UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY,
Petitioner,

v.

BAY MATERIALS, LLC,
Patent Owner.

Case IPR2022-01214
Patent No. 10,946,630

SECOND DECLARATION OF DR. TIM A. OSSWALD

ALIGN - EXHIBIT 2026
ClearCorrect Operating, LLC. v. Align Technology, Inc.
IPR2025-00819

TABLE OF CONTENTS

I. INTRODUCTION 1

II. QUALIFICATIONS 1

III. COMPENSATION 4

IV. MATERIALS CONSIDERED 4

V. THE PERSON OF ORDINARY SKILL IN THE ART 9

VI. LEGAL STANDARDS 11

VII. THE ’630 PATENT 12

A. Disclosure of the ’630 Patent 12

B. Claims of the ’630 Patent 15

VIII. TECHNOLOGICAL BACKGROUND 18

A. Overview of Relevant Mechanical Properties 18

1. Stress and Strain 18

2. Flexural Modulus and Tensile Modulus (Elastic Modulus) 19

3. Flexural Strength 24

4. Hardness 26

5. Stiffness 28

6. Tensile Modulus, Elastic Modulus, and Flexural Strength Are Intensive Properties Whereas Stiffness Is an Extensive Property 29

B. Effect of Temperature on Mechanical Properties 30

1. Glass Transition Temperature and Melting Temperature 30

2. Vicat Temperature 34

C. Flexural Modulus Calculation for Multilayer Systems 35

IX. PRIOR ART SUMMARY 40

A. Hinz 40

B. Durasoft Data Sheets 46

C. Sun 47

X. THE '630 PATENT CLAIMS WOULD NOT HAVE BEEN OBVIOUS 52

A. Grounds 1 and 2: Claims 1-4, 7-11, and 13 Would Not Have Been Obvious Over Hinz and the Durasoft Data Sheets 52

1. Neither Hinz nor the Durasoft Data Sheets Discloses Any Overall Flexural Modulus, Much Less the Claimed Flexural Modulus 52

2. A Person of Ordinary Skill Would Not Have Been Motivated by Hinz or the Durasoft Data Sheets to Select a Particular Combination of Thicknesses That Give the Claimed Flexural Modulus 53

3. Analysis of Dr. Giacomin's Flexural Modulus Calculations 58

4. The Claimed Flexural Modulus Is Not Inherent in Hinz and the Durasoft Data Sheets 63

B. Ground 3: Claims 1-4, 7-11, and 13 Would Not Have Been Obvious Over Hinz, the Durasoft Data Sheets, and Sun 76

1. A Person of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Sun with Hinz or the Durasoft Data Sheets 76

2. Sun Does Not Disclose an Overlapping Flexural Modulus Range 87

3. Flexural Modulus Cannot Be Routinely Optimized to Achieve "Better Insertion and Removal Behavior" 89

C. Grounds 1-3: The Elastic Beam Theory Calculation Petitioner Relies on to Obtain the Flexural Modulus Limitation Is Not Within the Common Knowledge of a Person of Ordinary Skill in the Art 93

D. Grounds 1-3: Claims 4 and 10 Would Not Have Been Obvious Over Hinz and the Durasoft Data Sheets, With or Without Sun 94

XI. Grounds 1-3: Claims 1-4 and 7-8 Would Not Have Been Obvious Over the Asserted Reference, Which Do Not Disclose a Polymeric Sheet with More Than Two Layers 95

XII. OBJECTIVE EVIDENCE OF NONOBVIOUSNESS 96

A. The ’630 Patent Claims Encompass Zendura™ FLX 96

B. Zendura™ FLX Demonstrates Unexpectedly Superior Properties 101

C. Petitioner Copied Zendura™ FLX 106

1. 3M and Clarity™ Aligners Flex + Forces 106

2. Testing 112

D. Zendura™ FLX Received Industry Praise 128

XIII. CONCLUSION 129

bonded to one another by deep-drawing." Ex. 1015 at 27:61-28:2. Meanwhile, Sun and the Durasoft Data Sheets disclose only single-layer or two-layer sheet compositions. *Supra* Section IX.B-C.

170. In my opinion, a skilled artisan would have understood that Hinz does not disclose a three-layer *sheet*, and that if Hinz had either invented such a sheet or was using a commercially available three-layer sheet, the reference would have disclosed that. It is therefore my opinion that claims 1-4 and 7-8 would not have been obvious over the asserted art, none of which discloses the claimed polymeric sheet composition with at least two outer layers and an elastomeric inner layer.

XII. OBJECTIVE EVIDENCE OF NONOBVIOUSNESS

A. The '630 Patent Claims Encompass Zendura™ FLX

171. Bay Materials' flagship product covered by the claims of the '630 patent is sold under the trade name Zendura™ FLX. Zendura™ FLX is used in clear aligners and was designed as an improvement on Bay Materials' previous single-layer polymeric material, Zendura™ A. *See* Ex. 2046 (zenduradental.com) 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 embodies and is coextensive with claim 1.

172. 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* Ex. 2046 (zenduradental.com) at 1-2. The image below, from the zenduradental.com website, shows the structure of the hard-soft-hard configuration of the polymeric sheet:

