UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC,	)	
	)	IPR2025-00818
Petitioner,	)	IPR2025-00819
	)	IPR2025-00820
vs.	)	IPR2025-00821
	)	
ALIGN TECHNOLOGY, INC.,	)	
	)	
Patent Owner.	)	
	)	

VIDEOCONFERENCE DEPOSITION OF DR. TIM A. OSSWALD

July 2, 2026

Taken Remotely Via Zoom

ALIGN – EXHIBIT 2036
ClearCorrect Operating, LLC. v. Align Technology, Inc. IPR2025-00819

Reporter: Teri Simons, CCR, RMR, CRR

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ALL PARTIES APPEARING VIA ZOOM

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EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION	PAGE NO.
Exhibit A	U.S. Patent 5,939,519.	34
Exhibit B	U.S. Patent 9,963,543.	45
Exhibit C	11-page article "Advanced polymerization and properties of biobased high T sub g polyester of isosorbide and 1,4-cyclohexanedicarboxylic acid through in situ acetylation."	54
Exhibit D	146-page transcript of a motions hearing, dated 6/27/26.	86
Exhibit E	253-page transcript of "July trial proceedings," dated 6/24/26.	102

BE IT REMEMBERED that on Thursday, July 2, 2026, at 7:01 A.M., before Terilynn Simons, Certified Court Reporter, CCR, RMR, CRR, CLR, appeared DR. TIM A. OSSWALD, the witness herein;

WHEREUPON, the following proceedings were had, to wit:

<<<<<< >>>>>>

DR. TIM A. OSSWALD, having been first duly sworn by the Certified Court Reporter, testified as follows:

EXAMINATION

BY MR. ARGENTI:

Q Good morning again, Dr. Osswald. 07:01:00

A Good morning. 07:01:02

Q Where are you located today? 07:01:03

A In Washington, D.C. 07:01:05

Q Are you in the offices of the Finnegan law firm? 07:01:07

A Yes, I am. 07:01:12

Q Is there anyone in the room with you today? 07:01:13

A Yes. Three attorneys. 07:01:16

Q Who are they? 07:01:19

A Charles Collins-Chase, Pier, and Kyle Howarth. 07:01:20

Q Do you have printed copies of your declarations and the cited exhibits that you can refer to today? 07:01:29 07:01:35

A I do. 07:01:37

Q And are those clean copies without any notes on them? 07:01:38
A Yes. 07:01:42
Q The same ground rules that we used for the last deposition also apply today. 07:01:42 07:01:49
I can go through them again if you'd like, but I'm happy to just jump ahead if you're familiar with them. 07:01:51 07:01:54
A I'm familiar with them. 07:01:57
Q Okay. Is there any reason that you cannot provide complete and accurate testimony today? 07:01:58 07:02:00
A No. 07:02:02
Q In your last deposition we spoke about the declarations that you had submitted in four IPRs, correct? 07:02:02 07:02:09
A Yes. 07:02:12
Q Since that deposition you have submitted a reply declaration in those four IPRs, right? 07:02:13 07:02:17
A Correct. 07:02:20
Q And you submitted the same reply declaration in each of the four IPRs, right? 07:02:21 07:02:25
A Yes. 07:02:26
Q So why don't we pull out a copy of that declaration, if you could pull out Exhibit No. 1148. 07:02:27 07:02:33
A Yes. 07:02:38
Q And which IPR is this copied from? What's the number at the bottom of the page? 07:02:39 07:02:47
A 00818. 07:02:48

Q Okay. And this document is your reply declaration, correct? 07:02:51 07:02:58
A Yes. 07:02:58
Q And it's the same reply declaration that was submitted in the other three IPRs, the '819 IPR, the '820 IPR, and the '821 IPR, right? 07:02:59 07:03:03 07:03:05
A Yes. 07:03:08
Q Anything about your reply declaration that you would like to modify or correct today? 07:03:08 07:03:13
A No. 07:03:15
Q How many hours did you spend preparing your reply declaration? 07:03:15 07:03:22
A I don't remember. Many hours. 07:03:23
Q How many hours did you spend preparing for this deposition? 07:03:26 07:03:32
A I mean, I've been here for two days, and before I prepared some, so also a lot of hours. 07:03:33 07:03:40
Q When you were preparing for your deposition, did you review any documents? 07:03:43 07:03:46
A Yes. 07:03:48
Q Did you review your reply declaration? 07:03:49
A Yes. 07:03:54
Q Did you review your four original declarations? 07:03:55
A Just one major-- a couple of them, yes. 07:03:59
Q Do you remember which one you reviewed? 07:04:06

A The 6-- the one pertaining to the '613 patent and I think the '091. 07:04:08 07:04:14
Q Did you review any other documents? 07:04:15
A Yes. Some of the references. 07:04:17
Q Those are all exhibits in these IPRs already? 07:04:21
A Yes. 07:04:25
Q In preparing for your deposition, did you review any documents that are not cited in your declarations? 07:04:25 07:04:30
A No. 07:04:33
Q Have you reviewed Align's patent owner responses in these IPRs? 07:04:33 07:04:40
A I don't think so. 07:04:41
Q What about Align's motion for routine or additional discovery, have you reviewed that? 07:04:43 07:04:50
A I don't think so. 07:04:51
Q So you said you have been at the Finnegan offices for a couple of days, I believe. 07:04:53 07:05:05
Who did you meet with to prepare for your deposition? 07:05:07 07:05:09
A With the same attorneys that are present here in the room today. 07:05:10 07:05:12
Q Okay. Is it accurate that you met with them over the two previous days? 07:05:13 07:05:18
A Yes. 07:05:19
Q About how long did those meetings last? 07:05:20

A The whole day. 07:05:24
Q Did you have any meetings to prepare, other than those two-day meetings? 07:05:25 07:05:30
A Yes. Online meetings. 07:05:31
Q How many online meetings did you have? 07:05:34
A I don't remember, maybe two or three. 07:05:36
Q And what was the duration of those, approximately? 07:05:39
A A couple of hours. 07:05:45
Q Let's look at your reply declaration now. 07:05:47
Let's turn to Page 11, please. We'll look at Paragraph No. 18 here. 07:05:53 07:06:01
A Yes. 07:06:07
Q You see the figures in the middle of Paragraph No. 18? 07:06:08
A Yes. 07:06:15
Q And on the right side of those figures, the one that has the arrow pointing to them, that's Formula VIII from the Tadros reference, right? 07:06:16 07:06:20 07:06:23
A Correct. 07:06:26
Q You've drawn a red box around the left side of Formula VIII and a blue box around the right side, correct? 07:06:27 07:06:33
A Yes. 07:06:35
Q And you did that to identify the constituent components of Formula VIII's PCCD; is that right? 07:06:36 07:06:42
MR. COLLINS-CHASE: Objection; form. 07:06:46
THE WITNESS: Those point to the 07:06:49

portions that make-- form-- were part of the original two monomers, or three monomers in this case, that were used to copolymerize the PCCD. 07:06:51 07:07:00 07:07:05

Q (By Mr. Argenti) The red box identifies CHDM, right? 07:07:11

A Yes. 07:07:14

Q And that is 1,4-cyclohexanedimethanol, correct? 07:07:14

MR. COLLINS-CHASE: Objection; form. 07:07:23

THE WITNESS: Yeah, it's poly-- well, that there is poly 1,4-cyclohexadiene, yes. 07:07:24 07:07:32

(Discussion off the record.) 07:09:00

Q (By Mr. Argenti) Dr. Osswald, you can see that I've pulled up for screen share a copy of Exhibit No. 1148, which is your reply declaration, correct? 07:09:01 07:09:04 07:09:08

A Yes. 07:09:10

Q And I will scroll down to Page 11 in Paragraph No. 18, which is the paragraph that we were just talking about, and my question had been that that CHDM component is cyclohexanedimethanol, and I believe-- correct me if I'm wrong, but I believe your response is that it is cyclohexylenedimethylene, the compound in red in the last line of that paragraph; is that right? 07:09:11 07:09:18 07:09:22 07:09:34 07:09:36 07:09:45 07:09:47

MR. COLLINS-CHASE: Objection; form. 07:09:51

THE WITNESS: Yeah, it's the CHDM portion in the Formula VIII, the PCCD copolymer. 07:09:52 07:09:57

Q (By Mr. Argenti) And I got cyclohexanedimethanol 07:10:08

from-- let me find this-- Paragraph 14, the first line of Paragraph No. 14 on Page 8 where it says, "PCCD is generally formed from the polycondensation of cyclohexanedimethanol with"-- the other materials listed there. 07:10:16 07:10:23 07:10:29 07:10:31 07:10:38

Do you see that? 07:10:39

A Yes. 07:10:39

Q What, if any, is the distinction between cyclohexanedimethanol, as listed in the first sentence of Paragraph No. 14, and cyclohexylenedimethylene that's highlighted in red in Paragraph No. 18? 07:10:40 07:10:48 07:10:50 07:10:57

A Well, it's the diol used in the monomer form. It's the diol used to polymerize the system. 07:11:01 07:11:08

Q So then you would agree that CHDM is a diol, right? 07:11:12

A Correct. 07:11:19

Q Looking at the blue box in the Figure 8 in Paragraph No. 18, that blue box you identify is either DMCD or CHDA, correct? 07:11:27 07:11:34 07:11:41

A Correct. 07:11:42

Q And DMCD is dimethyl cyclohexanedicarboxylate, correct? 07:11:45

A Well, the blue box corresponds to what is formed from the original monomers, either DMCD or CHDA. 07:11:54 07:12:02

Then after polymerization, copolymerization, that's what it ends up being in the molecule. 07:12:10 07:12:16

Q And for the benefit of the reporter and the record, I 07:12:18

will jump back again to Paragraph No. 14, and the first line where it lists "dimethyl cyclohexanedicarboxylate (DMCD) or cyclohexanedicarboxylic acid (CHDA." 07:12:21 07:12:27 07:12:36

That gives the more detailed description of what DMCD or CHDA is, correct? 07:12:47 07:12:52

MR. COLLINS-CHASE: Objection; form. 07:12:56

THE WITNESS: Yeah, these are the original monomers that are used to copolymerize the PCCD molecules. 07:12:59 07:13:00 07:13:08

Q (By Mr. Argenti) Both DMCD and CHDA are diacids, right? 07:13:10 07:13:16

A Correct. 07:13:17

MR. COLLINS-CHASE: Objection; form. 07:13:17

Q (By Mr. Argenti) Looking back at Paragraph No. 18 and the Figure 8-- sorry, Formula VIII figure on the right with the red box and the blue box, which of those two boxes, the red box or the blue box, has an ester in it? 07:13:20 07:13:27 07:13:31 07:13:34

MR. COLLINS-CHASE: Objection; form, foundation. 07:13:42 07:13:43

THE WITNESS: I think you are going deeper into the chemistry of the presentation. 07:13:43 07:13:45

If you can point me to where I wrote about it in my report, I can clarify that. 07:13:51 07:13:54

Q (By Mr. Argenti) Well, I'm asking you for your understanding of this annotated figure in your reply 07:14:01 07:14:02

declaration, Dr. Osswald. 07:14:07

Do either the red box or the blue box have an ester in them? 07:14:09 07:14:17

MR. COLLINS-CHASE: Objection; form. 07:14:18

THE WITNESS: Well, they are-- it's a copolyester formed of-- if you look at the original formulas on Page 9, you can see the DMCD that have esters in it before de-esterification. 07:14:20 07:14:21 07:14:26 07:14:48

Q (By Mr. Argenti) So you were referring to Page 9 of your reply declaration? 07:14:52 07:14:55

A Correct, which is part of the Paragraph 14. 07:14:56

Q Paragraph 14, and you were referring to DMCD? 07:15:03

A Correct. 07:15:08

Q And I believe you said DMCD is where you can see the ester or-- was it "ester" or "esters," singular or plural? 07:15:09 07:15:14 07:15:18

MR. COLLINS-CHASE: Objection; form. 07:15:19

THE WITNESS: There are two of them in the molecule on each end. 07:15:21 07:15:24

Q (By Mr. Argenti) Does CHDA have esters as well? 07:15:32

A I would have to review my basic chemistry. 07:15:34

I didn't write about the complete description of these monomers. 07:15:43 07:15:47

Q CHDM has no ester component, correct? 07:15:49

MR. COLLINS-CHASE: Objection; form. 07:15:58

THE WITNESS: Again, I would have to go back and review the chemistry of copolymerization of copolyesters, so I-- if I wrote it-- if I wrote about it in my report, I'm happy to answer a question about it. 07:16:00 07:16:01 07:16:09 07:16:13 07:16:16

Q (By Mr. Argenti) In the DMCD molecule, what specifically were you referring to as the esters? 07:16:18 07:16:22

MR. COLLINS-CHASE: Objection; form. 07:16:26

THE WITNESS: Again, I would have to go back and review the chemistry of it. 07:16:28 07:16:32

I did not prepare for that in this-- for this deposition. 07:16:35 07:16:41

I am happy to look at-- if you can point me in my report to where I discuss that, I will be happy to answer a question, give you an accurate answer. 07:16:41 07:16:47 07:16:51

Q (By Mr. Argenti) Dr. Osswald, you testified that DMCD has esters in it that you were able to identify. 07:16:55 07:16:59

I'm just asking where those are. 07:17:02

A At the end of the molecule, of the monomer. 07:17:04

Q Which portions of the figure here are the esters? 07:17:10

A Again, I would have to go back and review the chemistry of copolyester copolymerization. 07:17:16 07:17:25

If I wrote anything about it in my reply report, you can point me to it. Otherwise, I couldn't give you an accurate answer, so I'm happy to answer anything 07:17:30 07:17:34 07:17:40

that I wrote in my report. 07:17:44

Q Dr. Osswald, you are aware that a disputed issue in this case is whether Formula VIII discloses a copolyester, correct? 07:17:45 07:17:50 07:17:54

MR. COLLINS-CHASE: Objection; form. 07:17:57

THE WITNESS: I don't see it as disputed. 07:17:59 07:18:00

I think according to Tadros, that is a copolyester. 07:18:01 07:18:04

If you look at Tadros's description and embodiment and the specifications, he clearly talks about mixtures of isomers at various ratios, 3 to 1, 4 to 1, and he then also describes mixtures of isomers would lead to copolyester, PCCD copolyester. 07:18:06 07:18:11 07:18:19 07:18:28 07:18:33

I don't think that's disputed. I think that's part of the reference, the prior art. 07:18:40 07:18:43

Q (By Mr. Argenti) Dr. Osswald, would repeating units of CHDM on their own be considered a polyester? 07:18:48 07:18:50

MR. COLLINS-CHASE: Objection; form. 07:18:56

THE WITNESS: Well, I mean, in the sense of a copolymer, the definition of a copolymer, is having two monomers or more that are copolymerized, so if you have a diacid and you have a polyol, they are two monomers, so in my definition in my book, "Material Science of Polymers for Engineers," as well as the 07:18:57 07:18:59 07:19:05 07:19:12 07:19:18 07:19:23

definition given by Dr. Kimmel, that would be a copolymer or copolyester. 07:19:26 07:19:30

Q (By Mr. Argenti) In your answer just now you said if you have a diacid and a-- did you say "polyol"? 07:19:44 07:19:46

A Yes. Hang on. 07:19:52

A "diol," sorry. I-- that was a brain slip. A diol. 07:20:08 07:20:14

Q Right. 07:20:15

And I'm asking just about-- if we look at Paragraph No. 18, I think the red box designates -- and I might get these backwards, right -- the diol, and the blue box designates the diacid; is that right? 07:20:15 07:20:19 07:20:26 07:20:33

MR. COLLINS-CHASE: Objection; form. 07:20:36

THE WITNESS: Yeah, there's CHDM, which is used together with either DMCD or CHDA. 07:20:39 07:20:42

The CHDM would be the diol and the other ones would be a diacid. 07:20:46 07:20:50

Q (By Mr. Argenti) And my question was whether you repeated units of just CHDM, just the diol. 07:20:51 07:20:52

Would that be a polyester? 07:20:57

MR. COLLINS-CHASE: Objection; form. 07:21:01

THE WITNESS: Well, you're asking me to invent a polymer here, and I simply-- I am happy to answer the copolymerization of a diol and a diacid and not start inventing a chemistry here or synthesizing 07:21:02 07:21:03 07:21:10 07:21:14

new polymers. 07:21:20
I stay with my answer. 07:21:22
If you have two monomers and you copolymerize those two monomers, you have a copolymer, which is the same that Dr. Kimmel says in his report. 07:21:25 07:21:29 07:21:33
Q (By Mr. Argenti) All right. Let's take a look now at Paragraph No. 11 of your reply declaration, please. 07:22:19 07:23:07
In this Paragraph No. 11 and then the next paragraph, Paragraph No. 12, you discuss Exhibit 1153, which is an Eastman patent publication, right? 07:23:25 07:23:27 07:23:33
A Correct. 07:23:37
Q If we look at the back of your declaration, the appendix with the exhibit list, it looks like the Eastman patent publication is Exhibit No. 1151. 07:23:38 07:23:44 07:23:52
Do you see that? 07:23:59
A That's correct. 07:24:00
Q Why don't we take that Exhibit 1151 out, if you have a copy of it. 07:24:00 07:24:07
I have opened it up. It looks like I'm still screen sharing. 07:24:13 07:24:17
Can you see that on the screen? 07:24:18
A Yes. 07:24:19
Q Okay. Is this-- 07:24:19
MR. COLLINS-CHASE: Counsel, we are just getting the document out of the box. 07:24:24 07:24:25

MR. ARGENTI: Sure. 07:24:27

Q (By Mr. Argenti) I will scroll down, Dr. Osswald, so we can see the marking of Exhibit No. 1151 on the screen. 07:24:30 07:24:32 07:24:45

A I have it. 07:24:52

Q Okay. I am just trying to clarify the exhibit number. 07:24:53

I believe Paragraphs 11 and 12 of your declaration are meant to refer to this Exhibit 1151 as opposed to 1153. 07:24:57 07:25:01 07:25:06

Does that sound right to you? 07:25:07

A That sounds right, yes. 07:25:09

Q Okay. And in your reply declaration you cite Eastman, Exhibit 1151, as referring to a PCCD copolyester, right? 07:25:12 07:25:22 07:25:28

A Correct. 07:25:29

Q For example, you cite Paragraph 1 of Eastman, and that's at the bottom of Page 7 of your declaration. 07:25:29 07:25:39

Do you see that? 07:25:42

A Yes. 07:25:43

Q So I'm going to scroll down to Paragraph No. 1 and look at that paragraph. 07:25:43 07:25:51

There we go. 07:25:56

Can you read the second sentence of Paragraph No. 1 of Eastman for me? 07:25:57 07:26:07

A I see only one sentence. 07:26:22

Paragraph 1? 07:26:26

Q Paragraph 1, the first sentence is just, "Clear blends of two polymers are rare." 07:26:28 07:26:33

Can you read the second sentence for me? 07:26:35

A Sure. Yes. Yes. I'm sorry. 07:26:38

"Even rarer are clear blends of aromatic copolyesters (PTTMCD) and aliphatic copolyesters (PCCD) due to the unfavorable interactions that are common between saturated (free electron count is low) and unsaturated polymeric species (free electron count is high)." 07:26:41 07:26:44 07:26:53 07:26:56 07:27:02 07:27:09

Q If you look down at Paragraph 3 on the same page under the "Brief summary of the invention" heading, it looks like that paragraph does have just a single sentence. 07:27:09 07:27:09 07:27:11

Do you see that? 07:27:14

A Yes. 07:27:14

Q Can you read that sentence for me? 07:27:15

A "This invention provides blends of polyesters comprising units of terephthalic acid 2,2,4,4-tetramethy-1,3-cyclobutanedio (PTTMCD) with polyesters comprising units of 1,4 cyclohexanedicarboxylic acid and 1,4 cyclohexanedimethanol (PCCD) having excellent clarity, good heat resistance, and good toughness." 07:27:21 07:27:24 07:27:37 07:27:39 07:27:39 07:27:43 07:27:53

Q Thank you. 07:27:53

That sentence refers to PCCD as a polyester rather than a copolyester, right? 07:28:04 07:28:08

MR. COLLINS-CHASE: Objection; form. 07:28:10

THE WITNESS: Well, a copolyester is a polyester. 07:28:11 07:28:13

The bigger umbrella are polyesters, and copolyesters are polyesters as well, so-- 07:28:15 07:28:21

Q (By Mr. Argenti) But not all polyesters are copolyesters, correct? 07:28:23 07:28:25

MR. COLLINS-CHASE: Objection; form. 07:28:27

THE WITNESS: Well, it's a matter of definition. 07:28:29 07:28:30

If you have-- if you have two or more monomers that are copolymerized, then those polyesters are copolyesters. 07:28:31 07:28:36 07:28:40

Q (By Mr. Argenti) So under that definition, what would be an example of a polyester that is not a copolyester? 07:28:53 07:28:54

MR. COLLINS-CHASE: Objection; form. 07:28:59

THE WITNESS: Well, one would be polymerized from a single monomer. 07:29:00 07:29:03

Again, I'm not willing here today to synthesize different polymers. 07:29:05 07:29:14

I would have to go back to PCCD. 07:29:15

And in my report here I'm rebutting the report of Dr. Kimmel where he says that since Tadros refers to 07:29:20 07:29:26

PCCD acid polyester, that therefore it is a polyester not a copolyester, but that's not the case. 07:29:34 07:29:39

PCCD in Tadros is clearly a copolyester. Tadros himself says that, that when you use mixtures of isomers, of geometric isomers, you would have a copolyester, and all the embodiments that Tadros has of PCCD, they are mixtures, and so they are copolyester, and I think it would be hard to find a PCCD that is not a mixture of isomers. 07:29:41 07:29:49 07:29:53 07:29:58 07:30:06 07:30:13 07:30:17

So PCCD is clearly a copolyester. 07:30:19

Sure, people loosely exchange "polyesters" and "copolyesters," but polyesters include copolyesters, so referring to something as a polyester doesn't necessarily exclude it to be a copolyester. 07:30:25 07:30:28 07:30:35 07:30:38

Clearly this reference, at least in two points, the patent refers to PCCD as a copolyester, as a copolymer. 07:30:41 07:30:44 07:30:48

Q (By Mr. Argenti) Dr. Osswald, does a polyester have to have ester linkages in order to be considered a polyester? 07:31:00 07:31:03 07:31:08

MR. COLLINS-CHASE: Objection; form. 07:31:08

THE WITNESS: Again, I did not discuss what ester linkages, et cetera, are in PCCD or in polyesters. 07:31:09 07:31:11 07:31:18

I will stick to my report to give you accurate 07:31:20

responses. 07:31:23

Again, I mean, this reference itself also in Paragraph No. 462, as I reference there, also refers to a PCCD as a copolyester. 07:31:25 07:31:29 07:31:35

So clearly PCCD is a copolyester. 07:31:40

Q (By Mr. Argenti) And your testimony that a polyester is defined by being comprised of two different monomers, is that something that you took from Dr. Kimmel's testimony or is that something that you find in the art? 07:31:56 07:32:06 07:32:11 07:32:16 07:32:19

MR. COLLINS-CHASE: Objection; form, foundation. 07:32:20 07:32:22

THE WITNESS: I mean, I think a copolyester is one where you have two different monomers that are copolymerized. 07:32:23 07:32:26 07:32:33

People do use-- I mean, they have different definitions of polyesters and copolyesters in various books and treatises, but we have to go back here to the Tadros reference, which is really what is at hand here as prior art to the patents, and the Tadros reference refers to PCCD as a copolyester. 07:32:37 07:32:41 07:32:45 07:32:51 07:32:54 07:33:00

In fact, in his mixtures that Tadros proposes, there are at least two different copolyesters, clearly what people call copolyesters, like PETG is also one of the embodiments of Tadros that he refers to in his 07:33:05 07:33:10 07:33:16 07:33:21

mixtures. 07:33:26

It is clear that the Tadros reference has 07:33:27
copolyester mixtures, polycarbonate copolyester 07:33:34
mixtures. 07:33:39

Tadros refers to PCCD as a copolyester, so a 07:33:40
person having ordinary skill in the art would see that 07:33:46
reference and understand that Tadros uses a copolyester 07:33:50
in his mixtures to make the hard layer of an aligner. 07:33:56

Q (By Mr. Argenti) Dr. Osswald, what is your 07:34:03
understanding of what the word "comprising" means in 07:34:04
the context of a patent disclosure? 07:34:08

MR. COLLINS-CHASE: Objection; form, 07:34:11
calls for a legal conclusion. 07:34:12

THE WITNESS: I mean, I'm not an 07:34:13
attorney, but if you have "comprising," that means part 07:34:15
of it is whatever you're doing. It comprises many 07:34:24
aspects. One of them is or two of them are these 07:34:29
items. 07:34:33

Again, I'm not an attorney, so I'm not, I think, 07:34:33
qualified to do claim construction here in this 07:34:38
deposition. 07:34:44

Q (By Mr. Argenti) Right. 07:34:45

I'm just asking for your understanding, 07:34:46
Dr. Osswald. 07:34:48

So would you agree that "comprising" indicates an 07:34:49

open-ended disclosure as opposed to "consisting of" that's closed? 07:34:53 07:34:57

MR. COLLINS-CHASE: Objection; form. 07:34:59

THE WITNESS: I mean, again, I understand the word "comprising." 07:35:00 07:35:02

I am not qualified as an attorney or somebody to give you a more in-depth definition, so I prefer not to answer the-- I wouldn't be able to give you an accurate answer to the meaning of the term "comprising." 07:35:04 07:35:08 07:35:13 07:35:16

I already answered your question, I think. 07:35:22

Q (By Mr. Argenti) Looking back at Paragraph 3 of Eastman, it uses the word "comprising" when describing the composition of PCCD here, right? 07:35:25 07:35:29 07:35:34

MR. COLLINS-CHASE: Objection; form. 07:35:42

THE WITNESS: It says, "Polyesters comprising units of"-- and then it describes the units as having excellent clarity, good heat resistance, and good toughness. 07:35:44 07:35:46 07:35:53 07:35:57

Q (By Mr. Argenti) Let's turn to Claim 1 at the end of Eastman, Exhibit No. 1151. 07:36:03 07:36:05

A Yes. 07:36:32

Q Claim 1 recites a polymer blend. 07:36:33

Do you see that? 07:36:36

A Yes. 07:36:37

Q And it is a polymer blend comprising at least one 07:36:40

aliphatic-aromatic copolyester as recited in Section A and at least one aliphatic polyester as recited in Section B-- actually, strike that. I think I misspoke. Let me ask that question again, Dr. Osswald, before you get a chance to correct me. 07:36:48 07:36:55 07:37:00 07:37:03 07:37:06

So Claim 1 of Eastman recites a polymer blend comprising at least one aliphatic-aromatic copolyester as recited in Section A, and at least one aliphatic polyester as recited in Section B, right? 07:37:08 07:37:13 07:37:17 07:37:23

MR. COLLINS-CHASE: Objection; form. 07:37:25

THE WITNESS: Yeah, it would comprise A and B. 07:37:27 07:37:35

Q (By Mr. Argenti) The aliphatic-aromatic copolyester of Section A in Claim 1 is not PCCD? 07:37:38 07:37:42

MR. COLLINS-CHASE: Objection; form. 07:37:47

THE WITNESS: I would have to go back and study the whole reference to refresh my memory of what-- what mixture-- I think Table 1 gives you a different-- gives you pictures of Example 1 and comparative examples of 2 and 3. 07:37:49 07:37:56 07:38:02 07:38:11 07:38:15

Q (By Mr. Argenti) Well, just looking at the components recited in Claim 1, Section A, is that the composition of PCCD? 07:38:20 07:38:21 07:38:28

MR. COLLINS-CHASE: Objection; form. 07:38:33

THE WITNESS: It's not the 07:38:41

composition of PCCD. 07:38:42
Q (By Mr. Argenti) So then let's look at Section B where it lists an aliphatic polyester as comprising "A dicarboxylic acid component comprising cyclohexanedicarboxylic acid residues," right? 07:38:44 07:38:47 07:38:54 07:39:03
A I see that. 07:39:03
Q And that is also what we see in the blue box portion of Tadros Figure 8 in Paragraph No. 18 of your reply declaration, right? 07:39:04 07:39:09 07:39:14
MR. COLLINS-CHASE: Objection; form. 07:39:15
THE WITNESS: Yeah, the blue box is part of the repeat unit of PCCD, which are-- is composed of both the red and the blue box, which correspond to the initial components, the initial monomers that were used to copolymerize PCCD. 07:39:15 07:39:24 07:39:28 07:39:33 07:39:37
Q (By Mr. Argenti) Right. 07:39:42
And so specifically the blue box portion corresponds to Claim 1(B)(i) in Eastman, right? 07:39:42 07:39:45
MR. COLLINS-CHASE: Objection; form. 07:39:53
THE WITNESS: Yeah, it would correspond to the CHDA that was used as an initial monomer to make the PCCD copolymer. 07:40:44 07:40:45 07:40:49
Q (By Mr. Argenti) And if we continue on in Element B of Eastman Claim 1, it recites, starting in B(ii), "A glycol component comprising," and in B(ii)(a) it's "75 07:40:58 07:41:00 07:41:07

to 100 mole % cyclohexanedimethanol residues." 07:41:12

Do you see that? 07:41:18

A I see that. 07:41:19

Q That corresponds to the red box component of Tadros Formula VIII in your Paragraph 18, right? 07:41:20 07:41:27

MR. COLLINS-CHASE: Objection; form. 07:41:31

THE WITNESS: It corresponds to the CHDM monomer that was used to copolymerize the PCCD molecule shown in paragraph-- in my Paragraph No. 18. 07:41:32 07:41:34 07:41:43

Q (By Mr. Argenti) So the elements of Claim 1 that are labeled as B(i) and B(ii)(a) in Eastman, that corresponds to what we see in Tadros Formula VIII, right? 07:41:50 07:41:53 07:42:01 07:42:05

MR. COLLINS-CHASE: Objection; form. 07:42:05

THE WITNESS: Not necessarily. 07:42:07

I think Tadros's Formula VIII is an oversimplification of what is there. 07:42:08 07:42:14

Tadros-- I mean, that formula doesn't show that some of them are cis, some of them are trans, that they're mixtures of it, so it is overly simplified. 07:42:17 07:42:22 07:42:26

I think Tadros is clear in saying we're going to use geometric isomers as mixtures. 07:42:30 07:42:39

He even gives a preferred embodiment and ratio, 3 to 1, 4 to 1 of the geometric isomers. 07:42:46 07:42:54

I think this formula-- sure, Formula VIII is an 07:42:59

oversimplification, and it doesn't show that it's formed-- that it's formed by mixing different isomers. 07:43:02 07:43:05

We can't compare the formula here in Eastman to the actual embodiments in Tadros. 07:43:11 07:43:17

Tadros-- if you simply look at the equation, yeah, it doesn't show that it's formed by mixing different isomers. So it's not the same. 07:43:21 07:43:26 07:43:31

Q (By Mr. Argenti) If we continue further in Eastman, Claim 1, and we look at Element B(ii)(b), it goes on to list another type of glycol component, right? 07:43:40 07:43:42 07:43:48

A That's what it says, yes. 07:43:55

Q It says, "0 to 25 mole percent of one or more additional glycol or polymeric glycol residues," right? 07:43:56 07:44:00

