slightly different values when it comes to polymeric materials.

31. Elastic modulus can be determined through a tensile test, which produces a stress-strain curve. A tensile test is a relatively simple test conducted by pulling on a material. This process is used to determine how a material will behave under an axial stretching load. The image below further describes the test.

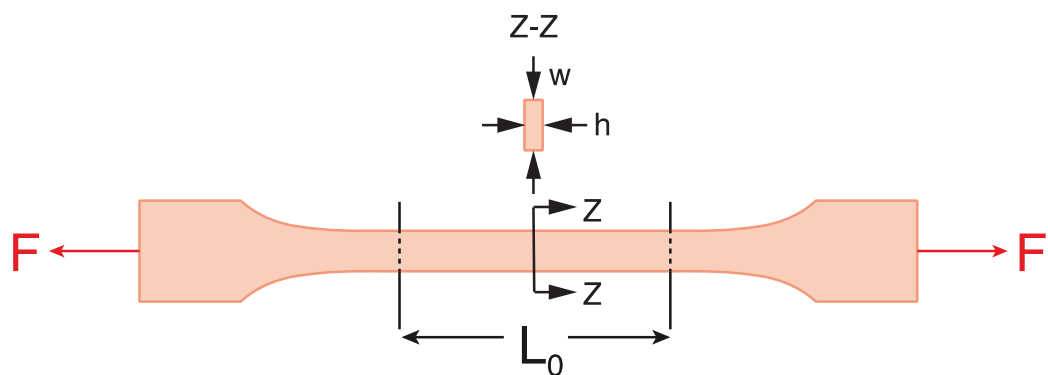


Figure 1: Tensile Test

32. A standard test used to measure the tensile modulus is the ASTM D638 standard, which gives instructions on how the test should be performed and defines the test specimen shape and dimensions.² The test provides information on the material in the form of a stress-strain curve. Stress is a physical quantity in a body subject to a deforming force measured as the internal force experienced by an object per unit of cross-sectional area. Strain is the measure of how much an object is stretched or deformed when a force is applied to the object, and it is described as a unitless ratio of the change in dimension to the initial dimension of the material. When a force acts on a body, it produces stress and strain in the material. For example, when one squeezes a football there is resistance. That resistance is the induced stress, while the change in dimension represents the strain. Both stress and strain can be plotted on an X-Y graph to produce a stress-strain curve, showing the changes in stress as strain increases. Various sections of a stress-strain curve describe different behaviors of materials and provide important information on the properties of the material being tested.

33. The test used to measure tensile modulus, depicted in Figure 1 above, involves stretching a sample of specified dimensions by applying force (F) in opposite directions. The tensile tester records the strain (ϵ) and the stress (σ). The instantaneous length (L) of the central portion of the test specimen is measured using an extensometer, and the length can be used to compute the strain according to the equation $\epsilon = \frac{L-L_0}{L_0}$. Strain thus is a ratio of the amount the sample stretches to its original length (L_0). The force (F) required to stretch the test specimen is measured using a load cell and is used to compute the stress according to the equation $\sigma = \frac{F}{wh}$, where w and h are the width and thickness of the test specimen's central region, respectively.

² The ASTM D638 standard test is also the test described in the '630 and '263 patents for measuring Plastics Tensile Strength. *See, e.g.,* '630 patent at 6:45-46.

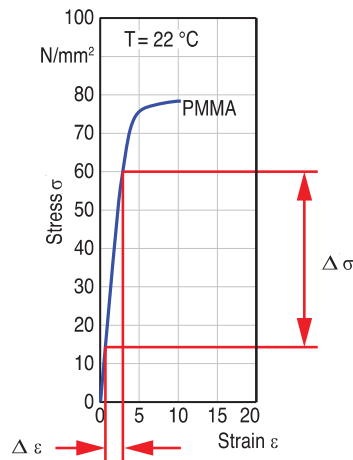


Figure 2: Stress-strain curve

34. The stress-strain curve produced during the tensile test can be used to determine a variety of other mechanical properties, including elastic limit, tensile strength, yield point, yield strength, elongation, and, as described above, the elastic modulus.

35. Flexural modulus is measured using the ASTM D790 standard test. That test uses a 3-point bending analysis on a rectangular beam of the material being tested, with two support points being placed on the bottom of the beam.³ With the beam sitting on the two support points, a force (F) is applied in the downward direction in between the two supports, creating a displacement (D) in the material, called deflection. The image below further illustrates the test.

³ The ASTM D790 standard test is also the test described in the '630 and '263 patents for measuring flexural modulus. *See, e.g.,* '630 patent at 7:14-16.

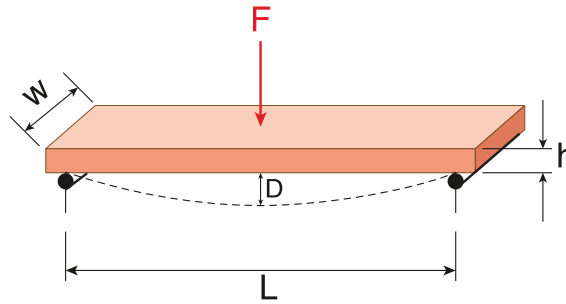


Figure 3: Flexural test

36. The flexural modulus is the ratio of stress and strain, which are calculated based on the sample dimensions, length between the supports, force applied, and displacement at the center due to the force applied. During bending, the test specimen is in compression on the top surface of the specimen and in tension on the bottom surface, with the stress varying linearly between the top and the bottom, as schematically depicted on the diagram below. As the figure below shows, when the test specimen is bent, the centerline maintains the original length of the beam, while the upper surface is shortened and the lower surface is lengthened somewhat. The stretched lower surface is in tension, while the compressed upper surface is in compression, as represented by the arrows in the diagram. Hence, the stress and strain must be computed at one location, namely the top or the bottom surface, in the middle of the beam between the two supports. The flexural strain at the outer surface in the center of the specimen is computed using $\epsilon_f = \frac{6Dh}{L^2}$, and the flexural stress is computed at the same location using $\sigma_f = \frac{3FL}{2wh^2}$. As mentioned above, the flexural modulus is the ratio of the two, which results in $E_f = \frac{FL^3}{4wDh^3}$.

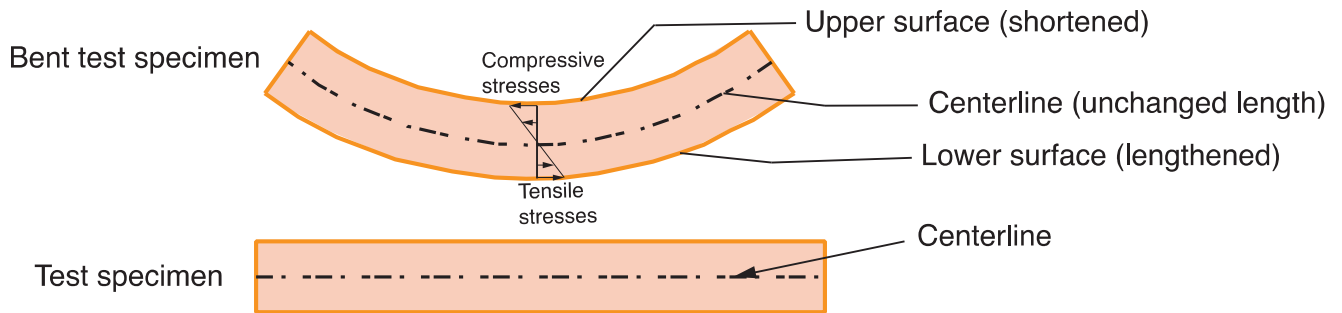


Figure 4: Schematic of stresses within a bent test specimen

37. Although the flexural modulus and elastic modulus can have slightly different values, in theory it is possible to determine the flexural modulus from the elastic modulus of a material, since both are defined by the ratios of stress to strain. The difference in the measurements arises from the fact that the tensile test is a simple test where the whole specimen's cross-section is subjected to a contact tensile stress, while the bending test subjects the specimen's cross-section to a stress distribution, as denoted in the diagram presented above.

38. The flexural and elastic modulus of a multilayer polymeric sheet composition can be determined using the test methods I described above; however, the flexural and elastic modulus of a multilayer polymeric sheet composition can also be calculated based on the modulus and thickness of each individual layer. The elastic modulus of a multilayer polymeric sheet composition is simply the average sum of the elastic modulus and thickness of each individual sheet. The flexural modulus of a multilayer polymeric sheet composition, however, will be affected more so by the properties of the outer layers. Thus, the flexural modulus of the multilayer polymeric sheet composition is greatly impacted by the location of each individual polymer sheet.

39. The flexural modulus of a multilayer polymeric sheet composition, such as shown in the figure below for a 5-layer system, can be computed using the thickness (h_i) and elastic modulus (E_i) of each layer i , where i varies from 1 to n (total number of layers, which in the figure below is 5).

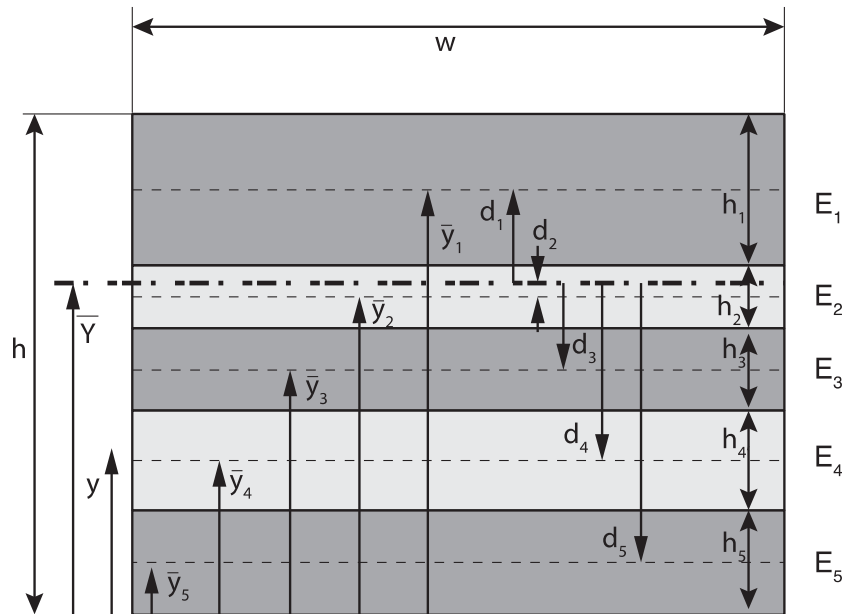


Figure 5: Multi-layer polymeric sheet

40. When using the ASTM D790 test to measure the flexural modulus of the multilayer system, the resulting modulus is an equivalent modulus E_f for a hypothetical single-layer system with that modulus. This equivalent modulus can be computed using the moduli and layer thicknesses of the multilayer system using the methodology presented below. See Ex. E at 230-233.

41. First, ratios of modulus to a reference modulus are calculated for each layer. If we choose layer 1 as the reference layer, the ratios are given by $n_1 = 1$, $n_2 = E_2/E_1$, $n_3 = E_3/E_1$, $n_4 = E_4/E_1$ and $n_5 = E_5/E_1$. Using this ratio, each layer is weighted according to its stiffness. If

the modulus of a specific layer is higher, the effect of that layer is weighted higher, and if it is lower, its effect is reduced accordingly.

42. Second, the ratios (n_i) and thicknesses (h_i) of each layer are used to calculate the location of the neutral axis ($\bar{Y}$) of the multi-layer system. The neutral axis is where the stress and strain are zero. In a symmetric multi-layer system and in a single layer system, the neutral axis is at the center of the sheet. The location of the neutral axis is computed using:

$$\bar{Y} = \frac{\sum n_i A_i \bar{y}_i}{\sum A_i} = \frac{w \sum n_i h_i \bar{y}_i}{w \sum h_i} = \frac{n_1 h_1 \bar{y}_1 + n_2 h_2 \bar{y}_2 + n_3 h_3 \bar{y}_3 + n_4 h_4 \bar{y}_4 + n_5 h_5 \bar{y}_5}{h}$$

43. Third, an equivalent area moment of inertia (I_e) is calculated, weighing each layer according to the ratio stiffness of each individual layer to the reference stiffness, and the distance between the center of the layer and the neutral axis, d_i , using:

$$I_e = \sum n_i A_i d_i^2 + \sum n_i I_i = w \sum n_i h_i d_i^2 + \frac{w}{12} \sum n_i h_i^3$$

44. Finally, the bending stiffness of the multi-layer sheet is computed using the reference stiffness:

$$H_{zz} = E_1 I_e$$

45. The bending stiffness can also be interpreted as a composite bending stiffness, as it would be measured using the ASTM D790 bending test, which would interpret the flexural modulus of the multi-layer sheet as the modulus of a single layer hypothetical system, using:

$$H_{zz} = E_f I$$

46. In the above equation, I is the area moment of inertia of a single layer sheet with a total thickness equal to the thickness of the multi-layer system, and is calculated using:

$$I = \frac{w h^3}{12}$$

47. Accordingly, the flexural modulus of a multilayer polymeric sheet composition can be estimated from the known properties of individual sheet compositions or from the measured bending stiffness of the multilayer polymeric sheet itself. In contrast to the flexural modulus, the elastic modulus of the composite sheet can be estimated using the following equation:

$$E = \frac{(E_1 h_1 + E_2 h_2 + E_3 h_3 + E_4 h_4 + E_5 h_5)}{h}$$

48. Shore hardness is another mechanical property claimed in the '630 and '263 patents. The device used to measure the hardness is called a durometer. The principle of the various hardness tests is similar, where an indenter is pressed into the material by a spring. The depth of penetration of the indenter into the test sample is related to the hardness of the sample. The figure below presents a photograph of a durometer in the zero position, that is, with a fully extended indenter, and schematics of a Shore A hardness durometer. The zero position, shown in the photograph, and the schematic of the durometer, shown in the middle of the figure, signifies a Shore A hardness of 0 (zero). The middle diagram depicts the durometer with the fully extended indenter protruding from the base. If 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 somewhat. The right side of the figure presents a schematic of an indenter pushing into the sample, with the somewhat compressed spring. *See Ex. D at 74.*