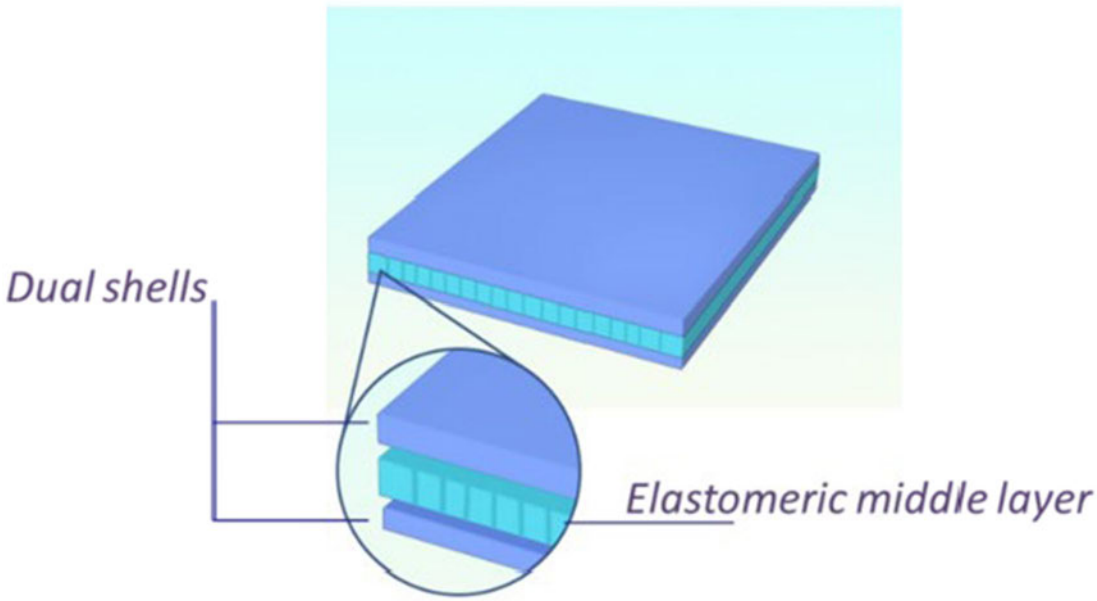


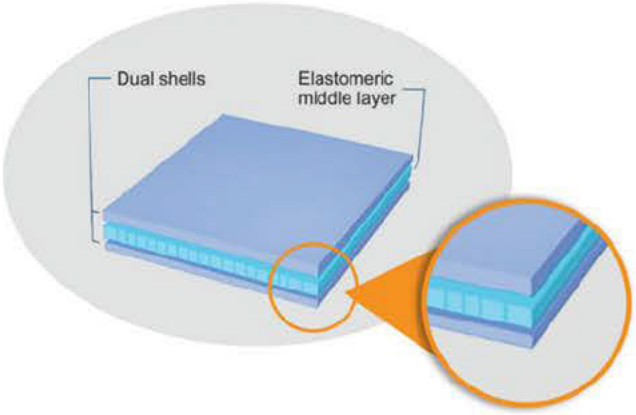
Figure 10: Zendura™ FLX diagram

173. The soft elastomeric inner layer of Zendura™ FLX is a [redacted], whereas the hard outer layers of the Zendura™ FLX are [redacted]. Ex. 2047 (Zendura® FLX SDS) at 2. The soft inner layer has a hardness of [redacted] (Ex. 2016 at 4; Ex. 2010 at 7. The hard outer layers have a flexural modulus of [redacted]. Ex. 2015 at 2; Ex. 2010 at 7.

174. Zendura™ FLX is sold as a multilayer polymeric sheet having a thickness of approximately [redacted]. *See* Ex. 2014 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.* at 1.

175. In my opinion, and as shown in the claim chart below, Zendura™ FLX embodies and is coextensive with at least claim 1 of the '630 patent. More specifically, as recited in claim 1 of the '630 patent, Zendura™ FLX is a polymeric sheet composition comprising two [redacted] 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 hardness of [redacted], which is between about A80 to D75. The overall multilayer polymeric sheet has a flexural modulus from about 750 MPa and 2,000 MPa.

Claim Element	Zendura™ FLX
1 [pre]. A polymeric sheet composition, comprising:	Zendura™ FLX is a multilayer polymeric composition. Ex. 2014 at 1.

Claim Element	Zendura™ FLX
[1a]. at least two outer layers A and C and an elastomeric inner layer B,	Zendura™ FLX has two hard or rigid polymeric outer layers and a soft elastomeric inner layer, as shown below:  Ex. 2013 at 1. The outer layers shown above are "layers A and C," and the inner layer is "an elastomeric inner layer B." *Id.*
[1b]. wherein one or more of the outer layers A and C is a polyester or co-polyester having a flexural modulus of	The hard outer layers of Zendura™ FLX, layers A and C, are [redacted] having a flexural modulus of [redacted]. Ex. 2015 at 2; Ex. 2010 ¶ 7.

Claim Element	Zendura™ FLX
from about 1,000 MPa to 2,500 MPa	
[1c]. the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75,	The elastomeric inner layer, layer B, is a [redacted] with a hardness [redacted] Ex. 2016 at 4; Ex. 2010 ¶ 7.
[1d]. and the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa.	Zendura™ FLX is advertised as having an overall flexural modulus of approximately [redacted]. Ex. 2014 at 1.

176. I have reviewed the Declaration of John Lahlouh, a Senior Polymer Scientist and Project Manager at Bay Materials, which is submitted as Ex. 2011. Mr. Lahlouh describes the process of developing Zendura™ FLX to achieve several desirable characteristics, including improved Trouser tear force, force retention, durability, shape recovery, and elastic recovery. Ex. 2011 ¶¶ 12-29. In my opinion, the superior properties of Zendura™ FLX are the result of its features recited in

claim 1, including its hard-soft-hard configuration and overall flexural modulus. *See infra* Section XII.B.

B. Zendura™ FLX Demonstrates Unexpectedly Superior Properties

177. Zendura™ FLX demonstrates superior properties compared to prior aligners and aligner materials that would have been unexpected to a person of skill in the art as of May 31, 2017. *See, e.g.*, Ex. 1001 at 16:33-17:46, 18:32-42, 18:59-19:25, 20:10-22. The unexpectedly superior properties of Zendura™ FLX are due to its claimed features, including the hard-soft-hard configuration and overall flexural modulus.

178. Prior to May 31, 2017, the conventional wisdom in the industry was that the outer layers of a multilayer aligner must be soft to provide patient comfort, overcome the propensity of the hard layer to crack under stress, and protect the hard layer from degrading under the environmental conditions inside the mouth. Ex. 1001 at 5:15-20, 19:63-66; Ex. 2011 ¶¶ 12-14; Ex. 2018 at 7:59-66; Ex. 2019 at 7:2-5; Ex. 2020 at 1:39-48; Ex. 2021 ¶ [0009]; Ex. 2022 at 9:48-10:9; Ex. 2023 at 4:66-5:3, 12:43-49, 17:1-14. Consistent with the prevailing industry wisdom, I understand that the only multilayer aligners on the market had soft outer layers and a hard inner layer. Ex. 2011 ¶ 14. This included the material used in the highest selling aligner at the time of invention, Align Technologies' SmartTrack material, which had a soft-