A Yes, it says that. 07:44:06

Q So the combination of some glycol or polymeric glycol residue, other than CHDM, with the diacid recited in Element B(i) provides a different polyester unit than the one resulting from B(ii)(a), right? 07:44:15 07:44:21 07:44:25 07:44:29

MR. COLLINS-CHASE: Objection; form. 07:44:34

THE WITNESS: Again, I would have to-- I mean, we're comparing now the formulation in Eastman. 07:44:35 07:44:41 07:44:43

If we look at Eastman, the Eastman reference, it clearly describes PCCD as a copolyester, so I'm not sure why we're taking apart the claims of the Eastman 07:44:45 07:44:48 07:44:52

reference and comparing them directly to the formulation that Tadros did. 07:45:00 07:45:03

I think it's not a fair comparison because Tadros explains the geometric isomers and their mixtures of geometric isomers that are used in the copolymerization of PCCD, and so we would be comparing different formulations, but when we go back, we see a PCCD in Eastman is clearly referred to as a copolyester. 07:45:06 07:45:09 07:45:13 07:45:18 07:45:26 07:45:33

I would have to go back to the Eastman reference to see if they use ratios of isomers-- isomer mixtures. 07:45:43 07:45:45

I would imagine they do, but I would have to go back and look at the full reference. 07:45:49 07:45:52

Q (By Mr. Argenti) Dr. Osswald, other than this Eastman exhibit, Exhibit No. 1151, you don't cite any other exhibits referring to PCCD as a copolyester, do you? 07:45:55 07:46:08 07:46:12

MR. COLLINS-CHASE: Objection; form. 07:46:17

THE WITNESS: I don't think I have to because the Tadros reference is a part of the prior art. 07:46:18 07:46:22 07:46:28

A person having ordinary skill in the art would have gone to Tadros when designing aligners, and Tadros is clear in stating that PCCD is a copolyester. 07:46:28 07:46:31 07:46:41

In fact, he describes it. 07:46:47

Not only that, Tadros not only uses PCCD but also PETG in his mixtures, which is also a copolyester. 07:46:49 07:46:55

So I think the Tadros reference is-- is part of the prior art that a person having ordinary skill in the art would have at hand, together with the other prior art references that I mentioned. 07:47:01 07:47:09 07:47:12 07:47:15

The rest is-- I mean, literature and all of that, sure a person having ordinary skill in the art can look at different literature, but the person having ordinary skill in the art would look at the Tadros reference together with the other references that I-- that are there. 07:47:17 07:47:21 07:47:23 07:47:27 07:47:28 07:47:33

The Tadros reference is clear, it's in the art, and it describes PCCD as a copolyester. 07:47:34 07:47:37

Not only that, it also describes a mixture with PETG, which is also clearly a copolyester. 07:47:42 07:47:46

Q (By Mr. Argenti) Dr. Osswald, are you familiar with the term "homopolyester"? 07:47:53 07:47:54

MR. COLLINS-CHASE: Objection; form. 07:47:56

THE WITNESS: I mean, I've heard of homopolymers, like, for example, polypropylene is a homopolymer. It could be a copolymer. 07:47:57 07:48:02 07:48:07

Q (By Mr. Argenti) Have you heard the term "homopolyester"? 07:48:11 07:48:14

MR. COLLINS-CHASE: Objection; form. 07:48:15

THE WITNESS: I've seen it, yes. 07:48:16

Q (By Mr. Argenti) And what is a homopolyester? 07:48:19

MR. COLLINS-CHASE: Objection; form. 07:48:22

THE WITNESS: Well, I mean, people 07:48:23

do describe different things, and sure, people name 07:48:24

things. 07:48:28

One thing is clear though. For example, even if 07:48:30

we look at PET, you copolymerize it with a diol and a 07:48:33

diacid to form a PET, so it is a copolyester. 07:48:40

People sometimes call it a polyester, and that's 07:48:46

one of the examples in the mixtures that Tadros gives, 07:48:51

but Tadros also gives polycarbonate-PCCD, 07:48:53

polycarbonate-PETG, so clearly copolyesters. 07:48:58

In the definition of Dr. Kimmel, a copolyester 07:49:04

made of-- or a polyester made of two monomers is a 07:49:10

copolyester, and that also is in my own references in 07:49:15

my book, "The Material Science of Polymers for 07:49:19

Engineers." If you have two or more monomers and you 07:49:23

copolymerize them, you have a copolymer. 07:49:24

In the case that you see here in the Equation 8, 07:49:26

which is oversimplified, there is clearly a copolymer. 07:49:32

Q (By Mr. Argenti) You said you were familiar with the 07:49:38

term "homopolymer." 07:49:40

Is a homopolymer a copolymer? 07:49:41

A In the case of polypropylene, homopolymer-- it is not a 07:49:45

copolymer, but, again, it is a matter of semantics and 07:49:56

of description. 07:49:56

One has to see how it was polymerized. 07:49:57

People can name things-- I mean, for example, Tadros names some of the copolyesters polyesters, which doesn't mean that they are polyesters. They still have copolyesters. They're part of the copolyester family. 07:50:00 07:50:05 07:50:13 07:50:19

Q You mentioned earlier that a polyester is a big umbrella, right? 07:50:23 07:50:28

MR. COLLINS-CHASE: Objection; form. 07:50:30

Q (By Mr. Argenti) Do you recall saying that? 07:50:32

A Yeah, polyester covers copolyesters. 07:50:33

Q And it covers homopolyesters as well, right? 07:50:36

A Well, it would cover polyesters that are-- that are polymerized from a single monomer. 07:50:40 07:50:50

Q So in the terminology "homopolymer" that you said you are familiar with, what does the premix "homo" mean? 07:50:52 07:51:00

A It means single, but-- homogeneous material, but, again, it's not a term that is used-- that is used widely, and it's not a term that would be-- that certainly is not used in the Tadros reference. 07:51:04 07:51:15 07:51:18 07:51:23

Q And the term "copolymer," what does the prefix "co" mean? 07:51:25 07:51:32

A That means together, copolymerized. 07:51:32

If you take two or more polymers, you copolymerize it. 07:51:35 07:51:41

Q And would you have the same understanding of what those 07:51:41

prefixes mean in the terms "homopolyester" and "copolyester"? 07:51:44 07:51:48

A It depends where it's used. 07:51:49

I mean, I'm sure some people may misuse the term "homopolymer." 07:51:50 07:51:56

It would-- one would have to go back and see is it made out of a single polymerized material or did you use two monomers. 07:52:00 07:52:03 07:52:08

If you used two monomers, you probably are using the word "homopolymer" as extending the usage of the word. 07:52:09 07:52:13 07:52:19

Q Other than the Eastman exhibit, Exhibit No. 1151, did you look for other documents to cite on the issue of whether PCCD is a copolyester? 07:52:19 07:52:26 07:52:30

MR. COLLINS-CHASE: Objection; form. 07:52:33

THE WITNESS: I mean, the Tadros reference is clear. 07:52:34 07:52:40

There are other references also in-- out of Sabic or out of GE Plastics that use the same terminology and also discuss the mixtures of isomers that are discussed in Paragraph 45 of Tadros. 07:52:43 07:52:50 07:52:54 07:52:58

This is something that a person having ordinary skill in the art would understand. 07:53:01 07:53:04

I think it's-- the Tadros reference is not sitting alone. They are defining those words-- this is 07:53:05 07:53:08

something that Eastman and, slash, GE Plastics have been using, and I do talk about that in my reply report. 07:53:14 07:53:20 07:53:23

Q (By Mr. Argenti) When you were preparing your opinions, did you perform a search yourself to find Eastman Exhibit No. 1151? 07:53:27 07:53:28 07:53:30

MR. COLLINS-CHASE: Objection; form. 07:53:32

THE WITNESS: I don't remember who found the reference. 07:53:33 07:53:38

I did find a bunch of references and I looked at a bunch of references when I was preparing the report, but I don't remember if I'm the one who found that reference or not. 07:53:39 07:53:40 07:53:42 07:53:46

I believe I did, but I'm not sure. 07:53:47

Q (By Mr. Argenti) Did you find any documents that indicated PCCD is not a copolyester? 07:53:49 07:53:51

MR. COLLINS-CHASE: Objection; form. 07:53:55

THE WITNESS: I mean, I think what we have to do is look at the Tadros reference as the prior art here, and the Tadros reference clearly describes PCCD as a copolyester, and really what is at hand here is the Tadros reference as the prior art of the '613 patent and all the other patents. 07:53:55 07:54:02 07:54:06 07:54:12 07:54:18 07:54:21

The Tadros reference-- Tadros does define PCCD as a copolyester, clearly. 07:54:24 07:54:28

I agree with how Tadros describes it and defines it. 07:54:31 07:54:36

Q (By Mr. Argenti) Dr. Osswald, that didn't answer my question. 07:54:37 07:54:38

My question, again, was: 07:54:38

When you were preparing your opinions here, did you find any documents that indicated PCCD is not a copolyester? 07:54:40 07:54:43 07:54:47

MR. COLLINS-CHASE: Objection; form. 07:54:48

THE WITNESS: But PCCD is a copolyester, so I'm not sure about your question. 07:54:51 07:54:58

I mean, sometimes they call PCCD a polyester, but it's clearly a copolyester, so I'm not sure-- I'm not sure what you're asking. 07:55:06 07:55:11 07:55:15

Q (By Mr. Argenti) Did you search for or find any documents, Dr. Osswald, that might refer to PCCD as a homopolyester? 07:55:21 07:55:22 07:55:26

MR. COLLINS-CHASE: Objection; form. 07:55:29

THE WITNESS: I have not come across that, no. 07:55:30 07:55:33

(Exhibit A marked for identification.) 07:55:33 07:55:33

Q (By Mr. Argenti) I am going to drop into the chat now a document that I will introduce and we will label as Exhibit A to this deposition. 07:55:45 07:55:47 07:55:58

I can bring it up on my screen too, but you're free to download it from the chat as well so that you have the complete copy. 07:56:03 07:56:06 07:56:09

A I downloaded-- I am not familiar with this computer, so-- 07:56:21 07:56:25

Q Sure. Take all the time you need. 07:56:25

Let me know when I should go ahead with my questions. 07:56:31 07:56:33

MR. COLLINS-CHASE: Sorry, is this an exhibit from the case or is this a new document? 07:56:39 07:56:41

MR. ARGENTI: This is a new document. 07:56:44 07:56:45

MR. COLLINS-CHASE: Before you ask any questions of Dr. Osswald about the document, I don't know if you want to introduce what the document is and I can make my objection then, and maybe that's easier for the record-- 07:57:08 07:57:11 07:57:16 07:57:18 07:57:21

MR. ARGENTI: Sure. 07:57:22

For the record, this document that we'll label as Exhibit A to this deposition is a copy of U.S. Patent No. 5,939,519. 07:57:23 07:57:26 07:57:31

MR. COLLINS-CHASE: I will object on the grounds of foundation, relevance, and this is a new document that's not of record in the proceeding, and so we'll object as new evidence that's not permitted to be 07:57:38 07:57:39 07:57:43 07:57:46

entered in the proceeding in connection with a patent sur-reply and may have other objections as well, scope of the reply report, given that this is not cited there and isn't of record, but it may have other objections as well, as we go through what I assume are going to be additional questions. 07:57:51 07:57:56 07:58:01 07:58:04 07:58:07 07:58:10

Q (By Mr. Argenti) Dr. Osswald, is it okay if I go ahead with some questions now or would you like more time to review this? 07:58:24 07:58:26 07:58:28

A Yeah, I think I would like to review this document. 07:58:29

This is a new document. It is not something I opined on in my-- in either one of my reports, so I would like to review this document before you ask questions. 07:58:33 07:58:36 07:58:40 07:58:45

Q Understood. 07:58:48

A I have skimmed over it. 08:00:55

This is a long reference, so I will answer the questions as accurately as I can, knowing that I did not review this prior to my deposition. 08:00:56 08:01:03 08:01:06

Q Okay. The named inventor on this Patent No. 5,939,519 is Daniel Joseph Brunelle. 08:01:09 08:01:21

Do you see that on the first page? 08:01:23

A I see that. 08:01:25

Q That's the same person as the author of Exhibit No. 2019 that's listed at the end of your reply 08:01:26 08:01:34

declaration, right? 08:01:36
MR. COLLINS-CHASE: Objection; 08:01:39
foundation, scope. 08:01:40
THE WITNESS: It's the same-- I 08:01:41
believe it would be the same Brunelle from the paper 08:01:42
that was cited by Dr. Kimmel. 08:01:46
Q (By Mr. Argenti) In Column 2 of the Brunelle 519 08:01:51
patent under the "Detailed description" heading, in 08:01:55
Line 58, he refers to PCCD as a homopolyester, right? 08:02:00
MR. COLLINS-CHASE: Objection; form. 08:02:06
THE WITNESS: I would have to open 08:02:07
it up again. I closed it up because I-- hang on. 08:02:09
Q (By Mr. Argenti) I am happy to go there using screen 08:02:14
share as well. 08:02:17
If we look at Column 2, Line 58, Mr. Brunelle 08:02:22
refers to PCCD as a homopolyester, correct? 08:02:27
MR. COLLINS-CHASE: Objection; form, 08:02:30
outside the scope of the report. 08:02:32
THE WITNESS: I mean, I think I-- as 08:02:35
I said, people will define and call things different 08:02:36
ways. 08:02:44
Also, the Eastman patent appeared later, refers to 08:02:44
PCCD as a copolyester, so-- I mean, you're showing me a 08:02:49
patent that is way before that time. 08:02:53
I'm not sure what the context of it is, but also 08:02:55

clearly Tadros-- we have to go back to Tadros, which is the reference at hand. 08:03:00 08:03:06

Tadros defines this PCCD as a copolyester. He's clear at that. 08:03:07 08:03:14

I don't know what the context is of this patent and what they're calling it, but Tadros, who was part of GE Plastics and-- slash, Sabic, calls the PCCD in the patent, in his patent, a copolyester. 08:03:18 08:03:21 08:03:24 08:03:35

You may find references that have it, but I think the Tadros reference, within the reference itself, a person having ordinary skill in the art would understand that in the mixtures that Tadros presented-- and that's what is really at hand here, the mixtures that Tadros presents, polycarbonate and something else. He has at least two copolyesters, PETG and PCCD, and he goes even further and says, "PCCD is a copolyester" by using mixtures of isomers. 08:03:39 08:03:46 08:03:53 08:03:55 08:03:59 08:04:02 08:04:07 08:04:15 08:04:20

A person having ordinary skill in the art reading Tadros and trying to find a material that is improved over polycarbonate would see the mixture of at least polycarbonate and PCCD that gives great results, great properties, lower temperature, processing temperatures, stiffnesses that fall within the range that are-- is given in the patents, and clearly the properties correspond to the mixtures that he proposes. 08:04:23 08:04:27 08:04:32 08:04:39 08:04:44 08:04:51 08:04:54 08:04:59

Those mixtures are polycarbonate and copolyesters, PCCD, PETG, and other materials. 08:05:02 08:05:07

Sure, I mean, there's another reference, but a person having ordinary skill in the art would take the Tadros reference and would be motivated, using the Tadros reference, to replace polycarbonate. That is clear. 08:05:09 08:05:14 08:05:16 08:05:22 08:05:27

Q (By Mr. Argenti) In your answer just now, Dr. Osswald, you mentioned the fact that Eastman came after this Brunelle patent. 08:05:29 08:05:31 08:05:36

What's the significance of the timing? 08:05:38

MR. COLLINS-CHASE: Objection; foundation, outside the scope. 08:05:41 08:05:42

THE WITNESS: It was just a comment. 08:05:43

I mean, it was just a comment, that is all. 08:05:44

There's no significance. 08:05:47

I mean, the Eastman reference that I use calls PCCD a copolyester, but even without the Eastman reference, Tadros is clear, PCCD is a copolyester, as described in his patent. 08:05:49 08:05:53 08:05:56 08:06:02

Q (By Mr. Argenti) Still looking at this Brunelle 519 patent, let's go to Column 5. 08:06:10 08:06:14

In the second paragraph of Column 5 Brunelle refers to Table 1, which compares examples three through nine to two PCCD homopolyesters used as 08:06:21 08:06:28 08:06:36

controls, right? 08:06:37

MR. COLLINS-CHASE: Objection; form, 08:06:38
foundation, outside the scope. 08:06:40

THE WITNESS: I mean, yeah, you're 08:06:42
showing me things in a patent that I haven't reviewed, 08:06:44
and I'm not really able to give you an accurate answer. 08:06:47

I do want to be as accurate and as truthful as I 08:06:52
can in this-- I mean-- and so I would really have to 08:06:56
study this reference and analyze it. 08:07:00

This is not something that I considered in my 08:07:07
report, and it falls way outside of my report and my 08:07:09
first report. 08:07:14

I still stand with my opinion that the Tadros 08:07:14
reference is clear. 08:07:20

The Tadros reference gives examples of mixtures of 08:07:22
polycarbonate with copolyesters. That's-- that can't 08:07:27
be disputed. That's there, and a person having 08:07:32
ordinary skill in the art would look at the Tadros 08:07:36
reference. A person having ordinary skill in the art 08:07:37
is making dental appliances, so the Tadros reference 08:07:41
falls right within the area of a person having ordinary 08:07:46
skill in the art. 08:07:53

Sure, I have the Eastman reference to show that 08:07:53
yes, it's not just Tadros but other people also refer 08:07:58
to PCCD as a copolyester. 08:08:01

If you find some reference out there that refers to it otherwise, I'd have to see what the mixtures were, how they were done, how-- what is actually there, but still, that doesn't eliminate the Tadros reference. 08:08:04 08:08:07 08:08:10 08:08:15

The Tadros reference is clear. 08:08:21

The Tadros reference uses polycarbonate with copolyester mixtures, and that is clear. 08:08:24 08:08:30

Q (By Mr. Argenti) Let's turn back to your reply declaration now, Dr. Osswald, but keep this Brunelle '519 patent handy. 08:08:34 08:08:35 08:08:40

Let's look at Paragraph No. 31 of your reply declaration. 08:08:41 08:08:45

Are you there? 08:09:01

A Yes, I'm there. 08:09:01

Q In Paragraph No. 31, you're discussing Exhibit No. 2019 by the same Brunelle author as the named inventor on the '519 patent, right? 08:09:03 08:09:10 08:09:13

MR. COLLINS-CHASE: Objection; foundation. 08:09:15 08:09:16

THE WITNESS: It appears to be at least the same last name, but yes. 08:09:17 08:09:19

Q (By Mr. Argenti) And six lines down in this paragraph there's a sentence, starting with the word "accordingly," that reads, "Accordingly, Brunelle further supports my opinions that (i) different 08:09:21 08:09:27 08:09:31 08:09:34

isomeric molecules are different monomers, (ii) using different monomers can result in varying properties, and (iii) a PCCD polymer formed from a mixture of cis/trans monomers is a copolyester - just as Tadros discloses." 08:09:39 08:09:43 08:09:47 08:09:52 08:09:56

Do you see that? 08:09:59

A I see that. 08:09:59

Q So is it your view that Brunelle understands PCCD formed from a mixture of cis and trans isomers to be a copolyester? 08:10:00 08:10:07 08:10:10

MR. COLLINS-CHASE: Objection; form. 08:10:11

THE WITNESS: No, I think what-- and Brunelle does understand in his paper that using different mixtures of cis and trans monomers would lead to different properties, crystallinity properties and other properties, and that makes sense. 08:10:12 08:10:18 08:10:23 08:10:27 08:10:31

Cis and trans molecules, while they have the same formula, they would lead to materials that have completely different properties, such as cis and trans polybutadiene, which I described, I think, earlier or later in my report. 08:10:33 08:10:41 08:10:45 08:10:49 08:10:53

That's precisely what Tadros says. 08:10:54

Tadros says a mixture of the cis and trans monomers leads to a copolyester, and that's all. 08:10:56 08:11:03

I mean, I think-- we don't have to go outside of 08:11:08

Tadros.

What I'm doing here is rebutting Dr. Kimmel's opinion. He's the one that brought this reference into the picture, and so it's a rebuttal of the Kimmel report.

Yeah, it is clear that in Brunelle's paper that those three points confirm my opinion.

Sure, you have here another reference that maybe contradicts Brunelle from the paper, but that's-- I don't have enough-- I didn't have enough time before to review this reference, and I don't think it's necessary.

I think the Tadros reference speaks for itself.

Q (By Mr. Argenti) Dr. Osswald, do you have an understanding of whether Daniel Brunelle viewed PCCD formed from a mixture of cis and trans isomers to be a copolyester?

MR. COLLINS-CHASE: Objection; form.

THE WITNESS: Well, he clearly used cis and trans mixtures to vary the properties of-- and he added another component-- I don't remember exactly the Brunelle paper, but, yeah, he used different mixtures of cis and trans, which from the Tadros reference is clearly a PCCD copolyester.

Q (By Mr. Argenti) Let's turn back to Exhibit A, the

Brunelle '519 patent, and we'll look at Column 2 again. 08:12:42
Actually, the bottom of Column 1. 08:12:48
Can you please read the sentence at the bottom of Column 1 that carries over to Column 2? 08:12:58
A "In one of its aspects, the invention includes cyclohexylene polyesteramides comprising structural units of the formula," and then it gives the formulas there. 08:13:01
One is "Alkylene, said units of formula II being present in an amount effective to afford a polyesteramide having a temperature of crystallization of at least 165 degrees C and at least nine degrees C higher than that of corresponding homopolyester having the same distribution of cis and trans isomers." 08:13:05
MR. COLLINS-CHASE: And I will interpose a form and a scope objection. 08:13:49
Q (By Mr. Argenti) The Brunelle patent says that a polyester, having a mixed distribution of cis and trans isomers, is a homopolyester not a copolyester, right? 08:13:53
MR. COLLINS-CHASE: Objection; form, outside the scope. 08:13:58
THE WITNESS: Again, this is a new reference, and I am talking about the Tadros reference, and Tadros is clear that a mixture of cis and trans is a copolyester. 08:14:00

And Tadros not only has PCCD copolyester as an example in his mixtures, but he also brings in PETG as a copolyester, and so really what is at issue here is the Tadros reference, and Dr. Kimmel rebutted the Tadros reference by using the original Brunelle paper. 08:14:23 08:14:27 08:14:31 08:14:40 08:14:44

The original Brunelle paper really confirmed what Tadros was doing. He was changing the properties of PCCD by changing-- by adding things and by having different ratios of cis and trans, which confirms Tadros, and now there's a new reference now, and we can continue going down the line, but as many references that we can dig out that talk about things, a person having ordinary skill in the art would go to the Tadros reference, and the Tadros reference clearly has polycarbonate and copolyesters as examples. 08:14:48 08:14:52 08:14:56 08:15:00 08:15:04 08:15:07 08:15:12 08:15:16 08:15:17 08:15:20

That's really the bottom line here. 08:15:24

Q (By Mr. Argenti) Okay. We can set Exhibit A aside, Dr. Osswald. 08:15:30 08:15:33

I am going to drop another exhibit into-- 08:15:33

MR. COLLINS-CHASE: I will just raise one more objection for authenticity of the Exhibit A, which is the '519 patent that you put in the chat. 08:15:37 08:15:37 08:15:42 08:15:47

(Exhibit B marked for identification.) 08:15:47 08:15:47

Q (By Mr. Argenti) Dr. Osswald, I have now dropped into the chat what we will label as Exhibit B to this deposition, which is a copy of U.S. Patent No. 9,963,543. 08:15:56 08:15:58 08:16:04 08:16:09

Let me know if you have any issues downloading that. I am also bringing it up on the screen share here. 08:16:17 08:16:19 08:16:22

MR. COLLINS-CHASE: And I will object on the basis of relevance, outside the scope of Dr. Osswald's report, this document is not of record in any of these proceedings, foundation, authenticity, and I may have additional objections-- I will object to these new exhibits on the basis of hearsay as well, to the extent that they'll be used for hearsay purposes. 08:16:33 08:16:33 08:16:37 08:16:40 08:16:45 08:16:48 08:16:51

THE WITNESS: My computer is stuck thinking here, sorry, so I haven't been able to review anything yet. 08:17:05 08:17:07 08:17:09

MR. ARGENTI: No problem. Let me know when you have it. 08:17:14 08:17:15

THE WITNESS: It keeps dropping here. I am not familiar with this computer here, so-- it keeps dropping-- the reference keeps dropping off every time I try opening it. 08:17:36 08:17:39 08:18:19 08:18:24

MR. COLLINS-CHASE: Why don't we-- we are printing a copy. 08:18:26 08:18:28

THE WITNESS: Yeah, that would be better. Yes. 08:18:29 08:18:30

MR. ARGENTI: Should we go off the record and take a five-minute break? It's been over an hour. We could use this as an opportunity if you're printing out a copy. 08:18:35 08:18:36 08:18:42 08:18:45

MR. COLLINS-CHASE: Dr. Osswald? 08:18:46

THE WITNESS: I'm fine right now, so I'm okay. Maybe I think if we break at noon for lunch, then that-- it's only 40 minutes away. 08:18:48 08:18:50 08:18:54

MR. COLLINS-CHASE: Okay. Do you want to look on the screen while the printed copy-- 08:18:57 08:18:58

THE WITNESS: Yeah, I can look on the screen, if I can open it here. 08:19:05 08:19:06

I am not familiar with this computer, so that's maybe my main problem here. 08:19:11 08:19:13

It opens and then it closes again. 08:19:18

Q (By Mr. Argenti) Well, the PDF, Dr. Osswald, if you are having trouble with the PDF, I do have this Exhibit B brought up on the screen share. 08:19:22 08:19:25 08:19:28

Can you see that? 08:19:29

A I can see it. 08:19:30

Again, I would like to mention that this is a new reference that I have not seen, and the Brunelle previous reference and the first Brunelle reference 08:19:34 08:19:38 08:19:47

were brought to rebuttal-- and the Tadros reference, and Tadros is clear-- I mean, I am completely convinced that a person having ordinary skill in the art would see this, the Tadros reference, as having PCCD as a copolyester. 08:19:52 08:19:58 08:20:05 08:20:08 08:20:12

There is no doubt about it. 08:20:12

Tadros is clear. He even gives the properties. He adjusted the properties of polycarbonate to bring the processing temperature to a reasonable number by mixing polycarbonate with other materials, which includes copolyesters, which include PCCD and PETG, so I think the first Brunelle reference was brought, and that's what I rebutted in my report. 08:20:18 08:20:21 08:20:27 08:20:31 08:20:35 08:20:39 08:20:46

I don't think it's fair that I now have to rebut other references that are brought on. 08:20:48 08:20:52

I mean, it takes time to review a reference and to rebut what it's saying. 08:20:54 08:21:00

It would not change my mind that a person having ordinary skill in the art clearly sees the Tadros reference as one that discloses PCCD as copolyester. 08:21:03 08:21:09 08:21:10

Q Dr. Osswald, my question was whether you could see the document on the screen share. 08:21:20 08:21:24

A I can see the document on the screen share, yes. 08:21:25

Q Okay. So until we have copies of the printed version, is it okay if we go forward with some questions based 08:21:27 08:21:36

on the screen share? 08:21:40

MR. COLLINS-CHASE: We do have a printed copy. I am just doing a page check to make sure that everything got in here, but yeah, we do have a printed copy. 08:21:41 08:21:42 08:21:45 08:21:48

This should be complete, Dr. Osswald. 08:22:02

THE WITNESS: I mean, this is a long, extensive patent, so I don't know if I can give you accurate answers to your questions, so-- 08:25:54 08:25:56 08:25:59

Q (By Mr. Argenti) My questions will be pretty straightforward, Dr. Osswald. 08:26:03 08:26:05

Have you seen this document before today? 08:26:06

A I have not. 08:26:08

Q Let's take a look at Column 2 of this '543 patent, Exhibit B. 08:26:09 08:26:17

A I see it. 08:26:20

Q If we look at the paragraph that starts at Line 10 of Column 2, could you read the first sentence for me, please? 08:26:21 08:26:29 08:26:32

MR. COLLINS-CHASE: I will object to scope, relevance, and foundation. 08:26:36 08:26:37

THE WITNESS: It says that "Poly (1,4-cyclohexylidene 1,4-cyclohexanedicarboxylate) (hereinafter referred to as a PCCD), a DMCD/CHDM homopolyester, is an example of commercially available 08:26:47 08:26:58 08:27:07 08:27:14

polymer materials developed by using DMCD." 08:27:17

Q (By Mr. Argenti) Thank you. 08:27:24

A And to add-- I mean, I would have to add that sure, that's what this reference says. I haven't had time-- it's a reference that is to make some form of a heat-resistant biobased polycarbonate mixture. 08:27:24 08:27:33 08:27:33 08:27:40

It falls outside, I think, of dental aligners. 08:27:48

If a person having ordinary skill in the art would look at the references that are available, I would go back to the Tadros reference that calls PCCD a copolyester by having mixtures of different isomers. 08:27:55 08:27:59 08:28:04 08:28:10

That's not disputed. 08:28:14

The Tadros reference also uses PETG and other materials to make a hard layer for dental aligners, which is really what is at hand here with the patents that are being discussed. 08:28:16 08:28:20 08:28:26 08:28:30

So the Tadros reference falls right on the lap of the person having ordinary skill in the art because that's what they were looking at, at the time. 08:28:32 08:28:35 08:28:38

Polycarbonate had processing temperatures that were a little bit higher when you use it with a soft layer, like the patents are, you would want to have the processing temperature a little bit lower. 08:28:43 08:28:47 08:28:50 08:28:57

What Tadros does is he solves that problem by adding a copolyester to polycarbonate to get the 08:28:59 08:29:02

processing temperatures that are-- that would be positive for the materials without having any degradation, if you combine that with other materials like Tadros recommends, soft layers, and still maintain the mechanical properties that are required of dental aligners, and that's really the art here. 08:29:09 08:29:16 08:29:19 08:29:24 08:29:32 08:29:38

Sure, you may bring more references that I haven't had time to review. 08:29:40 08:29:46

I have read out of-- literally in a vacuum some sentence that states what it states, but that still doesn't eliminate or dismiss the Tadros reference, which is there, which is an important reference in the art-- for the person having ordinary skill in the art. 08:29:47 08:29:53 08:30:00 08:30:04 08:30:08

I mean, I don't think it's fair to bring out new references that have nothing to do with neither one of my two reports. 08:30:11 08:30:14 08:30:19

Okay. So Brunelle-- I rebutted Brunelle because Dr. Kimmel used that to explain Tadros, but Dr. Kimmel ignores that Tadros had a PETG, and PCCD is also a copolyester, as stated clearly in Tadros. 08:30:21 08:30:26 08:30:32 08:30:43

I mean, yeah, I am not familiar with this reference. I haven't had time to study it, and it would take-- I mean, it would take a long time to study and to understand the reference completely. 08:30:45 08:30:50 08:30:53 08:30:56

Q Dr. Osswald, you mentioned a couple of times that the 08:30:58

references we are looking at today are not describing dental aligners, whereas Tadros is in that field. 08:31:04 08:31:06

Does the issue of whether PCCD is a copolyester turn on whether it's being used for a dental aligner? 08:31:09 08:31:13

MR. COLLINS-CHASE: Objection; form. 08:31:16

THE WITNESS: I mean, I am not an attorney, so all I'm saying is the Tadros reference is a reference that deals with dental aligners. 08:31:16 08:31:21 08:31:25