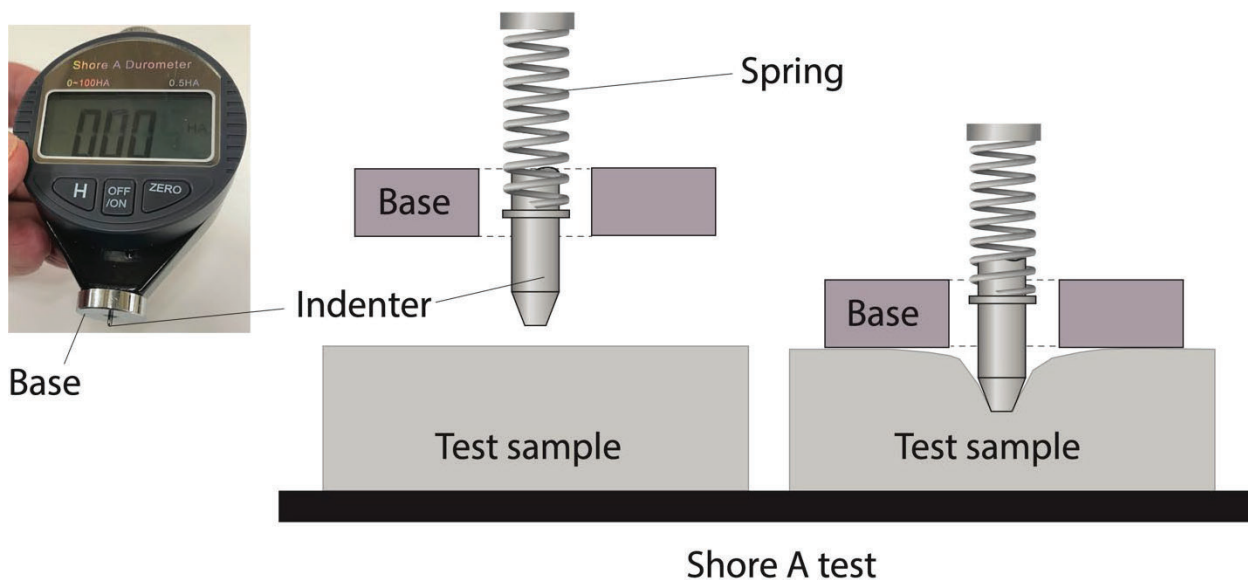


Figure 6: Photograph and Schematic of a Shore A Durometer

49. A Shore hardness of A 0 corresponds to a softer material, while a Shore hardness of A 100 describes a harder material. *See* Ex. F. The image below, taken from the same website, provides an idea of the Shore hardness scale:



Figure 7: Shore Hardness Scale

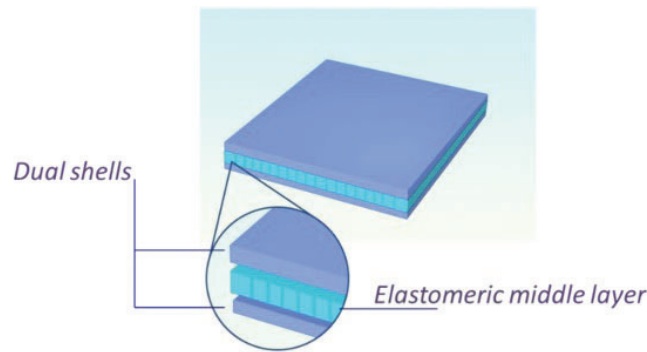
50. The process of manufacturing a multilayer polymeric sheet composition is described in the '630 and '263 patents. *See, e.g.*, '630 patent at 12:25-47. In my experience, the process of manufacturing a three-layer polymer compared to a five-layer polymer is substantially similar. A person of ordinary skill in the art would know, for example, that coextruding a 3- or 5-layer system is simply a matter of die design. A process to manufacture multi-layer systems would have the same number of extruders as the number of material types present in the multi-layer sheet. For example, manufacturing a 5-layer sheet where layers 1, 3, and 5 are made of one material, and layers 2 and 4 are made of a second material, would require 2 extruders. That is the same number of extruders that would be required to manufacture a 3-layer sheet, where the central core is made of one material and the outer layers are made of a second material. A person of ordinary skill in the art would know that the most important part that changes between a 3- and 5-layer system would be the design of the die. *See Ex. G at Chapter 6 - Coextrusion Dies for Thermoplastics.*⁴

C. Bay Materials and Zendura™ FLX

51. Bay Materials is a polymer research and development and product development company. *See Ex. H.* Bay Materials' flagship product covered by the claims of the '630 and '263 patents is sold under the trade name Zendura™ FLX. *See Ex. I.* Zendura™ FLX is used in clear aligners and was designed as an improvement on Bay Materials' previous Zendura™ A single-layer polymeric material. *See Ex. J at 1.* More specifically, Zendura™ FLX was designed with a unique 3-layer construction to improve on existing tooth-moving technologies while still reducing the level of discomfort to patients during use. *Id. at 1-2.* In my opinion, Zendura™ FLX falls within the scope of at least one claim of both the '630 and '263 patents.

⁴ The book *Extrusion Dies for Plastics and Rubber* has been a widely used reference available to the person of ordinary skill in the art since 1984.

52. Zendura™ FLX is a multilayer polymeric composition with two hard or rigid polymeric outer layers and a soft elastomeric middle layer, otherwise referred to as a “hard-soft-hard” structure. *See id.* The image below, from the zenduradental.com website, shows the structure of the hard-soft-hard configuration of the polymeric sheet:



53. The soft elastomeric inner layer of Zendura™ FLX is a thermoplastic urethane, whereas the hard outer layers of the Zendura™ FLX are co-polyesters. Ex. K at 2. [REDACTED]

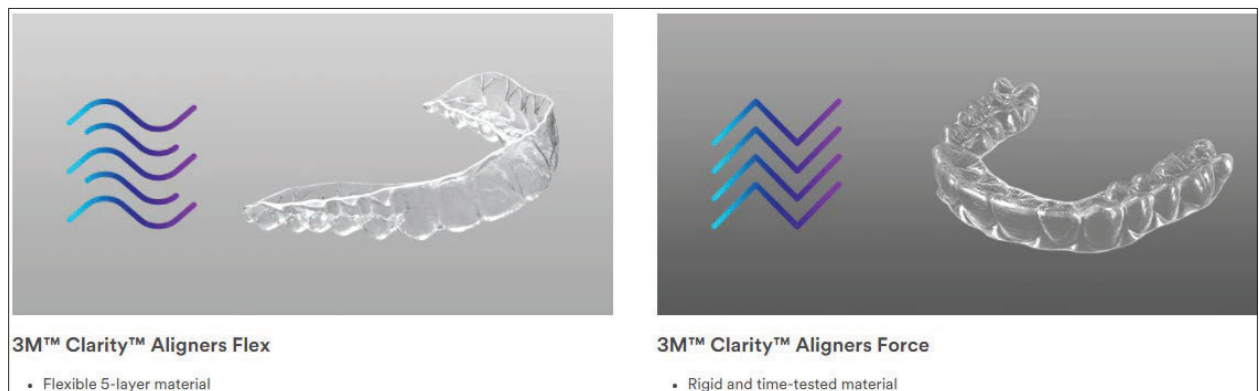
54. Zendura™ FLX is sold as a multilayer polymeric sheet having a thickness of approximately [REDACTED] microns. *See* Ex. N at 2. The tensile modulus of the overall Zendura™ FLX multilayer polymeric sheet is approximately [REDACTED] when measured using ASTM D638, or approximately [REDACTED], and the flexural modulus of the overall sheet is approximately [REDACTED] when measured using ASTM D790, or approximately [REDACTED]. *Id.*

55. In my opinion, Zendura™ FLX falls within the scope of at least claim 1 of the '630 patent and claim 1 of the '263 patent. More specifically, as recited in claim 1 of the '630 patent, Zendura™ FLX is a polymeric sheet composition comprising two co-polyester outer layers having a flexural modulus of [REDACTED], which is between 1,000 MPa to 2,500 MPa, and

an elastomeric inner layer [REDACTED] which is between about A80 to D75. The overall multilayer polymeric sheet has a flexural modulus of between 750 MPa and 2,000 MPa. In addition, as recited in claim 1 of the '263 patent, Zendura™ FLX is a polymeric sheet composition comprising two thermoplastic polymer outer layers having a flexural modulus of [REDACTED] which is between 1,000 MPa to 2,500 MPa and an elastomeric inner layer having a [REDACTED] which is about A60 to D95.

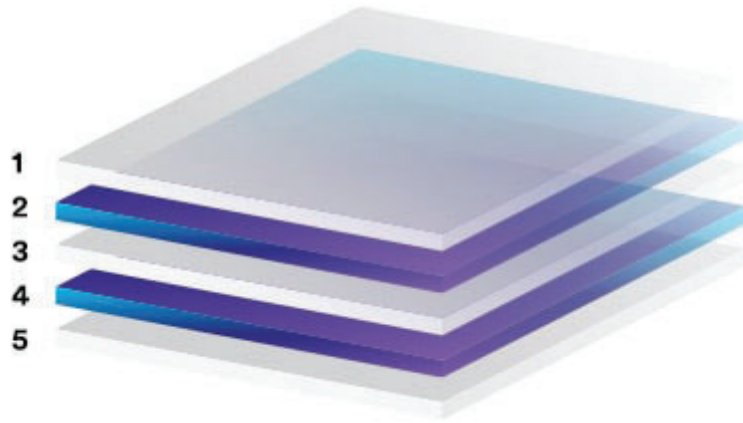
D. 3M and Clarity™ Aligners Flex + Forces

56. Earlier this year, 3M began marketing an orthodontic clear aligner known as the 3M Clarity™ Aligners Flex (“Flex Aligner”). *See* Ex. O. I understand the Flex Aligner is used in treatment alongside the 3M Clarity™ Aligners Force (“Force Aligner”). *See* Ex. P. Both the products are shown in the image below:



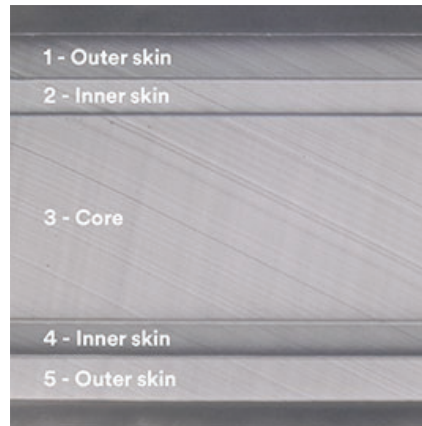
57. Although I understand the products are sold together based on 3M’s website, the focus of my infringement analysis is on the Flex Aligner.

58. The Flex Aligner is described as an orthodontic device made from a “[p]roprietary 5-layer blend of materials.” Ex. O at 1. According to the 3M website, the 5-layer material includes “[o]uter layers [that] resist staining and scratching” and “[i]nner layers [that] provide flexibility and resilience.” *Id.* The 3M website then concludes that the “[o]verall structure provides durability even with reduced thickness.” *Id.* The following image is provided by 3M:



59. From the above image, the descriptions of the material on 3M's website, and the additional available evidence, it is apparent to me that layers "1," "3," and "5" are made of the same materials and layers "2" and "4" are made of the same material.

60. 3M further explains that each material was chosen based on the desired properties: the outer layers should resist staining, scratching, and discoloration, and the inner layers should have cracking and tearing resistance, force persistence, flexibility, and resilience. *See* Ex. Q at 2. Consistent with the above image, 3M appears to have chosen a multilayer polymeric composition with at least two hard outer layers and two soft inner layers. *Id.* The image below, provided by 3M, shows the structure of the 5-layer composition, and further supports my conclusion that the multilayer polymeric composition is made of two separate materials: one material for layers "1 - Outer skin," "5 - Outer skin," and "3 - Core," and another material for layers "2 - Inner skin" and "4 - Inner skin":



61. 3M also explains that it “settled on a family of copolyesters as the materials” used in the 5-layer composition. *Id.* at 3. According to 3M, the combination of different polymers allowed it to develop a thin yet durable material, allegedly thinner than the Force Aligner material, as shown in the image below:



62. In addition, 3M claims that its Flex Aligner maintains a desired force over the course of weeks. *Id.* Specifically, the Flex Aligner allegedly “has excellent force persistence” and in fact retains “75% of its initial force” over a period of two weeks. *Id.* 3M provides the following graph demonstrating the elastic modulus of both its Flex and Force Aligners:



63. Thus, according to 3M’s website, the Flex Aligner has an elastic modulus of approximately 1.3 GPa. *Id.*

64. In addition to the information on 3M’s websites, I understand that 3M has filed patent applications describing multi-layer aligners. In particular, 3M filed a PCT application published as WO 2020/225657 (“the ’657 application”), Ex. R, titled “Multi-Layered Dental Appliance,” relating to 5-layer polymeric sheet compositions for use in dental aligners. The ’657 application is consistent with 3M’s advertising, and discloses, for example, appliances having “at least 5 polymeric layers, with softer polymeric interior layers disposed between a harder polymeric core layer and two harder polymeric outer layers.” *Id.*, ¶ [0009]. The ’657 application further discloses that the “multiple layers of high flexural modulus and low flexural modulus polymeric materials [] improve patient comfort while maintaining an acceptable level of force persistence” and, when combined, also provide “good stain resistance.” *Id.* ¶ [0008]. It further discloses that the “hard core layer can enhance dimensional stability, while the softer middle layers positioned close to the outer skin layers can improve patient comfort and strain recovery.” *Id.* ¶ [0009].

65. The ’657 application contains several examples of 5-layer films used to form dental appliances. *See, id.*, ¶¶ [0092]-[0097]. Of particular interest is Example 4. This example

discloses a “5-layer CBABC (MX710/ECDEL /MX710/ECDEL9967/ MX710) film” having an “overall sheet thickness” of 0.625 mm. *Id.*, ¶ [0097]. As I discussed above, the Flex Aligner is advertised as having a thickness of 0.625 mm. Additionally, Example 4 is described as using Eastman Tritan MX710 copolyester for the outer and core layers and Eastman Ecdel 9967, “copolyester ether elastomer from Eastman Chemicals,” for the inner layers. *Id.* Based on 3M’s own description of the Flex Aligner and my understanding of the materials disclosed in the ’657 application, it is my opinion that Example 4 of the ’657 application corresponds to the Flex Aligner.