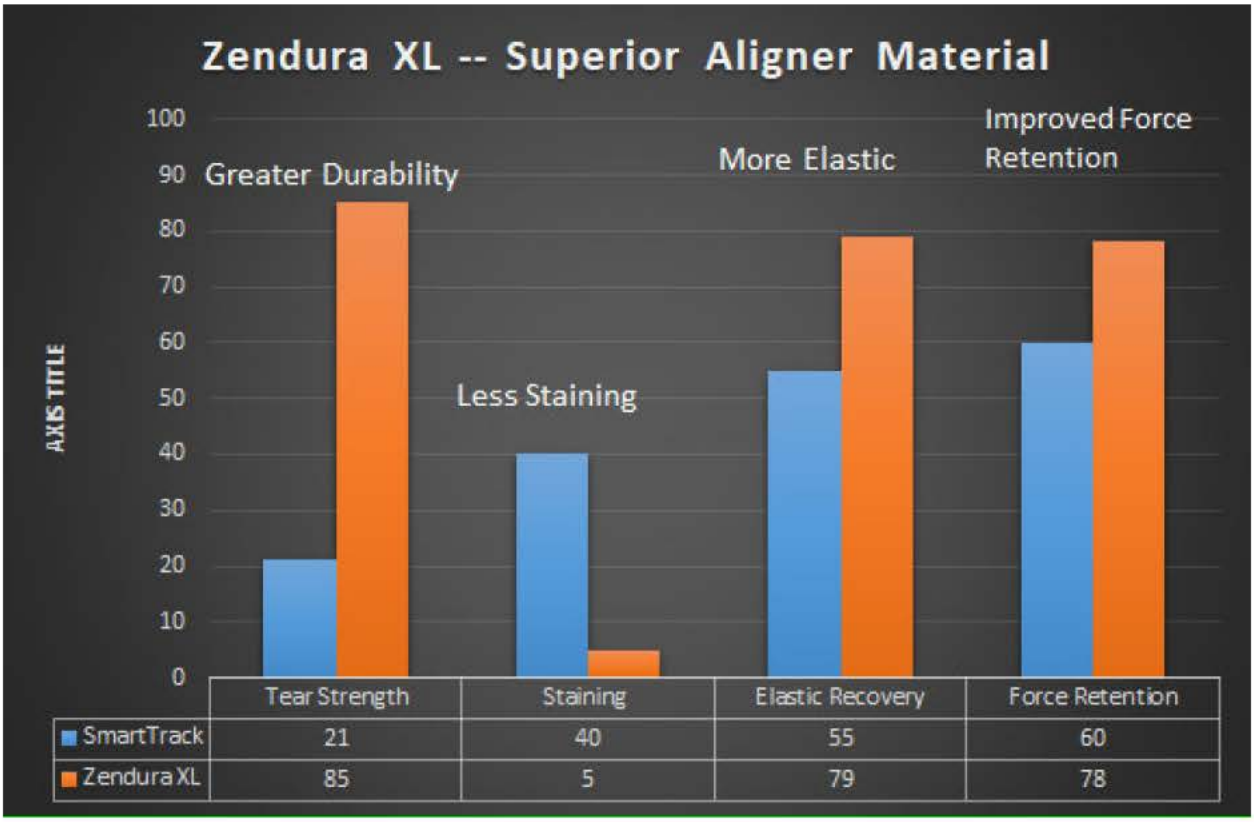
hard-soft configuration. *See* Ex. 2018. The Zendura™ FLX departed from the conventional wisdom by instead requiring hard outer layers and a soft inner layer.

179. In my opinion, a person of skill in the art would not have deviated from the prevailing industry practice because a hard-soft-hard configuration would have been expected to produce the problems I describe above with patient comfort, stress cracking, and degradation. Furthermore, a person of skill in the art would not have expected that deviating from the common industry practice of using soft-hard-soft materials would result in an aligner material with *improved* properties over the conventional aligner materials of the time. Thus, the favorable properties of Zendura™ FLX compared to Align's best-selling SmartTrack material would have been unexpected to a person of skill in the art. Ex. 2011 ¶¶ 11, 12, 15-20.

180. The innovative hard-soft-hard configuration and overall flexural modulus of Zendura™ FLX result in several advantages over prior aligner materials. For example, Zendura™ FLX and Align's SmartTrack material exert similar lower initial forces, but Zendura™ FLX retains its ability to exert that force more consistently on a patient's teeth over a longer period of time. Ex. 1001 at Table 3, 17:25-38; Ex. 2011 ¶¶ 17-20. Lower initial force is important for patient comfort, while force persistence enables dental aligners to move patient's teeth more effectively. *See* Ex. 2020 at 1:39-48. Zendura™ FLX also exhibits improved durability as shown by increased tear resistance and stain resistance and reduced

stress cracking compared to Align's product. Ex. 1001 at 17:22-24, 17:39-56, 20:10-22. Furthermore, despite the use of a hard-soft-hard configuration, Zendura™ FLX is more elastic than Align's product. Ex. 1001 at 17:22-24, 18:32-41.

181. Bay Materials' internal test data comparing Zendura™ FLX to [redacted] Align's SmartTrack material are presented in the figure below. The data show that the hard-soft-hard configuration and overall flexural modulus of Zendura™ FLX (referred to as Zendura XL in the figure) result in several improved properties. Zendura™ FLX outperforms Align's SmartTrack in elastic recovery and force retention. Ex. 2024 at 32. In addition, the data below show that Zendura™ FLX has improved durability and decreased staining. *Id.* Again, these properties contribute to the ability of Zendura™ FLX to function as a dental aligner more effectively. *Id.* at 30-31. None of the improvements to elastic recovery, force retention, durability, and/or staining would have been expected by a person of skill before the disclosure of the '630 patent.



182. The '630 patent presents additional data demonstrating unexpected superior properties of Zendura™ FLX. *E.g.*, Ex. 1001 at 15:27-22:5. Example 1 discloses comparative test data showing that two hard-soft-hard materials covered by the '630 patent claims (construction samples 1 and 2 in Table 3) have unexpectedly improved tear strength, lower initial forces, and greater force retention over three prior-art aligner materials (P1, P2, and P3). Ex. 1001 at Table 3, 17:25-31, 17:39-56. Prior art material P3 is a three-layer, soft-hard-soft material described in Align's U.S. Patent No. 9,655,693. *See* Ex. 2018; Ex. 1001 at 17:21-22. Example 4 discloses comparative durability testing of construction sample 2 against P1, P2, and P3 in a mouth wash test, designed to mimic a dental aligner's environmental

conditions. Ex. 1001 at Table 5, 18:59-19:14. This testing showed that the hard-soft-hard sample had unexpectedly improved shape recovery and resistance to stress cracking over existing aligner materials, including P3. *Id.*