That's all I'm saying, that Tadros uses-- makes a hard layer more processible and still maintaining the great properties of polycarbonate by adding a copolyester, by adding other polymers, including copolyesters. That's all that I'm saying. 08:31:28 08:31:32 08:31:37 08:31:40 08:31:43

Q (By Mr. Argenti) Would a person having ordinary skill in the art, reviewing these references, have the understanding that whether a PCCD is a copolyester or not is impacted by whether it's being used in a dental aligner? 08:31:45 08:31:47 08:31:50 08:31:59 08:32:01

MR. COLLINS-CHASE: Objection; form, asked and answered. 08:32:03 08:32:05

THE WITNESS: A person having ordinary skill in the art would look at Tadros and would be extremely motivated to change the polycarbonate hard layer, which was being used at the time, for a hard layer that had better processing 08:32:05 08:32:07 08:32:10 08:32:13 08:32:17

conditions and yet maintaining the excellent properties of polycarbonate, and that's what Tadros does. 08:32:20 08:32:24

Now, Tadros uses examples. In the Tadros examples, he has at least two copolyesters, PCCD and PETG, if not more in the list, so that's what a person having ordinary skill in the art would see and would be motivated to actually do to switch polycarbonate to a polycarbonate mixture. 08:32:27 08:32:35 08:32:41 08:32:47 08:32:48 08:32:55

Q (By Mr. Argenti) Dr. Osswald, again, you didn't answer my question. 08:32:57 08:32:59

My question is: 08:32:59

Would a person having ordinary skill in the art find it relevant whether PCCD was used in a dental application or not in terms of determining whether it was a copolyester? 08:33:00 08:33:04 08:33:09 08:33:12

MR. COLLINS-CHASE: Objection; form, asked and answered. 08:33:13 08:33:16

THE WITNESS: I don't think that's the point. 08:33:16 08:33:17

I mean, I think the point is that Tadros improves on the properties of polycarbonate by mixing polycarbonate with other materials to have a hard layer that still has the properties but is easier to process, and it happens that the mixture that Tadros recommends, among many mixtures, is polycarbonate with 08:33:18 08:33:22 08:33:27 08:33:29 08:33:32 08:33:41

copolyesters, and really that's all it is. 08:33:46

I think a person having ordinary skill in the art would be happy to have a material that behaves like polycarbonate but can be processed easier. 08:33:49 08:33:53 08:33:56

Q (By Mr. Argenti) This Exhibit B, the '543 patent, is another patent that calls PCCD a homopolyester, correct? 08:34:03 08:34:06 08:34:12

MR. COLLINS-CHASE: Objection; scope, relevance, foundation. 08:34:12 08:34:13

THE WITNESS: I mean, I think-- sure, this patent calls it a homopolyester. 08:34:14 08:34:16

I don't have time to review the full patent. 08:34:20

What doesn't-- what is not disputed is the Tadros reference and to use the Tadros reference as prior art to improve on the polycarbonate properties. 08:34:25 08:34:29 08:34:33

So a person having ordinary skill in the art would be extremely motivated to use Tadros and to replace the hard layer with a polycarbonate-copolyester mixture, and Tadros is clear in saying that. 08:34:38 08:34:42 08:34:45 08:34:50

Q (By Mr. Argenti) Okay. We can set Exhibit B aside, and I'm going to drop another exhibit into the chat, and I will bring it up on the screen share. 08:34:57 08:35:00 08:35:09

(Exhibit C marked for identification.) 08:35:09 08:35:09

Q (By Mr. Argenti) This one we will label as Exhibit C 08:35:15

to this deposition. 08:35:17

It's a copy of an article from a journal called Macromolecules. 08:35:18 08:35:24

The title of the article is "Advanced polymerization and properties of biobased high T sub G polyester of isosorbide and 1,4-cyclohexanedicarboxylic acid through in situ acetylation." 08:35:25 08:35:28 08:35:34 08:35:42

MR. COLLINS-CHASE: I will object to the document for the same bases as the previous two exhibits: authentication, hearsay, foundation, relevance, outside the scope of Dr. Osswald's open and reply report. 08:35:50 08:35:51 08:35:54 08:35:57 08:36:03

These documents are also post dating the patent, and I will just raise a general objection under 37 CFR 42.23 in terms of being new evidence. 08:36:04 08:36:08 08:36:13

MR. ARGENTI: Counsel, do we want to take a minute or two to get a printed copy of this? 08:36:20 08:36:21

THE WITNESS: I would also like to add, I mean, this is a technical paper from Macromolecules, a technical paper-- 08:36:25 08:36:26 08:36:29

Q (By Mr. Argenti) Dr. Osswald, I will ask you some questions in a bit. There is no question pending though. 08:36:33 08:36:34 08:36:34

A Okay. 08:36:34

MR. ARGENTI: The question was to 08:36:34

Counsel whether we wanted to take a minute and get a printed copy. 08:36:36 08:36:39

MR. COLLINS-CHASE: Yep, we're working on it. 08:36:40 08:36:41

MR. ARGENTI: Okay. 08:36:42

MR. COLLINS-CHASE: If you want-- I mean, we can print whatever you're going to use if you want-- 08:36:44 08:36:45 08:36:50

Q (By Mr. Argenti) Before we start asking questions about this particular document, maybe while we're printing it, I will ask you, Dr. Osswald, at the bottom of the page it says, "American Chemical Society." 08:36:53 08:36:54 08:36:57 08:37:06

Are you familiar with the American Chemical Society? 08:37:10 08:37:12

A Yes. 08:37:12

I'm familiar with Macromolecules as well. 08:37:13

Q You are a member of the American Chemical Society; is that right? 08:37:16 08:37:18

A I am a member of the rubber division of the American Chemical Society, yes. 08:37:19 08:37:25

Q And you published papers of your own in ACS journals including, I believe-- actually, I'm not sure. 08:37:26 08:37:30

Let me just ask, have you published papers of your own in ACS journals? 08:37:34 08:37:37

A I think I have. 08:37:40

I don't remember. I would have to go back to my list of publications. 08:37:41 08:37:43

Q Are you familiar with this Macromolecules journal? 08:37:44

MR. COLLINS-CHASE: Objection; form, scope. 08:37:48 08:37:50

THE WITNESS: Yes, I've heard of it. I've seen it. I've read papers in it. 08:37:50 08:37:52

Q (By Mr. Argenti) Well, that about exhausts my preliminary questions, so we can wait until we have a paper copy then, if you'd like, for the questions. 08:37:57 08:37:58 08:38:01

(Recess 8:38 to 8:40 a.m.) 08:38:01

THE WITNESS: Let me repeat, to give it a full read-- this is the first time I've seen this paper, so I don't think I can give very accurate answers to your questions without having studied either the patents that you just showed me or this paper. 08:40:37 08:40:38 08:40:40 08:40:45 08:40:48

Q (By Mr. Argenti) With that understanding, let's turn to Page 2935 of this article, "Advanced polymerization," et cetera, by Yoon, which is Exhibit C to the deposition. 08:40:51 08:40:57 08:41:09 08:41:13

Let me know when you are at Page 2935, which is the sixth page of the PDF. 08:41:14 08:41:20

A I have it. 08:41:24

Q In the last full paragraph in the column on the right, do you see where it talks about PCCD? 08:41:25 08:41:28

MR. COLLINS-CHASE: Objection; form, relevance, scope. 08:41:33 08:41:35

THE WITNESS: It talks about polymerization and cis, trans isomerization of PCCD, I see that. 08:41:36 08:41:39 08:41:44

Q (By Mr. Argenti) And it says that PCCD is made from CHDA and CHDM, right? 08:41:45 08:41:51

MR. COLLINS-CHASE: Objection; scope. 08:41:52 08:41:53

THE WITNESS: That's what it says. 08:41:54

Q (By Mr. Argenti) And those are the same as the PCCD components in Tadros, right? 08:41:55 08:41:57

MR. COLLINS-CHASE: Objection; form-- 08:42:00 08:42:01

THE WITNESS: I think one of the things is both these-- the patent and the paper have the same author, so the SK Chemicals in Korea-- so Mr. Oh and Mr. Kim are both in the patent and in this paper, so it's not a different reference. It's their thing. 08:42:01 08:42:02 08:42:08 08:42:16 08:42:20 08:42:23

Also, I would like to add that in the title, right, it says, "High T sub g polyester," and in the patent there's a graph that shows how to increase the glass transition temperature. 08:42:23 08:42:26 08:42:34 08:42:37

This falls completely outside of the art-- a 08:42:39

person having ordinary skill in the art would not even look at these references because they at the time didn't want to increase the glass transition temperature. They wanted to decrease the glass transition temperature to be able to process them easier. 08:42:41 08:42:43 08:42:45 08:42:47 08:42:50 08:42:52

Tadros gives that solution. 08:42:53

Tadros brings the glass transition temperature down so you can-- to improve the processability of the hard layer that happens to be a mixture of polycarbonate and a copolyester, and so I think what a person having ordinary skill in the art was looking for at the time was not increasing the glass transition temperature but actually decreasing it to be able to process it better and yet still maintain the properties. 08:42:55 08:42:58 08:43:03 08:43:06 08:43:16 08:43:16 08:43:19 08:43:21 08:43:23

Now, I don't have time to review, but those are the things that right away pop to my head. 08:43:24 08:43:26

Same authors, SK Chemicals-- I don't know if they were looking here to have higher glass transition temperatures, so in other words to make heat-resistant materials, which is not the case for dental aligners. 08:43:30 08:43:34 08:43:36 08:43:40

Dental aligners, you would want to process them at lower temperatures because you have different layers, soft and hard layers, that have different degradation 08:43:42 08:43:45 08:43:48

temperatures, and you want to bring those closer to one another. 08:43:52 08:43:55

A person having ordinary skill in the art would have to go back to Tadros because Tadros gives that solution. 08:43:55 08:43:59 08:44:01

A person having ordinary skill in the art would not be motivated to take this Macromolecules reference and use that in their picking of materials for their hard dental aligner. 08:44:03 08:44:05 08:44:09 08:44:13

They would rather go to something that can be processed at lower temperatures, and that is what Tadros brings. 08:44:14 08:44:16 08:44:19

I would need a day for each one of these to actually fully understand them and to do a comment and to be able to answer your questions in an accurate way. 08:44:23 08:44:26 08:44:29

Sure, they may say things like "homopolyester" and all of that. That still doesn't dismiss that Tadros is the reference that the person having ordinary skill in the art would have gone to, to be able to process the material in a more gentle way without causing degradation, and Tadros solves that problem. 08:44:33 08:44:38 08:44:41 08:44:45 08:44:50 08:44:52

He solves that problem by having polycarbonate, a polycarbonate mixture that lowers the processing temperatures, lowers the glass transition temperature. 08:44:54 08:44:58 08:45:00

Here, they're increased. 08:45:03

So they're really comparing apples to oranges here. 08:45:05 08:45:08

Q (By Mr. Argenti) You did it again, Dr. Osswald-- 08:45:09

MR. COLLINS-CHASE: I will just note that I made two objections, one for form and one for scope, and only the form objection seems to have shown up on the realtime transcript, so I just want to note that I believe at Timestamp 8:42 there was a form and scope objection prior to that question-- prior to that answer rather. 08:45:11 08:45:11 08:45:12 08:45:15 08:45:18 08:45:22 08:45:25

Q (By Mr. Argenti) Dr. Osswald, I was saying you just did it again. 08:45:27 08:45:29

Is it your view that a fact of whether PCCD is a copolyester changes depending on whether the goal is to increase the glass transition temperature versus decrease it? 08:45:30 08:45:36 08:45:39 08:45:42

MR. COLLINS-CHASE: Objection; form, scope. 08:45:45 08:45:47

THE WITNESS: I mean, all I'm stating is that the Tadros reference improves the processability by adding a copolyester to polycarbonate, and Tadros uses several polymers with polycarbonate and several mixtures, different mixtures, and one of those is polycarbonate with PCCD, one of those is polycarbonate with PETG. 08:45:47 08:45:49 08:45:55 08:46:01 08:46:05 08:46:10 08:46:14

PETG is clearly everywhere called a copolyester, and Tadros refers to PCCD as a copolyester because of the mixtures of isomers. 08:46:20 08:46:24 08:46:29

That's what a person with ordinary skill would see, and a person having ordinary skill in the art would be motivated to use Tadros to lower the glass transition temperature. 08:46:34 08:46:37 08:46:39 08:46:43

This one here, they're actually going in the opposite direction. They're increasing the glass transition temperature, as the title itself even says it, "High T sub g." 08:46:44 08:46:47 08:46:50 08:46:54

Q (By Mr. Argenti) Looking back at this paragraph on Page 2935 of the Yoon article, Exhibit C, in the second sentence, does Yoon say that PCCD is a copolyester or a homopolyester? 08:46:56 08:47:02 08:47:04 08:47:10

MR. COLLINS-CHASE: Objection; form, scope, relevance, foundation. 08:47:13 08:47:14

THE WITNESS: Well, I haven't seen exactly the whole paper and all of that, but, yeah, in that column they refer to it-- I would have to find it again in the-- it says-- which is a homopolyester-- that does not go along with Tadros's definition. 08:47:15 08:47:17 08:47:19 08:47:25 08:47:34

We are talking SK Chemicals, their papers and patents, compared to Tadros's papers and/or patents. 08:47:38 08:47:43

A person having ordinary skill in the art would be 08:47:53

satisfied with Tadros and would be motivated to use Tadros to replace the hard layer of polycarbonate with a hard layer of polycarbonate mixtures, and those mixtures happen to have a copolyester in them, and to lower the glass transition temperature. 08:47:55 08:47:58 08:48:04 08:48:07 08:48:11

MR. ARGENTI: Okay. I think it is time to take a break. We have been going close to two hours, and I guess you're probably approaching lunchtime on the East Coast, so why don't we go off the record, and then we can talk about length, if you want to have time to grab lunch. 08:48:19 08:48:20 08:48:22 08:48:26 08:48:29 08:48:32

Does 12:30 work as a time to reconvene or do you guys need longer than that? 08:48:37 08:48:40

THE WITNESS: I am fine with 12:30, yes. 08:48:44 08:48:46

(Discussion off the record.) 08:48:46

(Lunch recess 8:48 to 9:44 a.m.) 09:44:52

Q (By Mr. Argenti) Dr. Osswald, let's look again at your reply declaration, and let's turn to Page 52, please. 09:44:52 09:45:09

A Yes. 09:45:36

Q Okay. At the heading of Paragraph No. 82 is "Dr. Kimmel incorrectly equates an interfacial adhesive with a structural 'polymer layer,'" right? 09:45:37 09:45:43 09:45:46

A Yes. 09:45:50

Q And "polymer layer," that has quotes around it. 09:45:52

Do you see that? 09:45:55
A Yes. 09:45:56
Q That's a claim term, right? 09:45:56
"Polymer layer," that comes from the claims? 09:45:58
A Well, it's "polymer layer" as understood by a person having ordinary skill in the art, and the soft layer and the hard layer, that would be one of the polymer layers. 09:46:02 09:46:11 09:46:12 09:46:15
Q Let me ask you: 09:46:15
What is the significance of the quotation marks around the term "polymer layer" in that heading? 09:46:20 09:46:22
MR. COLLINS-CHASE: Objection; form. 09:46:25
THE WITNESS: Well, I mean, it's referring to the polymer layers as described in the prior art, either the hard layer or the soft layer in the patents, in the '613 and the other patents. 09:46:26 09:46:30 09:46:36 09:46:42
Q (By Mr. Argenti) Is it correct that in this section, starting at Paragraph No. 82 of your reply declaration, you are addressing whether the adhesive in your combination would be considered a layer in the context of the challenged claims? 09:46:50 09:46:52 09:46:57 09:47:00 09:47:02
MR. COLLINS-CHASE: Objection; form, foundation. 09:47:04 09:47:06
THE WITNESS: I mean, I'm rebutting here Dr. Kimmel's assertion that the adhesive layers, 09:47:06 09:47:09

interfacial adhesive, is considered a polymer layer, and so I'm-- this is a rebuttal to his declaration. 09:47:18 09:47:22

Q (By Mr. Argenti) The first sentence of Paragraph No. 82 reads, "Dr. Kimmel argues that an interfacial adhesive polymer applied between the soft and hard layers of the proposed obviousness combinations should be counted as a 'polymer layer' in the claims." 09:47:31 09:47:33 09:47:38 09:47:41 09:47:45

Do you see that? 09:47:49

A I see that, yes. 09:47:50

Q Is that the testimony from Dr. Kimmel that you are responding to? 09:47:51 09:47:54

MR. COLLINS-CHASE: Objection; form. 09:47:56

THE WITNESS: Yeah, in his declaration at Paragraphs 118 to 123 he calls the adhesive material, the interfacial adhesive, a polymer layer. 09:47:57 09:47:59 09:48:06 09:48:12

Q (By Mr. Argenti) And if we turn to Paragraph No. 91, at the end of this section, in the last sentence, when you're concluding your discussion, you say, "A POSITA would not understand thin, nonstructural adhesives to be, 'polymer layers,'" right? 09:48:16 09:48:19 09:48:25 09:48:29 09:48:34

A Correct. 09:48:38

Q Let's turn one page earlier and look at the end of Paragraph 89. 09:48:39 09:48:45

In the second to last sentence of Paragraph 89 you 09:48:51

say, "That is, the adhesive interlayer serves as a bonding interface and does not redefine the identity or function of the principal load-bearing layers." 09:48:54 09:48:57 09:49:03

Do you see that? 09:49:06

A I see that. 09:49:07

Q And then the next sentence after that is "That is why a POSITA would not have counted the thin amount of adhesive between structural layers, which does not contribute to the multi-layer sheet's properties, as a 'layer' within the meaning of Align's patents." 09:49:08 09:49:13 09:49:17 09:49:21 09:49:26

Do you see that? 09:49:31

A I see that. 09:49:32

Q The challenged claims don't require that the layers in the claim sheet be structural, do they? 09:49:32 09:49:39

MR. COLLINS-CHASE: Objection; form, foundation. 09:49:42 09:49:44

THE WITNESS: I mean, the claims talk about the stiffness and the strength of the hard and the soft layers, which refers to the structure of the aligners, so the stiffness is important. 09:49:44 09:49:45 09:49:52 09:50:00

It has to have a certain-- so the hard layer has to have certain properties to properly align the teeth, and the soft layers have to be soft to protect the gums of the-- and teeth of the people. 09:50:07 09:50:11 09:50:15 09:50:23

Yeah, those are structural functions. 09:50:24

Those are functions of the layers. 09:50:27
That function is not present-- the adhesive 09:50:31
material or coating is only there to adhere those two 09:50:39
layers when laminating them, or three layers. 09:50:43
Q (By Mr. Argenti) Do you have the '613 patent available 09:50:52
to you? 09:50:54
We can look at that one as an example. 09:50:55
A They're getting it. 09:50:58
Q Okay. And I can drop it into the chat as well. 09:50:59
A I have it. 09:52:06
Q Okay. Let's look at Claim 1 of the '613 patent. 09:52:07
I think it's a good example of the challenge 09:52:12
claims. 09:52:14
A Yes. 09:52:31
Q Okay. Do you see where Claim 1 says, "Providing a 09:52:31
sheet comprising three or more polymer layers"? 09:52:36
A Yes. 09:52:38
Q "Polymer layers," that's the language you were putting 09:52:44
in quotation marks in that section of your declaration, 09:52:48
right? 09:52:50
MR. COLLINS-CHASE: Objection; form. 09:52:51
THE WITNESS: That is describing 09:52:51
what is described as polymer layers in the patent, so 09:52:57
the hard and the soft layers, yes. 09:53:00
Q (By Mr. Argenti) And then it says, "The three or more 09:53:03

polymer layers comprising," and then it lists "A hard polymer layer and a soft polymer layer," right? 09:53:05 09:53:09

A Yes. 09:53:13

Q And what were you just referring to in your previous answer in terms of requiring that the polymer layers be structural? What claim language, please? 09:53:16 09:53:24 09:53:27

MR. COLLINS-CHASE: Objection; form. 09:53:32

THE WITNESS: I mean, I'm not an attorney, but a person having ordinary skill in the art would see the soft and the hard layer as having a function, some structural function, either the stiffness, be it a flexural modulus, be it a hardness, and those are all structural properties that are important in the aligning of the teeth. 09:53:33 09:53:34 09:53:38 09:53:42 09:53:46 09:53:51 09:53:54

In fact, some of the graphs in the patent show stresses, et cetera, which is a structural function. 09:53:57 09:54:02

What I'm stating in the paragraph that we read before is that the adhesive layer doesn't have a function other than just adhering either a soft to a hard layer or soft to soft or hard to hard. 09:54:06 09:54:09 09:54:15 09:54:21

Q (By Mr. Argenti) So because of the properties listed for the hard polymer layer and the soft polymer layer, that gives you an understanding that every one of the three or more polymer layers in the sheet must be structural? 09:54:28 09:54:30 09:54:36 09:54:42 09:54:45

Do I have that right? 09:54:45
MR. COLLINS-CHASE: Objection; form. 09:54:46
THE WITNESS: No. What I'm saying 09:54:47
is that the polymer coating or the adhesive coating 09:54:49
that is used to adhere two layers, their function is 09:54:54
only that. 09:55:00
They won't have a function as a hard or a soft 09:55:01
layer. 09:55:05
They don't have-- in fact, they are-- in the prior 09:55:05
art, even in these patents, the adhesive layer is 09:55:08
ignored. It doesn't play a role in the drawings. 09:55:12
If you look at Figure 2 of the patent, you see 09:55:16
that there is no adhesive layer. 09:55:20
Well, we talk about lamination. 09:55:24
The other patents, like the Tadros reference, also 09:55:27
laminates, also puts them together by disposing upon a 09:55:32
hard layer or a soft layer, which means it's 09:55:37
lamination, but Tadros doesn't count the adhesive as a 09:55:42
layer, the same in Kalili, the same in Wen. 09:55:46
Wen talks about adhesive lamination but doesn't 09:55:52
show layers of adhesive that are a part of a polymer 09:55:57
layer, like Dr. Kimmel argues, that the polymer-- that 09:56:02
the adhesive layer is a polymer layer, and that's what 09:56:08
I'm rebutting here. 09:56:12
Q (By Mr. Argenti) Anything else to add? 09:56:18

A No. 09:56:19
Q My question was about your understanding of the claims 09:56:19
of the challenged patents, in particular Claim 1 of the 09:56:24
'613 patent. 09:56:29
Did you use the prior art in this case to inform 09:56:29
your understanding of the claim requirements? 09:56:33
MR. COLLINS-CHASE: Objection; form, 09:56:36
legal conclusion. 09:56:38
THE WITNESS: I am not an attorney, 09:56:43
so I wouldn't even know how to start answering your 09:56:44
question. 09:56:46
All I know is at the time of the invention, there 09:56:46
were several references -- the Tadros reference, the 09:56:51
Kalili reference, the Porter reference, the Wen 09:56:58
reference -- and so people-- a person having ordinary 09:57:03
skill in the art, first of all, would have been 09:57:09
motivated to use Tadros to have a material that still 09:57:10
had the same good properties for the hard layer but at 09:57:16
lower processing temperatures. 09:57:22
So there was a motivation for doing that, to be 09:57:25
able to process it in more gentle conditions. 09:57:28
Also for thinner layers, Wen told us-- told a 09:57:36
person having ordinary skill in the art, "If you want 09:57:42
to have a better confirmation of the teeth geometry, 09:57:45
use thinner layers," and that includes thinner layers 09:57:49

that are either thermoformed separately or that are thermoformed together, and that would conform better to the teeth geometry, but also thinner layers create a better adhesion between the layers. 09:57:53 09:57:56 09:58:00 09:58:06

None of that is done by looking back from-- by using the claims in the patents to put that together. 09:58:08 09:58:12

It's just that's the way-- the train of thought with a person having ordinary skill in the art would have had at the time. 09:58:16 09:58:20 09:58:24

Then a person having ordinary skill in the art would have also known that eventually BPA was not the best thing, so they would have been motivated to switch the great properties that Tadros gave us with his hard layer and switching them with a copolyester Tritan that gives the same properties like polycarbonate, yet at the lower processing temperatures, like the Tadros reference. 09:58:25 09:58:28 09:58:31 09:58:34 09:58:39 09:58:47 09:58:51 09:58:56

So I'm not sure what you're asking about claim construction, all of those things-- I am not an attorney. I don't even want to try doing that. 09:58:56 09:59:01 09:59:04

I am looking at this from a lens of a person having ordinary skill in the art, who is also not an attorney, and as an expert in the field. 09:59:06 09:59:11 09:59:13

Q (By Mr. Argenti) Dr. Osswald, my question was about your understanding of the challenged claims, and you 09:59:13 09:59:21

responded with what sounded like a summary of your obviousness grounds, and in fact you even said, "None of that is done by using the claims in the patents." 09:59:21 09:59:24 09:59:28

I'm asking you about the claims. 09:59:32

I am not asking you about the prior art. 09:59:34

Do you understand that? 09:59:36

A I understand, and I'm not an attorney. 09:59:37

I mean, you can ask me what the term-- what properties are sought for the hard layer, what properties are sought for the soft layer, and I can respond from that, but I can't define terms. 09:59:42 09:59:46 09:59:50 09:59:54

Q Okay. Let's look again at Claim 1 of the '613 patent, and where it says, "A sheet comprising three or more polymer layers," do you see that? 09:59:58 10:00:03 10:00:06

A I see that. 10:00:07

Q Is it your understanding that each and every one of those three or more polymer layers must be structural? 10:00:08 10:00:12

MR. COLLINS-CHASE: Objection; form. 10:00:17

THE WITNESS: Well, those three or more polymer layers, if you look at the specifications of the patent, a person having ordinary skill in the art would understand that it's either a hard layer or a soft layer or it could be a hard layer sandwiched by soft layers, and the soft layers or hard layers could be subdivided in thinner layers. 10:00:18 10:00:25 10:00:28 10:00:32 10:00:35 10:00:38 10:00:43

Nowhere in there is a description-- none of those is actually an adhesive layer, and that's not how it's defined, how it's described in the patent, if you read the specifications. 10:00:45 10:00:48 10:00:53 10:00:56

Q (By Mr. Argenti) So it sounded like that answer is a yes, it is your understanding that each and every one of the three or more polymer layers recited here must be structural. 10:01:00 10:01:01 10:01:04 10:01:08

Do I have that right? 10:01:09

MR. COLLINS-CHASE: Objection; form. 10:01:10

THE WITNESS: I mean, that they had a function, either to align the teeth with a hard layer or to protect the gums and the teeth with softer layers. 10:01:11 10:01:13 10:01:18 10:01:22

Yes, there is a structural function in those layers. 10:01:22 10:01:26

Q (By Mr. Argenti) What's the function of the adhesive used in your combinations? 10:01:30 10:01:34

MR. COLLINS-CHASE: Objection; form. 10:01:37

THE WITNESS: I mean, the adhesives are there to join two layers. 10:01:38 10:01:40

Q (By Mr. Argenti) And is that a function? 10:01:43

MR. COLLINS-CHASE: Objection; form. 10:01:45

THE WITNESS: It's the only function for the adhesive, is to join two layers of two 10:01:46 10:01:48

materials, two different materials. 10:01:53
Q (By Mr. Argenti) And it's your opinion that that's within the scope of what's described in the specification here, right? 10:01:56 10:01:57 10:01:59
MR. COLLINS-CHASE: Objection; form. 10:02:00
THE WITNESS: Well, the specification ignores the adhesive. That's a given, that multilayered laminates are adhered or are fabricated with adhesive lamination, at least when it talks about laminating. 10:02:02 10:02:03 10:02:08 10:02:15 10:02:18
Q (By Mr. Argenti) Does the specification ever mention adhesive lamination? 10:02:26 10:02:28
A Well, the specification of the references and-- mention properties of the layer, and a person having ordinary skill in the art would want to-- would be motivated to preserving the properties of the hard layer or preserving the properties of the soft layer. 10:02:29 10:02:39 10:02:43 10:02:48 10:02:51
The only way to preserve the properties of those layers would be using adhesive lamination. 10:02:54 10:02:57
A person having ordinary skill in the art would be motivated to use adhesive lamination to preserve those properties, and the references talk about adhesive lamination or lamination. 10:02:59 10:03:02 10:03:06 10:03:09
It is understood by the person having ordinary skill in the art that they use that. 10:03:11 10:03:14

With Tadros, a person having ordinary skill in the art would want to preserve the properties of the hard layer and, for example, with the Kalili reference, a person having ordinary skill in the art would want to preserve the layer of the Texin 990R, which has excellent-- the facts state it has excellent properties or outstanding properties, and those outstanding properties would change if you use other forms of lamination, such as coextrusion lamination. 10:03:15 10:03:21 10:03:23 10:03:31 10:03:34 10:03:39 10:03:43 10:03:46 10:03:48

Q So I think you mentioned this earlier, but can you point me to anything in the specification that defines all polymer layers in the claimed sheet to be structural? 10:03:52 10:03:58 10:04:01 10:04:05

MR. COLLINS-CHASE: Objection; form. 10:04:07

THE WITNESS: I mean, it's understood by a person having ordinary skill in the art that the hard layer is there to align the teeth and the soft layer is there to protect the gums, and so yes, the hard and the soft layer that are described there, a person having ordinary skill in the art understands that they have the function, the structural function, of an aligner. 10:04:08 10:04:13 10:04:15 10:04:18 10:04:25 10:04:29 10:04:31 10:04:34

The adhesive layer in-between is not a functional layer, other than adhering the layers together. 10:04:38 10:04:42

In fact, you could even use a solvent as an 10:04:44

adhesive, and there is no layer left, it is just a solvent that softens the surface and conforms the two surfaces that you are joining together, and then the solvent then evaporates out, so it's gone. 10:04:51 10:04:55 10:04:58 10:05:00

No, an adhesive layer-- first of all, it is either extremely thin or it's not there after the adhesion process, after the solvent evaporates, and it certainly is not a structural component. 10:05:04 10:05:09 10:05:14 10:05:18

It would not affect the structure itself of the composite laminate. 10:05:20 10:05:23

Q (By Mr. Argenti) Let's look back at Paragraph No. 89 of your declaration, in that second to last sentence we looked at, where you talk about redefining the identity or function of the principal load-bearing layers. 10:05:26 10:05:30 10:05:33 10:05:36

What did you mean there by "identity or function"? 10:05:41

A Well, I mean, the identity or function of a layer, a hard layer or a soft layer, that's their identity and function. 10:05:45 10:05:52 10:05:55

As I mentioned before, the function of the hard layer is to align the teeth, and the soft layer is to protect the gums and the teeth themselves. 10:05:55 10:05:57 10:06:03

The bonding interface, as I say there, would not change that, would not redefine it. 10:06:05 10:06:11

It's-- in all adhesive lamination, the adhesive is not there to interfere with the function of the 10:06:13 10:06:21

product. It's there really only to adhere the two layers and not to change any or redefine the function of those layers that you're trying to bond together. 10:06:25 10:06:29 10:06:32

Q There's nothing in the claims or the specification that says that a material must redefine the identity or function of the principal load-bearing layers in order to be considered a layer itself, right? 10:06:36 10:06:40 10:06:44 10:06:48