66. The ’657 application describes the mechanical properties of the various polymers that can allegedly be used in the disclosed multilayer products. *Id.* at Table 1. For example, the ’657 application lists the flexural modulus of MX710 as 1.55 GPa. *Id.* The ’657 application also lists Tritan TX1000—which is closely related to TX1001—as having a flexural modulus of 1.55 GPa. *Id.* In fact, the ’657 application lists MX710 and TX1000 as having identical mechanical properties. *Id.* Thus, to the extent the Flex Aligner includes MX710, TX1000, or TX1001 as the “hard” layer, my analysis would not change.

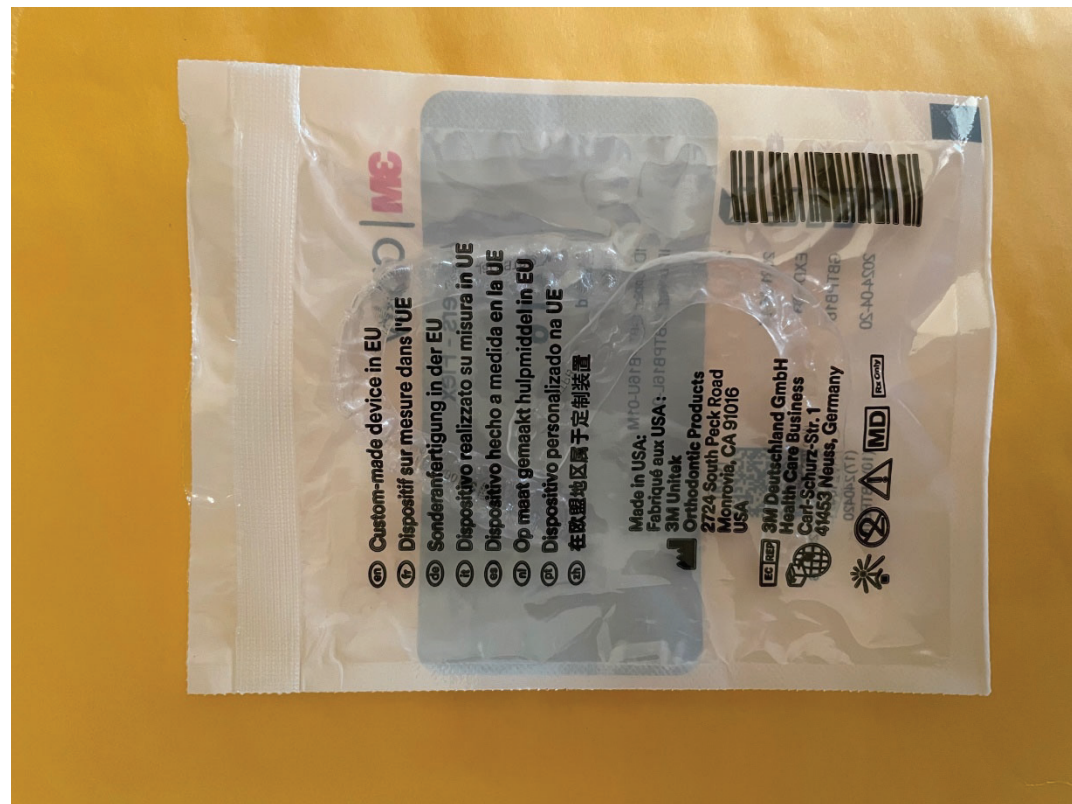
67. Both Eastman Tritan MX710 and Eastman Ecdel 9967 have publicly available technical specification sheets, which I have included as Exhibits M and S. Tritan MX710 is reported to have a flexural modulus of approximately 1,550 MPa (or 1.55 GPa) as measured according to ASTM D790. *See* Ex. M. Ecdel 9967 is reported to have a flexural modulus of approximately 150 MPa as measured according to ASTM D790 and a Shore hardness of A95 or D50. The tensile modulus was reported as 170 MPa for Ecdel 9967 and 1,550 MPa for Tritan MX710 as measured according to ASTM D638. *See* Exs. M & S.

VI. TESTING

68. To determine infringement of the '630 and '263 patents by the Flex Aligner, I oversaw testing to identify the polymers present in each layer of the appliance. First, I oversaw differential scanning calorimetry (DSC) testing conducted in my own laboratory ("DSC Testing"). Second, I oversaw microscopy and micro-Fourier transform infrared (FTIR) spectroscopy testing conducted in the laboratory of McCrone Associates, Inc., located in Westmont, IL ("McCrone Testing"). The results of the testing are summarized below.

A. Samples

69. For both the DSC Testing and McCrone Testing, samples of the Flex Aligner, Force Aligner, and three Eastman polymer samples Tritan MX710, TX1001, and Ecdel 9967 were all tested. I took receipt of the Flex Aligner and Force Aligner in the mail from Ashley Dial of the Finnegan law firm. Images of the sample packaging received from Finnegan are shown below:



70. I took receipt of the Eastman samples from Diyun Huang of Bay Materials. I understand Bay Materials sent some Eastman samples to McCrone for the McCrone Testing described below and the remaining samples to my lab for the DSC Testing described below.

B. DSC Testing

71. Prior to conducting the DSC testing, I developed a protocol to be used by my laboratory. The protocol is attached as Exhibit T. I oversaw all testing conducted.

72. In my lab, DSC testing was conducted on a sample of the Flex Aligner, Force Aligner, and three Eastman polymer samples. Those samples were Tritan MX710, TX1001, and Ecdel 9967. As discussed above, Tritan MX710 and Ecdel 9967 are the two copolyesters listed in Example 4 of the '657 application. *See supra* § V.D. TX1001 is related to TX1000, another copolyester described in the '657 application. *See* Ex. R, ¶ [0078]. Based on the publicly available information for the Flex Aligner and the descriptions in the '657 application, including in Example 4, it was hypothesized that the Flex Aligner consists of three Tritan MX710 layers (outer layers and core layer) and two Ecdel 9967 layers (inner layers). Thus, I compared the DSC of the Flex Aligner to the DSC of the Eastman polymers to determine if any of the melt profiles matched.

73. The samples were prepared and tested accorded to the protocol. *See* Ex. T. The results of the testing are described in detail the testing report, attached as Exhibit U.

74. The two figures below present thermograms for 5 different tests—the three Eastman materials Ecdel 9967 (Ecdel), Tritan MX710 (MX710), and TX1001, as well as the Flex Aligner (Upper-Dental) and the Force Aligner (Lower-Dental). The DSC curves in the two graphs were measured at heating rates of 5 K/minute and 10 K/minute. The thermograms presented in both figures all represent the behavior during the second heating. The standard form of conducting DSC tests is to heat a sample at a constant rate, then cool the sample to the starting

temperature. This erases the thermal history a material underwent before the test. Then, the sample is heated again to a high temperature, a heating processes referred to as “second heating.” After the second heating the sample is cooled a second time until it reaches the initial temperature. This DSC measurement protocol assures that all the samples have the same thermal history, allowing a fair comparison between samples. *See* Ex. U at 1-8.

75. Both graphs, with 5 K/minute and 10 K/minute heating rates, show that the Ecdel sample exhibits two melting peaks, a small one at around 90 °C, likely from a smaller component of the copolyester, and a larger one at around 210 °C which corresponds to the melting of the bulk material. The MX710 and TX1001 show a glass transition temperature around 110 °C. The peaks shown after the glass transitions reflect overshoot due to the fast heating rate. The multilayer (Upper-Dental) clearly shows a melting event at the temperature that corresponds to Ecdel 9967. Furthermore, the overshoot after the glass transition temperature of the multilayer (Upper-Dental) matches closely with the peak of the MX710 sample in the 10 K/minute test.

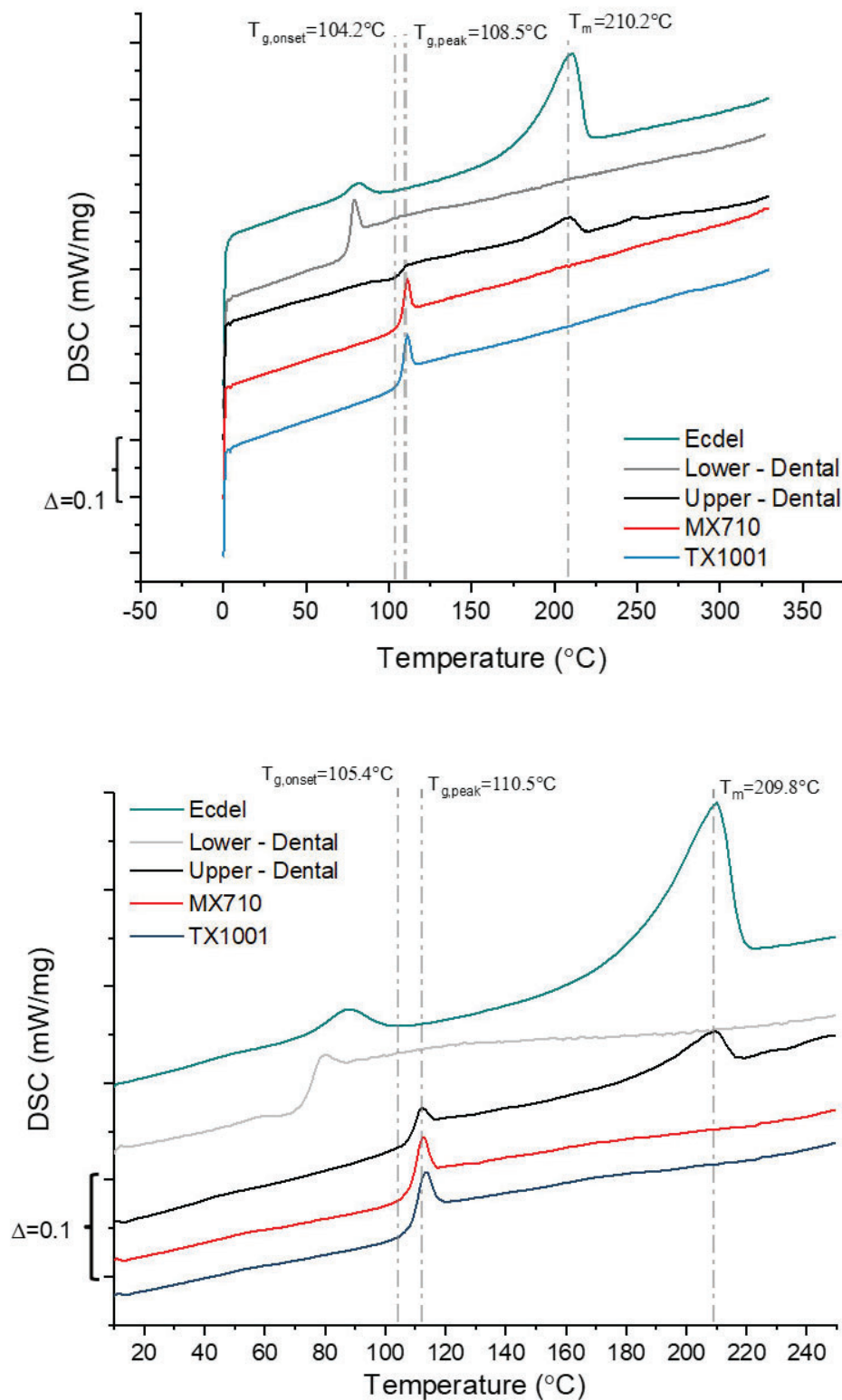


Figure 8: Thermograms of the 5 materials performed at 5 (top) and 10 (bottom) K/minute

76. The thermogram data was analyzed and interpreted using Netzsch's analyzing software, Proteus[®]. *Id.* at 1. The graph presented below clearly shows that the melting temperatures of Ecdel 9967 matches well the melting peak observed with the Flex Aligner sample at both heating rates of 5 K/minute and 10 K/minute. In this analysis, the melting temperature was defined as the temperature at the peak of the thermal event. All samples showed a melting temperature of around 210 °C. It should be noted that the error bars of the experiments performed at the lower heating rates of 5 K/minute are so small ($\pm 0.1^{\circ}\text{C}$) that they are not visible in the diagram.

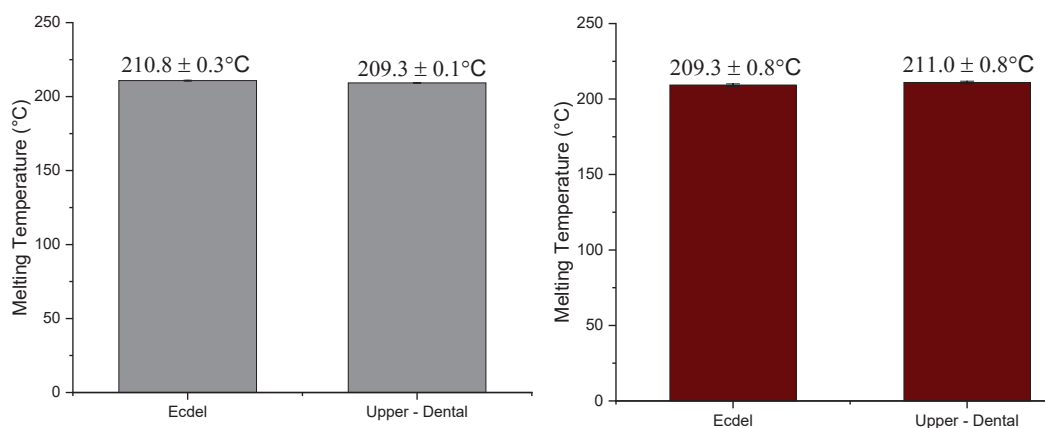


Figure 9: Melting Temperatures for Ecdel 9967 (left) and the Flex Aligner (Upper-Dental) samples measured at 5 (left) and 10 (right) K/minute

77. The graph presented below shows how the MX710 samples have the most similar glass transition temperatures of 103.6 and 103.1 °C, respectively, for the 5 K/minute heating rate. Similarly, the MX710 and Flex Aligner samples have the most similar glass transition temperatures of 110.5 and 110.9 °C, respectively, for the 10 K/minute heating rate. It should be noted that while the TX1001 samples' glass transition temperatures are somewhat different than the MX710 material and the glass transition observed with the Flex Aligner samples, TX1001 is

also a viable material that could be found within the Flex Aligner. Both MX710 and TX1001 are amorphous copolyesters from Eastman Chemical with similar mechanical properties and glass transition temperatures.