TABLE 3

Monolayer and Multilayer Sheets

	Material Property						
Construction	P1 Monolayer	P2 Monolayer	P3 ABA	1 ABC	2 ABC	3 ABC	4 ABC
P1 layer/ microns	Isoplast 2530	Polyester A 250	Texin 950 75	Polyester B 250	Polyester B 250	Isoplast 2531	Polyester B 175
P2 layer/ microns	Isoplast 2530	Polyester A 250	Polyester A 600	Elastollan 1185A	Texin RxT 50D	Texin RxT 65D	Texin 950 LW
P3 layer/ microns	Isoplast 2530	Polyester A 250	Texin 950 75	Polyester B 250	Polyester B 250	Isoplast 2531	Polyester B 175
Flexural Modulus	1910 Mpa	1750 Mpa	675 Mpa	824 Mpa	968 Mpa	729 Mpa	575 Mpa
Elongation to break (%)	100-130	100-130	100-130	100-130	100-130	100-130	100-130
Impact Strength J/mm	15.2	6.9	—	—	9.2	14	—
Trouser Tear Force (N)	18	48	51	156	165	187	170
Load retention g (1)							
0 days	4244	3956	2664	2638	2739	2567	1598
1 day	707	853	875	1329	1469	1534	1232
2 days	498	601	823	1257	1389	1398	1247
Color change dB(2)	0.97	2.1	44	2.6	2.3	1.1	2.2

* Polyester A is a copolyester marketed by Eastman Chemical (Eastar 6763). Polyester B is cycloaliphatic copolyester marketed by Eastman Chemical under the tradename Tritan
(1) - 5% strain/37° C./water
(2)Mustard/24 hr/22° C.

C. Petitioner Copied Zendura™ FLX

1. 3M and Clarity™ Aligners Flex + Forces

183. In 2021, 3M began marketing an orthodontic clear aligner known as the 3M Clarity™ Aligners Flex ("Flex Aligner"). *See* Ex. 2048 (3M™ Clarity™ Aligners Webpage). I understand the Flex Aligner is used in treatment alongside the 3M Clarity™ Aligners Force ("Force Aligner"). *See* Ex. 2080. Both the products are shown in the images in **Figure 11** below:

Figure 11: 3M Clarity™ Aligners

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

185. The Flex Aligner is described as an orthodontic device made from a "[p]roprietary 5-layer blend of materials." Ex. 2048 (3M™ Clarity™ Aligners Webpage) 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.* **Figure 12** below is an image provided by 3M:

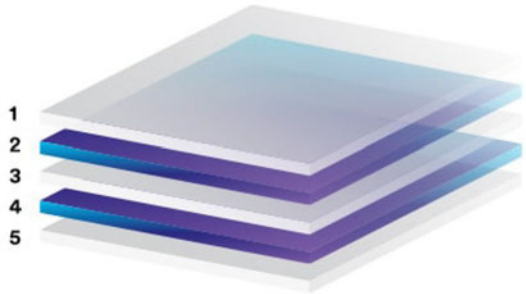


Figure 12: 3M Clarity™ Flex Aligner Layer Diagram

186. From the image in **Figure 12** above, 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.

187. 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. 2033 at 1. 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.* **Figure 13** below, an image 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":

Figure 13: 3M Clarity™ Flex Aligner Layer Composition (Ex. 2033 at 1)

188. 3M also explains that it "settled on a family of copolyesters as the materials" used in the 5-layer composition. *Id.* at 2. 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 **Figure 14** below:

Figure 14: 3M Clarity™ Aligner Thickness Diagram (Ex. 2033 at 2)

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 (**Figure 15**) demonstrating the elastic modulus of both its Flex and Force Aligners:

Figure 15: 3M Clarity™ Aligner Elastic Modulus Graph (Ex. 2033 at 2)

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

190. In addition to the information on 3M's website, 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. 2081, 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].

191. 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.* ¶¶ [0078], [0097]. 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.

192. 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.

193. Both Eastman Tritan MX710 and Eastman Ecdel 9967 have publicly available technical specification sheets, which I have included as Exhibits 2082 and 2083. 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. 2082 (Tritan™ Copolyester MX710 Data Sheet) at 1. 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. Ex. 2083 (Ecdel™ Elastomer 9967 Data Sheet) at 2. The tensile modulus was reported as 170 MPa for Ecdel 9967 and 1,550 MPa for Tritan MX710 as measured according to ASTM D638. Ex. 2082 (Tritan™ Copolyester MX710 Data Sheet) at 1; Ex. 2083 (Ecdel™ Elastomer 9967 Data Sheet) at 2.

194. I also understand that 3M internal documents show that it performed testing on Zendura™ FLX before introducing its Clarity Flex multilayer aligner product. The 3M documents I have reviewed indicate that in 2018, 3M obtained Zendura™ FLX samples and performed testing on those samples. Exs. 2030, 2031.

These documents show that 3M decided to prioritize improving force retention in its product, using Zendura™ FLX as a standard for comparison. Ex. 2031 at 6, 7, 11, 12. Other 3M internal documents show that 3M acquired further samples of Zendura™ FLX in January 2020, and that 3M attempted to license the ’630 patent. Exs. 2032, 2034. In my opinion, these documents reinforce that 3M copied Zendura™ FLX with their Clarity Flex product.

2. **Testing**

195. 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

196. 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:

FedEx
TO TIM OSWALD
1809 MADISON ST
MADISON WI 53711
TUE - 14 SEP 10:30A
PRIORITY OVERNIGHT
2836 2379 9953
XH MSNA
53711
MSN
Insert shipping document here.

3M | Clarity
3M | Clarity
Esthetic Orthodontic Solutions
UPPER ALIGNER FLEX
LOWER ALIGNER FORCE
2021-04-21
EXD:003
G8TPB16
2024-04-20

197. 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 Analysis

198. Prior to conducting the DSC testing, I developed a protocol to be used by my laboratory. Ex. 2084 (Osswald Protocol). I oversaw all testing conducted.

199. 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* Section XII.C.1. TX1001 is related to TX1000, another copolyester described in the ’657 application. *See* Ex. 2081 (the ’657 application) ¶ [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.

200. The samples were prepared and tested accorded to the protocol. *See* Ex. 2084 (Osswald Protocol). The results of the testing are described in detail in the testing report. Ex. 2085 (Osswald Report).

201. **Figure 16** below presents 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). *Id.* at 1. The DSC curves in the two graphs were measured at heating rates of 5 K/minute and 10 K/minute. *Id.* The thermograms presented in both figures all represent the behavior during the second heating. *Id.* at 1-2. The standard form of conducting DSC tests is to heat a sample at a constant rate, then cool the sample to the starting temperature. *Id.* at 2. This erases the thermal history a material underwent before the test. *Id.* Then, the sample is heated again to a high temperature, a heating processes referred to as "second heating." *See id.* at 1-2. 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. 2085 (Osswald Report) at 1-2.

202. Both graphs in **Figure 16**, 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. *See id.*, Figs. 3, 4. The MX710 and TX1001 show a glass transition temperature around 110 °C. *See id.* 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. *See id.* 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. *See id.* at Fig. 4.