MR. COLLINS-CHASE: Objection; form. 10:06:52

THE WITNESS: Well, the specifications are clear. 10:06:53 10:06:56

I mean, if you look at Figure 2, which I show, I believe, on the page before, at Paragraph 89, you can see-- I mean, I colored it, but you can see that the hard layer in the middle, which is formed by three different layers, thinner layers, and you see the two soft layers on either side, which are also-- which also can be subdivided into thinner layers, all of that is done-- is done using adhesive lamination, and there are no interfaces-- there are no layers identified in-between. 10:06:57 10:07:02 10:07:07 10:07:11 10:07:13 10:07:17 10:07:21 10:07:25 10:07:32 10:07:35

Really what you want is that soft layer and that hard layer. 10:07:36 10:07:40

Figure 2 doesn't show any adhesive layers in-between. 10:07:42 10:07:47

Q (By Mr. Argenti) The claims don't recite a particular 10:07:55

thickness requirement for the polymer layers, do they? 10:07:56
MR. COLLINS-CHASE: Objection; form. 10:08:02
THE WITNESS: I mean, I'm not an 10:08:02
attorney in opining, but the claims do recite that one 10:08:07
has three or more polymer layers that comprise either a 10:08:15
hard or a soft polymer layer. 10:08:20
The adhesive layer-- 10:08:24
Q (By Mr. Argenti) Sorry, where is "either"? 10:08:26
I don't mean to cut you off, but you said they 10:08:28
comprise either a hard layer or a soft layer. 10:08:30
Where does that come from? 10:08:33
A Sorry, I misspoke. 10:08:34
They comprise-- either-- if I said "either," I 10:08:38
didn't mean to say-- they compromise a hard layer and a 10:08:48
soft layer. 10:08:51
Q And then at least one other layer, right? 10:08:52
A And at least another layer, correct. 10:08:55
Q And it doesn't say what's in that other layer, right? 10:08:57
A In the specifications, if you look at Figure 2, it 10:09:00
shows that the other layer is also a soft layer. 10:09:05
Q Does the specification define a particular thickness in 10:09:09
order for something to be considered a polymer layer? 10:09:17
MR. COLLINS-CHASE: Objection; form. 10:09:19
THE WITNESS: No. In the 10:09:20
specifications, the thickness-- they give ranges of 10:09:26

thickness, but no, a thickness is not-- there shouldn't be a specific thickness, but the point is an adhesive layer is not considered one of those three layers that are given in the claim. 10:09:30 10:09:35 10:09:41 10:09:46

An adhesive layer, in polymer engineering and manufacture of multi-layered films, et cetera, by any method, the adhesive layer is not-- its task is really only to join the layers. 10:09:51 10:09:57 10:10:01 10:10:06

You can look at Tadros. You can look at Kalili. Again, none of them show an adhesive layer between the other layers adhering it. That's a given. 10:10:09 10:10:15 10:10:22

A person having ordinary skill in the art would know that one would have an adhesive or can have, if needed, an adhesive to join two layers by adhesive lamination, or would have, actually. 10:10:24 10:10:27 10:10:32 10:10:35

Q (By Mr. Argenti) Let's now turn to Paragraph No. 76 of your reply declaration, please. 10:10:47 10:10:51

A I see that. 10:11:17

Q Here is where you address whether the combinations that you propose in your original declaration would have had predictable results, right? 10:11:18 10:11:21 10:11:25

MR. COLLINS-CHASE: Objection; form. 10:11:28

THE WITNESS: Yeah, in my original declaration one would want to have predictable results, and that would mean if you had a hard layer, the hard 10:11:29 10:11:32 10:11:38

layer should behave as such. If you have a soft layer, it would have that, and adhesive lamination, it would give predictable results in the properties of the laminate. 10:11:41 10:11:44 10:11:49 10:11:53

Q (By Mr. Argenti) Right. 10:11:56

So let's look near the bottom of Page 47. 10:11:56

Do you see the sentence where it says, "Rather, the motivation to preserve the desirable properties of polymers identified in the prior art as suitable for dental aligners is reason enough to select adhesive lamination." 10:12:02 10:12:05 10:12:08 10:12:12 10:12:17

Do you see that? 10:12:18

A I see that. 10:12:19

Q So here you're saying that the prior art disclosed desirable properties of polymers identified as suitable for dental aligners, correct? 10:12:20 10:12:24 10:12:28

A Yes. 10:12:30

Q Then you say that "Adhesive lamination would have provided a predictable method of manufacturing that would not have altered those desirable properties," correct? 10:12:32 10:12:38 10:12:42 10:12:45

MR. COLLINS-CHASE: Objection; form. 10:12:49

THE WITNESS: Which sentence are you reading there? 10:12:50 10:12:51

Q (By Mr. Argenti) Well, the next sentence says, 10:12:54

"Indeed, a POSITA would have been motivated to select a predictable method of manufacturing dental appliances that would not alter layer properties that the prior art discloses would be effective," right? 10:12:55 10:13:00 10:13:02 10:13:04

A Yes. 10:13:08

Q And you are saying that adhesive lamination provides that predictable method of manufacturing dental appliances, right? 10:13:08 10:13:11 10:13:16

A Well, adhesive lamination is one that would result in laminated structures with unchanged properties in each one of the layers. 10:13:17 10:13:24 10:13:29

This is compared to coextrusion, which is also a lamination technique that is used where you don't preserve the properties. 10:13:30 10:13:35 10:13:38

First, you have high temperatures. Second, the shear and the high temperatures cause the diffusion of the molecules and interpenetration of the molecular structure from one layer to another one, so you have a blurred line, a blurred change in properties, so it's not predictable. 10:13:39 10:13:44 10:13:46 10:13:51 10:13:55 10:14:00

You change the properties of the layers. 10:14:02

So if you have a layer-- properties in the layer, like in Tadros, where you have exactly what you want for the hard layer, or you have Kalili's soft layer, you want to preserve that, and the way to preserve that 10:14:04 10:14:07 10:14:11 10:14:17

is by using adhesive lamination not using other manufacturing techniques that would cause the changes in the properties of the layers. 10:14:20 10:14:23 10:14:26

A person having ordinary skill in the art is motivated for doing that and preserving those properties. 10:14:30 10:14:33 10:14:37

Q Okay. So do I understand correctly that in your view selecting a polymer for use in a dental aligner is not unpredictable if the prior art provides guidance? 10:14:37 10:14:43 10:14:48

MR. COLLINS-CHASE: Objection; form. 10:14:51

THE WITNESS: Well, Tadros gives us guidance and tells us that the hard layer that he has works really well and can be processed at gentle temperatures, so Tadros gives us a material, and you don't want to change those properties. You want it to be predictable. You want it to have the properties that Tadros gives, and so yes, you want predictability. You want to maintain the properties that are in the laminated structure described by Tadros and by Kalili. 10:14:52 10:14:55 10:15:00 10:15:04 10:15:07 10:15:09 10:15:12 10:15:18 10:15:22

Q (By Mr. Argenti) Again, selecting the polymer for use in a dental aligner is not unpredictable, if the prior art, like Tadros, provides guidance; do I have that right? 10:15:34 10:15:35 10:15:40 10:15:43

MR. COLLINS-CHASE: Objection; form, asked and answered. 10:15:43 10:15:45

THE WITNESS: Yes, a person having ordinary skill in the art would want to preserve the properties of Tadros, and by using adhesive lamination, those properties are preserved. 10:15:45 10:15:50 10:15:53 10:15:59

Then, of course, eventually a person having ordinary skill in the art would also be motivated at switching then the Tadros material for one that doesn't have BPA, as time goes by and people start thinking about BPA issues, et cetera, so then there is a material like Tritan that has the same properties, behaves the same way as polycarbonate, and has the lower process conditions so a person having ordinary skill in the art would then be motivated at switching to this copolyester through Tritan. 10:16:01 10:16:05 10:16:07 10:16:11 10:16:15 10:16:19 10:16:22 10:16:27 10:16:30 10:16:32

Then of course you want to preserve those properties. 10:16:39 10:16:41

You still want to control what the properties of your aligner-- you want to have a predictable result, and the predictable result is actually by not having some diffusion or degradation or cross-linking that occurs in a process such as a coextrusion. 10:16:41 10:16:44 10:16:47 10:16:51 10:16:55

So if you want to have a predictable result, you use adhesive lamination, and the reference is to use adhesive lamination. 10:16:59 10:17:02 10:17:11

Q (By Mr. Argenti) Let me ask my question this way: 10:17:14

Is selecting materials for use in a dental aligner predictable or unpredictable? 10:17:15 10:17:19

MR. COLLINS-CHASE: Objection; form. 10:17:21

THE WITNESS: Well, if you follow Tadros at the time of when Tadros came out, a person having ordinary skill in the art would have known that polycarbonate mixtures with copolyesters give the results that one wants, and so it has a stiffness, has the properties that one would want, the range of the properties that one would want, and so that's predictable. 10:17:22 10:17:28 10:17:34 10:17:37 10:17:42 10:17:49 10:17:53 10:17:56

A person having ordinary skill in the art would know, "Okay. I am between 1500 and 2500. Yes, I am going to use Tadros's mixtures because I know it will fall in there, and so that-- I don't want to change that. I don't want to mess by using some other manufacturing techniques that would change those properties," and that's when it becomes unpredictable, by using processes that will actually change the properties that Tadros lauds in his reference. 10:17:56 10:17:59 10:18:03 10:18:08 10:18:10 10:18:13 10:18:17 10:18:20 10:18:22

Q (By Mr. Argenti) So I think you were getting into my next question, which is: 10:18:29 10:18:30

Does the method of manufacture of a dental aligner impact whether its performance is predictable or unpredictable? 10:18:32 10:18:40 10:18:44

MR. COLLINS-CHASE: Objection; form. 10:18:45

THE WITNESS: Well, I mean, if you look at Tadros and if you look at Kalili and you use the manufacturing process such as a coextrusion to manufacture the product, yes, you introduce an unpredictability because you no longer have the nice layers. You have a layer, a transition, and another layer, so literally you could have like something in-between that is not predictable that deviates from it. 10:18:47 10:18:48 10:18:53 10:18:58 10:19:02 10:19:06 10:19:10 10:19:13 10:19:18

Yeah, a person having ordinary skill in the art wouldn't want that, would want to have a predictable result, and that is to use the same manufacturing process that Tadros used and that Kalili used, and other references, and that is adhesive lamination. 10:19:18 10:19:21 10:19:24 10:19:26 10:19:30

That is why adhesive lamination still gives you a predictable result, because you maintain the properties of those materials. 10:19:32 10:19:37 10:19:40

A person having ordinary skill in the art would be motivated to have the excellent properties of Texin 990R and have the excellent properties of polycarbonate mixtures, and you don't want to change it by having some process condition that is going to affect those properties and introduce an unpredictability. 10:19:41 10:19:43 10:19:52 10:19:58 10:20:01 10:20:06

Q (By Mr. Argenti) So using coextrusion introduces 10:20:12

unpredictability, whereas using adhesive lamination preserves predictability; is that your opinion? 10:20:15 10:20:19

MR. COLLINS-CHASE: Objection; form. 10:20:22

THE WITNESS: Using adhesive lamination, you would have predictable layer behavior. 10:20:23 10:20:26

Using coextrusion, the layers become diffused with one another because of diffusion of molecules, so you would have a whole region where there is a mixture, there is cross-linking, there are high temperatures. 10:20:31 10:20:35 10:20:39 10:20:42

Yeah, coextrusion would be-- would give unpredictable results as far as the properties because you no longer have the properties of the individual layers. You have other things happening in there, and so it doesn't produce unpredictability. 10:20:45 10:20:49 10:20:52 10:20:54 10:20:57

(Exhibit D marked for identification.) 10:20:57 10:20:57

Q (By Mr. Argenti) I am going to drop into the chat a document that we will designate Exhibit D for this deposition. 10:21:04 10:21:08 10:21:11

Just to introduce it, this is a copy of a transcript held in-- of a hearing held in the District Court litigation between the parties here: Align Technology Inc. and ClearCorrect Operating LLC. 10:21:18 10:21:29 10:21:34 10:21:37

Specifically it's a motions hearing from May 27th, 2026. 10:21:44 10:21:48

MR. COLLINS-CHASE: I will raise the same objections as to the prior documents that are not of record in these proceedings on the basis of authenticity, hearsay to the extent it's used for hearsay purposes, lack of foundation, lack of relevance, and outside the scope of either of Dr. Osswald's reports, and certainly outside the scope of his reply declaration. 10:21:52 10:21:53 10:21:56 10:22:00 10:22:03 10:22:06 10:22:09 10:22:11

Q (By Mr. Argenti) I see you flipping through a printed-out document, Dr. Osswald. 10:22:24 10:22:28

Is that this transcript? 10:22:30

A No. It's my report, which is what I'm preparing for today to answer questions. 10:22:32 10:22:35

Q Understood. 10:22:38

I will represent that this is a document that is not cited in your reply declaration or your opening declarations. 10:22:39 10:22:41 10:22:45

Since we took a break, I will just confirm, I guess, are you able to see the copy of this transcript, Exhibit D, on the screen using screen share? 10:22:48 10:22:50 10:22:53

A I can see it, yes. 10:22:56

Q And the document is-- the PDF is 146 pages long. 10:22:58

Do we need to take a break and get a printed copy or can we look at the version on the screen? 10:23:04 10:23:07

MR. COLLINS-CHASE: I was going to 10:23:10

ask you the same question. 10:23:11

I guess if you're intending to ask many questions about this, I guess we'll print a copy. 10:23:13 10:23:15

You know, I-- 10:23:18

MR. ARGENTI: I do have some questions. It's about a limited set of pages, but obviously I want to make sure you have the full access to the full document. 10:23:20 10:23:21 10:23:24 10:23:29

Are you able to download the document, Dr. Osswald, and flip through the pages on your own on a computer? 10:23:30 10:23:33 10:23:35

THE WITNESS: No. There are issues with the PDF files here, so I can't. 10:23:36 10:23:38

MR. ARGENTI: Okay. In that case I'm happy to go off the record if we want to get a printed copy. 10:23:42 10:23:43 10:23:45

MR. COLLINS-CHASE: Sure, yeah, we can do that. 10:23:47 10:23:48

Just so you know, I think the issue is Dr. Osswald is just on like a sort of blank laptop computer that doesn't-- I'm not sure it has-- I'm not sure what capabilities he has, but he seems to have an issue to get PDFs to open up outside of the Zoom. 10:23:49 10:23:52 10:23:56 10:23:59 10:24:02

Yeah, we can go off the record, and we'll print a copy of this for him. 10:24:04 10:24:07

(Recess 10:24 to 10:33 a.m.) 10:33:27

Q (By Mr. Argenti) Dr. Osswald, now that I understand you have a printed copy of this transcript, which we'll designate Exhibit D to the deposition, have you seen this document before? 10:33:39 10:33:40 10:33:44 10:33:48

A No, I have not. 10:33:50

MR. COLLINS-CHASE: I think I made my scope foundation, relevance, hearsay objections before, but I will make those again, and authenticity. 10:33:54 10:33:56 10:34:00

Q (By Mr. Argenti) As I mentioned earlier, Dr. Osswald, if we look at the first page, this is a transcript of a motions hearing from the Western District of Texas litigation between the parties in this IPR: Align and ClearCorrect. 10:34:05 10:34:08 10:34:12 10:34:16 10:34:19

Do you see that? 10:34:20

A I see that. 10:34:20

Q Are you serving as an expert in that litigation, the District Court case? 10:34:21 10:34:25

MR. COLLINS-CHASE: Objection; form. 10:34:26

THE WITNESS: Actually, you are asking-- I know I'm an expert here today in a patent validity case. 10:34:27 10:34:31 10:34:38

I don't know what this is. 10:34:39

I have not seen this before nor heard "Texas" or anything like that. I don't know. 10:34:41 10:34:45

Q (By Mr. Argenti) As far as you understand, have you offered any testimony in this District Court case? 10:34:47 10:34:49

MR. COLLINS-CHASE: Objection; form. 10:34:51

THE WITNESS: I have offered-- I mean, the opinions-- the two reports that you have seen, and I haven't written any other documents about it. 10:34:52 10:34:56 10:35:00 10:35:03

Q (By Mr. Argenti) Did you attend this hearing that's recorded in this transcript? 10:35:06 10:35:10

MR. COLLINS-CHASE: Objection; form. 10:35:11

THE WITNESS: No. 10:35:12

MR. COLLINS-CHASE: Scope, relevance. 10:35:14 10:35:15

Q (By Mr. Argenti) At the bottom of the first page, going on to the second page, do you see that the Defendant, ClearCorrect, is represented by a number of attorneys? 10:35:15 10:35:18 10:35:21 10:35:24

MR. COLLINS-CHASE: Same objections. 10:35:25

Q (By Mr. Argenti) Just to clarify, the first attorney I am referring to is from Gillam & Smith, and then the other attorneys are from the WilmerHale law firm. 10:35:34 10:35:36 10:35:41

Do you see that? 10:35:45

A And to the second page-- yes, I see that. 10:35:46

Q Have you ever spoken to any of those attorneys? 10:35:53

A The name "Wilmer" rings a bell. I may have met with 10:35:55

them before the previous-- the last deposition, but I don't remember, yeah. 10:36:09 10:36:13

Q Do you know whether you have ever spoken to Joseph Mueller from WilmerHale? 10:36:14 10:36:17

A I don't remember the names. 10:36:19

I think there were two attorneys present in a meeting, but I don't remember-- it must have been before the previous deposition, was at the beginning of the case or something. 10:36:21 10:36:25 10:36:26 10:36:30

Q Was it before preparing your original declarations? 10:36:31

MR. COLLINS-CHASE: Objection. 10:36:38

Dr. Osswald, I will just caution you, since the question is about discussion with attorneys, not to reveal any substance of any discussion you have had with any attorneys in connection with this case. 10:36:39 10:36:42 10:36:45 10:36:47

Q (By Mr. Argenti) Just a "yes" or "no" question as to the timing-- 10:36:51 10:36:52

A I don't remember. 10:36:53

I remember I was asked a lot of questions, but I don't remember regarding what, so-- 10:36:54 10:36:57

Q Let's turn to Page 55 of this transcript. 10:36:59

I just want to point out-- let me know when you're there. 10:37:15 10:37:18

A I'm on Page 55. 10:37:19

Q Okay. I just want to point out here, if we look at 10:37:21

Line No. 3, we see that ClearCorrect's attorney, Mr. Mueller, is speaking to the Court. 10:37:24 10:37:29

Do you see that? 10:37:31

MR. COLLINS-CHASE: Objection; form, scope, relevance, foundation. 10:37:34 10:37:36

THE WITNESS: I see that. 10:37:38

I mean, I don't know what context this is. 10:37:38

I have never seen this report, so I am kind of reluctant to answer any questions regarding this or reading off statements of something that I have never seen before and haven't been able to study. 10:37:40 10:37:44 10:37:46 10:37:50

Q (By Mr. Argenti) If we turn to the next page, Page 56 of the Exhibit D transcript, and the paragraph that starts at Line 13, do you see that? 10:37:59 10:38:02 10:38:13

A I see that. 10:38:16

Q Can you read that paragraph for me, please? 10:38:18

MR. COLLINS-CHASE: Objection; scope, foundation, relevance, hearsay. 10:38:21 10:38:23

THE WITNESS: I see that paragraph, yes. 10:39:11 10:39:12

Q (By Mr. Argenti) Can you read it out loud for me, please? 10:39:13 10:39:15

MR. COLLINS-CHASE: Same objections. 10:39:15

THE WITNESS: I mean, it says, "And I'll make one note here, Your Honor, which we'll pick 10:39:17 10:39:20

up as we go through this. This is not a so-called predictable art in terms of developing these clear aligners. The particular research and development process required to develop an efficacious clear aligner is very complicated and, frankly, very unpredictable, and it takes a lot of experimentation to develop an efficacious clear aligner that will function for its purpose of straightening teeth that will be safe, that will be sufficiently comfortable, sufficiently stain resistant. This takes an enormous amount of work to develop these types of aligners." 10:39:23 10:39:26 10:39:30 10:39:32 10:39:36 10:39:39 10:39:43 10:39:46 10:39:50 10:39:54 10:39:57

Q (By Mr. Argenti) Thank you. 10:40:02

A I mean, I can comment on this. 10:40:03

This doesn't contradict what I've said, precisely. 10:40:06

Because it's a complicated process, you want to have predictable results, and that's what Tadros does. 10:40:14 10:40:17

With Tadros, you don't have to waste your time doing all kinds of experimentation and all kinds of changes, because that's unpredictable. 10:40:20 10:40:22 10:40:25

Tadros and Kalili, and all the references, if you follow them and if you use them, which a person having ordinary skill in the art would have done, would have resulted in predictable results, and that's why a person having ordinary skill in the art would be motivated to use those references. 10:40:27 10:40:30 10:40:35 10:40:36 10:40:40 10:40:42

I don't know where this statement goes, but yeah, it is a complicated thing, and that is precisely why you want predictable results that are given in the reference by Tadros and the other references that I referenced in my-- in this case. 10:40:43 10:40:46 10:40:49 10:40:53 10:40:55

This is solely out of context. 10:41:01

I don't know what he's talking about, but as I understand, it's that it's a complicated process, and that's precisely the point that I'm making in this case, with predictability. 10:41:02 10:41:04 10:41:08 10:41:12

You want predictability because if you don't, you are going to, as they say here, do all kinds of different experimentations. 10:41:13 10:41:19 10:41:23

Q ClearCorrect's lawyer here didn't say developing a clear aligner is, frankly, very unpredictable unless the prior art gives you guidance on what materials to use, did he? 10:41:27 10:41:32 10:41:35 10:41:38

MR. COLLINS-CHASE: Objection; hearsay, foundation, relevance, scope. 10:41:39 10:41:41

THE WITNESS: I don't know what the ClearCorrect attorney was saying here, but precisely that is why a person having ordinary skill in the art would appreciate having guidance that would give predictable results and that would work. 10:41:43 10:41:44 10:41:49 10:41:54 10:42:00

I mean, the comfort-- they talk about comfort, 10:42:01

yeah, that's the soft layers in Kalili, the soft layers in Tadros, it's the Texin 990R is given. 10:42:05 10:42:10

The hard layer that works really well, yes, that's the one from Tadros that can be processed really easily, and so that you want to maintain. You don't want to mess with that. 10:42:13 10:42:16 10:42:19 10:42:23

If you do, then you end up having some unpredictable results, and a person with ordinary skill of the art doesn't want to do it. 10:42:23 10:42:27 10:42:30

A person having ordinary skill in the art wants predictable results. That's why they use adhesive lamination, going back to adhesive lamination, to maintain predictability. 10:42:32 10:42:35 10:42:37 10:42:40

Q (By Mr. Argenti) ClearCorrect's lawyer also didn't say, "Developing a clear aligner is, frankly, very unpredictable unless you use adhesive lamination," right? 10:42:43 10:42:45 10:42:46 10:42:49

MR. COLLINS-CHASE: Objection; foundation, relevance, outside the scope, hearsay. 10:42:52 10:42:53

THE WITNESS: I don't know what the ClearCorrect attorney was thinking when he said that, but I still stand with using adhesive lamination will maintain the properties of a layer. It won't mess with the properties of the layers, won't change them, and so that results in a predictable result, and that's why a 10:42:55 10:42:57 10:43:02 10:43:05 10:43:09 10:43:12

person having ordinary skill in the art would want to use adhesive lamination to have the predictable properties of the hard layer from Tadros and the soft layer from Kalili. 10:43:15 10:43:18 10:43:20 10:43:23

Q (By Mr. Argenti) Let's turn now to Page 115 of the Exhibit D transcript, please. 10:43:32 10:43:34

A I have it. 10:43:47

Q Do you see the sentence that begins, "As I mentioned" on Line No. 6? 10:43:48 10:44:01

A Yes. 10:44:02

Q Can you read out loud that sentence down through Line No. 23 of this page? 10:44:07 10:44:11

MR. COLLINS-CHASE: Objection; relevance, scope. 10:44:13 10:44:13

THE WITNESS: Again, I don't know what I'm reading here out of context, but my comment on this is the same as before. 10:44:14 10:44:21 10:44:26

What I see there is that Dr. Li, some inventor, is saying that this is an unpredictable science, and if you have the guidance of the Tadros, of the Kalili, of the Porter, of the Wen, you don't have unpredictability. 10:44:30 10:44:38 10:44:42 10:44:49 10:44:51

That is precisely the point here, is by the time of the invention those were all problems-- quote, unquote, "unpredictable problems" were solved. 10:44:53 10:45:00 10:45:04

You don't want to mess with the properties of those good layers. You want to have a predictable result. Otherwise, you produce unpredictability. 10:45:06 10:45:08 10:45:12

Q (By Mr. Argenti) Can you read that portion I asked you to read, please? 10:45:20 10:45:22

MR. COLLINS-CHASE: Same objections. 10:45:23

THE WITNESS: "As I mentioned earlier, Your Honor, Dr. Li, the inventor, one of the inventors in this patent family, herself told the Patent Office years ago, this is an unpredictable science. That's what she said years ago to the Patent Office." 10:45:24 10:45:25 10:45:28 10:45:32 10:45:35 10:45:41

Q (By Mr. Argenti) And continue down to Line 23. 10:45:41

A "And that was right. 10:45:47

"I mean, that was, in fact, correct. 10:45:47

"This is an unpredictable field for which experimentation is required to determine if particular compositions of materials are efficacious in terms of arriving at teeth distributions that the dentists want to achieve within a mouth of a patient, safety, stain resistance, comfort, on and on, and those customer or patient-facing characteristics rest on technological characteristics that are hard to achieve." 10:45:49 10:45:52 10:45:54 10:45:58 10:46:01 10:46:05 10:46:10 10:46:13

To that, I do add, yeah, that's all resolved in the prior art of Tadros and Kalili and Wen and the 10:46:17 10:46:25

other references. That would take away that unpredictability that he's talking about. 10:46:31 10:46:35

I don't know under which context he is saying that or what he's thinking, so-- 10:46:37 10:46:39

Q (By Mr. Argenti) Could you read the last paragraph as well, please? 10:46:41 10:46:43

MR. COLLINS-CHASE: Same objections. 10:46:45

THE WITNESS: "Dr. Li had it right in her original declaration when she said that this is an unpredictable science." 10:46:46 10:46:49 10:46:51

Q (By Mr. Argenti) ClearCorrect's lawyer doesn't say that it's an unpredictable science except when the prior art gives you guidance about material selection, right? 10:46:53 10:46:55 10:46:58 10:47:01

MR. COLLINS-CHASE: Objection; form, foundation, relevance, scope, hearsay. 10:47:02 10:47:04

THE WITNESS: I have no idea what the attorney was saying there, so I can't comment on what this person was thinking, but yes, the unpredictability is taken away by using the references, by having the prior art. 10:47:07 10:47:08 10:47:12 10:47:17 10:47:21

I think that's the point in my reports. 10:47:23

Q (By Mr. Argenti) The date of this transcript is May 27th, 2026, right? 10:47:28 10:47:30

MR. COLLINS-CHASE: Objection; 10:47:33

scope. 10:47:35
THE WITNESS: That's what it says. 10:47:35
Q (By Mr. Argenti) Which is, I believe, two days before you submitted your reply declaration on these IPRs, correct? 10:47:39 10:47:42 10:47:46
MR. COLLINS-CHASE: Objection; scope, form. 10:47:47 10:47:48
THE WITNESS: Possibly, yes. 10:47:49
I see what date it was, but I-- let me look. 10:47:54
Yes, that's correct. 10:47:57
Q (By Mr. Argenti) When you were preparing and signing your reply declaration, were you aware that ClearCorrect's counsel had told the District Court that this is an unpredictable field? 10:48:19 10:48:21 10:48:24 10:48:28
MR. COLLINS-CHASE: Objection; relevance, scope. 10:48:31 10:48:33
THE WITNESS: I have no idea what you're talking about, so I don't know. I have not seen this result. I don't know what "District Court" means, what-- where we are, et cetera, right? 10:48:33 10:48:34 10:48:37 10:48:40
I have a vague understanding, but I have not seen this document. I don't know what their train of thought is. I can't-- without reading the whole report and probably talking to attorneys for a couple of days-- 10:48:43 10:48:45 10:48:47 10:48:50 10:48:53

Q (By Mr. Argenti) So no one told you about what ClearCorrect was saying in this hearing; is that right? 10:48:54 10:48:55

MR. COLLINS-CHASE: Objection; form, scope, foundation-- 10:48:59 10:49:01

THE WITNESS: I have never heard of the hearing. 10:49:02 10:49:03

Q (By Mr. Argenti) Wouldn't you have wanted to know about what ClearCorrect was saying in this hearing, what ClearCorrect's lawyer was representing to the Court, before you signed your reply declaration? 10:49:04 10:49:07 10:49:07 10:49:10

MR. COLLINS-CHASE: Objection; form, scope, relevance-- 10:49:12 10:49:14

THE WITNESS: I stand with my reply declaration, and I stand with my opinion that you want to have predictable results. 10:49:15 10:49:19 10:49:26

If you start from zero, yeah, things are unpredictable, the science is probably unpredictable, but you are not starting from zero. You are starting from references that give a person having ordinary skill in the art guidance. 10:49:30 10:49:33 10:49:37 10:49:40 10:49:43

Tadros has a hard layer, Kalili has a soft layer, and describes-- describes the materials, and a person having ordinary skill in the art would want to hold onto that because they want that. 10:49:44 10:49:53 10:49:58 10:49:59

They want-- and they want to have predictable 10:50:01

results. 10:50:05

I don't know-- it's a matter of what is predictable in the case-- in this case you want-- my opinion is you want predictable results. You want to maintain the properties of the layers. 10:50:06 10:50:09 10:50:12 10:50:16

You don't want to mess with them by using processes that will change those properties, so adhesive lamination will assure the person having ordinary skill in the art that the hard layer has the properties of the hard layer, and the soft layer has the properties of the soft layer, so that's all. 10:50:18 10:50:20 10:50:27 10:50:32 10:50:34 10:50:37

I don't know what they mean here with predictable and unpredictable and the science and all of that. 10:50:39 10:50:42

I stand with my report, and I don't think-- even reading this doesn't change my mind. 10:50:44 10:50:47

Q (By Mr. Argenti) Are you aware that the District Court patent infringement trial is underway between ClearCorrect and Align? 10:50:53 10:50:55 10:50:58

MR. COLLINS-CHASE: Objection; relevance, scope. 10:50:59 10:51:02

THE WITNESS: I don't know. I don't know. 10:51:03 10:51:04

Q (By Mr. Argenti) So you haven't attended any portion of that trial that's currently going on? 10:51:05 10:51:07

MR. COLLINS-CHASE: Objection; 10:51:10

relevance, scope. 10:51:11
THE WITNESS: No. 10:51:12
Q (By Mr. Argenti) Have you seen any transcripts from that trial? 10:51:14 10:51:15
MR. COLLINS-CHASE: Objection; relevance, scope. 10:51:17 10:51:18
THE WITNESS: No. 10:51:19
(Exhibit E marked for identification.) 10:51:19 10:51:19
Q (By Mr. Argenti) I am going to introduce a document that we will designate as Exhibit E to this deposition, which is a copy of Volume III of the jury trial proceeding transcript as between Align Technology Inc. and ClearCorrect Operating Inc. in the Western District of Texas. 10:51:24 10:51:28 10:51:37 10:51:40 10:51:47 10:51:49
This Volume III is dated June 24th, 2026. 10:51:50
I suspect we may need to take another break to get a copy of that for you. 10:51:57 10:52:01
MR. COLLINS-CHASE: Yeah, I'll object on authenticity, hearsay, foundation, relevance, outside the scope of Dr. Osswald's reports, and, again, just, you know, this is improper new evidence being inserted into the deposition. 10:52:02 10:52:03 10:52:07 10:52:13 10:52:16
I guess with that, we can pause and print the document. 10:52:17 10:52:20