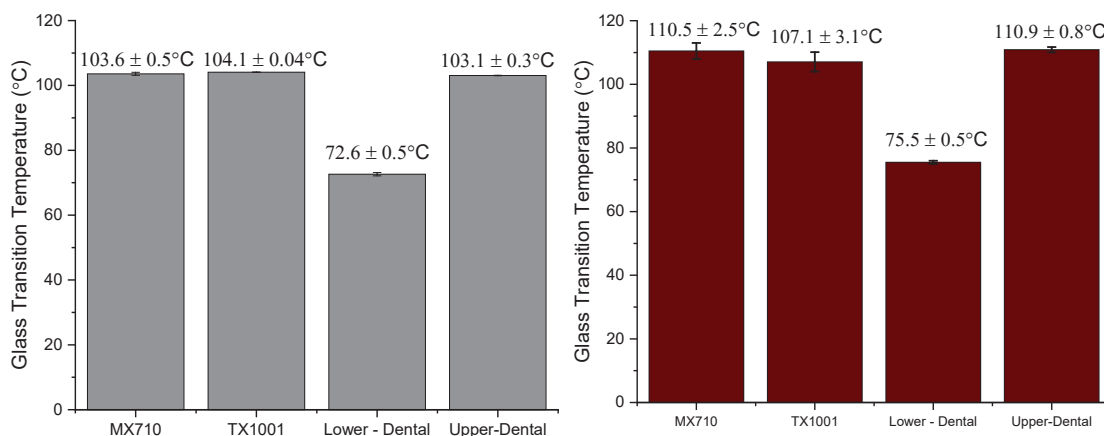


Figure 10: Glass Transition Temperature for four samples measured at 5 (left) and 10 (right) K/minute

78. The 5 K/minute and 10 K/minute tests above were all repeated three times to assure accuracy. *Id.* at 1. In all cases the tests provided similar results, with normal experimental variability between the tests, demonstrated by the small error bars in the two figures above. The thermographs presented in the figure below, corresponding to samples taken from the Flex Aligner (Upper-Dental), compare the heating rates of 5 K/minute and 10 K/minute. It is clear that both curves show approximately the same glass transition temperature and the same melting event. The area between a baseline and the phase change peak corresponds to the heat of fusion of the Flex Aligner samples. It is clear that both rates, taken with two separate samples, result in nearly the same heat of fusion of 4.33 and 4.353 J/g for the 5 K/minute and 10 K/minute samples, respectively.

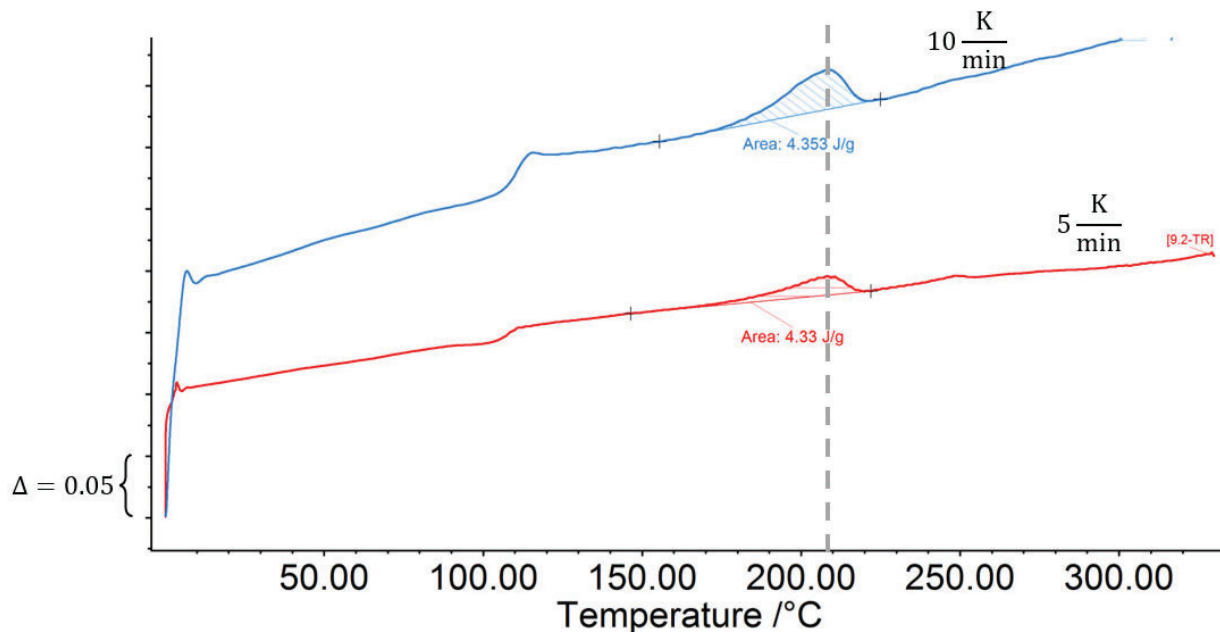


Figure 11: Thermograms that correspond to Flex Aligner samples taken at 5 and 10 K/minute heating rates

79. The graph below presents the thermograms of Ecdel 9967 samples taken at 5 and 10 K/minute heating rates.

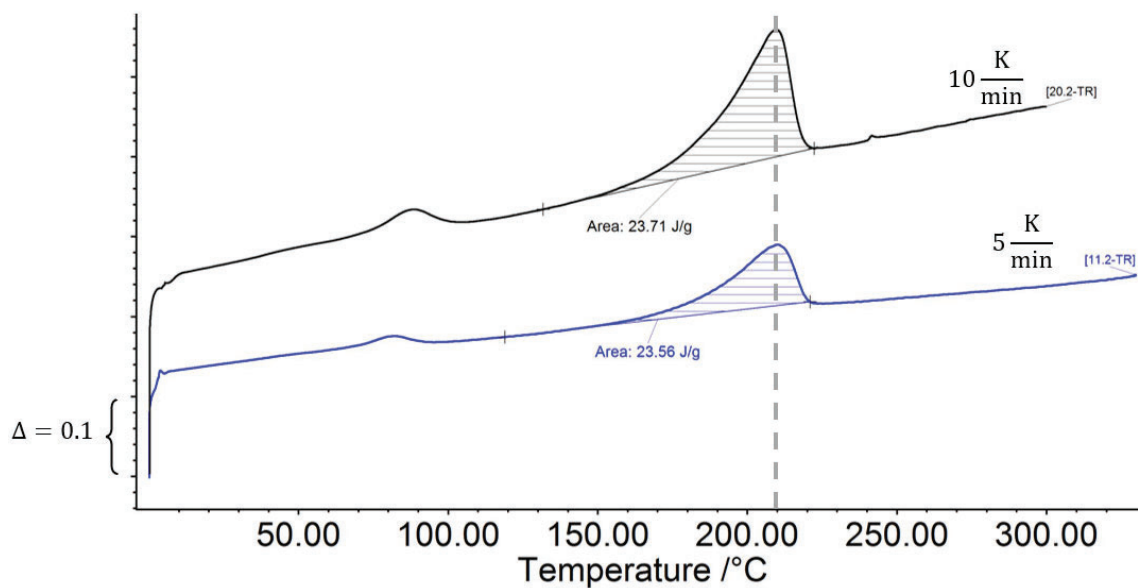


Figure 12: Thermograms of Ecdel 9967 taken at 5 and 10 K/minute heating rates

80. Again, the heat of fusion for both samples is nearly the same: 23.56 and 23.71 J/g for 5 K/minute and 10 K/minute heating rates, respectively. If we use the heat of fusion of the

Flex Aligner samples and divide them by the heat of fusion of the Ecdel 9967 samples, we can estimate the fraction of Ecdel 9967 present in the Flex Aligner samples. For the 5 K/minute samples the fraction is predicted to be around 18.3% for both heating rates. *See id.* at 10. This is congruent with the micrograph from the McCrone Testing, where the fraction of the two inner layers 2 and 4 is approximately 21% of the total thickness. *See infra* § VI.C. Moreover, the two micrographs shown in the DSC Report, which correspond to the crown tip and the gum line regions, result in an average layer 2 and 4 fraction thickness of 21.5%. *See Ex. U* at 8-9. It should be noted that using the DSC to predict amounts of a certain component present is only a rough estimate. However, the DSC measurements point to the fact that about 20% of Ecdel 9967 is present in the Flex Aligner. *Id.* at 8-11.

81. In my opinion, the Flex Aligner glass transition temperature at approximately 105 °C is sufficiently close to the Tritan MX710 glass transition temperature such that, when considered in combination with the other evidence discussed below, there is likely Tritan MX710 present in the Flex Aligner. Accordingly, in my opinion based on the available evidence, outer layers 1 and 5 and core layer 3 are made from Tritan MX710 or a polymer blend primarily consisting of Tritan MX710 such that their properties would be governed by Tritan MX710. Similarly, in my opinion, the Flex Aligner melting temperature at around approximately 210 °C is sufficiently close to the Ecdel 9967 phase transition temperature such that, when considered in combination with the other evidence discussed below, there is likely Ecdel 9967 present in the Flex Aligner. In addition, the heat of fusion found in the Flex Aligner sample is a fraction of the heat of fusion of the Ecdel 9967 material congruent with the fraction of the layer thickness that corresponds to layers 2 and 4 of the 5-layer system, further confirming that the two inner layers

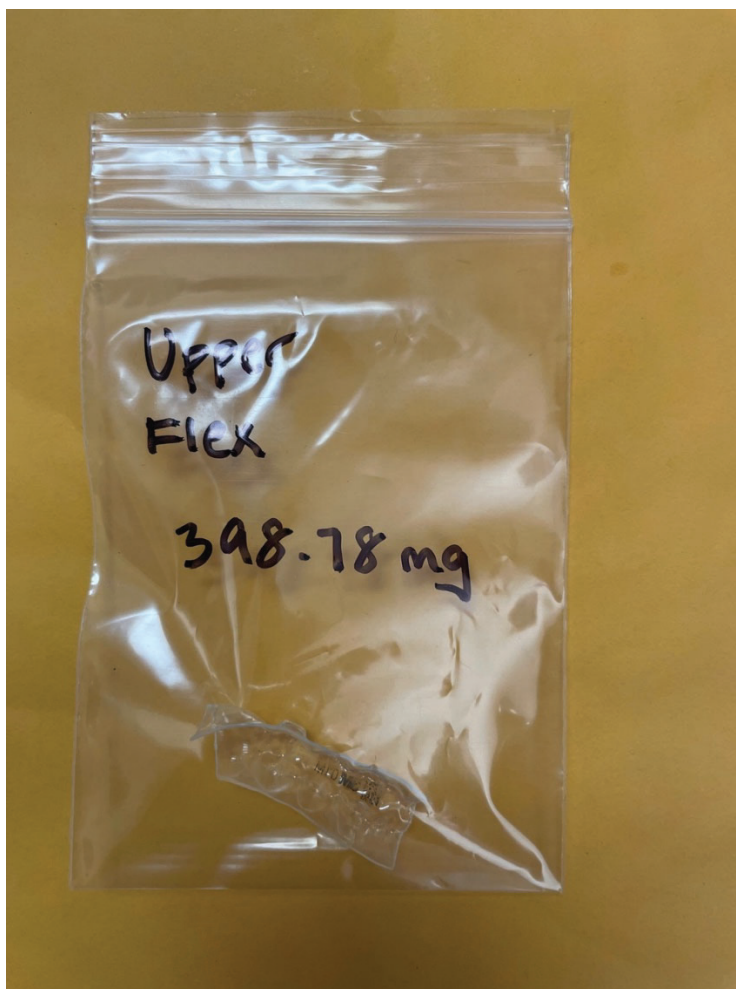
are made from Ecdel 9967 or a polymer blend primarily consisting of Ecdel 9967 such that their properties would be governed by Ecdel 9967.

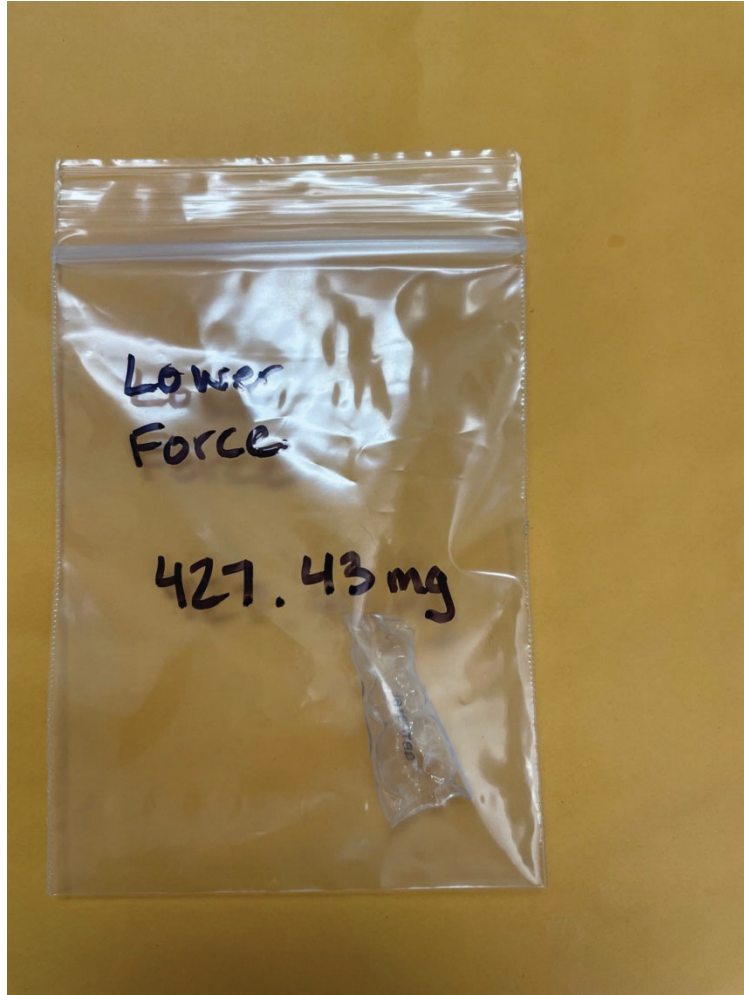
C. McCrone Testing

82. To further confirm the composition of the polymer layers in the Flex Aligner, I developed the protocol shown in Exhibit V for McCrone to use.