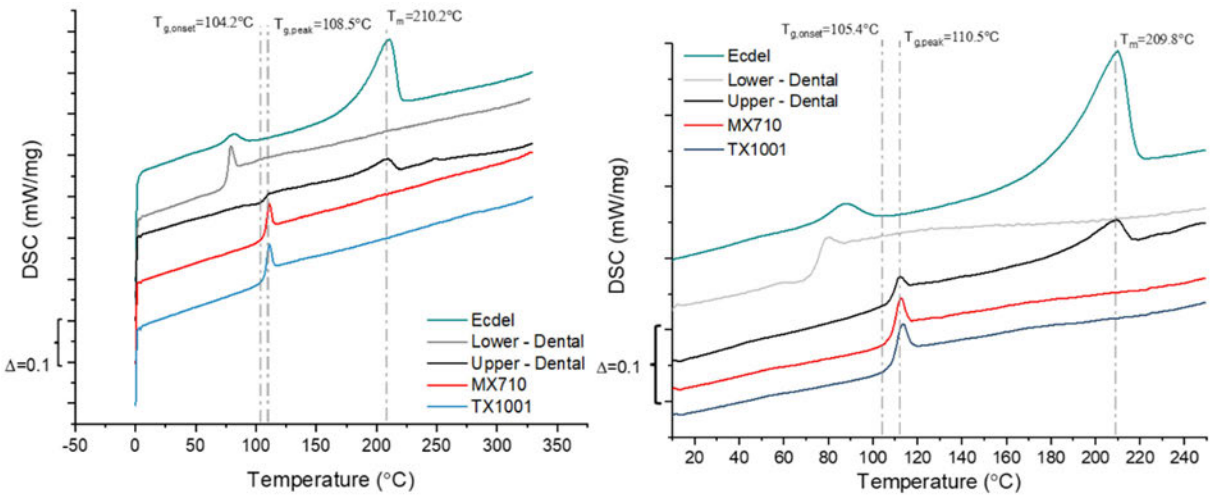


Figure 16: Thermograms of the 5 materials performed at 5 (left) and 10 (right) K/minute (Ex. 2085, Figs. 3, 4)

203. The thermogram data was analyzed and interpreted using Netzsch's analyzing software, Proteus®. *Id.* at 1.

204. The graph presented in **Figure 17** 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. *See id.*, Fig. 5(a)-(b). 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. *Id.* It should be noted that the error bars of the experiments performed at the lower heating rates of 5 K/minute are so small (±0.1 °C) that they are not visible in the diagram. *Id.*

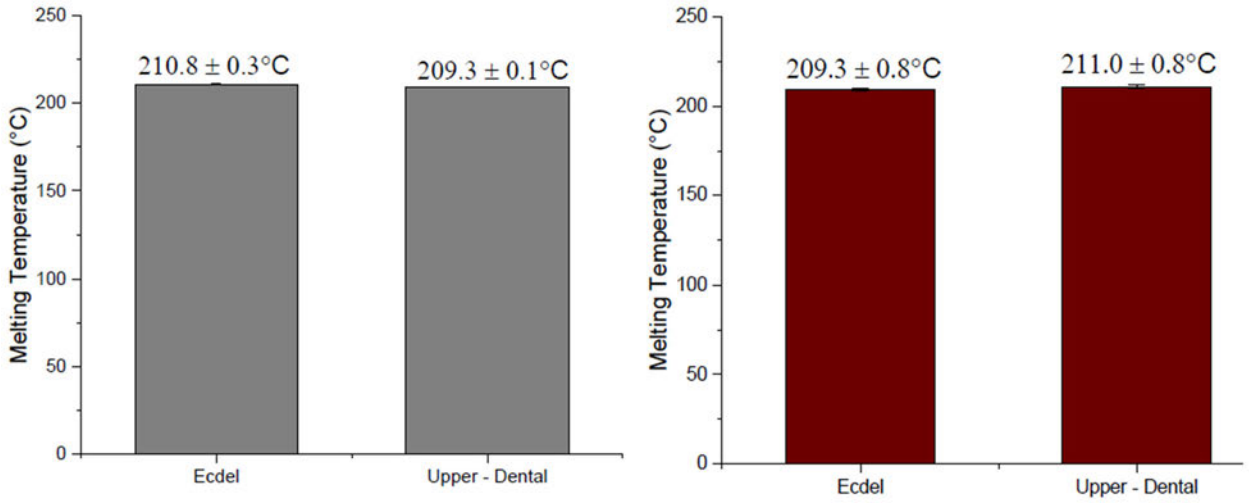


Figure 17: Melting Temperatures for Ecdel 9967 (left) and the Flex Aligner (Upper-Dental) samples measured at 5 (left) and 10 (right) K/minute (Ex. 2085, Fig. 5)

205. The graph presented in **Figure 18** 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. *Id.*, Fig. 5(a). 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. *Id.*, Fig. 5(b). 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.

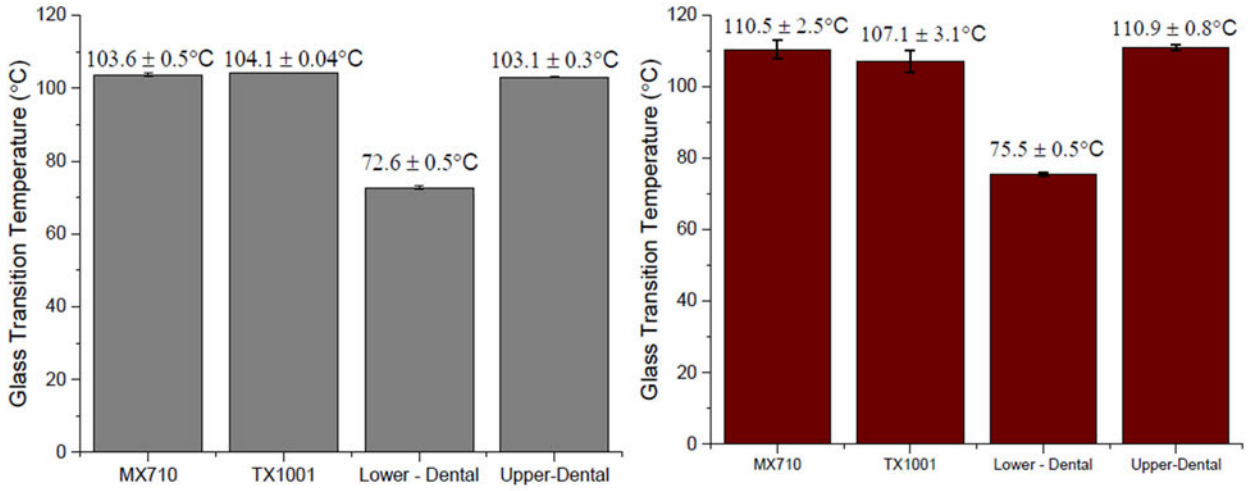


Figure 18: Glass Transition Temperature for four samples measured at 5 (left) and 10 (right) K/minute (Ex. 2085, Fig. 6)

206. 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 graphs in **Figure 18** above. *Id.*, Fig. 5(a)-(b). The thermographs presented in **Figure 19** below, corresponding to samples taken from the Flex Aligner (Upper-Dental), compare the heating rates of 5 K/minute and 10 K/minute. *Id.* at 7, Fig. 8. It is clear that both curves show approximately the same glass transition temperature and the same melting event. *Id.*, Fig. 8. The area between a baseline and the phase change peak corresponds to the heat of fusion of the Flex Aligner samples. *Id.* at 6-7. 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. *Id.*, Fig. 8.