MR. ARGENTI: We'll take another five-minute break maybe, and hopefully that's enough time to get a copy. 10:52:25 10:52:27 10:52:31

(Recess 10:52 to 11:09 a.m.) 10:52:35

Q (By Mr. Argenti) Dr. Osswald, do you now have a printed copy of Exhibit E? 11:09:10 11:09:11

A I was just given it. Here it is. 11:09:14

Q And given that I perhaps optimistically thought we would be taking about a five-minute break and it ended up being a 17-minute break where no one on the Finnegan side was responding when I asked about status, I gather folks may have stepped out of the conference room there. 11:09:18 11:09:22 11:09:26 11:09:30 11:09:33 11:09:36

During that break, or any of our breaks today, Dr. Osswald, have you discussed your testimony with Finnegan? 11:09:36 11:09:39 11:09:43

A No, I have not. 11:09:43

Q Have you discussed these exhibits and their content that I've been introducing today? 11:09:44 11:09:49

A No. I was walking around. 11:09:53

Q So turning back to the Exhibit E trial transcript, have you-- 11:09:55 11:10:03

MR. COLLINS-CHASE: Since you mentioned it, it takes a little while to print a 246-page document that we have seen for the first time 11:10:03 11:10:04 11:10:08

today, so we printed a few copies, and that's how long it takes to print the document. 11:10:10 11:10:13

There's nothing we can do about the timing. 11:10:15

We have every exhibit that's of record in these proceedings ready to go in a box, and we don't have these, so that's why it look as long as it took. 11:10:17 11:10:19 11:10:22

MR. ARGENTI: Understood. 11:10:25

That's why I said "optimistically thinking five minutes." 11:10:27 11:10:31

Q (By Mr. Argenti) Looking at the Exhibit E trial transcript, Dr. Osswald, have you seen this document before? 11:10:33 11:10:34 11:10:35

MR. COLLINS-CHASE: Objection; scope, relevance. 11:10:36 11:10:37

THE WITNESS: No. 11:10:38

Q (By Mr. Argenti) As you can see from the first page, this is the transcript of the third day of the trial between Align and ClearCorrect, dated June 24, 2026, which is just last week. 11:10:38 11:10:41 11:10:43 11:10:49

Do you see that? 11:10:50

MR. COLLINS-CHASE: Objection; scope, relevance, foundation. 11:10:51 11:10:52

THE WITNESS: I see that. 11:10:54

Q (By Mr. Argenti) And if we turn to Page 697, which is the third page of the PDF, because I think the page 11:10:56 11:11:04

numbering continues from Volume II, the previous day, at Line 8 we see the same ClearCorrect lawyer from the previous hearing, Mr. Mueller, addressing the Court. 11:11:08 11:11:13 11:11:17

Do you see that? 11:11:21

MR. COLLINS-CHASE: Objection; scope, relevance. 11:11:22 11:11:23

THE WITNESS: Yes. 11:11:24

Q (By Mr. Argenti) And on that same page at Line 10 ClearCorrect calls its witness, Dr. Stephen Spielberg. 11:11:26 11:11:29

Do you see that name-- "Spiegelberg." I'm sorry. 11:11:34

MR. COLLINS-CHASE: Objection; scope, relevance. 11:11:40 11:11:41

THE WITNESS: I see it, yes. 11:11:44

Q (By Mr. Argenti) Do you know Dr. Spiegelberg? 11:11:46

A I do, yes. 11:11:48

Q In what context do you know Dr. Spiegelberg? 11:11:49

MR. COLLINS-CHASE: Objection; scope, relevance. 11:11:51 11:11:53

THE WITNESS: I don't remember. We may have met at a conference or something, somewhere, and I know him from other-- anyway, I know him. 11:11:54 11:11:55 11:11:57

Q (By Mr. Argenti) So you know him professionally from your work other than on this case; is that right? 11:12:04 11:12:06

A Yes. 11:12:07

MR. COLLINS-CHASE: Objection; 11:12:08

scope, relevance. 11:12:09
Q (By Mr. Argenti) About how long ago did you first become acquainted with Dr. Spiegelberg? 11:12:19 11:12:21
MR. COLLINS-CHASE: Same objections. 11:12:24
THE WITNESS: I don't remember. 11:12:26
Q (By Mr. Argenti) Have you ever spoken to Dr. Spiegelberg about this case? 11:12:29 11:12:31
MR. COLLINS-CHASE: Same objections. 11:12:34
THE WITNESS: I don't think so. 11:12:35
I don't think I've talked to him in this case. I don't think so. 11:12:36 11:12:40
Q (By Mr. Argenti) When is the last time you spoke to Dr. Spiegelberg? 11:12:41 11:12:43
MR. COLLINS-CHASE: Objection; relevance, scope. 11:12:44 11:12:45
THE WITNESS: I don't remember. 11:12:46
Q (By Mr. Argenti) If we turn to the next page, which I've flipped to on the screen here, which is Page 698, at the bottom of the page, starting at Line 21, Dr. Spiegelberg testifies that he's been asked to do two main things: to assess whether or not the ClearCorrect products infringe the materials patents of Align and whether or not the Align patents are valid. 11:12:53 11:12:54 11:12:58 11:13:04 11:13:07 11:13:10 11:13:13
Do you see that? 11:13:17
MR. COLLINS-CHASE: Objection; 11:13:18

scope, relevance, hearsay. 11:13:19
THE WITNESS: I see that. 11:13:21
Q (By Mr. Argenti) So Dr. Spiegelberg is an expert witness for ClearCorrect testifying in the District Court case. 11:13:23 11:13:24 11:13:27
Is that your understanding? 11:13:27
MR. COLLINS-CHASE: Objection; scope, relevance, foundation. 11:13:28 11:13:29
THE WITNESS: I am not sure. From this statement, yeah, maybe. 11:13:31 11:13:35
Yeah, this is the first time I've seen this, so-- 11:13:36
Q (By Mr. Argenti) Do you think Dr. Spiegelberg is a credible expert in the field of material science? 11:13:40 11:13:43
MR. COLLINS-CHASE: Objection; form, scope, relevance. 11:13:47 11:13:48
THE WITNESS: I mean, he's a good scientist. 11:13:48 11:13:49
Q (By Mr. Argenti) Let's turn now to Page 771. 11:13:55
Do you see starting at Line No. 2 where the question reads, "If you need a lot of trial and error, does that make a-- an art-- a field predictable or unpredictable," and his answer is, "A lot of trial and error means it is unpredictable"? 11:13:59 11:14:28 11:14:32 11:14:38 11:14:40
Do you see that? 11:14:44
MR. COLLINS-CHASE: Objection; 11:14:45

scope, form, relevance, hearsay. 11:14:46
THE WITNESS: I see that. 11:14:48
Q (By Mr. Argenti) And the next question reads, "Now, is making a multi-layer material for use in a dental aligner, is that predictable or unpredictable?" 11:14:49 11:14:51 11:14:54
Answer, "It is unpredictable." 11:14:58
Did I read that correctly? 11:15:01
MR. COLLINS-CHASE: Objection; form, scope, relevance, hearsay. 11:15:03 11:15:05
THE WITNESS: Yes, that's what it says here. 11:15:06 11:15:07
Q (By Mr. Argenti) Unlike you, Dr. Spiegelberg doesn't note any exceptions to the unpredictability in this field, does he? 11:15:08 11:15:10 11:15:13
MR. COLLINS-CHASE: Objection; scope, relevance, hearsay, foundation, form. 11:15:14 11:15:15
THE WITNESS: I don't know under which context Dr. Spiegelberg is giving this, but my opinion about wanting to have predictable results, if you have the Tadros reference and if you have the other references-- that's what my opinion was. 11:15:19 11:15:20 11:15:28 11:15:35 11:15:38
You want to keep the predictability of those properties, and I don't know which context they're talking about here. 11:15:42 11:15:45 11:15:48
I still stand with my opinion. 11:15:48

Q (By Mr. Argenti) Dr. Spiegelberg doesn't say, "This field is unpredictable unless you look at the prior art," right? 11:15:52 11:15:54 11:15:57

MR. COLLINS-CHASE: Objection; scope, relevance, foundation, hearsay. 11:15:58 11:15:59

THE WITNESS: Again, I don't know under which context Dr. Spiegelberg is saying that, so I don't know. 11:16:01 11:16:02 11:16:06

Q (By Mr. Argenti) The next question after that, starting at Line 11 is "Is there any dispute in this case about that, sir?" 11:16:09 11:16:11 11:16:14

Dr. Spiegelberg's answer is, "No. There doesn't appear to be," right? 11:16:16 11:16:21

MR. COLLINS-CHASE: Objection; scope, relevance, foundation, hearsay. 11:16:22 11:16:23

THE WITNESS: That's what it says. 11:16:26

Q (By Mr. Argenti) Dr. Osswald, before your deposition today were you aware that ClearCorrect's expert witness testified in the infringement case that it was undisputed that making a multi-layered material for a dental aligner is unpredictable? 11:16:28 11:16:29 11:16:32 11:16:35 11:16:38

MR. COLLINS-CHASE: Objection; scope, relevance. 11:16:40 11:16:41

THE WITNESS: I hadn't seen this before, and as I say, I still stand with my report, in 11:16:42 11:16:45

that by having guidance, by having a solution, you want to maintain that solution to have predictable results. 11:16:51 11:16:58

That's all I'm saying by using Tadros and the other references. 11:17:02 11:17:05

Q (By Mr. Argenti) Let's turn back now to Page 704 of this Exhibit E transcript, please. 11:17:09 11:17:13

A I see it. 11:17:34

Q Starting at Line 7, Dr. Spiegelberg was asked whether Align invented TPUs, and his answer is, "No, they did not." 11:17:35 11:17:39 11:17:44

Do you see that? 11:17:45

MR. COLLINS-CHASE: Objection; relevance, scope, hearsay. 11:17:46 11:17:46

THE WITNESS: I see it. 11:17:48

Q (By Mr. Argenti) Do you agree that Align did not invent TPUs? 11:17:49 11:17:51

MR. COLLINS-CHASE: Same objections. 11:17:52

THE WITNESS: I assume they weren't the ones who invented TPUs. 11:17:53 11:17:58

Q (By Mr. Argenti) Dr. Spiegelberg then testified that all TPUs are not the same, "Rather, they are quite varied," right? 11:18:00 11:18:02 11:18:06

MR. COLLINS-CHASE: Objection; form, relevance, scope, hearsay. 11:18:07 11:18:08

THE WITNESS: That's what it says 11:18:09

there. 11:18:10

Q (By Mr. Argenti) And then he testified that there are hundreds to thousands of types of TPUs. 11:18:18 11:18:19

Do you agree that there are hundreds to thousands of types of TPUs? 11:18:22 11:18:24

MR. COLLINS-CHASE: Objection; scope, relevance. 11:18:26 11:18:27

THE WITNESS: I don't know how many TPUs there are, but I know Kalili suggests one single TPU, which is Texin 990R, which showed excellent results. 11:18:28 11:18:29 11:18:34 11:18:41

Q (By Mr. Argenti) You are not aware of how many different types of TPUs there are; is that right? 11:18:44 11:18:45

MR. COLLINS-CHASE: Objection; scope, relevance. 11:18:48 11:18:49

THE WITNESS: I haven't counted them. 11:18:50 11:18:51

Q (By Mr. Argenti) Do you know if it's more than a hundred? 11:18:51 11:18:53

MR. COLLINS-CHASE: Same objections. 11:18:55

THE WITNESS: Again, I haven't counted them. 11:18:57 11:18:58

I know Texin 990R and Kalili is one that works quite well. 11:18:58 11:19:03

Q (By Mr. Argenti) So you can't say whether it's 11:19:04

accurate that there are hundreds to thousands of types of TPUs, sitting here today; is that correct? 11:19:05 11:19:08

MR. COLLINS-CHASE: Objection; scope, relevance, asked and answered. 11:19:11 11:19:12

THE WITNESS: I haven't counted them. 11:19:15 11:19:16

Q (By Mr. Argenti) Dr. Spiegelberg was then asked similar questions about copolyesters, and he testified that there are hundreds of copolyesters. 11:19:21 11:19:22 11:19:24

Do you see that? 11:19:26

MR. COLLINS-CHASE: Objection; form, hearsay, relevance, scope. 11:19:27 11:19:30

THE WITNESS: I see that. 11:19:31

Q (By Mr. Argenti) Do you agree that there are hundreds of copolyesters? 11:19:34 11:19:36

MR. COLLINS-CHASE: Same objections. 11:19:37

THE WITNESS: There are quite a few copolyesters. 11:19:38 11:19:40

Again, I have not counted them. 11:19:41

I know the ones that are mentioned in the prior art, but I don't know, I haven't counted them. 11:19:49 11:19:51

Q (By Mr. Argenti) We can set this Exhibit E aside now. 11:19:54

Let's turn back to your reply declaration. 11:19:58

Let's look at Paragraph 2 on Page 1, please. 11:20:10

A Yes. 11:20:38

Q Here in the bullet points in Paragraph No. 2 you list the topics you address in your reply declaration, correct? 11:20:38 11:20:42 11:20:44

A Yes. 11:20:44

MR. COLLINS-CHASE: Objection; form. 11:20:45

Q (By Mr. Argenti) You don't mention addressing secondary considerations of nonobviousness, correct? 11:20:49 11:20:51

A I am mentioning the "Tadros copolyester disclosures," the "Wen's disclosures of using multiple thinner layers," "Porter's disclosures of Tritan as a BPA-free alternative to polycarbonate," "and adhesive lamination and whether a 'tie layer' results in another polymer layer in a multilayer sheet." 11:20:55 11:21:00 11:21:04 11:21:09 11:21:13 11:21:16

Q Secondary considerations are also sometimes referred to as objective indicia or secondary indicia. 11:21:20 11:21:23

You don't mention any of those, do you? 11:21:28

MR. COLLINS-CHASE: Objection; form. 11:21:29

THE WITNESS: That's not covered in my report. 11:21:30 11:21:34

Q (By Mr. Argenti) You are aware that Dr. Kimmel addressed a number of categories of secondary considerations in his declaration, right? 11:21:37 11:21:39 11:21:42

MR. COLLINS-CHASE: Objection; foundation. 11:21:43 11:21:45

THE WITNESS: I recall reading about 11:21:45

it, yes. 11:21:50
Q (By Mr. Argenti) And yet you elected not to address 11:21:52
that aspect of his testimony. 11:21:55
Why not? 11:21:57
MR. COLLINS-CHASE: Objection; form. 11:22:01
THE WITNESS: I believe these are 11:22:02
the technical issues that are at hand in the prior art. 11:22:03
Q (By Mr. Argenti) Let's look at Paragraph No. 92 of 11:22:15
your reply declaration, please. 11:22:17
In Paragraph No. 92 you say, "It is still my 11:22:47
opinion, as set forth in my opening declaration, that 11:22:50
all of the challenged claims of the '613, '384, 090, 11:22:53
and '091 patent would have been obvious to a person 11:22:58
having ordinary skill in the art as of the patent's 11:23:04
earliest possible priority date." 11:23:05
Do you see that? 11:23:08
A I see that. 11:23:09
Q Let's pull out your opening declaration regarding the 11:23:10
'613 patent as an example. 11:23:19
That's Exhibit No. 1007 in IPR 2025-00818. 11:23:20
A I have it. 11:23:34
Q Starting at Paragraph No. 16 you address the applicable 11:23:35
legal standards, right? 11:23:52
A Page 16 of the-- it says, "Thermoforming using 11:23:53
multi-layer films and sheets"-- 11:24:12

Q I am looking at Exhibit No. 1007 from the '818 IPR-- sorry if I said Page 16. I meant Paragraph No. 16. 11:24:13 11:24:18
A Oh. 11:24:22
I see that, yes. 11:24:29
Q In Paragraph No. 21 of the legal standard section, you say, "I understand that assessing obviousness entails consideration of four things," right? 11:24:30 11:24:35 11:24:39
A Yes. 11:24:41
Q And the fourth consideration listed is "Any secondary consideration of nonobviousness," correct? 11:24:44 11:24:51
A Yes. 11:24:53
Q Beyond this listing of the relevant legal standard, you don't address secondary considerations in your opening report either, correct? 11:24:54 11:25:05 11:25:06
MR. COLLINS-CHASE: Objection; form, foundation. 11:25:08 11:25:10
THE WITNESS: I believe not. 11:25:11
Q (By Mr. Argenti) And that goes for all four opening declarations across the four IPRs, right? 11:25:13 11:25:15
MR. COLLINS-CHASE: Objection; form, foundation. 11:25:19 11:25:20
THE WITNESS: Yes. 11:25:21
Q (By Mr. Argenti) Do you recall at your first deposition in these IPRs we discussed your involvement in a case between Bay Materials and 3M, where you 11:25:35 11:25:38 11:25:40

worked as an expert for Bay Materials? 11:25:44
MR. COLLINS-CHASE: Objection; 11:25:47
scope. 11:25:48
THE WITNESS: I recall discussing 11:25:49
about it. 11:25:51
Yeah, it was a while back, but yes. 11:25:52
Q (By Mr. Argenti) You submitted a declaration in an IPR 11:25:55
involving a patent owned by Bay Materials in that 11:25:58
dispute, right? 11:26:01
MR. COLLINS-CHASE: Objection; 11:26:02
outside the scope of either of his reports. 11:26:03
THE WITNESS: I don't remember. 11:26:05
Q (By Mr. Argenti) Do you have Exhibit No. 2026 from 11:26:09
these IPRs available to you? 11:26:12
A I don't know. The attorneys are looking for them. 11:26:14
Q While they look, I can drop it into the chat. 11:26:23
This is already an exhibit in the IPRs. 11:26:30
I am bringing it up here on the screen share as 11:26:44
well. 11:26:47
MR. ARGENTI: Counsel, do we need to 11:26:55
take a break or can we go forward with some questions 11:26:57
based on the electronic copy of this exhibit? 11:26:59
MR. COLLINS-CHASE: Yeah, we'll 11:27:00
print a copy. I am happy to go off the record to save 11:27:01
you time. 11:27:05

I think it's 40 pages, so this should be five minutes or less to print this, since it's short. 11:27:05 11:27:09

MR. ARGENTI: Sounds good. 11:27:11

Off the record then. 11:27:12

(Recess 11:27 to 11:32 a.m.) 11:27:14

Q (By Mr. Argenti) Dr. Osswald, it is my understanding that you now have a paper copy of what has been submitted as Exhibit No. 2026 in these IPRs. 11:32:29 11:32:31 11:32:33

You also have it on the screen share in front of you. 11:32:43 11:32:45

This is, I will represent, an excerpted version of the declaration that I was referring to, not the complete version, so I don't want there to be any confusion about that, but this is portions of it that have been submitted in this IPR. 11:32:45 11:32:50 11:32:53 11:32:56 11:33:00

This is an excerpted copy of your second declaration from IPR 2022-01214; is that right? 11:33:01 11:33:07

MR. COLLINS-CHASE: We'll just object on relevance and scope and the completeness of the exhibit. 11:33:13 11:33:14 11:33:18

THE WITNESS: I see that. 11:33:19

Q (By Mr. Argenti) And this declaration involves Patent No. 10,946,630, right? 11:33:24 11:33:28

MR. COLLINS-CHASE: Objection; form. 11:33:35

THE WITNESS: That's what it says 11:33:36

there. 11:33:37
Q (By Mr. Argenti) And that is a patent owned by patent owner Bay Materials, correct? 11:33:38 11:33:41
MR. COLLINS-CHASE: Objection; scope. 11:33:43 11:33:44
THE WITNESS: Again, that's what it says there. 11:33:44 11:33:46
Q (By Mr. Argenti) And you were submitting your testimony on behalf of patent owner Bay Materials in that case, right? 11:33:46 11:33:48 11:33:51
MR. COLLINS-CHASE: Objection; form. 11:33:52
THE WITNESS: Yes. 11:33:53
Q (By Mr. Argenti) Now that you see this document, do you remember submitting this declaration in that IPR? 11:33:58 11:34:00
MR. COLLINS-CHASE: Objection; form relevance. 11:34:02 11:34:07
THE WITNESS: It's been a while. 11:34:08
I do remember submitting a report, but I would have to go back and review the whole thing to see the context of it. 11:34:09 11:34:11 11:34:14
Q (By Mr. Argenti) Bay Materials' counsel in that IPR was the same team from Finnegan as you are working with in this IPR, right? 11:34:16 11:34:19 11:34:23
MR. COLLINS-CHASE: Objection; relevance, scope, foundation. 11:34:24 11:34:25

THE WITNESS: Some of the attorneys are. 11:34:27 11:34:28

Q (By Mr. Argenti) For example, Charles Collins-Chase, who is here today, was lead counsel in that IPR; is that right? 11:34:31 11:34:35 11:34:35

MR. COLLINS-CHASE: Objection; form, scope, relevance. 11:34:36 11:34:38

THE WITNESS: I believe so. 11:34:39

Q (By Mr. Argenti) Unlike these IPRs against the Align patents, in the Bay Materials IPR you did address secondary considerations, right? 11:34:42 11:34:46 11:34:49

MR. COLLINS-CHASE: Objection; scope, relevance. 11:34:50 11:34:52

THE WITNESS: I don't remember. 11:34:53

I mean, this was a different-- completely different case. 11:34:54 11:34:56

There were different patents. 11:34:57

There were different products. 11:34:59

I don't remember. 11:35:05

This is a whole-- I don't think we can compare one to the other one, and I don't remember what the context was with all of that. 11:35:05 11:35:08 11:35:10

Q (By Mr. Argenti) Let's turn to Page 4 of this document, please, which is the last page of the table of contents. 11:35:12 11:35:14 11:35:18

This shows that you addressed objective evidence of nonobviousness, right? 11:35:24 11:35:33

MR. COLLINS-CHASE: Objection; scope, relevance. 11:35:35 11:35:37

THE WITNESS: That's what it says there, yes. 11:35:38 11:35:39

Q (By Mr. Argenti) Does that refresh your recollection as to whether you addressed secondary considerations in this case? 11:35:40 11:35:41 11:35:44

MR. COLLINS-CHASE: Objection; scope, relevance. 11:35:44 11:35:45

THE WITNESS: I mean, again, this-- it says what it is. 11:35:46 11:35:48

I mean, again, this is a different case. 11:35:49

It was years ago. 11:35:51

It was a different patent, different products, different companies. 11:35:54 11:36:02

Q (By Mr. Argenti) In the table of contents section addressing objective evidence of nonobviousness, it refers to Zendura FLX. 11:36:04 11:36:07 11:36:10

Do you see that? 11:36:14

MR. COLLINS-CHASE: Objection; scope. 11:36:14 11:36:16

THE WITNESS: I see that. 11:36:16

Q (By Mr. Argenti) That was a Bay Materials product, 11:36:17

right? 11:36:20
MR. COLLINS-CHASE: Objection; 11:36:20
scope, foundation. 11:36:21
THE WITNESS: I don't remember. 11:36:22
Q (By Mr. Argenti) You don't remember whether Zendura 11:36:26
FLX was a Bay Materials product? 11:36:29
MR. COLLINS-CHASE: Same objections. 11:36:31
THE WITNESS: I don't remember. 11:36:32
Q (By Mr. Argenti) The table of contents states that you 11:36:38
addressed objective evidence of nonobviousness, 11:36:39
including Zendura FLX embodying the claims and 11:36:41
exhibiting unexpectedly superior properties, 3M copying 11:36:46
Zendura FLX, and Zendura FLX receiving industry praise, 11:36:51
right? 11:36:57
MR. COLLINS-CHASE: Objection; 11:36:58
scope, relevance. 11:36:59
THE WITNESS: I see that, yes. 11:37:00
Q (By Mr. Argenti) Are you aware that the ClearCorrect 11:37:01
aligners at issue in the infringement case that's 11:37:03
currently going on are made of Zendura FLX? 11:37:06
MR. COLLINS-CHASE: Objection; 11:37:10
scope, relevance, foundation. 11:37:12
THE WITNESS: I don't know. 11:37:13
Q (By Mr. Argenti) You were not aware, before I just 11:37:18
asked you the question, that the ClearCorrect aligners 11:37:20

at issue in the case involving Align's patents that are challenged in the IPR are made from Zendura FLX? 11:37:23 11:37:28

MR. COLLINS-CHASE: Objection; scope, relevance, foundation. 11:37:32 11:37:33

THE WITNESS: I'm not aware. I don't know. 11:37:35 11:37:36

Q (By Mr. Argenti) Looking back at the three categories of secondary considerations that you addressed in this Bay Materials IPR, as reflected in the table of contents, your opinion here was that each of those categories helped demonstrate nonobviousness, right? 11:37:40 11:37:42 11:37:45 11:37:49 11:37:51

MR. COLLINS-CHASE: Objection; scope, relevance. 11:37:55 11:37:56

THE WITNESS: Again, this has been a case that's a long time ago. 11:37:57 11:38:01

There were different patents. 11:38:02

This was a different case, different companies, different type of products, so-- 11:38:05 11:38:07

Q (By Mr. Argenti) Does that answer my question? I don't think it does. 11:38:15 11:38:16

Your opinion regarding the three categories of secondary considerations that you address here was that they help demonstrate nonobviousness, right? 11:38:18 11:38:21 11:38:24

MR. COLLINS-CHASE: Objection; form, scope, relevance. 11:38:27 11:38:30

THE WITNESS: Again, that's-- I don't know exact-- I don't remember the whole context of it, and I don't remember the case exactly, but the title says, "Objective evidence of nonobviousness," so I would imagine-- I would have to review it. 11:38:31 11:38:33 11:38:36 11:38:39 11:38:42

Again, these are different patents. 11:38:45

It's a different case, different products. 11:38:48

Q (By Mr. Argenti) Let's look at Paragraph 175-- actually, sorry, before we get to that one, your discussion with secondary considerations in this Bay Materials declaration starts at Paragraph No. 171 on Page 100, right? 11:38:55 11:38:59 11:39:02 11:39:05 11:39:08

MR. COLLINS-CHASE: Objection; scope, relevance. 11:39:09 11:39:11

THE WITNESS: That's what it says there. 11:39:12 11:39:13

Q (By Mr. Argenti) Now let's look at Paragraph 175. 11:39:15

In this paragraph you say, "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." 11:39:19 11:39:35 11:39:39 11:39:43

Did I read that right? 11:39:44

A I see that, yes. 11:39:45

Q If we look below that at the claim chart, Claim 1 recites "A polymeric composition sheet comprising." 11:39:49 11:39:55

Do you see that?
MR. COLLINS-CHASE: Objection; form, scope.
THE WITNESS: I see that, yes.
Q (By Mr. Argenti) Again, "comprising" means that the claims require the elements that follow, but the sheets could have other un-recited elements, right?
MR. COLLINS-CHASE: Objection; form.
THE WITNESS: Yes.
Q (By Mr. Argenti) If we go to the next page and look at Element 1(A), it recites, "At least two outer layers A and C and an elastomeric inner layer B," right?
MR. COLLINS-CHASE: Objection; relevance, outside the scope.
THE WITNESS: Again, this is a completely different patent, a different case, a different time, so a different product.
Q (By Mr. Argenti) Claim 1 requires that the sheet have at least three layers but could also have more, right?
MR. COLLINS-CHASE: Objection; scope, relevance.
THE WITNESS: It talks about two outer layers, A and C, and an elastomeric inner layer B.
Q (By Mr. Argenti) Right.