83. Part of the McCrone testing was conducted on the Flex and Force Aligners, as well as the three Eastman polymers. The FTIR spectra of the Flex Aligner was compared to the FTIR spectra of the Eastman polymers to determine if any of the FTIR spectra matched.

84. I prepared samples of the Flex and Force Aligners according to the protocol and sent the prepared samples to Mary Stellmack at McCrone. Images of the prepared samples I sent to Mary Stellmack at McCrone are shown below:





85. McCrone ran the FTIR and microscopy tests according to the protocol I developed. *See* Ex. V. The results of the testing are described in detail in the testing report, attached as Exhibit W.

86. The McCrone testing includes micrographs taken of three different cross sections of the Flex Aligner. *See* Ex. W at 2-4, 5-12, Figs. 1-8. The B cross-section of the Flex Aligner sample is shown below, photographed at 200X using a polarizing light microscope. *Id.* at 11, Fig. 7. The total thickness and thickness of each layer was determined using a calibrated ocular scale. *Id.* at 3. The image below shows the B cross-section micrograph:

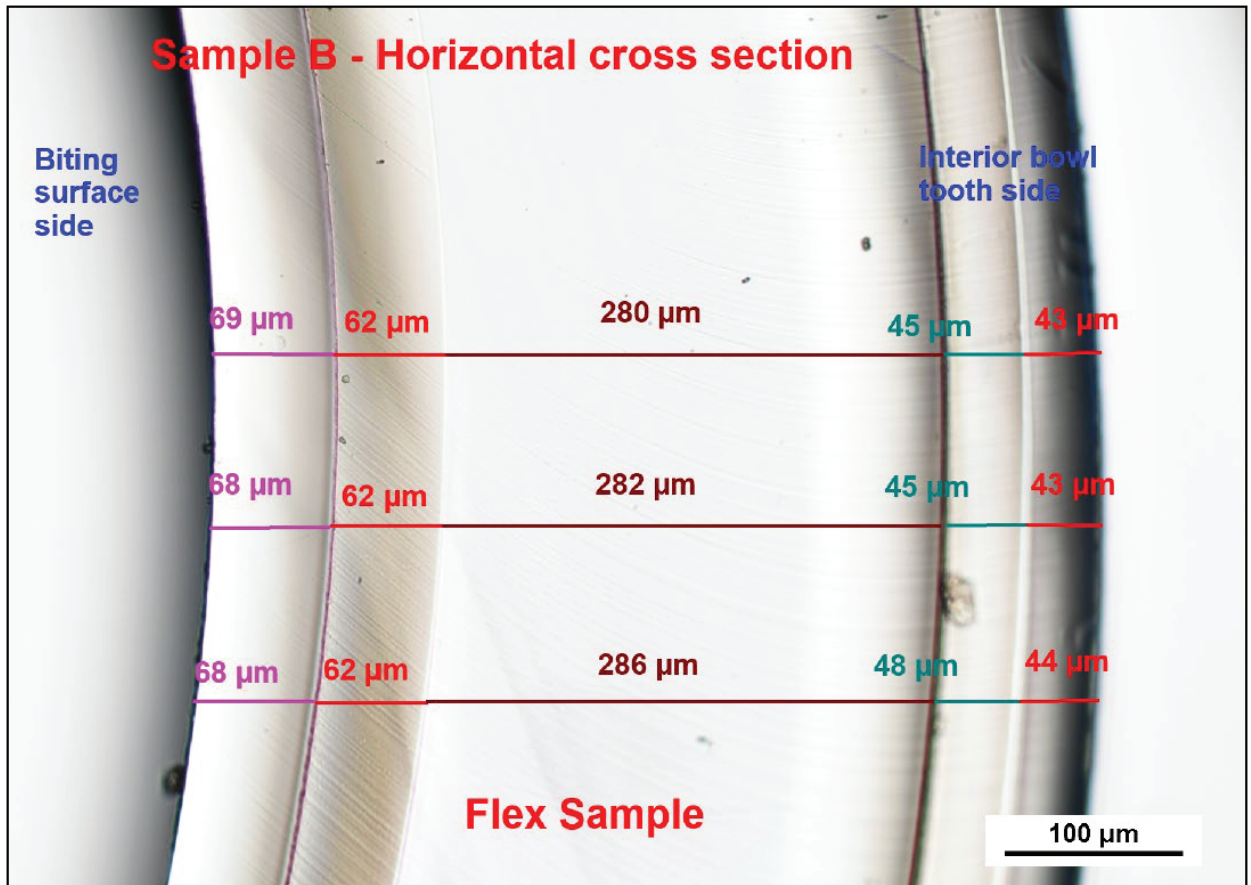


Figure 13: Five-Layer Sheet Micrograph taken from the Accused Product

87. As seen in the image above, the total aligner thickness was measured three different times. The overall thickness of the cross section was measured at 499 microns, 500 microns, and 508 microns, depending on the location of the measurement. All thickness measurements can be seen in the table summarized in the McCrone Report. *Id.* at 2, 4.

88. Next, the FTIR spectra for each sample was determined. Portions of each of the five layers from the Flex Aligner, as well as for the Force Aligner and Eastman samples, were pressed onto a KBr crystal for transmission micro-FTIR. *See id.* at 4. The FTIR spectra for the Tritan MX710, Ecdel 9967, and TX1001 samples are shown in Figures 9, 10, and 11 of the McCrone Report, respectively. *Id.* at 13-15. According to the McCrone Report, the FTIR spectra for Tritan MX710 and Tritan TX1001 are “not distinguishable” from each other. *Id.* at 2, 4.

89. The FTIR spectra for each of the five layers in the Flex Aligner are shown in Figure 12-16 of the McCrone Report.⁵ *Id.* at 16-20. The McCrone Report concludes that Flex Aligner layers “1,” “3,” and “5” are “[v]ery similar to both Tritan samples.” *Id.* at 2, 4. Similarly, the McCrone Report concludes that Flex Aligner layers “2” and “4” are “[v]ery similar to Ecdel 9967.” *Id.* I agree. I have reproduced from the McCrone Report Figure 9, showing the FTIR spectrum of Tritan MX710, and Figure 12, showing the FTIR spectrum of layer 1, below.

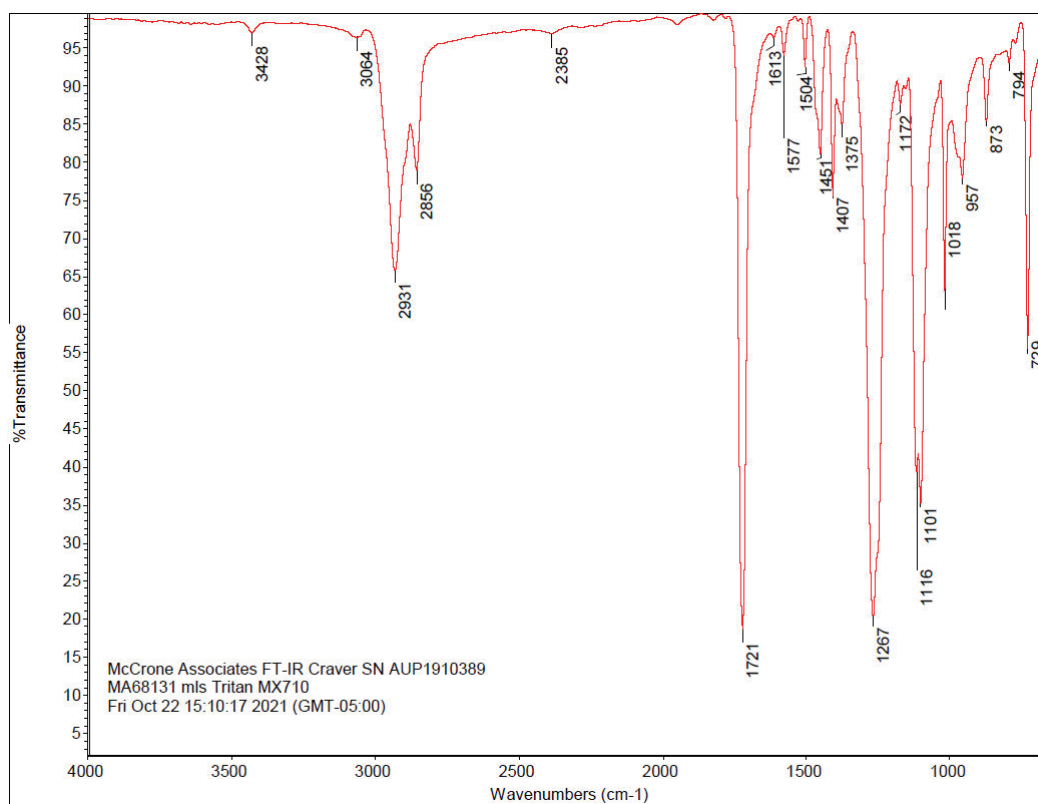


Figure 14: Tritan MX710 FTIR Spectrum

⁵ The FTIR spectrum for the Force Aligner can be seen in the McCrone report. *See* Ex. W at 21, Fig. 17.

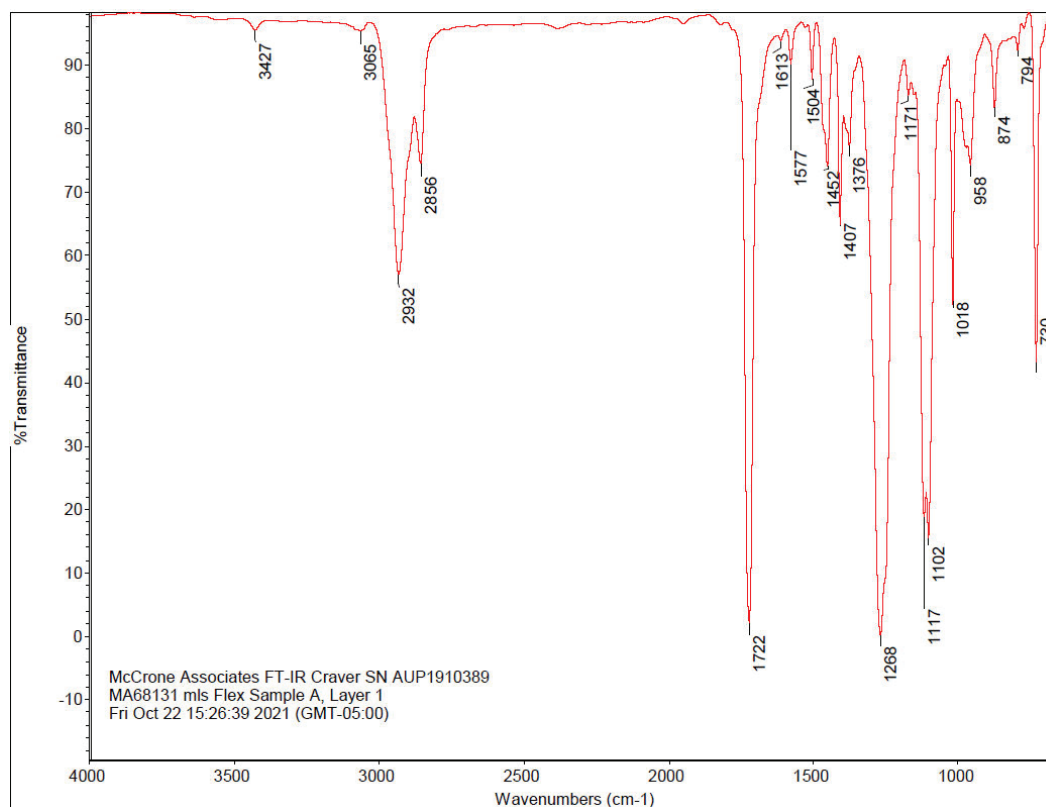


Figure 15: Flex Aligner Layer 1 FTIR Spectrum

90. In my opinion, based on the images reproduced above, the FTIR spectrum for the Tritan MX710 sample is nearly identical to the FTIR spectrum for layer 1 of the Flex Aligner. My analysis is the same when comparing Tritan MX710 to layers 3 and 5 of the Flex Aligner. *See id.* at Figs. 14 & 16. In addition, my analysis is the same when comparing Tritan TX1001 to layers 1, 3, and 5 of the Flex Aligner. *See id.* at Figs. 10, 12, 14, & 16. Both MX710 and Tritan TX1001 have nearly identical mechanical properties, and thus my analysis would not change for either polymer. In my opinion, however, the FTIR spectra show that, consistent with the DSC testing and Example 4 of the '657 application, outer layers 1 and 5 and core layer 3 are likely made from Tritan MX710 or a polymer blend primarily consisting of Tritan MX710 such that their properties would be governed by Tritan MX710.

91. I have also reproduced from the McCrone Report Figure 11, showing the FTIR spectra of Ecdel 9967, and Figure 13, showing the FTIR spectrum of layer 2, below.