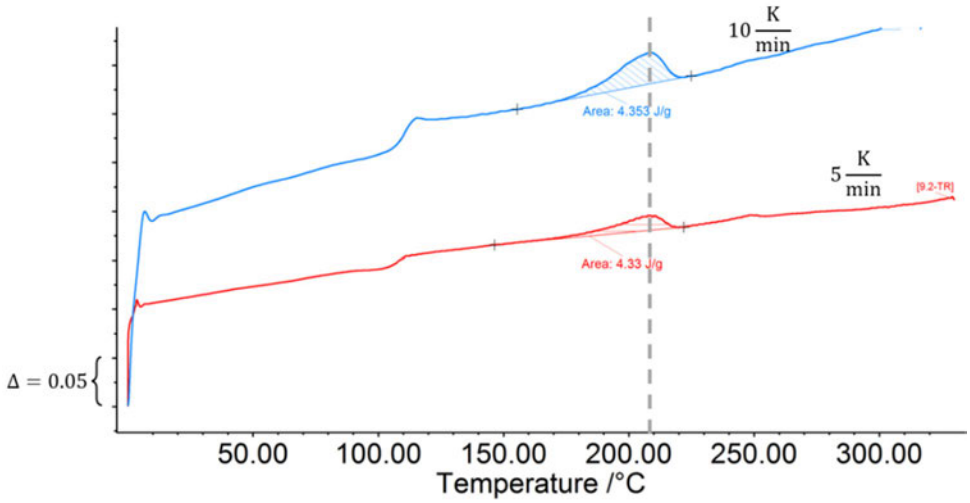


Figure 19: Thermograms that correspond to Flex Aligner samples taken at 5 and 10 K/minute heating rates (Ex. 2085, Fig. 8)

207. The graph in **Figure 20** below presents the thermograms of Ecdel 9967 samples taken at 5 and 10 K/minute heating rates. *Id.* at 6, Fig. 7.

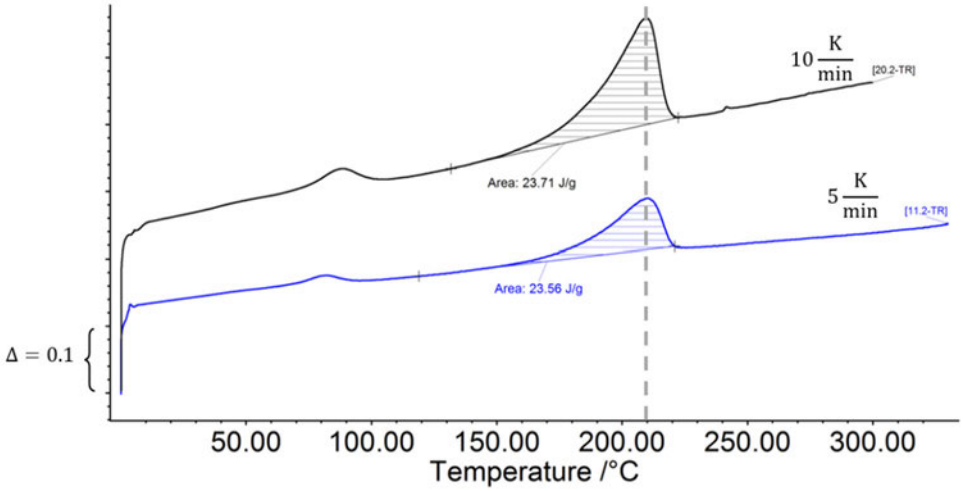


Figure 20: Thermograms of Ecdel 9967 taken at 5 and 10 K/minute heating rates (Ex. 2085, Fig. 7)

208. 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. *Id.*, Fig. 7. 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 11. 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* Section XII.C.2.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. 2085 (Osswald Report) at 9-10. 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 11.

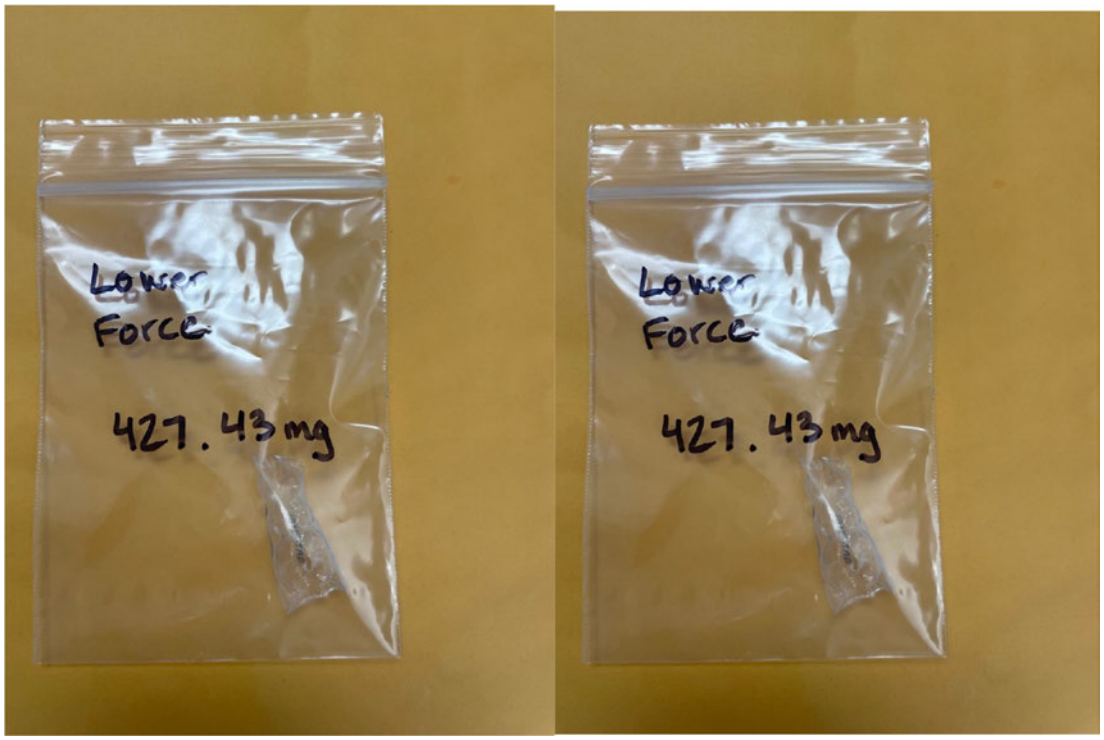
209. In my opinion, the Flex Aligner glass transition temperature at approximately 105 °C is sufficiently close to the Tritan MX710 glass transition temperature such that, when considered in combination with the other evidence discussed below, there is likely Tritan MX710 present in the Flex Aligner. 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