And it says that the sheet comprises that, so it could have more than those three layers, right? 11:41:10 11:41:13

MR. COLLINS-CHASE: Objection; form, scope, relevance. 11:41:16 11:41:17

THE WITNESS: Again, that's what it says, right? 11:41:19 11:41:22

Q (By Mr. Argenti) So Claim 1 of this patent is not limited to three layers, correct? 11:41:25 11:41:27

MR. COLLINS-CHASE: Objection; scope, relevance, form. 11:41:29 11:41:30

THE WITNESS: It's comprising that, yes. 11:41:31 11:41:37

Q (By Mr. Argenti) If we look down at Element 1(B), it says, "One or more of the outer layers is a polyester or copolyester having a flexural modulus from about 1,000 MPA to 2500 MPA," right? 11:41:38 11:41:41 11:41:44 11:41:49

MR. COLLINS-CHASE: Objection; scope, relevance. 11:41:54 11:41:55

THE WITNESS: That's what it says. 11:41:56

Q (By Mr. Argenti) And your analysis for this claim, if we look at the right-hand side of the chart, maps that to Zendura FLX hard outer layers, correct? 11:42:00 11:42:02 11:42:07

MR. COLLINS-CHASE: Objection; scope, relevance. 11:42:13 11:42:15

THE WITNESS: That's what it says 11:42:15

there. 11:42:17
Q (By Mr. Argenti) By the language of the claim, only one of the recited layers A and C has to be a hard layer, correct? 11:42:18 11:42:20 11:42:24
MR. COLLINS-CHASE: Objection; scope, relevance, form. 11:42:24 11:42:26
THE WITNESS: It says one or more of the outer layers A and C is a polyester or copolyester. 11:42:27 11:42:41
Q (By Mr. Argenti) So Claim 1 of this Bay Materials patent is not limited to three layers and only requires one hard layer. 11:42:47 11:42:49 11:42:53
Do you agree? 11:42:54
MR. COLLINS-CHASE: Objection; form, scope, relevance, foundation. 11:42:55 11:42:56
THE WITNESS: I mean, this is a while back. 11:42:58 11:42:59
I would have to look. 11:42:59
It's a different patent at a different time, different companies, different products. 11:43:03 11:43:07
Q (By Mr. Argenti) Do you know whether Claim 1 of the Bay Materials patent is limited to three layers and requires more than one hard layer? 11:43:20 11:43:22 11:43:28
MR. COLLINS-CHASE: Objection; form, scope, relevance, asked and answered. 11:43:30 11:43:32
THE WITNESS: It says what it says, 11:43:33

right? 11:43:37
"One or more of the outer layers A and C is a polyester or copolyester having a flexural modulus from about 1,000 MPa to 2,500 MPa." 11:43:37 11:43:43 11:43:43
Q (By Mr. Argenti) And yet you say in this declaration that the hard, soft, hard Bay Materials product, Zendura FLX, is coextensive with this claim, right? 11:43:50 11:43:52 11:43:56
MR. COLLINS-CHASE: Objection; form. 11:44:00
THE WITNESS: I don't remember the terminology. 11:44:02 11:44:03
I would have to go back and look at that. 11:44:04
Q (By Mr. Argenti) We could go back-- we already saw it. It's in the first sentence of Paragraph No. 175. 11:44:07 11:44:09
Do you remember that? 11:44:15
MR. COLLINS-CHASE: Objection; scope, relevance. 11:44:16 11:44:17
THE WITNESS: I see that, yes. 11:44:28
Q (By Mr. Argenti) And, in fact, the 3M product that you say was copied from Zendura FLX had five layers, right? 11:44:29 11:44:32
MR. COLLINS-CHASE: Objection; relevance, scope, foundation. 11:44:37 11:44:38
THE WITNESS: I don't remember. 11:44:42
I mean, it's been a while. 11:44:43
Again, it was a different case, different patent. 11:44:44
It was three or four years ago. 11:44:47

Q (By Mr. Argenti) We could go down and take a look at Paragraph No. 185 of this declaration, which is on Page 110. 11:44:52 11:44:54 11:44:58

Does that refresh your recollection whether the 3M product that you say was copied from something that embodies and is coextensive with Claim 1 had five layers? 11:45:12 11:45:15 11:45:17 11:45:21

MR. COLLINS-CHASE: Objection; scope, relevance, form. 11:45:22 11:45:23

THE WITNESS: That's what it says there, "Proprietary five-layer blend of materials from a 3M"-- 11:45:25 11:45:32 11:45:36

Q (By Mr. Argenti) Do you still have a copy of this declaration from the Bay Materials IPR in your files? 11:45:41 11:45:43

MR. COLLINS-CHASE: Objection; scope, relevance, form. 11:45:46 11:45:47

THE WITNESS: Probably not. I don't know. 11:45:49 11:45:50

I usually delete things when a case settles or is done with. 11:45:50 11:45:54

Q (By Mr. Argenti) Did you review this declaration when you were preparing your opinions in these IPRs? 11:45:59 11:46:00

A I don't remember. 11:46:03

I remember reviewing some document that I had from this, but I don't remember. 11:46:07 11:46:09

I don't know. 11:46:11
Q Was it a declaration that you reviewed? 11:46:14
MR. COLLINS-CHASE: Objection; form. 11:46:17
THE WITNESS: I don't remember. 11:46:18
Q (By Mr. Argenti) When did you review that? 11:46:21
MR. COLLINS-CHASE: Objection; form. 11:46:22
THE WITNESS: I don't remember either. 11:46:23
Maybe last year sometime. 11:46:29
I don't know. I'm not sure. 11:46:30
Q (By Mr. Argenti) Did you at any point consider whether the opinions that you are offering in these IPRs were consistent or inconsistent with the opinions you had in the Bay Materials IPR? 11:46:33
MR. COLLINS-CHASE: Objection; scope, form. 11:46:34
THE WITNESS: I mean, I stand with my opinion, previous opinion. 11:46:35
I don't remember. I have to go back and see what my opinions were, and I stand with-- I certainly didn't-- I don't think I'm contradicting myself. 11:46:39
I know I'm not contradicting myself, and I know that I'm consistent with my opinion. 11:46:42
The opinion in this case is clear, so-- and it's a totally different case. It's a different patent. 11:46:43

I mean, sure, it's the same art, but it's a different patent, different companies, different properties. 11:47:19 11:47:22 11:47:25

Q (By Mr. Argenti) But you testified repeatedly that you don't remember what you said in the Bay Materials IPR, right? 11:47:27 11:47:31 11:47:33

MR. COLLINS-CHASE: Objection; form, scope, relevance. 11:47:34 11:47:35

THE WITNESS: I say it's a different case, yeah, and I don't remember. 11:47:36 11:47:39

If I write a report, I certainly would not make things up. I mean, so that's-- so I stand with my reports. 11:47:41 11:47:44 11:47:48

I always stand with my reports, and so I can assure you I don't contradict myself, neither in my writings, technical writings, nor in my-- nor in my expert reports. 11:47:48 11:47:52 11:47:57 11:48:04

Q (By Mr. Argenti) Did you discuss your Bay Materials declarations with ClearCorrect's counsel in these IPRs when preparing your opinions in these cases? 11:48:10 11:48:13 11:48:16

MR. COLLINS-CHASE: Objection. 11:48:18

Whether or not that occurred, the question goes to the contents of a discussion with counsel, and so I am going to instruct you not to answer that on the basis of requesting attorney-client privileged communication. 11:48:22 11:48:24 11:48:28 11:48:30

THE WITNESS: Okay. 11:48:35
Q (By Mr. Argenti) Are you going to follow the 11:48:37
instruction not to answer that question? 11:48:38
A Yes. 11:48:40
The thing is, I don't remember what-- all the 11:48:41
things that we discussed, so-- and I prefer not to have 11:48:44
discussion on confidential information with attorneys. 11:48:48
Q Do you recall whether ClearCorrect's IPR counsel ever 11:48:52
suggested to you that you should review your Bay 11:49:08
Materials IPR declaration to ensure that your opinions 11:49:11
here were consistent with what you said there? 11:49:14
MR. COLLINS-CHASE: I will object on 11:49:16
the basis of the question explicitly seeking the 11:49:17
contents of attorney-client privileged communications, 11:49:21
so I will instruct you not to answer, Dr. Osswald. 11:49:25
THE WITNESS: Okay. 11:49:30
Q (By Mr. Argenti) Again, you are going to follow 11:49:30
Counsel's instruction not to answer that question, just 11:49:33
to be perfectly clear; is that right? 11:49:38
A Correct, and I don't remember what was discussed 11:49:40
anyway, so the question is moot anyway. 11:49:43
MR. ARGENTI: I think that is about 11:49:49
everything I had to ask, but can we take a short break 11:49:51
just so I can confirm that? Maybe five minutes, and 11:49:54
then we can come back. 11:49:58

MR. COLLINS-CHASE: Sure. 11:50:00
THE WITNESS: Okay. 11:50:00
(Recess 11:50 to 11:57 a.m.) 11:50:05
MR. ARGENTI: That's it from me. 11:57:34
Barring any redirect, follow-up, I don't have any 11:57:35
further questions, so I'll pass the witness. 11:57:38
MR. COLLINS-CHASE: We'll take five 11:57:40
minutes just to confer and then come back on. 11:57:41
MR. ARGENTI: Okay. 11:57:44
(Recess 11:58 a.m. to 12:04 p.m.) 11:58:04
MR. COLLINS-CHASE: We just 12:04:15
reiterate our objection to the exhibits that were 12:04:22
introduced today -- I believe it's A through E that 12:04:24
were not of record in this case -- on the basis of 12:04:27
authenticity, hearsay, foundation, relevance, scope, 12:04:29
and under 42.23, but we have no questions for 12:04:33
Dr. Osswald. 12:04:38
Thank you, Dr. Osswald. 12:04:38
THE WITNESS: Thank you. 12:04:40
I like hearing that. 12:04:40
MR. ARGENTI: Thank you for your 12:04:43
time, Dr. Osswald. 12:04:44
(Discussion off the record.) 12:04:51
COURT REPORTER: Mr. Argenti-- 12:05:19
MR. ARGENTI: I know we had the long 12:14:07

holiday weekend coming up here, but you said three business days would be the standard delivery for the final? 12:14:09 12:14:13 12:14:13

COURT REPORTER: And then do you want an expedite sooner than three days? 12:14:34 12:14:35

MR. ARGENTI: Patrick, what do you think? 12:14:40 12:14:49

Why don't we do-- if we could do by the end of Monday, I think that's great. I don't think we need it by tonight, but probably sooner than Wednesday next week would be appreciated. 12:14:53 12:15:13 12:15:15 12:15:18

COURT REPORTER: And for you, Mr. Collins-Chase? 12:15:20 12:15:23

MR. COLLINS-CHASE: End of day Monday is great. 12:15:23 12:15:25

COURT REPORTER: And then rough drafts for both of you? 12:15:28 12:15:29

MR. ARGENTI: Yes, please. 12:15:30

COURT REPORTER: And for you, Mr. Collins-Chase? 12:15:34 12:15:34

MR. COLLINS-CHASE: Yes, please. 12:15:36

(Deposition concluded at 12:15 p.m.)

(Signature reserved.)

C E R T I F I C A T E

STATE OF WASHINGTON)
) ss.
COUNTY OF KING)

I, the undersigned Washington Certified Court Reporter, pursuant to RCW 5.28.010, authorized to administer oaths and affirmations in and for the State of Washington, do hereby certify: That the foregoing deposition of the witness named herein was taken stenographically before me and reduced to a typed format under my direction;

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That I am not a relative or employee of any attorney or counsel of participant and that I am not financially or otherwise interested in the action or the outcome herein;

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Terrilynn Simons

/S/TERILYNN SIMONS, CCR, RPR, RMR, CRR
State of Washington CCR #2047
My CCR certification expires on 7/7/26

Reference No.: 15071528

Case: Clearconnect vs Align Technology

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

_____

Dr. Tim A. Osswald

NOTARIZATION OF CHANGES

(If Required)

Subscribed and sworn to on the _____ day of

_____, 20____ before me,

(Notary Sign)_____

(Print Name) Notary Public,

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Reference No.: 15071528
Case: Clearconnect vs Align Technology

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Dr. Tim A. Osswald

Reference No.: 15071528
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Dr. Tim A. Osswald

US005939519A

United States Patent [19]

Brunelle

[11] **Patent Number: 5,939,519**

[45] **Date of Patent: Aug. 17, 1999**

[54] **POLYESTERAMIDES OF HIGH CRYSTALLINITY AND REAGENTS FOR THEIR PREPARATION**

[75] Inventor: **Daniel Joseph Brunelle**, Burnt Hills, N.Y.

[73] Assignee: **General Electric Co.**, Schenectady, N.Y.

[21] Appl. No.: **09/075,914**

[22] Filed: **May 11, 1998**

[51] **Int. Cl.**[6] **C08G 69/44**

[52] **U.S. Cl.** **528/336**; 528/170; 528/272; 528/274; 528/288; 528/310; 528/322; 528/332; 528/335

[58] **Field of Search** 528/272, 288, 528/274, 310, 322, 170, 332, 335, 336

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,891,930 6/1959 Caldwell et al. 528/272

2,901,466 8/1959 Kibler et al. 525/425

OTHER PUBLICATIONS

"Nucleation of Polyethylene Terephthalate by Copolymerization", Bouma et al., Polym. Prep., 38, 486 (1997).

"Polyesters With Diamide Segments", Gaymans et al., Polym. Prep., 38, 402 (1997).

"Segmented Copolymers With Poly(Ester Amide) Units of Uniform Length: Synthesis", Gaymans et al., Polymer, 34, 4360 (1993).

Primary Examiner—P. Hampton-Hightower

Attorney, Agent, or Firm—Noreen C. Johnson; Douglas E. Stoner

[57] **ABSTRACT**

The crystallinity of poly(1,4-cyclohexanedimethyl 1,4-cyclohexanedicarboxylate) is enhanced by the incorporation of amide units, preferably derived from such compounds as 1,6-bis(4-carbomethoxycyclohexylcarboxamido)hexane. Crystallization temperatures increase, as do heats of crystallization.

10 Claims, No Drawings

EXHIBIT A
WITNESS: T. Osswald
Date: July 2, 2026
Reporter: Teri Simons, CCR, RMR, CRR, RDR

POLYESTERAMIDES OF HIGH CRYSTALLINITY AND REAGENTS FOR THEIR PREPARATION

BACKGROUND OF THE INVENTION

This invention relates to polyesters, and more particularly to the modification of polyesters to enhance their crystallinity.

Poly(1,4-cyclohexanedimethyl 1,4-cyclohexanedicarboxylate), hereinafter sometimes designated "PCCD" for brevity, is a known polyester; reference is made, for example, to U.S. Pat. No. 2,891,930. It is characterized by such advantageous properties as crystallinity and resistance to weathering under conditions of exposure to ultraviolet radiation. These properties have increased interest in commercialization in recent years.

However, the crystallinity of PCCD is not as high as that of such commercially available polyesters as poly(1,4-butylene terephthalate), or "PBT". While the crystalline melting temperature, Tm, of PCCD is in the range of 225–235° C., a relatively high figure, its temperature of crystallization, Tc, is on the order of 152–171° C. Therefore, its solvent resistance is not as high as might be desired. There is interest in increasing the crystallinity of PCCD, and concomitantly increasing its Tc.

Various researchers have reported increases in the Tc of other polyesters as a result of incorporating amide segments therein. For example, Bouma et al., *Polym. Prep.,* 38, 486 (1997), reports previous work by Van Bennekom demonstrating such a phenomenon as a result of the incorporation in PBT or poly(ethylene terephthalate) of ethyleneterephthalamide or 1,4-butyleneterephthalamide units. Further work has shown that increased crystallinity generally has two requirements: a very uniform copolymer (i.e., one in which the amide units are fairly evenly spaced as opposed to being present in blocks) and the presence of alkylene groups separating the nitrogen atoms which have the same molecular structure as the alkylene groups of the polyester. It was also found that side reactions, including methylation of the diamine corresponding to the amide units, occurred in significant amount during preparation of the amide functionality from a diamine. This was particularly true of the one-pot reaction in which tetramethylenediamine first underwent reaction with dimethyl terephthalate and 1,4-butanediol was subsequently added.

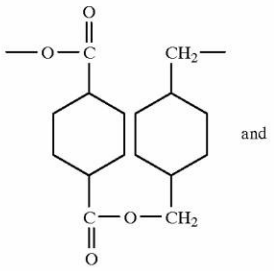
U.S. Pat. No. 2,901,466 discloses the preparation of polyesteramides comprising PCCD units in combination with, for example, 1,6-hexyleneterephthalamide units, the latter being present in proportions on the order of 20 mole percent of the polyesteramide. There is no suggestion, however, of an increase in crystallinity as a result of the presence of amide units.

SUMMARY OF THE INVENTION

The present invention is based on the discovery that polyesteramides derived from PCCD and having increased crystallinity as compared to the corresponding polyester may be prepared by incorporating alkylene-1,4-cyclohexanedicarboxamide and especially 1,6-hexylene-1,4-cyclohexanedicarboxamide units therein. This is surprising, since the alkylene groups in the amide units are not the 1,4-cyclohexanedimethylene groups present in the ester units.

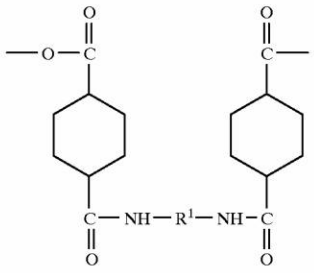
In one of its aspects, the invention includes cyclohexylene polyesteramides comprising structural units of the formulas

(I)



and

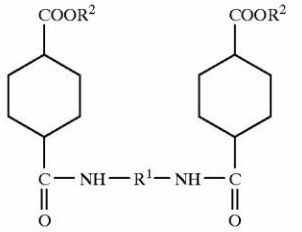
(II)



wherein R^1 is C_{2-10} alkylene, said units of formula II being present in an amount effective to afford a polyesteramide having a temperature of crystallization of at least 165° C. and at least 9° C. higher than that of a corresponding homopolyester having the same distribution of cis and trans isomers.

Another aspect of the invention is bisesteramides capable of reaction to form said polyesteramides. They are cyclohexylenebisesteramides of the formula

(III)



wherein R^1 is as previously defined and each R^2 is hydrogen or C_{1-6} alkyl.

DETAILED DESCRIPTION; PREFERRED EMBODIMENTS

The structural units of formula I in the polyesteramides of the invention are PCCD units. Those of formula II are amide units whose presence is responsible for the increase in Tc compared to that in PCCD homopolyester. Said amide units are typically present in minor proportion, preferably up to about 20, more preferably in the range of about 0.5–18.0 and most preferably about 0.5–10.0 mole percent based on total ester and amide units.

The R^1 radical may be any C_{2-10} alkylene radical. It is preferably a linear radical and especially one containing 4–8 carbon atoms. The hexamethylene radical is most preferred, since the resulting amide units apparently have a molecular conformation similar to that of the atoms in the 1,4-

cyclohexanedimethylene radical. Thus, the molecular configuration of said radical makes such units behave as though the 1,4-cyclohexanedimethylene radical were present.

The R^2 radicals are each hydrogen or C_{1-6} alkyl. They are preferably methyl.

The polyesteramides of this invention may be prepared by at least two methods. The first is the reaction of a combination of 1,4-cyclohexanedimethanol (hereinafter sometimes "CHDM") and an amine corresponding to the amide moiety in formula II with 1,4-cyclohexanedicarboxylic acid or a functional derivative thereof. Most often, a dialkyl ester of the acid is used as a derivative, with the dimethyl ester (hereinafter sometimes "DMCD") being preferred by reason of its ease of preparation and relatively low cost.

In this first method, it is possible to prepare a blend of CHDM, the diamine and DMCD in the desired proportions. Subsequently, a suitable catalyst such as a tetraalkyl titanate is added and the reaction mixture heated at a temperature in the range of about 120–200° C. to effect transesterification with formation of a polyesteramide oligomer. Alternatively, the diamine and DMCD may undergo an initial amide-forming reaction, after which catalyst and CHDM are added and the transesterification reaction conducted. In either case, a final molecular weight-building polymerization reaction under melt or solid state conditions is typically carried out under conventional conditions.

DMCD and CHDM exist in cis and trans isomeric forms. The polyesteramides of the invention preferably have high proportions of units with trans configuration, especially in the acid moieties. In general, melting and crystallization temperatures increase with the proportion of totally trans-configured units of formula I. Said proportion is usually in the amount of about 90–95 mole percent, though trans percentages of 100% can be obtained from highly purified monomers.

The second method for preparing the polyesteramides includes a first step of preparing a bisesteramide of formula III, as illustrated by 1,6-bis(4-carbomethoxycyclohexylcarboxamido)hexane. Such bisesteramides are believed to be novel compounds and they constitute the second aspect of the invention. A reaction is then carried out involving the bisesteramide, CHDM and DMCD in proportions effective to produce a polyesteramide having the desired proportions of structural units.

The intermediate bisesteramides of the invention may be prepared by the reaction of 1,4-cyclohexanedicarboxylic acid or a functional derivative thereof, preferably a dialkyl ester, with a diamine of the formula $H_2N—R^1—NH_2$, the former being present in excess. A typical molar ratio of acid to diamine is in the range of about 3–6:1. The reaction may be conducted at temperatures in the range of about 150–200° C., neat or in solution in a solvent such as toluene, xylene, chlorobenzene, o-dichlorobenzene or anisole. The product may be isolated and purified by conventional means such as separation as a solid followed by recrystallization.

Irrespective of the method of preparation of the polyesteramide, it is conventional to employ DMCD in a slight excess, usually about 0.2–1.0 mole percent based on total of CHDM and diamine. Catalyst is typically present in the amount of about 0.05–0.5 mole percent based on DMCD.

As previously mentioned, PCCD homopolyester ordinarily has a Tm on the order of 225–235° C. and a Tc on the order of 152–171° C. The absolute values of these parameters are uniformly higher for polymers prepared from all-trans monomers than those prepared from cis-trans monomer mixtures. The polyesteramides of the present invention typically have Tm values in the range of about 220–240° C., not substantially different from that of PCCD. However, the Tc values of said polyesteramides are at least 165° C. and are often in the range of about 180–190° C., being in each instance at least 9° C. higher than those of the corresponding homopolyester having the same cis-trans distribution. Thus, the presence of amide units leads to a substantially higher degree of crystallinity, which can be expected to improve such properties as resistance to the effects of heat and solvents.

The invention is illustrated by the following examples. Polymer molecular weights were determined from intrinsic viscosity in a mixture of phenol and tetrachloroethane.

EXAMPLE 1

A mixture of 4.0 g (20 mmol) of DMCD and 1.0 ml of a 4.0 M solution of hexamethylenediamine in toluene (4 mmol) was heated at 160° C. in a nitrogen atmosphere, with stirring. After 1.5 hours, the entire reaction mixture was solid and no amine was detected by vapor phase chromatographic analysis. The solid was triturated with ethyl acetate, separated by filtration and dried in vacuum, yielding 1.28 g of the desired 1,6-bis(4-carbomethoxycyclohexylcarboxamido)hexane having a melting point of 240° C. Analysis by gel permeation chromatography showed the presence of about 75% (by weight) monomer and 25% dimer.

EXAMPLE 2

A mixture of 20 g (100 mmol) of DMCD and 5.0 ml of a 4.0 M solution of hexamethylenediamine in toluene (5 mmol) was heated for 16 hours under reflux in 20 ml of xylene in a nitrogen atmosphere, with stirring. The reaction mixture was diluted with ethyl acetate, filtered and worked up as in Example 1, yielding the desired 1,6-bis(4-carbomethoxycyclohexylcarboxamido)hexane in 96% yield. Analytical results were similar to those in Example 1. Similar results were obtained using anisole as solvent and refluxing for 5 hours.

EXAMPLES 3–5

A number of 100-ml round-bottomed 3-necked flasks fitted with stirrers, elastomeric septa, thermometers and distillation apparati were charged with 19.6 g (98 mmol) of DMCD (95% trans isomer), 14.4 g (100 mmol) of CHDM (cis-trans mixture) and various proportions of hexamethylenebis(4-carbomethoxycyclohexylcarboxamide). The mixtures were blanketed with nitrogen and heated at 170° C. in an oil bath, with stirring, until homogeneous. Tetraisopropyl titanate, 35 μl, was added by injection, whereupon methanol began collecting in the distillation vessel. The temperature was increased to 230° C. over 15 minutes, and heating was continued for 20 minutes whereupon methanol evolution ceased. The reaction flask was evacuated carefully, so as not to strip off remaining monomer, and heating was continued until material began to solidify on the stirrer shaft.

The hot product was dissolved in chloroform, precipitated into methanol and vacuum filtered. The filter cake was dried overnight in a vacuum oven. A 10-g sample thereof was subjected to solid state polymerization at 200–205° C., and the products were analyzed for trans isomer, weight and number average molecular weight, Tm, Tc and heat of crystallization crystallization (ΔH).

EXAMPLES 6–9

The procedure of Examples 3–5 was repeated, using 100% trans DMCD.

The results of Examples 3–9 are listed in Table I, in camparison with two PCCD homopolyesters as controls.

TABLE I

Example	Bisamide, %	Trans, %	Mw	Tm, ° C.	Tc, ° C.	ΔH, J/g
Control 1	0	93	69,800	225	153	−23
3	0.5	95.5	83,400	230	186	−33
4	1.0	96.6	89,100	229	181	−29
5	5.0	97.2	84,700	224	178	−26
Control 2	0	100	82,400	230	171	−28
6	0.5	100	83,000	231	180	−28
7	1.0	100	81,300	230	182	−28
8	2.5	100	75,000	235	190	−30
9	5.0	100	85,500	230	185	−27

It is apparent that the copolyesteramides of the invention have Tc values substantially higher than those of the controls, with the minimum difference being 9° C. between the product of Example 6 and Control 2. By contrast, the Tm values did not vary as much.

EXAMPLE 10

A mixture of 20.123 g (100.5 mmol) of DMCD (95% trans isomer) and 0.5 ml of a 4.0 M solution of hexamethylenediamine in toluene (2 mmol) was heated for 1.5 hours at 160° C. under nitrogen, with stiring, after which 14.135 g (98 mmol) of CHDM and 30 μl of tetraisopropyl titanate were added. The mixture was heated at 170° C. for 2 hours with distillation of methanol, and then at 230° C. for 30 minutes. Vacuum was applied gradually, whereupon the polymeric product pulled away from the walls of the reaction flask. The polyesteramide was worked up and subjected to solid state polymerization as in Examples 3–5, yielding a product with a weight average molecular weight of 89,200, a Tm of 228° C., a Tc of 187° C. and a heat of crystallization of −26.3 J/g.

EXAMPLE 11

The procedure of Example 10 was repeated, using 5 mmol of hexamethylenediamine. The product copolyesteramide had a weight average molecular weight of 77,000, a Tm of 230° C., a Tc of 177° C. and a heat of crystallization of −33.4 J/g.

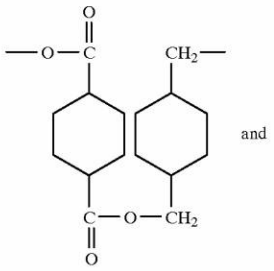
EXAMPLE 12

A mixture of 29.884 g (149.25 mmol) of DMCD (95% trans isomer), 21.63 g (150 mmol) of CHDM and 0.375 ml of a 4 M solution of hexamethylenediamine in toluene (1.5 mmol) was heated for 2 hours at 160° C. under nitrogen, with stirring. Tetraisopropyl titanate, 52 μl, was added and the polymerization was conducted as described in Example 10. Upon solid state polymerization, the product copolyesteramide had a weight average molecular weight of 85,100, a Tm of 227° C., a Tc of 185° C. and a heat of crystallization of −28.3 J/g.

What is claimed is:

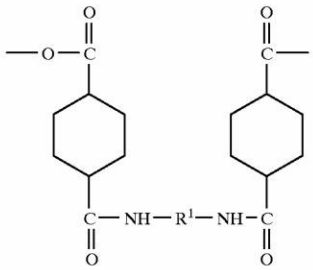
1. A cyclohexylene polyesteramide comprising structural units of the formulas

(I)



and

(II)



wherein R^1 is $C_{2\text{-}10}$ alkylene, said units of formula II being present in proportions of up to about 18 mole percent based on total ester and amide units, whereby said polyesteramide has a temperature of crystallization of at least 165° C. and at least 9° C. higher than that of a corresponding homopolyester having the same distribution of cis and trans isomers.

2. A cyclohexylene polyesteramide according to claim **1** wherein R^1 contains 4–8 carbon atoms.

3. A cyclohexylene polyesteramide according to claim **2** wherein R^1 is hexamethylene.

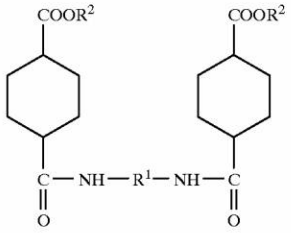
4. A cyclohexylene polyesteramide according to claim **1** wherein said units of formula II are present in a proportion in the range of about 0.5–10.0 mole percent based on total ester and amide units.

5. A cyclohexylene polyesteramide according to claim **1** wherein the proportion of trans-configured units of formula I is in the range of about 90–95 mole percent.

6. A cyclohexylene polyesteramide according to claim **1** wherein the proportion of trans-configured units of formula I is 100 mole percent.

7. A cyclohexylenebisesteramide of the formula

(III)



wherein R^1 is $C_{2\text{-}10}$ alkylene and each R^2 is $C_{1\text{-}6}$ alkyl.

8. A cyclohexylenebisesteramide according to claim **7** wherein R^1 contains 4–8 carbon atoms.

9. A cyclohexylenebisesteramide according to claim **8** wherein R^1 is hexamethylene.

10. A cyclohexylenebisesteramide according to claim **8** wherein R^2 is a methyl.

* * * * *

EXHIBIT B
WITNESS: T. Osswald
Date: July 2, 2026
Reporter: Teri Simons, CCR, RMR, CRR, RDR

US009963543B2

(12) **United States Patent**
Oh et al.

(10) **Patent No.: US 9,963,543 B2**
(45) **Date of Patent: May 8, 2018**

(54) **HIGHLY HEAT-RESISTANT AND HIGHLY TRANSPARENT POLYCARBONATE ESTER, AND PREPARATION METHOD THEREFOR**

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(73) Assignee: **SK CHEMICALS CO., LTD.**, Seongnam-si, Gyeonggi-do (KR)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days. days.

(21) Appl. No.: **14/903,401**

(22) PCT Filed: **Jul. 24, 2014**

(86) PCT No.: **PCT/KR2014/006755**
§ 371 (c)(1),
(2) Date: **Jan. 7, 2016**

(87) PCT Pub. No.: **WO2015/012619**
PCT Pub. Date: **Jan. 29, 2015**

(65) **Prior Publication Data**

US 2016/0152767 A1 Jun. 2, 2016

(30) **Foreign Application Priority Data**

Jul. 24, 2013 (KR) 10-2013-0087638

(51) **Int. Cl.**
C08G 63/66 (2006.01)
C08G 63/78 (2006.01)
C08G 63/64 (2006.01)
C08G 63/672 (2006.01)

(52) **U.S. Cl.**
CPC ***C08G 63/66*** (2013.01); ***C08G 63/64*** (2013.01); ***C08G 63/672*** (2013.01); ***C08G 63/78*** (2013.01)

(58) **Field of Classification Search**
CPC C08G 63/64; C08G 63/66; C08G 63/672; C08G 63/78
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

8,962,770	B2	2/2015	de Brouwer et al.	
2008/0015331	A1*	1/2008	Terado	C08G 63/64 528/271
2010/0105854	A1	4/2010	Miyake et al.	528/27
2010/0184884	A1	7/2010	Miyake et al.	523/452
2011/0003101	A1	1/2011	Fuji et al.	
2011/0160422	A1*	6/2011	Kamps	C08L 69/00 528/201
2012/0041169	A1	2/2012	Fuertes et al.	

FOREIGN PATENT DOCUMENTS

EP	2 123 692 A1	11/2009	..... C08G 64/02
JP	2013-515841 A	5/2013	
KR	1019970009333 B1	6/1997	

(Continued)

OTHER PUBLICATIONS

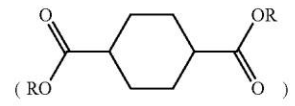
Yoon et al "Advanced Polymerization and Properties of Biobased High Tg polyester of Isosorbide and 1,4-Cyclohexanedicarboxylic Acid through in Situ Acetylation", Macromolecules, Apr. 3, 2013, pp. 2930-2940.*

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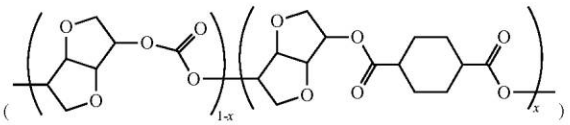
Primary Examiner — Ling Choi
Assistant Examiner — Gennadiy Mesh
(74) *Attorney, Agent, or Firm* — Harness, Dickey & Pierce, P.L.C.

(57) **ABSTRACT**

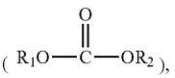
Disclosed is a bio-based polycarbonate ester comprising: (i) repeat unit 1 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and carbonate; and (ii) repeat unit 2 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and 1,4-cyclohexanedicarboxylate; and a preparation method for the bio-based polycarbonate ester, comprising the steps of: (1) preparing a compound 1,4-diphenyl-cyclohexanedicarboxylate through a trans-esterification or esterification reaction of a compound represented by formula 2



and phenol; and (2) preparing a compound comprising a repeat unit represented by formula 1



through a polycarbonate melt polycondensation reaction of the 1,4-diphenyl-cyclohexanedicarboxylate prepared in step (1), a compound represented by formula 4



and 1,4:3,6-dianhydrohexitol.

4 Claims, 3 Drawing Sheets

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

KR	1020120121477 A	11/2012	
WO	WO 2012/123267	9/2012	..... C08G 63/18

OTHER PUBLICATIONS

Okada et al."Biodegradable Polymers Based on Renewable Resources",J Appl Polym Sci 86, pp. 872-880, 2002.*

Turner et al. "Amorphous and Crystalline Polyesters based on 1,4-Cyclohexanedimethanol", Modern Polyesters: Chemistry and Technology of Polyesters and Copolyesters. Edited by J. Scheirs and T. E. Long © 2003 John Wiley & Sons, Ltd ISBN: 0-471-49856-4.*

Fenouillot, F. et al., "Polymers from renewable 1,4:3,6-dianhydrohexitols (isosorbide, isomannide and isoidide): A review", Progress in Polymer Science, Oct. 2010, vol. 35, No. 5, pp. 578-622.

Extended European Search Report (EESR) dated Mar. 13, 2017 in European Application No. 14829080.2.