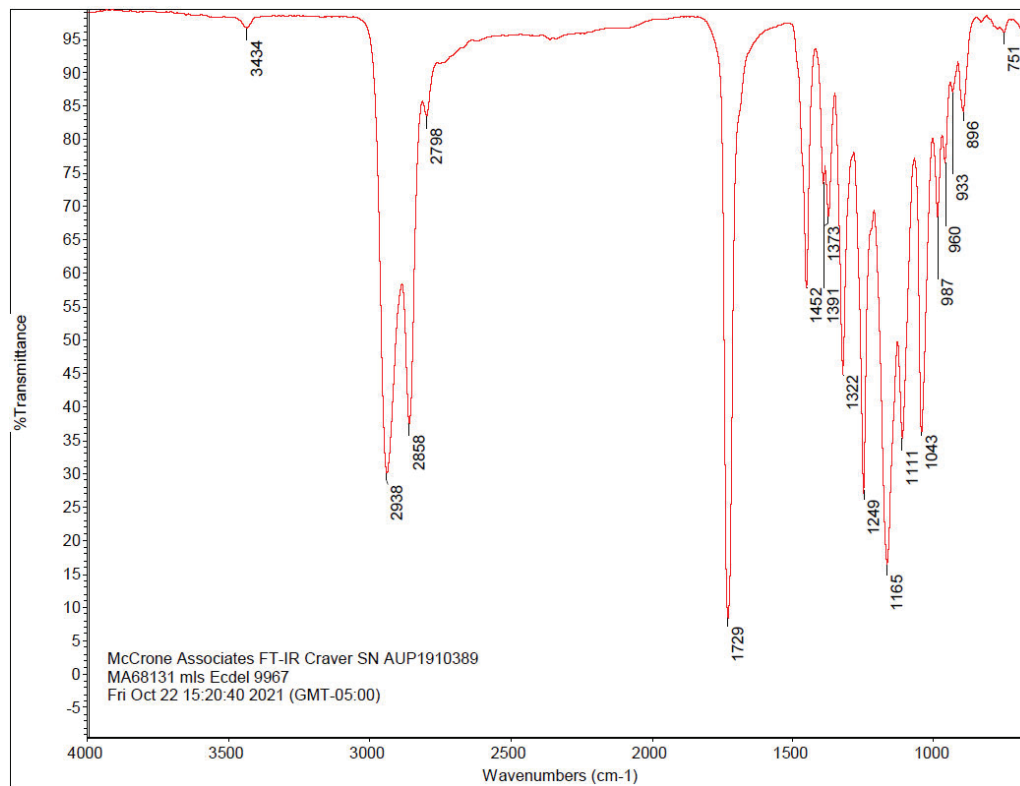


Figure 16: Ecdel 9967 FTIR Spectrum

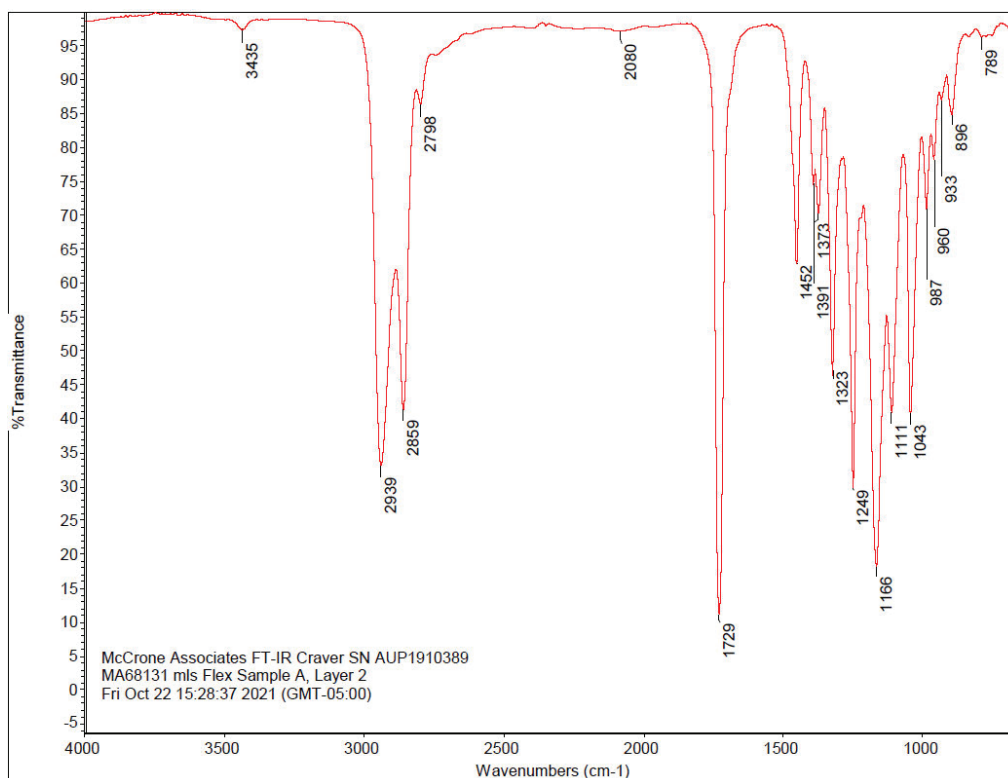


Figure 17: Flex Aligner Layer 2 FTIR Spectrum

92. In my opinion, based on the images reproduced above, the FTIR spectrum for the Ecdel 9967 sample is nearly identical to the FTIR spectrum for layer 2 of the Flex Aligner. My analysis is the same when comparing Ecdel 9967 to layer 4 of the Flex Aligner. *See id.* at Fig.

15. In my opinion, the FTIR spectra show that, in combination with the other evidence discussed above, inner layers 2 and 4 are made from Ecdel 9967 or a polymer blend primarily consisting of Ecdel 9967 such that their properties would be governed by the Ecdel 9967.

VII. INFRINGEMENT ANALYSIS

A. 3M Clarity™ Aligners Flex Infringe At Least Claim 1 of the '630 Patent

93. In my opinion, the publicly available evidence plus the testing conducted by my lab and by McCrone demonstrates that the polymer materials used in the Flex Aligner meets all the limitations of at least claim 1, 2, and 9 of the '630 patent, Ex. B.

94. Claims 1, 2, and 9 of the '630 patent recite:

1. A polymeric sheet composition, comprising:
at least two outer layers A and C and an elastic inner layer B,
wherein one or more of the outer layers A and C is a polyester or
co-polyester having a flexural modulus of from about 1,000 MPa
to 2,500 MPa, the inner layer B is comprised of an elastomeric
material having a hardness from about A80 to D75, and the
polymeric sheet composition has a flexural modulus of from about
750 MPa to 2,000 MPa.

2. The polymeric sheet composition of claim 1, wherein the A, B
and C layers of the polymeric sheet composition have a combined
thickness of from about 250 microns to 2,000 microns.

9. A dental appliance conformal to one or more teeth comprising a
polymeric sheet composition according to claim 2.

95. In my opinion, the Flex Aligner meets all the claim limitations of claims 1, 2, and

9. My analysis for each claim limitation is shown below.

a. 1[pre] A polymeric sheet composition comprising:

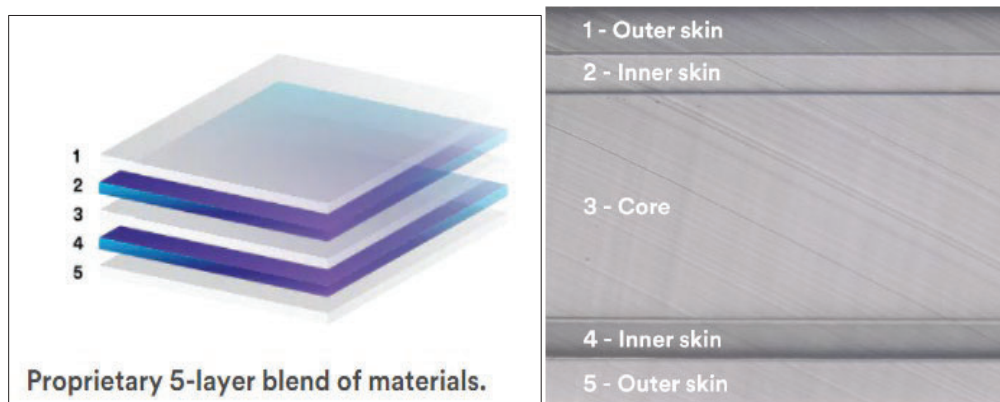
96. In my opinion, the Flex Aligner meets the limitation of a “polymeric sheet
composition.” 3M advertises the product as being made from “multi-layer material for the
aligner tray application.” See Ex. Q at 1. Furthermore, as I discussed above in section V.D, 3M
advertises its product as aligners made from multilayer polymeric sheet compositions.

97. The testing I oversaw further confirms that this limitation is met. The DSC testing
for the Flex Aligner is substantially similar to those of two Eastman polymer samples tested, thus
indicating that the Flex Aligner comprises a polymeric material. *See* Ex. U at 1-7. Furthermore,
the McCrone testing report describes the Flex Aligner as a multi-layer polymeric material. *See*
Ex. W at 3. The McCrone testing indicates the multi-layer polymeric material is likely comprised
only of two different polymeric materials, as demonstrated by the sample’s FTIR spectra
matching with the FTIR spectra of two known Eastman polymer samples. *Id.* at 2, 4.

b. 1[a] at least two outer layers A and C and an elastomeric inner layer B

98. In my opinion, the Flex Aligner meets the limitation of “at least two outer layers A and C and an elastomeric inner layer B.” As discussed above in section V.D, 3M describes the Flex Aligner as containing “proprietary 5-layer copolymer materials.” Ex. O at 1. Moreover, the 3M website states the 5-layer material includes “[o]uter layers [that] resist staining and scratching” and “[i]nner layers [that] provide flexibility and resilience.” *Id.* I therefore understand the 3M product to contain at least two outer layers and an inner layer comprised of different materials.

99. My opinion is further confirmed by the following two images, taken from 3M’s websites, showing five layers with two “Outer skin” layers and two “Inner skin” layers:⁶



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

101. 3M’s publicly filed patent application, the ’657 application, indicates that the “Inner skin,” corresponding to inner layer B in the claim, is an elastomer. As I discussed above in section V.D, I believe Example 4 of the ’657 application corresponds to the Flex Aligner.

⁶ Ex. O at 1; Ex. Q at 2.

Example 4 specifically discloses a “5-layer CBABC (MX710/ECDEL /MX710/ECDEL9967/MX710) film” having an “overall sheet thickness” of 0.625 mm. Ex. Q, ¶ [0097]. Ecdel 9967 is a “copolyester ether elastomer from Eastman Chemicals.” *Id.*, ¶ [0077]; *see also id.*, ¶ [0097] (“The middle layer (B) extruder was fed with a second thermoplastic elastomeric resin, ECDEL, and....”). Finally, the Eastman technical data sheet for Ecdel 9967 describes the polymer as an elastomer. Ex. S at 1. Accordingly, the Flex Aligner contains an elastomeric inner layer B.

102. The testing I oversaw further confirms that the composition of each Flex Aligner layer is consistent with the polymers disclosed in Example 4 of the '657 application. *See supra* §§ VI.B,C. The DSC testing demonstrates that Flex Aligner layers “1,” “3,” and “5” have substantially similar glass transition temperatures as Tritan MX710. *See supra* § VI.B. The DSC testing also demonstrates that Flex Aligner layers “2” and “4” have substantially similar melting temperatures as Ecdel 9967. *Id.* As shown in the graph from section VI.B, reproduced again below, the multilayer (Upper-Dental) shows a glass transition temperature and a crystalline melting event at the temperatures corresponding to MX710 and Ecdel 9967, respectively.

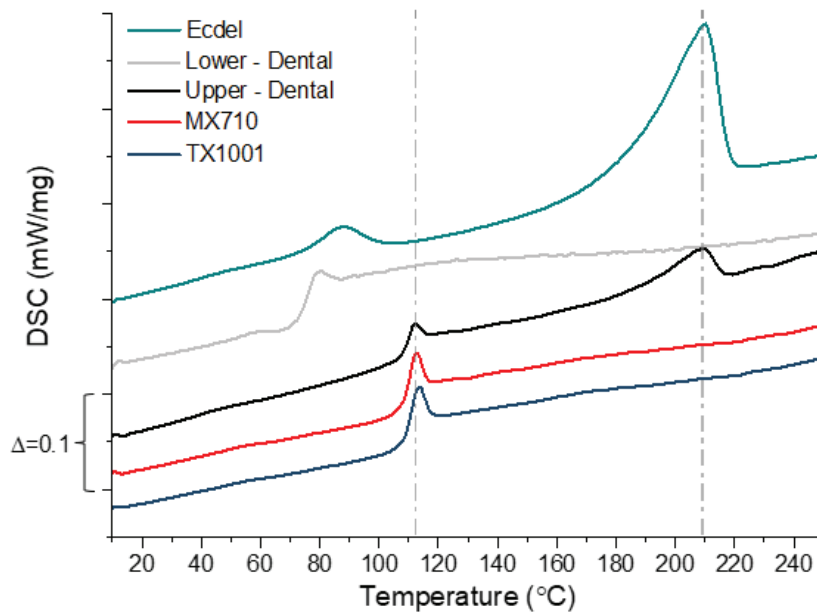


Figure 18: Thermograms of the 5 materials performed at 10K/minute

103. Next, as discussed above, the McCrone testing indicates that Flex Aligner layers “1,” “3,” and “5” have substantially similar FTIR spectra to that of Tritan MX710. The McCrone testing also demonstrates that Flex Aligner layers “2” and “4” have substantially similar FTIR spectra to that of Ecdel 9967. *See supra* § VI.C. Therefore, in my opinion, the inner layer B of the Flex Aligner comprises Ecdel 9967, an elastomeric material.

c. 1[b] wherein one or more of the outer layers A and C is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa

104. In my opinion, the Flex Aligner meets the limitation of “one or more of the outer layers A and C is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa.” 3M’s website explains that it “settled on a family of copolyesters as the materials” used in the Flex Aligner 5-layer composition. Ex. Q at 3. Moreover, as I discussed above for claim element 1[a] and in sections V.D, VI.B, and VI.C, the polymer used for outer layers 1 and 5 (“A” and “C”) comprises, in my opinion, Tritan MX710. The Eastman technical data sheet for Tritan MX710 refers to the polymer as a copolyester. *See* Ex. R. Additionally, the

'657 application describes Tritan MX730—a nearly identical polymer to MX710—as a “copolyester from Eastman Chemicals.” Ex. R, ¶ [0078].