210. To further confirm the composition of the polymer layers in the Flex Aligner, I developed a protocol for McCrone to use. *See* Ex. 2086 (McCrone Protocol).

211. 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.

212. 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:



McCrone ran the FTIR and microscopy tests according to the protocol I developed. *See* Ex. 2086 (McCrone Protocol). The results of the testing are described in detail in the testing report, attached as Exhibit 2087 (McCrone Report).

213. The McCrone testing includes micrographs taken of three different cross sections of the Flex Aligner. *See* Ex. 2087 (McCrone Report) at 2-12, Figs. 1-8. The B cross-section of the Flex Aligner sample is shown in **Figure 21** 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:

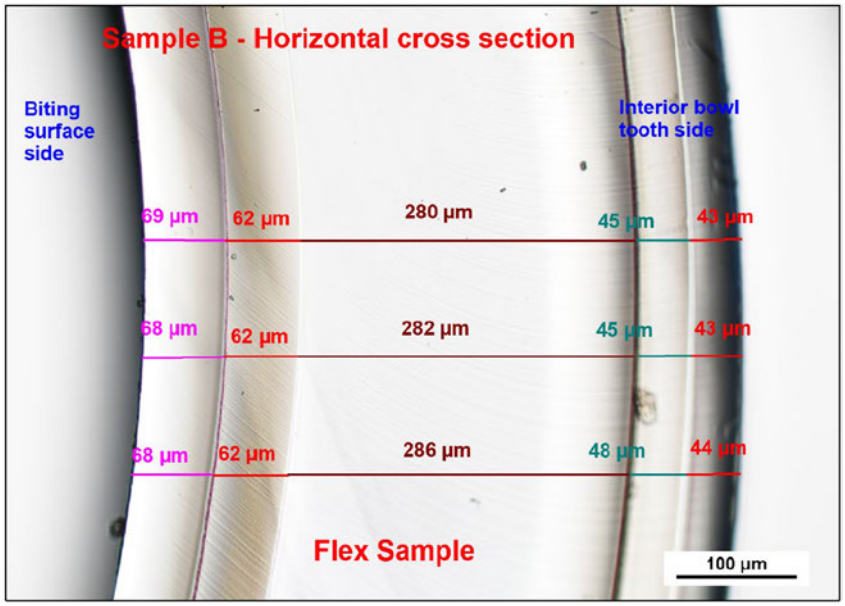


Figure 21: Five-Layer Sheet Micrograph Taken of the Flex Aligner Sample (Ex. 2087, Fig. 7)

214. As seen in the image in **Figure 21** above, the total aligner thickness was measured three different times. *Id.*, Fig. 7. The overall thickness of the cross section was measured at 499 microns, 500 microns, and 508 microns, depending on the location of the measurement. *Id.* All thickness measurements can be seen in the table summarized in the McCrone Report. *Id.* at 2, 4.

215. 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. The FTIR spectra for each of the five layers in the Flex Aligner are shown in Figures 12-16 of the McCrone Report.[7] *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

[7] The FTIR spectrum for the Force Aligner can be seen in the McCrone report. *See* Ex. 2087 (McCrone Report) at 21, Fig. 17.

Report Figure 9, showing the FTIR spectrum of Tritan MX710, and Figure 12, showing the FTIR spectrum of layer 1, as **Figures 22** and **23** below.

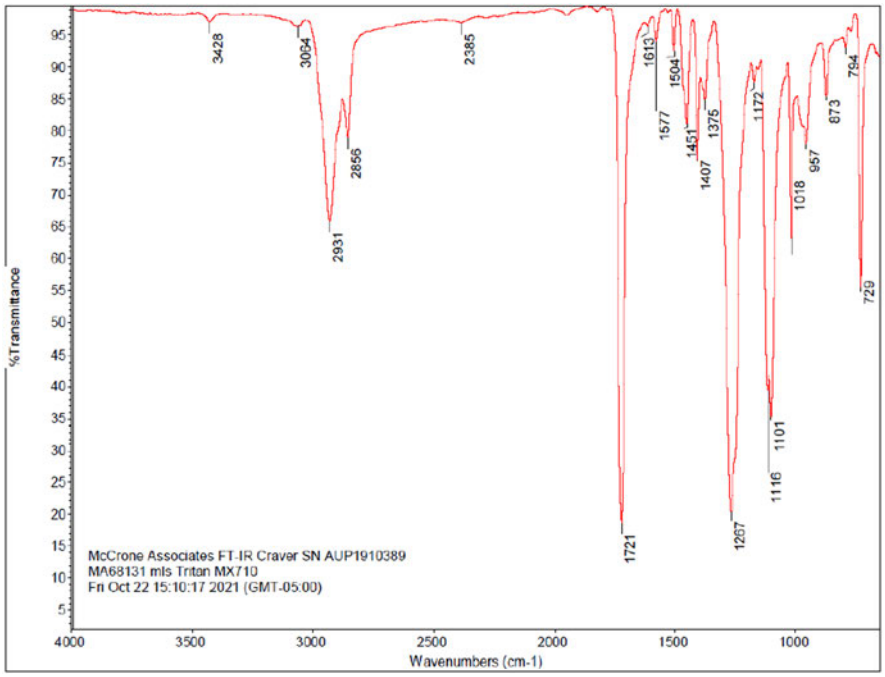


Figure 22: Tritan MX710 FTIR Spectrum (Ex. 2087, Fig. 9)