Japanese Office Action from corresponding Japanese Patent Application No. 2016-529713 dated Jan. 30, 2018.

* cited by examiner

FIG. 1

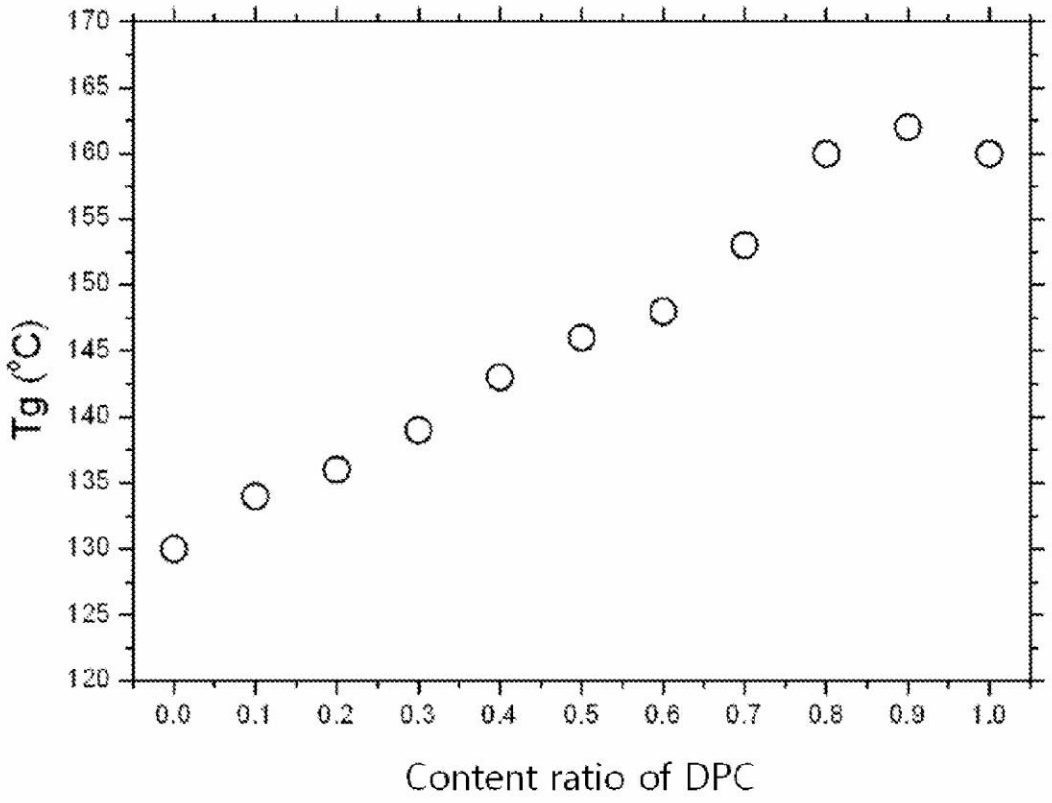

Tg (°C)
170
165
160
155
150
145
140
135
130
125
120
0.0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1.0
Content ratio of DPC

FIG. 2

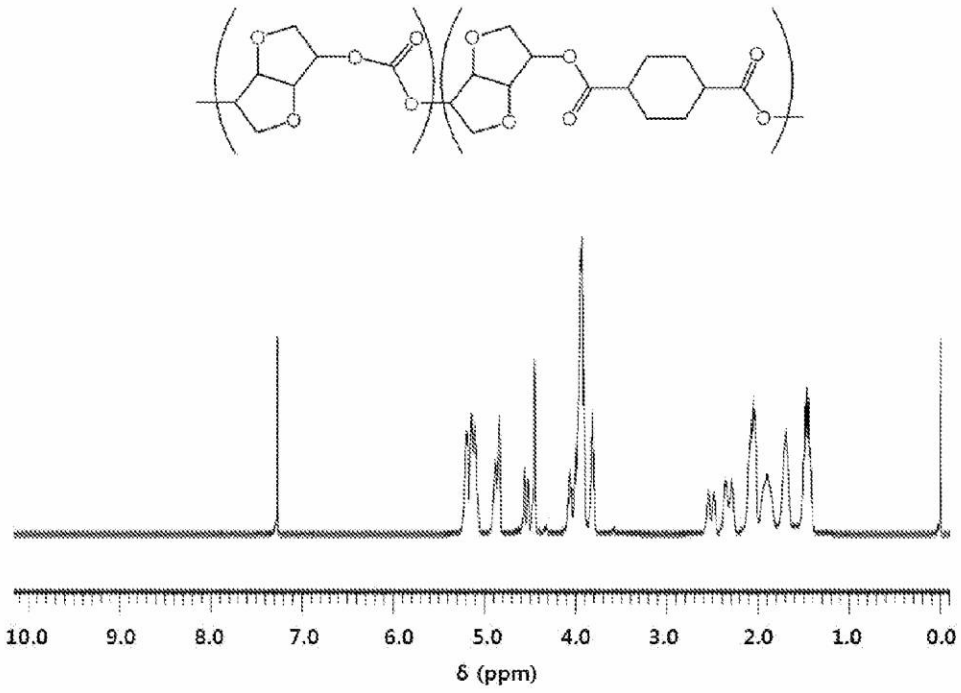
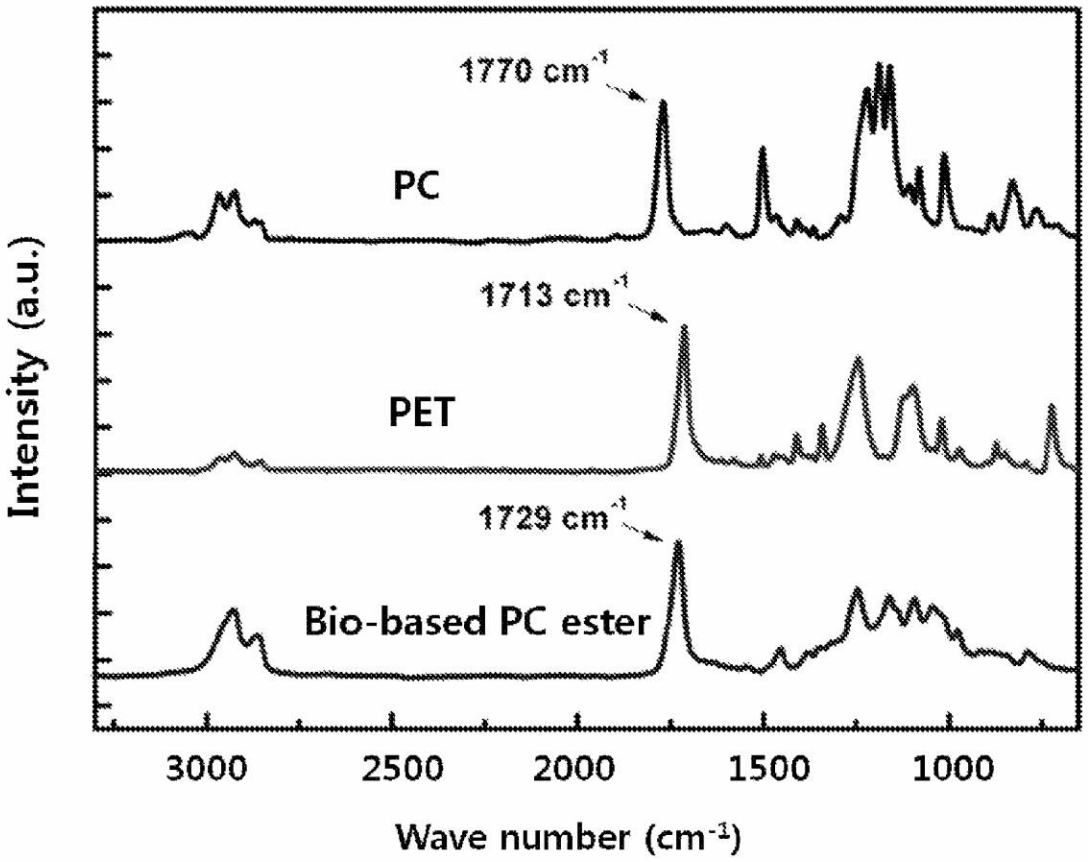


FIG. 3


1770 cm-1
PC
1713 cm-1
PET
1729 cm-1
Bio-based PC ester
Intensity (a.u.)
3000
2500
2000
1500
1000
Wave number (cm-1)

HIGHLY HEAT-RESISTANT AND HIGHLY TRANSPARENT POLYCARBONATE ESTER, AND PREPARATION METHOD THEREFOR

FIELD OF THE INVENTION

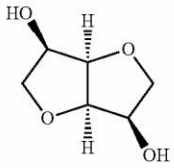
The present invention relates to a polycarbonate ester having high heat resistance and transparency, and a preparation method thereof. More specifically, it relates to a biomass-based polycarbonate ester having repeating units which are obtained from a reaction of 1,4:3,6-dianhydrohexitol and a carbonate or an 1,4-cyclohexanedicarboxylate.

BACKGROUND OF THE INVENTION

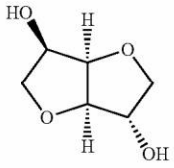
Unlike conventional resources based on petrochemical industry, 1,4:3,6-dianhydrohexitol is a bio-based material derived from a biomass, i.e., a renewable resource containing polysaccharide as its components such as corn, wheat, sugar, and the like. Particularly, in case of a bioplastic containing a bio-based material, carbon dioxide (CO_2) produced during waste disposal processes after the use of a bioplastic can be reused for the growth of biomass, and thus the bioplastic has been noticed as a carbon dioxide reduction material to prevent global warming, which is a serious worldwide issue.

1,4:3,6-Dianhydrohexitol exists in three different forms of stereoisomers, which has different chemical properties depending on the difference in the relative configuration of two hydroxyl groups present therein: isomannide (as shown in formula a below, mp: 81-85° C.), isosorbide (as shown in formula b below, mp: 61-62° C.), and isoidide (as shown in formula c below, mp: 64° C.). Particularly, in a case where 1,4:3,6-dianhydrohexitol is used as a monomer material of polycarbonate which is one of representative engineering plastics, the polycarbonate thus prepared can have good thermal and optical properties owing to molecular structural characteristics of 1,4:3,6-dianhydrohexitol, i.e., rigidity and saturated heterocyclic structure, together with the advantages of a bioplastic.

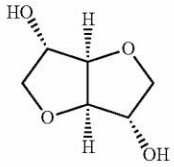
[Formula a]



[Formula b]



[Formula c]



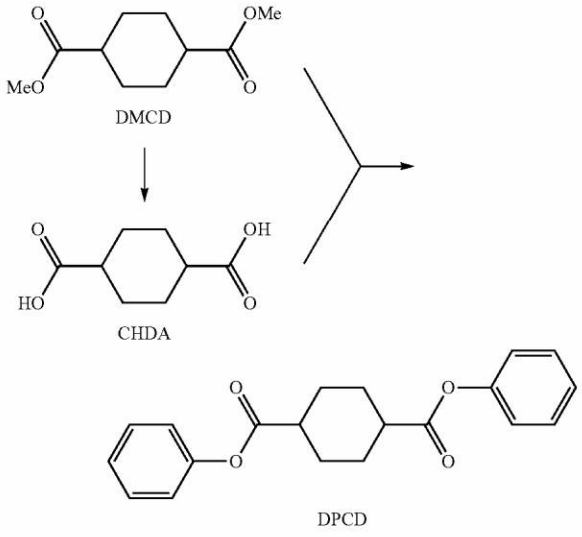
Since 1,4-dimethyl-cyclohexane dicarboxylate (hereinafter referred to as DMCD) or 1,4-cyclohexanedicarboxylic acid (hereinafter referred to as CHDA), a hydrolysis product of DMCD, has a cyclohexane ring structure in the center of the molecule. Thus, if these materials are introduced into a polymer chain, they improve the weatherability and UV stability of the polymer, and also allow the polymer to have excellent material properties, such as gloss retention, yellowing resistance, hydrolytic stability, corrosion resistance, and chemical resistance, owing to its unique combination of flexibility and hardness in the molecular structure.

Poly(1,4-cyclohexylidene 1,4-cyclohexanedicarboxylate) (hereinafter referred to as PCCD), a DMCD/CHDM homopolyester, is an example of commercially available polymer materials developed by using DMCD. Owing to its superior properties such as weatherability, chemical resistance, flowability, and a low refractive index, PCCD has been used to develop a polycarbonate/PCCD alloy (product name: Xyrex) by DuPont (USA) in order to improve transparency of polycarbonate.

A commercial manufacturing process of polycarbonate can be divided into two processes: solution polymerization and melt polycondensation. Unlike the solution polymerization process where phosgene is used as a source material for carbonate, diphenyl carbonate (hereinafter referred to as DPC) is used in the melt polycondensation process. Thus, raw materials used in the conventional melt polycondensation process generally include DPC and bisphenol A (hereinafter referred to as BPA), which is a diol; and a transesterification reaction of BPA with DPC produces phenol as a byproduct of the melt polycondensation.

Meanwhile, it is required to convert a functional group present in DMCD or CHDA into another functional group, which may cause the production of phenol as a byproduct via a transesterification reaction with diol, in order to use DMCD or CHDA in the polycarbonate melt polycondensation. For example, dimethyl ester of DMCD or dicarboxylic acid of CHDA needs to be converted into diphenyl ester. Thus, an example of diphenyl ester derivatives of DMCD or CHDA which can be used for the polycarbonate melt polycondensation is 1,4-diphenyl-cyclohexanedicarboxylate (hereinafter referred to as DPCD), and is synthesized by a reaction of DMCD or CHDA with phenol, as represented by Reaction Scheme 1 below:

[Reaction Scheme 1]



In general, in case of 1,4-dimethyl-terephthalate (a tertiary dimethyl ester) and terephthalic acid (a diacid), a reaction does not occur therebetween if either one of their functional groups, i.e., one of acid and alcohol, is not activated. In case of DMCD (a secondary dimethyl ester) and CHDA (a diacid), however, they can react with phenol in a molten state, and thus it is easier to conduct DPCD synthesis.

The present invention employs DPCD, which is used as a material for forming an ester bond in the polymer chain, to provide an isosorbide-based polycarbonate ester (or polyester carbonate). The polycarbonate ester thus obtained is a novel bioplastic having high heat resistance and transparency whose properties and forming processability can be adjusted according to its needs by varying the DPCD content. The bio-based polycarbonate ester according to the present invention can exhibit the same level of heat resistance as compared to the conventional bioplastic disclosed in US 2011/0003101 A1, even comprising a less amount of isosorbide, and thus have a relative advantage in terms of production costs.

SUMMARY OF THE INVENTION

Therefore, it is an object of the present invention to provide a bio-based polycarbonate ester having high heat resistance and transparency with a high degree of polymerization and good mechanical properties, comprising a rigid polymer repeating unit with no BPA causing an environmental hormone, which is useful in various applications, e.g., glass alternative for automobile, optical lens and film, feeding bottle, food container, etc. In addition, it is another object of the present invention to provide a preparation method of the bio-based polycarbonate ester.

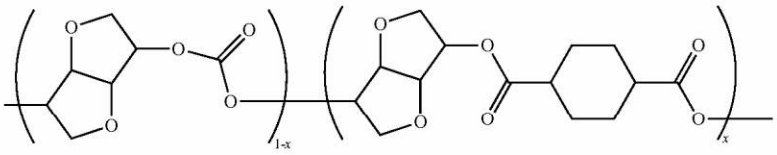
In accordance with one aspect of the present invention, there is provided a bio-based polycarbonate ester comprising: (i) Repeating Unit 1 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and a carbonate; and (ii) Repeating Unit 2 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and an 1,4-cyclohexanedicarboxylate.

In accordance with another aspect of the present invention, there is provided a method for manufacturing a bio-based polycarbonate ester comprising the steps of:

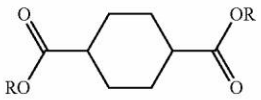
(1) subjecting a compound of formula 2 and phenol to a transesterification or esterification reaction to obtain a compound of formula 3; and

(2) subjecting the compound of formula 3 obtained in Step (1), a compound of formula 4, and 1,4:3,6-dianhydrohexitol to a polycarbonate melt polycondensation reaction to prepare a compound comprising a repeating unit of formula 1:

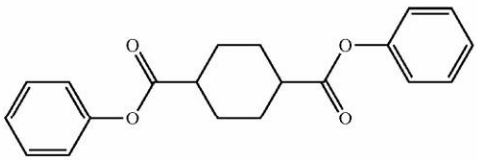
[Formula 1]



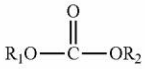
[Formula 2]



[Formula 3]



[Formula 4]



wherein, in formula 1, x satisfies $0<x<1$,

in formula 2, R is methyl or hydrogen, and,

in formula 4, R_1 and R_2 are each independently an aliphatic group having 1 to 18 carbon atoms or an aromatic group having 6 to 20 carbon atoms which may have an optional substituent.

The bio-based polycarbonate ester according to the present invention exhibits high heat resistance and transparency, and has an advantage that properties deriving from (i) Repeating Unit 1 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and a carbonate, and (ii) Repeating Unit 2 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and an 1,4-cyclohexanedicarboxylate can be controlled by regulating the contents thereof. Thus, the inventive bio-based polycarbonate ester can be useful in various applications such as glass alternative for automobile, optical lens and film, feeding bottle, food container, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features and other advantages of the present invention will be more clearly understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

FIG. **1** is a graph showing the change in glass transition temperature (Tg) of polymers depending on the content ratio of DPC.

FIG. **2** is an ^1H NMR spectrum of a bio-based polycarbonate ester prepared in Example 1.

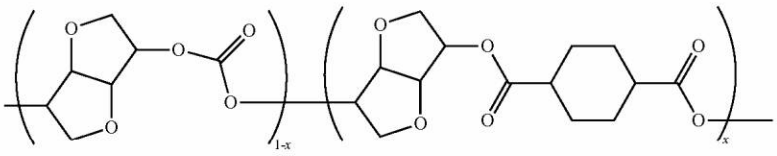
FIG. **3** is an IR spectrum of a bio-based polycarbonate ester prepared in Example 1.

DETAILED DESCRIPTION OF THE INVENTION

Hereinafter, the present invention will be described in detail.

A bio-based polycarbonate according to the present invention comprises (i) Repeating Unit 1 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and a carbonate, and (ii) Repeating Unit 2 obtained from a condensation reaction of 1,4:3,6-dianhydrohexitol and an 1,4-cyclohexanedicarboxylate, and may comprises a repeating unit of formula 1 below:

[Formula 1]



wherein x satisfies 0<x<1.

In the repeating unit of formula 1 above, the ratio of cis/trans cyclohexanedicarboxylate unit may be 1/99% to 99/1%, preferably 20/80% to 80/20%, more preferably 30/70% to 70/30%.

When the content of trans cyclohexanedicarboxylate unit increases, heat resistance improves owing to an increase in the glass transition temperature (Tg) although transparency relatively decreases. In contrast, if there is a decrease in the content of trans cyclohexanedicarboxylate unit, transparency improves while there is a reduction in heat resistance due to a decrease in Tg. Thus, the ratio of cis/trans cyclohexanedicarboxylate unit may be controlled within a suitable range, preferably 20/80% to 80/20%, more preferably 30/70% to 70/30%, so that desirable heat resistance and transparency can be obtained.

The 1,4:3,6-dianhydrohexitol may be isomannide, isosorbide or isoidide, preferably isosorbide.

The bio-based polycarbonate ester according to the present invention may be obtained by a preparation method comprising the steps of:

(1) subjecting a compound of formula 2 and phenol to a transesterification or esterification reaction to obtain a compound of formula 3; and

(2) subjecting the compound of formula 3 obtained in Step (1), a compound of formula 4, and 1,4:3,6-dianhydrohexitol to a polycarbonate melt polycondensation reaction to prepare a compound comprising a repeating unit of formula 1:

wherein, in formula 1, x satisfies 0<x<1,

in formula 2, R is methyl or hydrogen, and,

in formula 4, R_1 and R_2 are each independently an aliphatic group having 1 to 18 carbon atoms or an aromatic group having 6 to 20 carbon atoms which may have an optional substituent.

In the definitions of R_1 and R_2, examples of the aliphatic group having 1 to 18 carbon atoms is C_{1-18} alkyl, C_{2-18} alkenyl, C_{2-18} alkynyl, C_{3-18} cycloalkyl and the like, and examples of the aromatic group having 6 to 20 carbon atoms is C_{6-20} aryl and the like. The R_1 and R_2 may each independently contains one or more heteroatoms selected from the group consisting of N, S and O atoms. The R_1 and R_2 may each independently have one or more substituents. The substituents of R_1 and R_2 may be each independently C_{1-10} alkyl or C_{6-10} aryl which may contain one or more heteroatoms selected from the group consisting of N, S and O atoms.

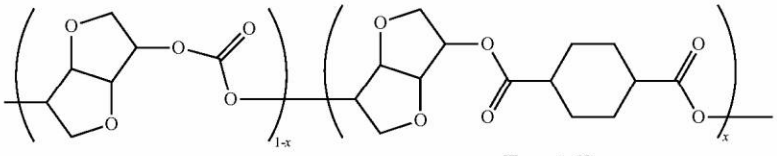
In Step (1), the compound of formula 3, i.e., 1,4-diphenyl-cyclohexanedicarboxylate, is obtained by subjecting the compound of formula 2 and phenol to a transesterification or esterification reaction.

Specifically, dimethyl ester of DMCD (the compound of formula 2 wherein R is methyl) or dicarboxylic acid of CHDA (the compound of formula 2 wherein R is H) is converted into diphenyl ester through Step (1) above, and thereby forming 1,4-diphenyl-cyclohexanedicarboxylate which can be reacted with diol to produce phenol as a byproduct via a transesterification reaction in the subsequent Step (2).

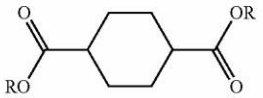
In case of DMCD and CHDA, since these compounds can react with phenol in a molten state, it is easy to manufacture DPCD.

Various compounds including primary, secondary, tertiary dicarboxylate or dicarboxylic acid may be also used together, in addition to the compound of formula 2, depending on the desired properties, as a starting material for forming an ester bond in the polymer chain of the present invention. Such compounds may be converted into diphenyl ester by the reaction with phenol, and then used for polycarbonate melt polycondensation, together with the compound of formula 3.

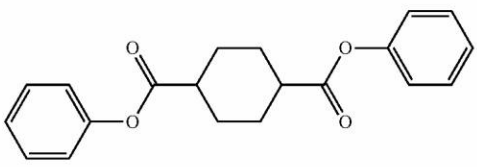
[Formula 1]



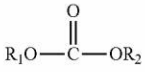
[Formula 2]



[Formula 3]



[Formula 4]



In this case, when the amount of diphenyl ester compound used other than the compound of formula 3 is z, the amount of the compound of formula 3 is 1−z. As such, z satisfies $0 \leq z < 1$.

The diphenyl ester compound other than the compound of formula 3 may be one kind or a mixture of two or more kinds.

In order to give the bio-based polycarbonate ester of the present invention high heat resistance and transparency, and improved weatherability and UV stability, the diphenyl ester compound other than the compound of formula 2 may be dicarboxylate or dicarboxylic acid having a single or fused saturated homocycle or heterocycle in its molecular center, for example, at least one dicarboxylate or dicarboxylic acid compound selected from the group consisting of: dicarboxylate such as tetrahydro-2,5-dimethyl-furandicarboxylate, 1,2-dimethyl-cyclohexanedicarboxylate, 1,3-dimethyl-cyclohexanedicarboxylate, decahydro-2,4-dimethyl-naphthalenedicarboxylate, decahydro-2,5-dimethyl-naphthalenedicarboxylate, decahydro-2,6-dimethyl-naphthalenedicarboxylate, decahydro-2,7-dimethyl-naphthalenedicarboxylate, and the like; and dicarboxylic acid such as tetrahydro-2,5-furandicarboxylic acid, 1,2-cyclohexanedicarboxylic acid, 1,3-cyclohexanedicarboxylic acid, decahydro-2,4-naphthalenedicarboxylic acid, decahydro-2,5-naphthalenedicarboxylic acid, decahydro-2,6-naphthalenedicarboxylic acid, decahydro-2,7-naphthalenedicarboxylic acid, and the like. Such compounds are preferably decahydro-2,6-dimethyl-naphthalenedicarboxylate or decahydro-2,6-naphthalenedicarboxylic acid and, a compound obtainable from a bio-based material, tetrahydro-2,5-dimethyl-furandicarboxylate or tetrahydro-2,5-furandicarboxylic acid.

The phenyl ester substitution reaction may be conducted at 150 to 250° C. under a normal pressure, or at 150 to 300° C. under an elevated pressure of 0.1 to 10 bar, preferably 0.5 to 5 bar. The reaction time may be 5 minutes to 48 hours, preferably 10 minutes to 24 hours.

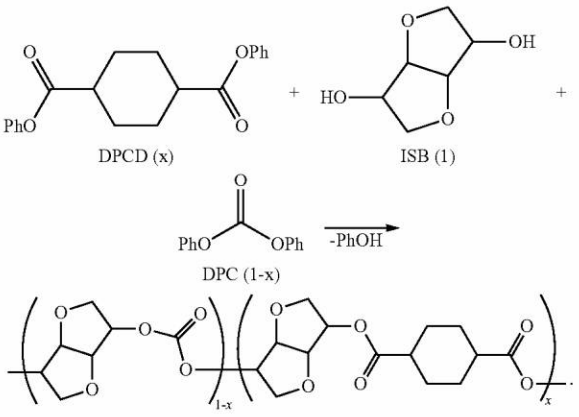
Phenol may be used in an amount of 2 to 50 times, preferably 4 to 20 times of the total mole number of the compound of formula 2, i.e., 2 to 50 times, preferably 4 to 20 times of the stoichiometric amount of phenol required for esterification of all methyl ester (when R is methyl) or carboxylic acid (when R is H) of the compound of formula 2. If the amount of phenol used is not within said range, the final yield of the compound of formula 3 may be reduced.

In Step (2), the compound of formula 3 obtained in Step (1), the compound of formula 4, and 1,4:3,6-dianhydrohexitol are subjected to a polycarbonate melt polycondensation to obtain the compound comprising the repeating unit of formula 1.

In Step (2), the reaction of 1,4:3,6-dianhydrohexitol with the compound of formula 4 forms a carbonate bond (Repeating Unit 1) and the reaction of 1,4:3,6-dianhydrohexitol with the compound of formula 3 forms an ester bond (Repeating Unit 2). A repeating unit containing these bonds is represented by formula 1 above.

If the amount of 1,4:3,6-dianhydrohexitol is 1 and the amount of the compound of formula 3 is x, the amount of compound of formula 4 used can be determined as 1−x, as shown in Reaction Scheme 2 below:

[Reaction Scheme 2]



For example, in a case where a melt polycondensation is carried out by using isosorbide (1,4:3,6-dianhydrohexitol) and diphenyl carbonate (the compound of formula 4) so that the amount of compound of formula 3 is 0, isosorbide homopolycarbonate (Tg 160° C.) is produced. When the amount of the compound of formula 3 increases, the amount of ester bond in the polymer chain increases as well. If the amount of the compound of formula 3 becomes 1, a melt polycondensation only takes place between isosorbide and the compound of formula 3, thereby producing homopolyester (Tg 130° C.; *Macromolecules,* 2013, 46, 2930). FIG. **1** illustrates the change in Tg of the polymers depending on the amount of DPC.

In conclusion, the ratio of carbonate and ester bonds in the polymer chain varies depending on the added amount of the compound of formula 3. If carbonate and ester bonds coexist in the polymer chain, the polycarbonate ester of the present invention has a higher heat resistance as compared to the copolymer polycarbonate formed between isosorbide and 1,4-cyclohexanedimethanol as disclosed in US 2011/0003101 A1, although comprising the same amount of isosorbide. Polycarbonate generally shows high heat resistance and good mechanical properties when compared with polyester, but has relatively poor chemical resistance, residual stress, and molding cycle time. The polycarbonate ester comprising both carbonate and ester bonds in a single chain, however, redresses the drawbacks of each bond type and also provides some advantages.

The 1,4:3,6-dianhydrohexitol may be isomannide, isosorbide or isoidide, preferably isosorbide.

Meanwhile, it is very important to maintain a high purity of 1,4:3,6-dianhydrohexitol which is used in the melt polycondensation, in order to obtain a high degree of polymerization for high heat resistance and transparency, as well as excellent mechanical properties of the bio-based polycarbonate ester.

The 1,4:3,6-dianhydrohexitol may be used in the form of powder, flake or in an aqueous solution. However, an excessive exposure to air may cause oxidation and discoloration, and it may lead to dissatisfying color and molecular weight of the final polymer. Thus, the time of exposure to air must be minimized, and the compound must be stored with a deoxidizing agent such as an oxygen absorber after the exposure. Particularly, it is very important to remove impurities obtained in multi-step preparation process of 1,4:3,6-dianhydrohexitol. During the purification of 1,4:3,6-dianhydrohexitol by distillation, it is necessary to remove a liquid

component containing a trace-level of acid which can be removed by an initial separation, and an alkali metal component which be removed by a residue separation. Each of these two impurities should be kept at 10 ppm or lower, preferably 5 ppm or lower, more preferably 3 ppm or lower.

Examples of the compound of formula 4 may be at least one compound selected from a group consisting of dimethyl carbonate, diethyl carbonate, di-t-butyl carbonate, diphenyl carbonate, and a substituted diphenyl carbonate (e.g., ditolyl carbonate). Since the polycarbonate melt polycondensation reaction is carried out under a reduced pressure condition, diphenyl carbonate and a substituted diphenyl carbonate are preferred.

In Step (2) above, besides 1,4:3,6-dianhydrohexitol, any kind of a diol compound may also be used, without limitation. Various compounds including primary, secondary, or tertiary diol compounds may be used in combination with 1,4:3,6-dianhydrohexitol. In this case, when the amount of diol compound used other than 1,4:3,6-dianhydrohexitol is referred to as y, the added amount of 1,4:3,6-dianhydrohexitol is 1−y.

Particularly, in a case where a petrochemical-based diol compound is used, the final bio-based content (ASTM-D6866) contained in the polymer which is derived from 1,4:3,6-dianhydrohexitol may be at least 1%, wherein y satisfies $0 \leq y < 0.99$. In other words, the additional diol compound may be used in an amount of less than 99 mol %, based on 100 mol % of 1,4:3,6-dianhydrohexitol.

In this step, it is preferred to use a diol compound having a single or fused saturated homocycle or heterocycle in its molecular center in order to give the polycarbonate ester high heat resistance and transparency, and improved weatherability and UV stability. In general, heat resistance increases when the size of a ring is big and the hydroxyl groups are in a symmetrical structure. However, optical properties are not dependent on the ring size and the position of the hydroxyl groups, but rather vary in accordance with the properties of each material. When the size of the ring becomes big, it becomes difficult to use the compound for commercial production and utilization. The diol may be selected from the group consisting of 1,2-cyclohexanedimethanol, 1,3-cyclohexanedimethanol, 1,4-cyclohexanedimethanol, tricyclodecandimethanol, 3,9-bis(1,1-dimethyl-2-hydroxyethyl)-2,4,8,10-tetraoxaspiro[5.5]undecane, 2,2-bis(4-hydroxycyclohexyl)propane, and tetrahydro-2,5-furandimethanol that is obtainable from a bio-based material. The preferable diols are 1,4-cyclohexanedimethanol, 2,2-bis(4-hydroxycyclohexyl)propane, and tetrahydro-2,5-furandimethanol.