105. The '657 application discloses a table with properties, such as flexural modulus, of polymers identified as suitable for use in its dental appliances. *Id.* at Table 1. Tritan MX710 is listed as having a flexural modulus of 1.55 GPa, or 1,550 MPa. *Id.* This is consistent with the Tritan MX710 technical data sheet, which states that Tritan MX710 has a flexural modulus of 1,550 MPa when measured according to the ASTM D 638 standard. *See* Ex. M at 1. To the extent layers “1,” “3,” and “5” are comprised of TX1000 or TX1001, both polymers have nearly identical mechanical properties as Tritan MX710. *See* Ex. R at Table 1. Accordingly, the Flex Aligner contains outer layers A and C which are copolyesters having a flexural modulus of from about 1,000 MPa to 2,500 MPa.

d. 1[c] the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75

106. In my opinion, the Flex Aligner meets the limitation of “the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75.” As I discussed above for claim element 1[a] and in sections V.D, VI.B, and VI.C, the polymer used for inner layers B comprises the Ecdel 9967 elastomer. The Eastman technical data sheet for Ecdel 9967 states that the polymer has a Shore hardness of A95 or D55, as measured according to the ASTM D 2240 standard. *See* Ex. S at 2. As seen in the annotated image below, the Shore hardness of A95 or D55 (shown with a purple line) falls squarely in the middle of the claimed range (enclosed in a yellow box):



Figure 19: Shore Hardness Scale with the yellow box showing the claimed range and the purple line showing the approximate hardness of Ecdel 9967

107. Accordingly, the inner layer B of the Flex Aligner is comprised of an elastomer having a Shore hardness of from about A80 to D75.

e. 1[d] and the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa

108. In my opinion, the Flex Aligner meets the limitation of “the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa.” As an initial matter, 3M advertises on its websites that the elastic modulus of the Flex Aligner is approximately 1.3 GPa or 1,300 MPa. *See* Ex. Q at 3.

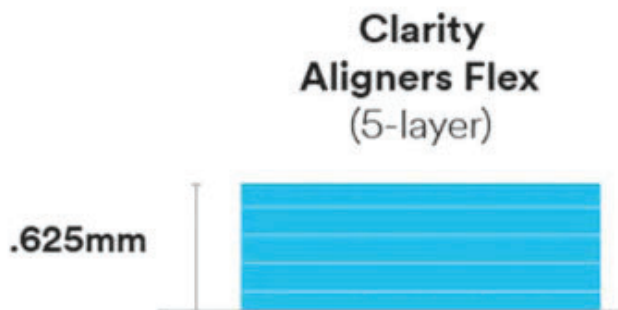
109. Moreover, as I explained in section V.B, the flexural modulus would be expected to be similar to the elastic modulus and the two can be related using specific equations. Using the equations I explained in section V.B above and the layer dimensions taken from a micrograph of the accused product (*see* sections VI.B,C), I calculated the predicted flexural modulus (E_f) of the 5-layer system based on 3M’s disclosed elastic modulus. This calculation shows a flexural

modulus $E_f = 1266$ MPa, or approximately 1.3 GPa (1300 MPa), as advertised on the 3M website. I have attached my calculations as Exhibit X. Using the equations given above, the elastic modulus of the composite sheet is calculated to be $E = 1247$ MPa, which is similar to the calculated flexural modulus and also in line with the 1300 MPa modulus advertised by 3M.

110. Accordingly, the overall polymeric sheet composition is in the range of 750 MPa to 2,000 MPa.

f. 2: The polymeric sheet composition of claim 1, wherein the A, B and C layers of the polymeric sheet composition have a combined thickness of from about 250 microns to 2,000 microns

111. In my opinion, the Flex Aligner meets the limitation of a “polymeric sheet composition of claim 1, wherein the A, B and C layers of the polymeric sheet composition have a combined thickness of from about 250 microns to 2,000 microns.” On its website, 3M describes the Clarity Aligners Flex as “5-layer” aligners with “uniformed material thickness of 0.625 mm.” Ex. Q at 3. The below image is taken from the same 3M website:



112. The McCrone testing shows the overall thickness of the thermoformed Flex Aligner to be between approximately 422-508 microns, depending on where on the aligner the cross-section measurement was taken. *See* Ex. W at 2, 4. The micrograph for cross-section B is reproduced below.

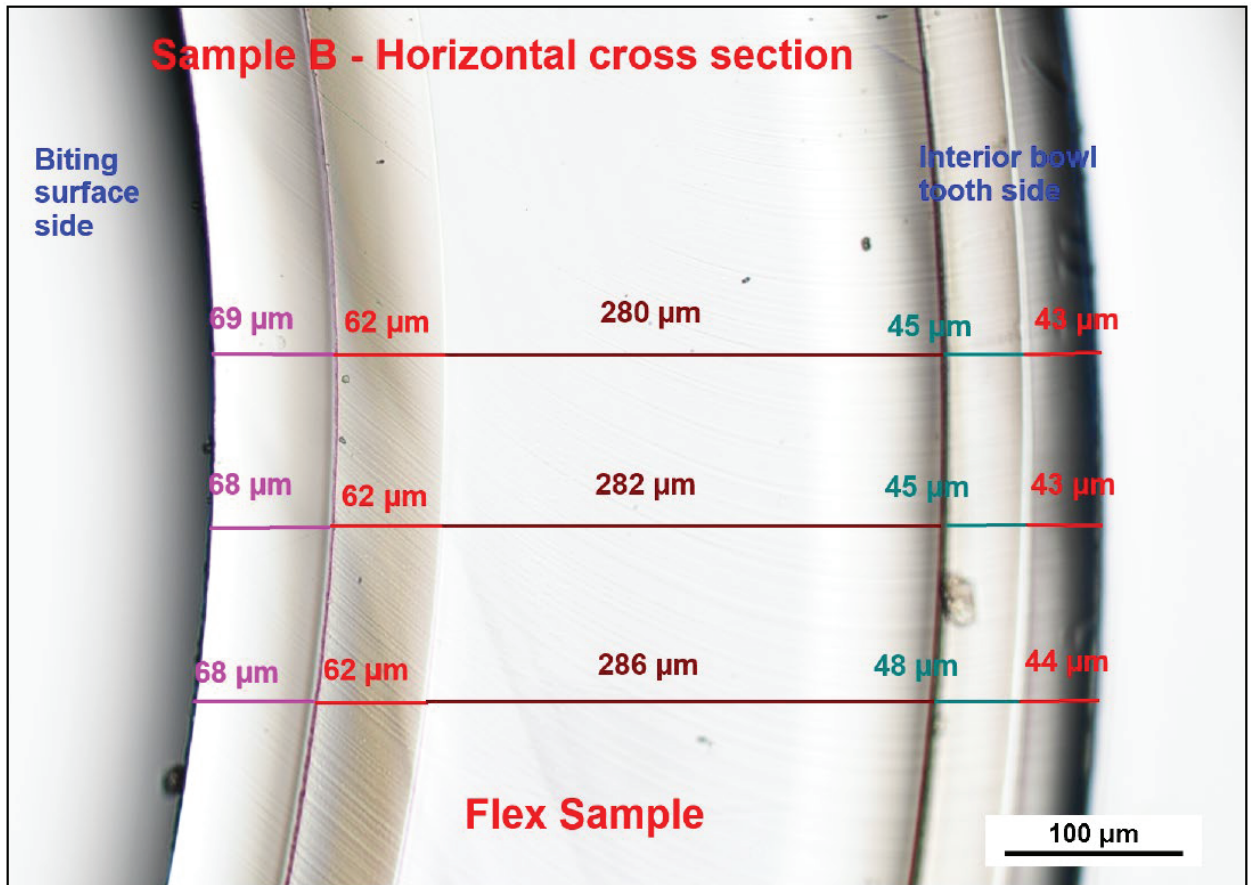


Figure 17: Five-Layer Sheet Micrograph taken from the Accused Product

113. In the micrograph of cross-section B, the first thickness measurement shows a total thickness of 499 microns. For all the cross-sections measured, the thicknesses varied between 422-508 microns, which is consistent with the thickness of a 625-micron polymeric sheet that has been thermoformed to create a dental aligner. I would expect a thermoformed aligner to be thinner than the original polymeric sheet composition due to the thermoforming process. The thickness advertised on 3M's website (625 microns) is approximately 25% greater than the thickness of the first measurement shown above for cross-section B, and generally it is approximately 23-48% greater than the values measured by McCrone (422-508 microns).

114. Micrographs taken in my own lab confirm the change in thickness due to thermoforming. See Section VI.B. The micrographs presented in the figure below, show the

thickness distribution of the 5 layers in the crown region (left) and the gumline region (right).

The crown region experienced the most thinning during the forming process, being approximately 50 μm thinner than the gumline region. The table below the images presents the average thicknesses of the layers taken at 6 different locations, in each one of the 5 layers, in the crown and gumline regions respectively.

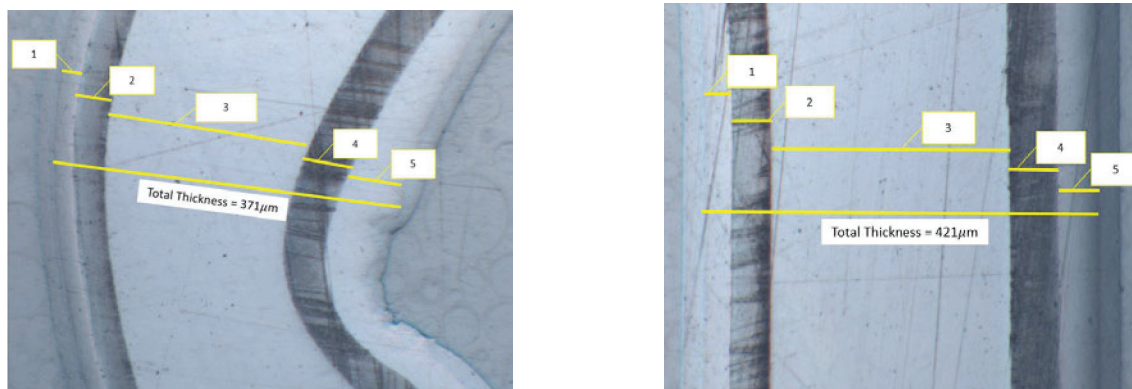


Figure 20: Five-Layer Sheet Micrographs taken from the Accused Thermoformed Product. Crown region (left) and Gumline region (right)

Layer	Thickness (Gumline) [mm]	Thickness (Crown) [mm]
1	48.46	24.05
2	39.98	34.02
3	243.91	205.94
4	49.62	46.93
5	39.75	60.40

115.

[REDACTED]

[REDACTED]

[REDACTED].

116. As I noted, 3M reports that the polymeric sheet used for the Flex Aligner is 625 microns, which is within the claimed range of 250 microns to 2,000 microns. Even considering just the outer layers A and C of the Flex Aligner and the elastomeric layers of the Flex Aligner, the McCrone testing for the first thickness measurement of cross-section B shown above, those layers have a combined thickness of 218 microns after thermoforming. As I mentioned above, the thermoforming process would be expected to reduce the thickness of the overall polymeric sheet composition and each individual polymer layer by approximately the same percentage. Because the 625 micron Flex Aligner thickness advertised on 3M's website is approximately 20% greater than the 499 micron value measured by McCrone, each of the individual layer thicknesses measured by McCrone would have been 25% thicker before thermoforming. In other words, the outer layer and elastomeric layers would have had a combined thickness of around 273 microns, which is within the claimed range of 250 to 2,000 microns. A similar calculation for each of the other thickness measurements confirms that the combined thickness of layers 1, 2, 4, and 5 of the Flex Aligner would be approximately 270-280 microns.

117. Accordingly, the Flex Aligners has at least outer layers and elastomeric layers having a combined thickness in the range of 250-2,000 microns.

g. 9: A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 2

118. In my opinion, the Flex Aligner meets the limitation of a "dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 2." 3M's website promotes the Flex Aligner as an orthodontic device. *See* Ex. O. Additionally, 3M's

submission to the FDA prepared April 21, 2021, describes the Flex Aligner as a device “composed of thermoplastic resin” that “moves the teeth by continuous gentle force for treatment of minor tooth malocclusion.” Ex. Z at 1. Accordingly, the Flex Aligner is a dental appliance conformal to one or more teeth comprising the polymeric sheet composition described in claim 2.

119. Therefore, in my opinion, the Flex Aligner meets the limitations of claim 9 of the '630 patent.

B. 3M Clarity™ Aligners Flex Infringe At Least Claims 11, 12, 18 of the '263 Patent

120. In my opinion, the publicly available evidence plus the testing conducted by my lab and by McCrone demonstrates that the polymer materials used in the Flex Aligner meets all the limitations of at least claims 11, 12, and 18 of the '263 patent, Ex. C.

121. Claims 11, 12, and 18 of the '263 patent recite:

11. A polymeric sheet composition, comprised of at least two rigid or hard outer layers A and C, at least two soft inner layers B and B', and at least a rigid or hard inner layer, D, wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.

12. The polymeric sheet composition of claim 11, wherein the polymeric sheet composition has a combined thickness of from about 250 microns to 2,000 microns and a flexural modulus of from about 500 MPa to 1,500 MPa.

18. A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.

122. In my opinion, the Flex Aligner meets all the claim limitations of claims 11, 12, and 18. My analysis for each claim limitation is shown below.