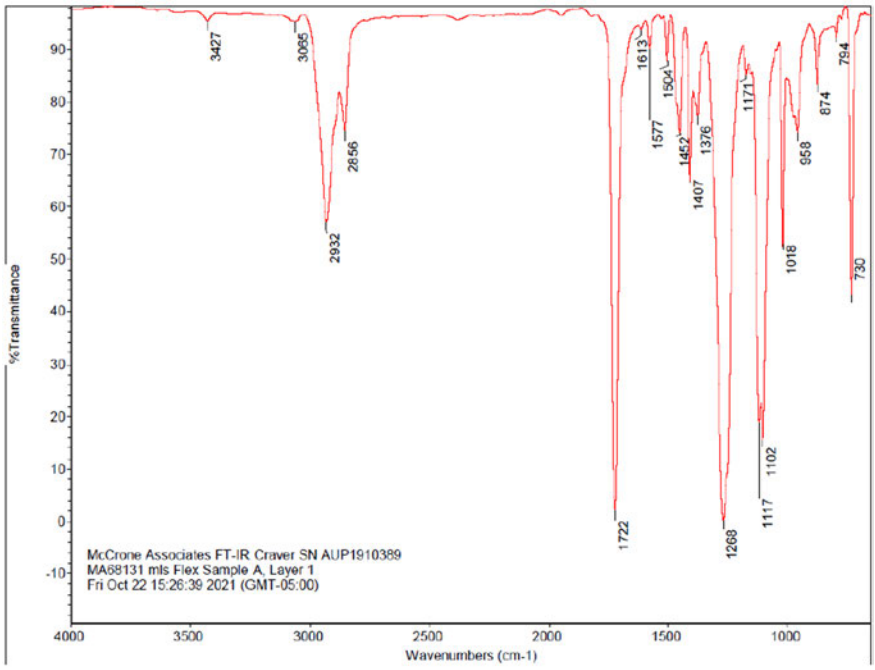


Figure 23: Flex Aligner Layer 1 FTIR Spectrum (Ex. 2087, Fig. 12)

216. 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. 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, as **Figures 24** and **25** below.

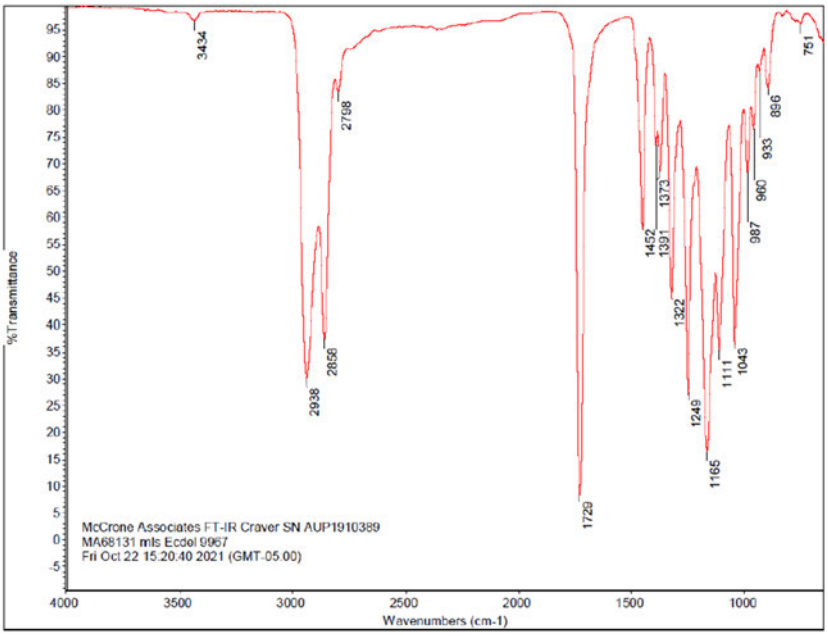


Figure 24: Ecdel 9967 FTIR Spectrum (Ex. 2087, Fig. 11)

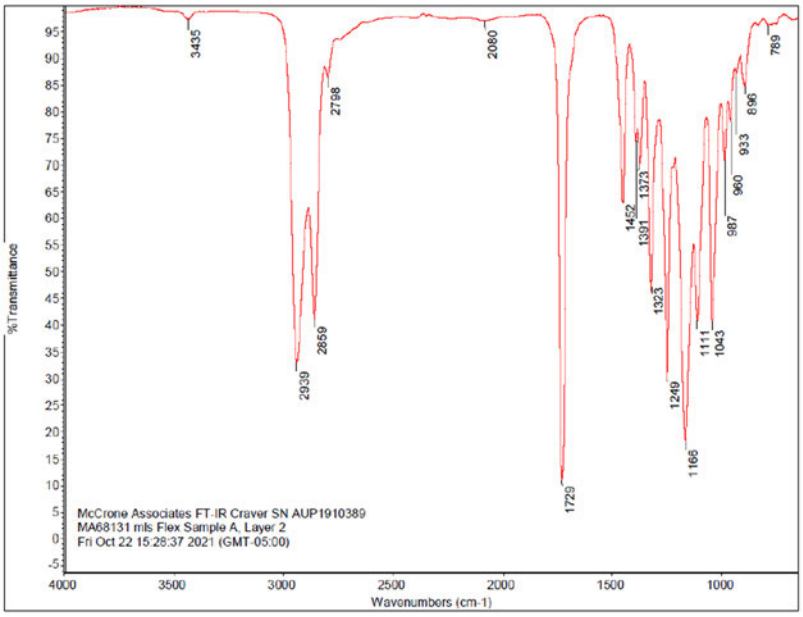


Figure 25: Flex Aligner Layer 2 FTIR Spectrum (Ex. 2087, Fig. 13)

217. 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.

D. Zendura™ FLX Received Industry Praise

218. In my opinion, a skilled artisan would have understood that the Zendura™ FLX received industry praise based on the features claimed in the ’630 patent. Indeed, the Zendura™ FLX quickly became the industry baseline material

for clear, multi-layer aligners. And competitors, including Petitioner, have praised Zendura™ FLX's desirable performance characteristics. Petitioner's internal documents, for example, state that Zendura™ FLX provides "excellent stain resistance and force retention . . . compared to Invisalign." Ex. 2025 at 6. Petitioner also stated that Zendura™ FLX stains less than Align's product and provides "[i]mproved stress retention." Ex. 2025 at 2. In my opinion, a skilled artisan would have understood that this praise for the features of Zendura™ FLX disclosed and claimed in the '630 patent is additional objective evidence of nonobviousness.

XIII. CONCLUSION

219. For the reasons set forth above, it is my opinion that claims 1-4, 7-11, and 13 would not have been obvious to a person of ordinary skill in the art at the time of invention.

220. In signing this Declaration, I understand it 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 understand 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.

221. I declare 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.

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

Date: 4/12/23

Dr. Tim A. Osswald