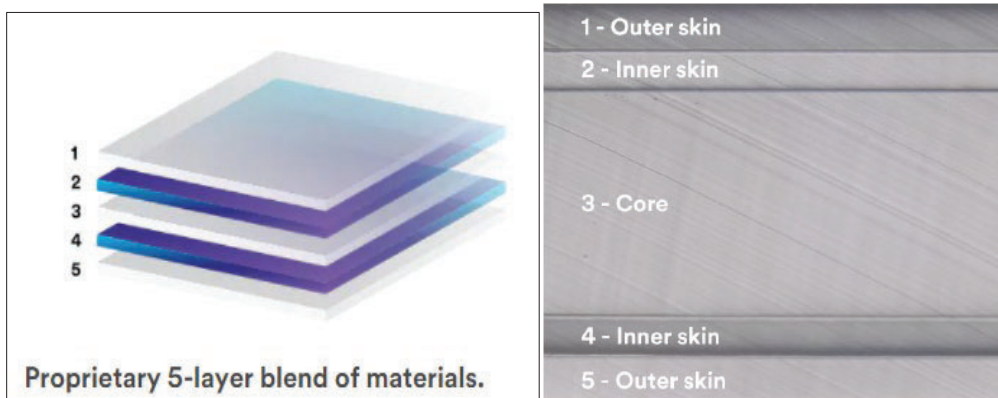
h. 11[pre] A polymeric sheet comprised of:

123. In my opinion, the Flex Aligner meets this limitation for the same reasons discussed above for claim limitation 1[pre] of the '630 patent. *See supra* § VII.A.a.

i. 11[a] at least two rigid or hard outer layers A and C, at least two soft inner layers B and B', and at least a rigid or hard inner layer, D

124. In my opinion, the Flex Aligner meets this limitation. As discussed above in section V.D, 3M describes the Flex Aligner as containing “proprietary 5-layer copolymer materials.” Ex. O at 1. Moreover, the 3M website states that the 5-layer material includes “[o]uter layers [that] resist staining and scratching” and “[i]nner layers [that] provide flexibility and resilience.” *Id.* In my opinion, an outer layer that resists staining and scratching would be expected to be hard or rigid when compared to a flexible and resilient layer. I therefore understand the Flex Aligner to comprise at least two rigid or hard outer layers and at least two softer inner layers.

125. My opinion is further confirmed by the following two images, taken from 3M’s websites, showing five layers including two “Outer skin” layers, two “Inner skin” layers, and a “Core” inner layer:⁷



⁷ Ex. O at 1; Ex. Q at 2.

126. According to the above images, “Outer skin” layers 1 and 5 correspond to the hard or rigid outer layers A and C, “Core” layer 3 corresponds to hard or rigid inner layer D and is shown as being the same material as layers “1” and “5”, and “Inner skin” layers 2 and 4 correspond to inner layers B and B'. As I will discuss further below, layers “1,” “3,” and “5” of the Flex Aligner all comprise the same hard or rigid copolyester, and layers “2” and “4” both comprise the same soft elastomeric material.

127. 3M’s publicly filed patent application confirms the polymeric structure of the Flex Aligner. As I discussed above in section V.D, the ’657 application discloses appliances having “at least 5 polymeric layers, with softer polymeric interior layers disposed between a harder polymeric core layer and two harder polymeric outer layers.” Ex. R, ¶ [0009]. The ’657 application further discloses that the “multiple layers of high flexural modulus and low flexural modulus polymeric materials [] improve patient comfort while maintaining an acceptable level of force persistence” and, when combined, also provide “good stain resistance.” *Id.*, ¶ [0008]. It further discloses that the “hard core layer can enhance dimensional stability, while the softer middle layers positioned close to the outer skin layers can improve patient comfort and strain recovery.” *Id.*, ¶ [0009].

128. Consistent with the above description, Example 4 of the ’657 application—which I believe corresponds to the Flex Aligner—discloses a “5-layer CBABC (MX710/ECDEL /MX710/ECDEL9967/ MX710) film” having an “overall sheet thickness” of 0.625 mm. *Id.*, ¶ [0097]. Example 4 describes Tritan MX710 as a “rigid resin” and the Ecdel 9967 as a “thermoplastic elastomeric resin.” *Id.* According to the ’657 application, the Tritan MX710 would be the “harder polymeric core layer and two harder polymeric outer layers” and the Ecdel 9967 would be the “softer polymer interior layers.” *Id.*, ¶ [0009]. Moreover, the flexural modulus

of both polymers listed in Example 4 is consistent with the “hard” layer having a high flexural modulus and the “soft” layer having a low flexural modulus.⁸ The Tritan MX710 data sheet describes the polymer as having a flexural modulus of 1,550 MPa (or 1.55 GPa) (Ex. M), whereas the Ecdel 9967 technical data sheet describes the polymer as having a flexural modulus of 150 MPa, (Ex. S). Thus, the “A,” “C,” and “D,” layers comprising Tritan MX710 are, in my opinion, “rigid or hard” and the “B” and “B” layers comprising Ecdel 9967 are, in my opinion, “soft.”

129. The testing I oversaw further confirms that the composition of each Flex Aligner layer is consistent with the polymers disclosed in Example 4 of the '657 application. *See supra* §§ VI.B,C. The DSC testing demonstrates that Flex Aligner layers “1,” “3,” and “5” have substantially similar glass transition temperatures as Tritan MX710. *See supra* § VI.B. The DSC testing also demonstrates that Flex Aligner layers “2” and “4” have substantially similar melting temperatures as Ecdel 9967. *Id.* As shown in the graph from section VI.B, reproduced here again below, the multilayer (Upper-Dental) clearly shows a glass transition temperature and a crystalline melting event at the temperatures corresponding to MX710 and Ecdel 9967, respectively.

⁸ To the extent layers “1,” “3,” and “5” are comprised of TX1000 or TX1001, both polymers have nearly identical mechanical properties as Tritan MX710 and are thus considered “hard” polymers. *See* Ex. R at Table 1.

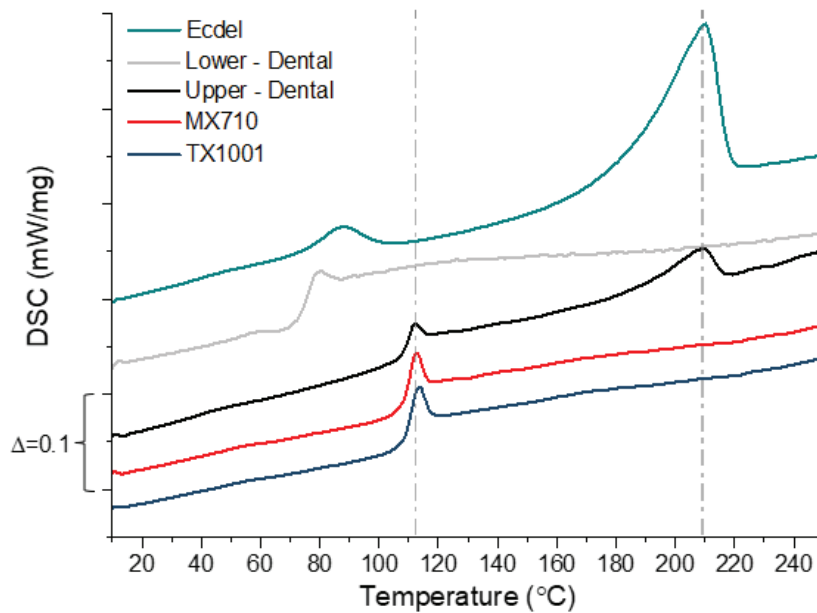


Figure 21: Thermograms of the 5 materials performed at 10K/minute

130. Next, the McCrone testing indicates that Flex Aligner layers “1,” “3,” and “5” have substantially similar FTIR spectra to that of Tritan MX710. *See supra* § VI.C. The McCrone testing also demonstrates that Flex Aligner layers “2” and “4” have substantially similar FTIR spectra to that of Ecdel 9967. *Id.*

131. Therefore, in my opinion, outer layers A and C and core layer D are comprised of the “rigid or hard” polymer Tritan MX710, and inner layers B and B' are comprised of the “soft” polymer Ecdel 9967.

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

132. In my opinion, the Flex Aligner meets this limitation. As I discussed above for claim limitation 11[a], the “rigid or hard layers, A, C, and D”—layers “1,” “3,” and “5” of the Flex Aligner—comprise Eastman’s Tritan MX710 copolyester. *See supra* § VII.A.b. According to the Tritan MX710 technical data sheet, the polymer has a tensile modulus of 1,550 MPa (or

1.55 GPa) when measured according to the ASTM D 638 standard.⁹ *See* Ex. M at 1.

Accordingly, the rigid or hard layers “1,” “3,” and “5” of the Flex Aligner have a modulus in the range of about 1,000 MPa to 2,500 MPa.

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

133. In my opinion, the Flex Aligner meets this limitation. As I discussed above for claim element 11[a] and in sections V.D, VI.B, and VI.C, it is my opinion that the polymer used for soft inner layers B and B' is comprised of the Ecdel 9967 elastomer. The Eastman technical data sheet for Ecdel 9967 states that the polymer has a Shore hardness of A95 or D55, as measured according to the ASTM D 2240 standard. *See* Ex. S at 2. As seen in the annotated image below, the Shore hardness of A95 or D55 (shown with a purple line) falls squarely in the middle of the claimed range (enclosed in a yellow box):

⁹ To the extent layers “1,” “3,” and “5” are comprised of TX1000 or TX1001, both polymers have nearly identical mechanical properties as Tritan MX710 and thus are well within the claimed range. *See* Ex. R at Table 1.

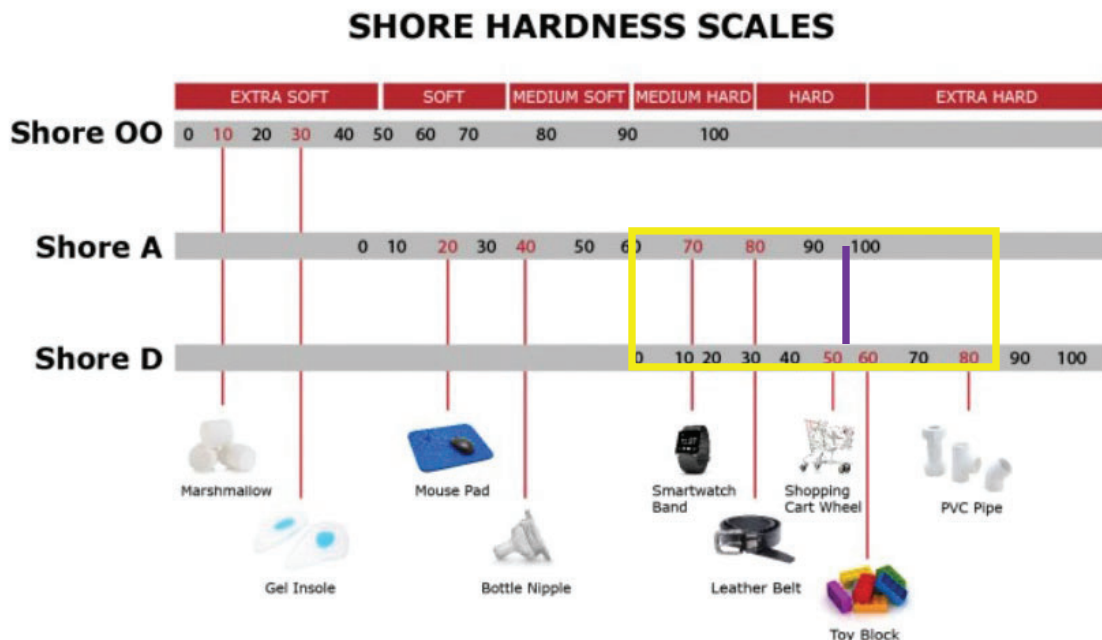
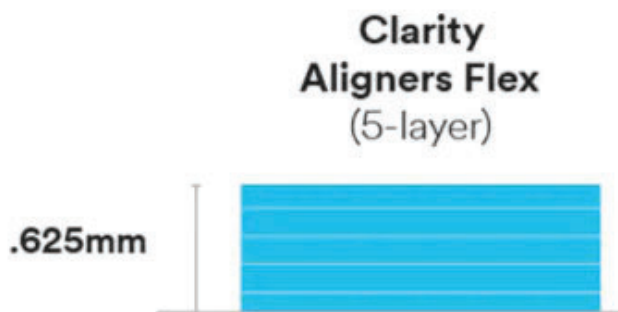


Figure 22: Shore Hardness Scale with the yellow box showing the claimed range and the purple line showing the approximate hardness of Ecadel 9967

134. Accordingly, the soft inner layers B and B' of the Flex Aligner is comprised of an elastomer having a Shore hardness of from about A60 to D85.

l. 12[a] The polymeric sheet composition of claim 11, wherein the polymeric sheet composition has a combined thickness of from 250 microns to 2,000 microns and

135. In my opinion, the Flex Aligner meets this limitation. On its website, 3M describes the Clarity Aligners Flex as “5-layer” aligners with “uniformed material thickness of 0.625 mm.” Ex. Q at 3. The below image is taken from the same 3M website:



136. Moreover, the McCrone testing further shows the thickness of the polymeric sheet is within the claimed range. Specifically, the McCrone testing shows the overall thickness of the thermoformed Flex Aligner to be between approximately 422-508 microns, depending on where in the aligner the cross-section was measured. *See* Ex. W at 2, 4.

137. In my opinion, therefore, the polymeric sheet composition has a thickness in the range of about 250 microns to 2,000 microns.

m. 12[b] a flexural modulus of from 500 MPa to 1,500 MPa

138. In my opinion, the Flex Aligner meets this limitation for the same reasons discussed above for claim limitation 1[d] of the '630 patent. *See supra* § VII.A.e. More specifically, using the dimensions represented in Figure 13 above, along with the properties from Ecdel 9967 and Tritan MX710 given in the materials data sheets, I calculated the Flex Aligner to have a flexural modulus of 1,266 MPa and an elastic modulus of 1247 MPa, both close to the 3M advertised modulus of 1,300 MPa and within the claimed 500-1,500 MPa range. *Id.* Accordingly, in my opinion, the Flex Aligner infringes claim 12 of the '263 patent.

n. 18: A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12

139. In my opinion, the Flex Aligner meets this limitation for the same reasons discussed above for claim 9 of the '630 patent. *See supra* § VII.A.g.

VIII. CONCLUSIONS

140. In my opinion, for all the reasons I described above, the Flex Aligner meets all the limitations of claims 1, 2, and 9 of the '630 patent and claims 11, 12, and 18 of the '263 patent.

IX. COMPENSATION

141. I will be compensated for my time preparing for and testifying in this matter at the rate of \$650/hour. No part of my compensation is contingent upon the outcome of this matter or any issue in it.

I declare under penalty of perjury under the laws of the United States that the forgoing is true and correct.

November 12, 2021

Date

A handwritten signature consisting of two overlapping loops, resembling a stylized 'O' or 'T', written in black ink.

Dr. Tim A. Osswald