The cis/trans ratio of the compound of formula 3 may be 1/99% to 99/1%, preferably 10/90% to 90/10%, more preferably 20/80% to 80/20%. Additionally, the cis/trans ratio of cyclohexanedicarboxylate in the repeating unit of formula 1 may be 1/99% to 99/1%, preferably 20/80% to 80/20%, more preferably 30/70% to 70/30%.

When the content of trans cyclohexanedicarboxylate unit increases, heat resistance improves owing to an increase in Tg while transparency relatively decreases. In contrast, if the trans content decreases, transparency improves while heat resistance reduces due to a decrease in Tg. Thus, the ratio of cis/trans cyclohexanedicarboxylate unit is preferably controlled within 20/80% to 80/20%, more preferably 30/70% to 70/30%, so that desirable heat resistance and transparency can be obtained.

In the melt polycondensation of Step (2), when the amount of 1,4:3,6-dianhydrohexitol used is 1, the total amount of the compounds of formula 3 and formula 4 may be 0.7 to 1.3 times, preferably 0.9 to 1.1 times, more preferably 0.95 to 1.05 times of the amount of 1,4:3,6-dianhydrohexitol. The temperature of the melt polycondensation reaction may be elevated at a rate of 0.1 to 10° C./min, preferably 0.2 to 5° C./min, more preferably 0.5 to 2° C./min. The reaction temperature may be 120 to 320° C., preferably 150 to 290° C., more preferably 180 to 270° C., and the reaction time may be 1 to 10 hours, preferably 3 to 8 hours.

Meanwhile, phenol produced as a byproduct during the melt polycondensation should be distilled out of the reactor in order to shift the reaction equilibrium towards polycarbonate ester. In particular, if the rate of temperature elevation goes out of said range, the phenol may evaporate or sublime together with the raw materials. The bio-based polycarbonate ester may be prepared via a batch or continuous process.

The method for manufacturing a bio-based polycarbonate ester according to the present invention may additionally use a catalyst for increasing the reactivity of the melt polycondensation reaction. Any conventional alkali metal and/or alkali earth metal catalyst commonly used for the polycarbonate melt polycondensation may be used as such catalyst. The catalyst may be used in combination with a basic ammonium or amine, a basic phosphorous, or a basic boron compound. However, it is preferable to use the catalyst alone. Examples of the alkali metal catalysts may include LiOH, NaOH, KOH, CsOH, Li_2CO_3, Na_2CO_3, K_2CO_3, Cs_2CO_3, LiOAc, NaOAc, KOAc, CsOAc, and the like, and examples of the alkali earth metal catalysts may include $Ca(OH)_2$, $Ba(OH)_2$, $Mg(OH)_2$, $Sr(OH)_2$, $CaCO_3$, $BaCO_3$, $MgCO_3$, $SrCO_3$, $Ca(OAc)_2$, $Ba(OAc)_2$, $Mg(OAc)_2$, $Sr(OAc)_2$, and the like. These alkali metal and/or alkali earth metal catalysts may be used alone or in combination of two or more.

The catalyst may be used in an amount of 0.1 to 30 μmol, preferably 0.5 to 25 μmol, more preferably 0.5 to 20 μmol, per mole of the total amount of the diol (1,4:3,6-dianhydrohexitol and an additional diol) used in the melt polycondensation reaction. Although the catalyst may be employed at any time regardless of the progress of the melt polycondensation reaction, it is preferable to introduce the catalyst before the initiation of the melt polycondensation reaction. When the amount of the catalyst used is less than 0.1 μmol per mole of the total amount of the diol, it is difficult to obtain a targeted degree of polymerization. If the amount of the catalyst exceeds 30 μmol it causes side reactions and thus directly affects deterioration of target properties such as reduced transparency.

In addition, in the method for manufacturing a bio-based polycarbonate ester according to the present invention, as the melt polycondensation reaction takes place in a molten state which has a high viscosity due to the increase in polymerization level, it is necessary to quickly remove byproducts from the molten state. Also, temperature elevation and pressure reduction take place stepwise in order to promote the rate of the polymerization reaction.

After the raw materials are introduced, the first part of the reaction may be carried out at a temperature of 130 to 250° C., preferably 140 to 240° C., more preferably 150 to 230° C., for 0.1 to 10 hours, preferably 0.5 to 3 hours. When the pressure is reduced in said temperature range, the reduced pressure condition may be 5 to 700 Torr, preferably 10 to 600 Torr.

The second part of the reaction may be carried out at a temperature of 210 to 290° C., preferably 220 to 280° C., more preferably 230 to 270° C., for 0.1 to 10 hours,

preferably 0.5 to 3 hours. When the pressure is reduced in said temperature range, the reduced pressure condition may be 20 Torr or less, preferably 10 Torr or less.

Additionally, the method for manufacturing a bio-based polycarbonate ester according to the present invention may further comprise various additives, if necessary. For example, the employable additive may include an antioxidant and a thermal stabilizer such as hindered phenol, hydroquinone, phosphite, and a substituted compound thereof; a UV-absorber such as resorcinol, salicylate, etc.; a color-protecting agent such as phosphite, hydrophosphite, etc.; and a lubricant such as montanic acid, stearyl alcohol, etc. Also, a dye and pigment may be used as a colorant; carbon black may be used as a conductive agent, colorant or nucleation agent; and a flame retardant, a plasticizer, an antistatic agent and the like may also be used. As such, the aforementioned additives may be included in an amount that does not cause adverse effects on the final properties of the polymer, especially on transparency.

The bio-based polycarbonate ester comprising a repeating unit of formula 1 prepared by the method for manufacturing a polycarbonate ester according to the present invention may have a final intrinsic viscosity (hereinafter referred to as IV) of 0.3 to 2.0 dL/g.

Hereinafter, the present invention is described more specifically by following examples. However, these examples are provided only for illustration purposes, and the present invention is not limited thereto.

Preparation Example 1: Synthesis of DPCD by Using CHDA

100 g (0.58 mol) of CHDA (SK Chemicals) with a cis/trans ratio of 95/5%, 218 g (2.32 mol) of phenol, 0.1 g (0.55 mmol) of $Zn(OAc)_2$ catalyst, and a magnetic stirrer were introduced into a 500 mL one-neck flask. A distillation head, a thermometer, and a cooling condenser were equipped to the flask, and the flask was heated to 200° C. A reaction was carried out at the same temperature for 24 hours, and water which was generated as a byproduct of the reaction was disposed from the flask. Upon completion of the reaction, the reactant thus obtained was cooled down to room temperature, and excessively introduced phenol was removed therefrom by using an evaporator. The solid compound thus obtained was added with excessive water, and mechanically stirred to remove the residual phenol. After 24 hours vacuum drying at 90° C., 111 g of DPCD was obtained (yield: 59%). The cis/trans ratio had been changed to 55/45% as a result of the reaction with phenol under the said reaction conditions: the cis content was decreased, whereas the trans content was increased.

Preparation Example 2: Synthesis of DPCD by Using DMCD

100 g (0.50 mol) of DMCD (SK Chemicals) with a cis/trans ratio of 77/23%, 188 g (2.00 mol) of phenol, 100 mL of water, and 1.0 g (5.81 mmol) of p-toluensulfonic acid catalyst were introduced into a 500 mL one-neck flask, together with a magnetic stirrer. The flask was equipped with a cooling condenser, heated to 100° C., and refluxed under stirring for 10 hours. Upon completion of the reaction, the reactant thus obtained was cooled down to room temperature, and then water and phenol were removed therefrom by distillation. Subsequently, the remaining reactant was heated to 200° C., and the reaction was carried out at the same temperature for 24 hours, followed by disposing water which was generated as a byproduct of the reaction. Upon completion of the reaction, the reactant thus obtained was cooled down to room temperature, and excessively introduced phenol was removed therefrom by using an evaporator. The solid compound thus obtained was added with excessive water, and mechanically stirred to remove the residual phenol. After 24 hours vacuum drying at 90° C., 86 g of DPCD was obtained (yield: 53%). The cis/trans ratio had been changed to 52/48% as a result of the reaction with phenol under the said reaction conditions: the cis content was decreased, whereas the trans content was increased.

Example 1: Preparation of Bio-Based Polycarbonate Ester

A distillation head, a thermometer, a cooling condenser, and a mechanical stirrer were equipped to a 500 mL three-neck flask. 102.3 g (0.7 mol) of isosorbide (Roquette Freres), 97.3 g (0.3 mol) of DPCD obtained from Preparation Example 1, 85.7 g (0.4 mol) of DPC (Aldrich), and 5.9×10^{-4} g (1.8×10^{-3} mmol) of cesium carbonate (Cs_2CO_3), as a catalyst, were added to the flask and the flask was heated to 150° C. Once the temperature reached 150° C., the pressure was reduced to 400 Torr, and the temperature was elevated to 190° C. over 1 hour. During the temperature elevation, phenol started to form as a byproduct of polymerization reaction. When the temperature reached 190° C., the pressure was reduced to 100 Torr, maintained for 20 minutes, and then the temperature was elevated to 230° C. over 20 minutes. Once the temperature reached 230° C., the pressure was reduced to 10 Torr, and then the temperature was elevated to 250° C. over 10 minutes. The pressure was reduced to 1 Torr or less at 250° C., and the reaction was continued until it reached a desired stirring torque. When the stirring torque reached the desired value, the reaction was terminated, and the temperature was cooled down to room temperature. The cis/trans ratio of the cyclohexanedicarboxylate unit in the polymer chain obtained as a final product had been changed to 40/60%. The cis content was decreased, whereas the trans content was increased, as compared to its starting material DPCD. The bio-based polycarbonate ester thus prepared had Tg of 143° C., and IV of 0.48 dL/g. The ^1H NMR and IR spectrum of the final product are shown in FIGS. **2** and **3**.

Comparative Example 1: Preparation of Bio-Based Polycarbonate Ester by Using CHDM

A bio-based polycarbonate ester was prepared by using the same procedure as Example 1, except for using 10.1 g (0.07 mol) of CHDM (SK Chemicals) along with DPCD and DPC, and 92.1 g (0.63 mol) of isosorbide (Roquette Freres). The cis/trans ratio of the cyclohexanedicarboxylate unit in the polymer chain thus obtained as a final product had been changed to 38/62%. The bio-based polycarbonate ester thus prepared had Tg of 129° C., and IV of 0.51 dL/g.

Comparative Example 2: Preparation of Isosorbide Homopolycarbonate

An isosorbide homopolycarbonate was prepared by using the same procedure as Example 1, except for using 150.0 g (0.7 mol) of DPC (Aldrich), with no use of DPCD. The isosorbide homopolycarbonate thus obtained had Tg of 160° C., and IV of 0.49 dL/g.

Comparative Example 3: Preparation of Isosorbide/DPCD Homopolyester

A bio-based isosorbide/DPCD polyester was prepared by using the same procedure as Example 1, except for using 227.1 (0.7 mol) of DPCD with no use of DPC. The cis/trans ratio of the cyclohexanedicarboxylate unit in the polymer chain thus obtained as a final product had been changed to 36/64%. The bio-based polycarbonate ester thus prepared had Tg of 130° C., and IV of 0.46 dL/g.

Comparative Example 4: Preparation of DDDA Copolymerized Isosorbide Polycarbonate Ester

A DDDA copolymerized isosorbide polycarbonate ester was prepared by using the same procedure as Example 1, except for using 32.2 g (0.14 mol) of dodecanedioic acid (hereinafter referred to as DDDA, Aldrich) instead of DPCD, and 120.0 g (0.56 mol) of DPC (Aldrich). The DDDA copolymerized isosorbide polycarbonate ester had Tg of 121° C., and IV of 0.34 dL/g.

Comparative Example 5: Preparation of Bio-Based Polycarbonate Ester with High Cis Content

A bio-based polycarbonate ester was prepared by using the same procedure as Example 1, except for using 97.3 g (0.3 mol) of DPCD having a cis/trans ratio of 90/10%. The cis/trans ratio of the cyclohexanedicarboxylate unit in the polymer chain thus obtained as a final product had been changed to 85/15%. The bio-based polycarbonate ester thus prepared had Tg of 113° C., and IV of 0.37 dL/g.

<Light Transmittance Measurement>

The light transmittance of sheets prepared from the copolymerized samples obtained in Example 1 and Comparative Examples 1 to 5 in the visible range was measured by using a UV-VIS spectrometer in the range of 200 to 800 nm.

The content ratios and the property test results of the polymer samples obtained in Example 1 and Comparative Examples 1 to 5 are shown in Table 1 below.

TABLE 1

						ISB		CHDM				cis/		
	ISB	CHDM	DPCD	DDDA	DPC	c^1-ISB	e^2-ISB	c^1-CHDM	e^2-CHDM	e^2-CD	e^2-DD	trans (%)	Tg (° C.)	T^3 (%)
Ex. 1	1	0	0.6	0	0.4	0.4	0.3	0	0	0.3	0	40/60	143	92
Comp. Ex. 1	0.9	0.1	0.6	0	0.4	0.36	0.27	0.04	0.03	0.3	0	38/62	129	91
Comp. Ex. 2	1	0	0	0	1	1	0	0	0	0	0	—	160	89
Comp. Ex. 3	1	0	1	0	0	0	0.5	0	0	0.5	0	36/64	130	89
Comp. Ex. 4	1	0	0	0.2	0.8	0.8	0.1	0	0	0	0.1	—	121	87
Comp. Ex. 5	1	0	0.6	0	0.4	0.4	0.3	0	0	0.3	0	85/15	113	90

[1]c, carbonate;
[2]e, ester;
[3]T, transmittance;
CD: cyclohexanedicarboxylate;
DD: dodecanedioate.

As shown in Table 1 above, when a bio-based polycarbonate ester was prepared from 1,4-diphenyl-cyclohexanedicarboxylate of formula 3 which was prepared according to the inventive method, the bio-based polycarbonate ester exhibits improved heat resistance as compared to a conventional biopolycarbonate prepared from 1,4:3,6-dianhydrohexitol and 1,4-cyclohexanedimethanol, although comprising the same amount of isosorbide. The inventive polycarbonate ester has an advantage that the amount of isosorbide in the polymer can be reduced owing to improved heat resistance.

Also, in case of Comparative Example 4, the optical transmittance level was dropped down from highly transparent poly(methyl methacrylate) (PMMA) level to a general BPA-based polycarbonate level due to the presence of a long chain aliphatic diacid which induces an increase in the photoelastic coefficient, and it was also found that the glass transition temperature was relatively low.

In particular, in case of Comparative Example 5, the glass transition temperature was significantly decreased as compared to Example 1 due to the high cis content of cyclohexanedicarboxylate unit in the polymer chain so obtained, and it was also confirmed that the optical transmittance level was reduced.

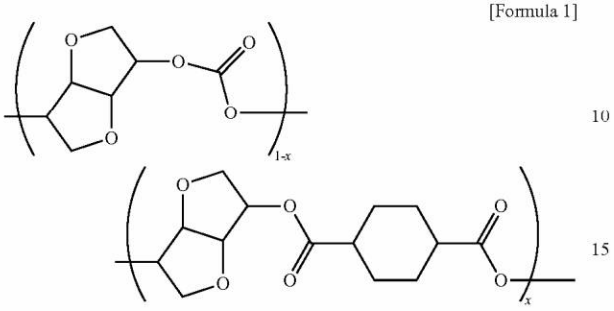
Accordingly, it is possible to control the properties deriving from the carbonate bond and the ester bond by adjusting the ratio thereof to give a desirable property according to its needs. Therefore, the polycarbonate ester prepared according to the present invention exhibits high heat resistance and transparency, and thus can be useful in various applications, e.g., glass alternative for automobile, optical lens and film, feeding bottle, food container, etc.

What is claimed is:

1. A bio-based polycarbonate ester consisting of:

a repeating unit represented by Formula 1:

[Formula 1]



wherein x satisfies 0<x<1, and

wherein the ratio of cis/trans cyclohexanedicarboxylate unit is 20/80% to 80/20% in the repeating unit of Formula 1.

2. The bio-based polycarbonate ester of claim **1**, wherein the ratio of cis/trans cyclohexanedicarboxylate unit is 30/70% to 70/30% in the repeating unit of Formula 1.

3. The bio-based polycarbonate ester of claim **1**, wherein the ratio of cis/trans cyclohexanedicarboxylate unit is 40/60% in the repeating unit of Formula 1.

4. The bio-based polycarbonate ester of claim **1**, wherein the 1,4:3,6-dianhydrohexitol is isosorbide.

* * * * *

Macromolecules

EXHIBIT C
WITNESS: T. Osswald
Date: July 2, 2026
Reporter: Teri Simons, CCR, RMR, CRR, RDR

Article
pubs.acs.org/Macromolecules

Advanced Polymerization and Properties of Biobased High T_g polyester of Isosorbide and 1,4-Cyclohexanedicarboxylic Acid through *in Situ* Acetylation

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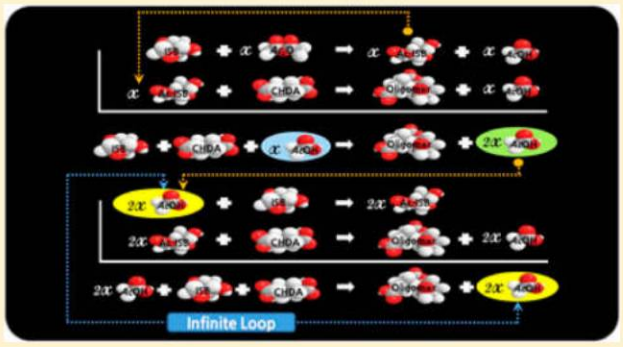
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Supporting Information

ABSTRACT: The synthetic problems associated with melt polymerizations to form homopolyesters of isosorbide (ISB) and rigid diacids could potentially be solved by using catalyst systems with acetic anhydride (Ac_2O). A catalyst consisting of dibutyltin oxide, germanium oxide, and Ac_2O exhibited excellent performance characteristics in syntheses of a high-molecular-weight homopolyester of ISB and *cis*/*trans*-1,4-cyclohexanedicarboxylic acid (CHDA), also referred to as poly(isosorbide *cis*/*trans*-1,4-cyclohexanedicarboxylate) (PICD). The acetylation of ISB using Ac_2O during esterification decreased the steric hindrance of ISB and accelerated the chain growth of PICD. Gel permeation chromatography data confirmed the formation of a high-molecular-weight PICD (71 100 weight-average molecular weight and 14 300 number-average molecular weight) using 0.02 mol of Ac_2O. The glass transition temperature of PICD was almost 131 °C at 0.02 mol of Ac_2O and decreased with increasing amounts of Ac_2O due to the breaking of the rigid ring of ISB at higher concentrations of Ac_2O. The structure of opened ring ISB was confirmed using two-dimensional nuclear magnetic resonance (NMR) and distortionless enhancement by polarization transfer NMR.



INTRODUCTION

1,4:3,6-Dianhydrohexitol, a biobased material that can be derived from biomass such as wheat, sugar, and corn, has been used in various polymer preparations, pharmaceuticals, and cosmetics.[1−6] It has three stereoisomers which are isosorbide (ISB), isomannide, and isoidide, respectively obtained from glucose, mannose, and fructose.[7,8] Among its three stereoisomers, ISB is the most easily accessible and affordable monomer for polymer synthesis[8,9] and is one of the most favorable candidates for renewable monomers used in addressing environmental issues and the depletion of petroleum resources.[10] When ISB is used as a monomer of polyester, the resulting polyester is not only environmentally desirable, but also has superior thermal and optical properties due to its molecular rigidity and the chirality of its asymmetrical hydroxyl groups. Several reports describe attempts to synthesize various polymers containing ISB, including polyesters,[11−24] polyurethanes,[25−29] epoxy,[30,31] polyamides,[32,33] polycarbonates, and liquid crystalline polymers.[34−38]

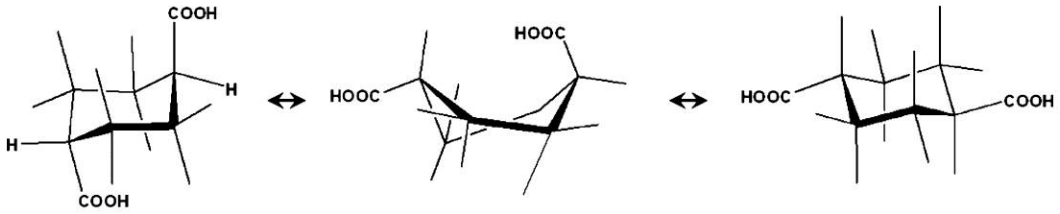
In homopolyesters made with ISB, the incorporation of terephthalic acid (TPA), an aromatic diacid, results in materials with high thermal stability and desirable mechanical properties. However, the formation of a homogeneous system during polymerization is problematic because both TPA and ISB are solid powders and TPA does not dissolve in ISB melts.[13] Furthermore, the low reactivity and volatility of ISB make it difficult to obtain a high-molecular weight polymer. Previous studies by Quintana et al.[10] describe syntheses of polyterephthalates from ethylene glycol (EG), 1,4-cyclohexanedimethanol (CHDM), and ISB. They reported the number-average molecular weights (M_n) and weight-average molecular weights (M_w) of PE(CIs)T terpolyester containing 15 mol % of CHDM and ISB of only 13 400 and 25 900 g mol^{-1}, respectively. A disadvantage of using TPA in a melt polymerization is that the molecular weight obtainable with ISB is low.[8] The fraction of unreacted terephthalic acid groups in PIT (homopolyester with TPA and ISB) is much higher than that in PET.[13]

Received: January 21, 2013
Revised: March 28, 2013
Published: April 3, 2013

ACS Publications © 2013 American Chemical Society

dx.doi.org/10.1021/ma4001435 | Macromolecules 2013, 46, 2930−2940

Scheme 1. Conformation of CHDA through a Twisted-Boat Intermediate



a,a-*trans* CHDA | twisted-boat (2 and 5 position) | e,e-*trans* CHDA

1,4-Cyclohexanedicarboxylic acid (CHDA), one of monomers used in the current study, has a lower melting point than TPA. The structure of CHDA is based on cyclohexane while the structure of TPA is based on a benzene ring. As a result, CHDA has better weatherability,[39] higher impact strength,[40] and faster stress relaxation.[41] CHDA has three isomers with chair conformations: axial, axial (a,a) *trans*-isomer, as well as an equatorial, equatorial (e,e) *trans*-isomer and an a,e *cis*-isomer. The transition between the *trans* conformations occurs through a twisted boat intermediate conformation. This results in high impact resistance and strong mechanical properties, as illustrated in Scheme 1.[40,41]

Noordover et al.[17,42] synthesized polyesters of succinic acid and ISB with titanium(IV) *n*-butoxide by melt polymerization and reported a final molecular weight of up to 2500 g mol^{-1}. This limitation is due to the low reactivity and intramolecular hydrogen bonding of the endohydroxyl group of ISB. Garaleh et al.[43] prepared homopolyesters of CHDA and ISB using three different methods. Of these, only the polycondensation of ISB and CHDA dichloride, which is more reactive than CHDA, yielded a M_n as high as 11 000 g mol^{-1}. This method, however, is not suitable for commercial polyester manufacture and it is not environmentally friendly.

A successful approach for improving the reactivity of ISB was to substitute an acetyl group at the end of the monomer and polymer chain during polymerization. Acetylation of ISB with acetic anhydride (Ac_2O) substantially accelerates chain growth during polymerization. In addition, a small amount of Ac_2O (2 mol % to ISB) drastically increases the molecular weight of ISB homopolyesters, much like a catalyst. This *in situ* acetylation method also activates the epimerization of CHDA toward a higher *trans* ratio from 22 mol % to 66 mol % at thermal equilibrium. The current report explores the cause of this epimerization and characterizes the thermal properties of PICD polymer. A proposed mechanism for PICD homopolyester polymerization by Ac_2O is also provided.

EXPERIMENTAL SECTION

Materials. CHDA (99.8%) with 22 mol % *trans*-isomer and ISB (99.8%, Roquette Freres S.A.) were supplied by SK Chemicals. The monomers were high-purity commercial products and used as received. Solvents and chemical reagents used for acetylation and characterization, including Ac_2O, AcOH, chloroform, *o*-chlorophenol, dichloromethane, and sodium bicarbonate, were all high-purity grade and used as received.

Synthesis of Polyesters. PICD was prepared using a 3-L bench reactor with a jacketed stainless steel vessel. The reactor was fitted with an anchor agitator, condenser, and a trap and was used for the esterification reaction. CHDA (1220 g, 7.09 mol), ISB (1040.8 g, 7.12 mol), germanium dioxide (200 ppm) and dibutyl tin oxide (150 ppm) were weighed into the reactor in a molar ratio of CHDA/ISB = 1/1.003. Ac_2O was added to the reactor at levels of 0−75 mol % relative to the level of ISB. After flushing three times with nitrogen to remove oxygen from the reactor, the reaction mixture was heated at 120 °C under 1 bar of nitrogen. After 1 h, the temperature was raised to 250 °C at rate of 100 °C per hour and held at 250 °C for an additional 2 h to reach the end point of esterification. Most of the H_2O and AcOH generated during the esterification reaction were distilled out at this stage. A sample of oligomer was carefully removed from the esterification reactor for analysis prior to polycondensation. The polycondensation reaction was performed in a different reactor fitted with a spiral agitator. The oligomer was transported from the esterification reactor to the polycondensation reactor through preheated pipeline at 250 °C. The temperature was then slowly increased to 265 °C while stirring at 98 rpm. The stirring speed was slowly decreased to 30 rpm with increasing degree of polymerization and the vacuum was reduced gradually to 0.4 mbar. Polycondensation was performed under isothermal conditions until the torque measured by the stirrer reached 2 N m. Finally, the pressure was returned to atmospheric pressure using nitrogen to prevent degradation by oxidation. The resulting polyester was removed from the reactor, quenched in a water bath, and analyzed.

Epimerization Test. *Acetylation of CHDA and Heat Treatment.* CHDA (50 g) was reacted with 65.2 g (2.2 mol) of Ac_2O in a nitrogen atmosphere in a 250-mL flask with a reflux system and a magnetic stir bar. The flask was heated gradually from room temperature to 120 °C and the mixture was stirred for 1 h in a closed system. The reacted mixture was removed from the flask and any remaining Ac_2O and AcOH were extracted using an evaporator under reduced pressure at 100 °C for 1 h.

Acetylated CHDA (Ac-CHDA) was divided into six different 50-mL flasks for heat treatment. Each flask was filled with 10 mL of Ac-CHDA and a magnetic stir bar. The Ac-CHDA was stirred for 1 h in a closed system at various temperatures between 200 and 250 °C.

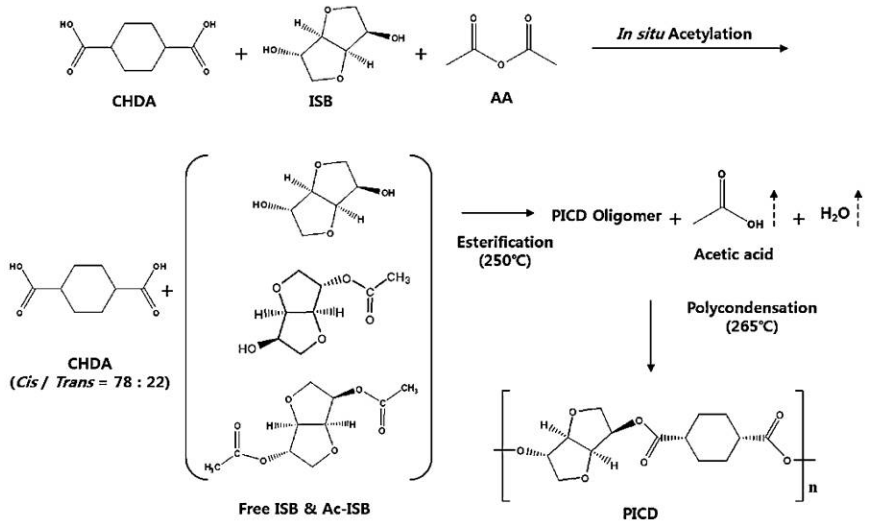
Characterizations. *Intrinsic Viscosity.* The intrinsic viscosities of the polymers were measured using an automated Ubbelohde viscometer at 25 °C. Polymer samples (0.36 g) were carefully weighed and dissolved in 30 mL of *o*-chlorophenol. This solution was heated at 150 °C for 15 min and stirred with a magnetic stir bar to ensure complete dissolution. Each solution was then cooled to room temperature. Intrinsic viscosity values were calculated from relative viscosities.

Size Exclusion Chromatography (SEC). The M_n and polydispersity (M_w/M_n) were determined by gel permeation chromatography (GPC) using two Shodex LF804 columns at 40 °C (mixed bed, maximum pore size 3000 Å) equipped with a Malvern TDA 305 refractive index detector. Thirty milligrams of sample was predissolved in 3 mL of *o*-chlorophenol at 150 °C for 15 min, and 9 mL of chloroform was added at room temperature. *o*-Chlorophenol/chloroform (1/3) was used as the mobile phase at a velocity of 0.7 mL min^{-1}. Sample solutions were filtered through polytetrafluoroethylene microporous membranes (Merck Millipore) with a pore size of 0.45 μm prior to injection. Narrow and broad linear polystyrene standards were used for universal calibration.

Nuclear Magnetic Resonance (NMR). ^{1}H NMR spectra were obtained on a JEOL Oxford 600 spectrometer operating at 600 MHz.

dx.doi.org/10.1021/ma4001435 | *Macromolecules* 2013, 46, 2930−2940

Scheme 2. Polymerization Step of PICD Using *in Situ* Acetylation



Deuterated chloroform was used as the solvent. Tetramethylsilane (TMS) was used as an internal standard and as a reference for chemical shift. Sixteen scans with 16K data points each were acquired for each ^{1}H NMR spectrum. Relaxation delays were 5 s. ^{13}C NMR spectra were recorded at 150 MHz using the same NMR spectrometer and solvent mixture. Each ^{13}C NMR spectrum was composed of 8192 scans with 64K data points each. Relaxation delays were 2 s.

Differential Scanning Calorimetry (DSC). DSC measurements were performed with a Mettler-Toledo DSC 820 calorimeter. Pellet samples of 8 ± 0.5 mg of PICD were enclosed in standard 40-μL aluminum cells. The samples were melted at 300 °C for 3 min, then quenched to 40 °C at a rate of 300 °C min^{-1}. The temperature was then raised at 10 °C min^{-1} from 40 to 300 °C in a nitrogen atmosphere. The glass transition temperature (T_g) was taken as the onset of the change in heat capacity associated with a transition.

■ RESULTS AND DISCUSSION

Synthesis and Proposed Mechanism. High-molecular-weight homopolyesters of CHDA and ISB have not been successfully synthesized through both melt and solution polymerization due to the low reactivity of ISB.[43] ISB is a V-shaped secondary diol having two fused rings at 120° to each other and two chemically nonequivalent hydroxyl groups.[8,10] The C5-OH is endo-oriented to form an intramolecular hydrogen bond with the oxygen atom of the adjacent tetrahydrofuran ring. The C5-OH is significantly less reactive than its exo-oriented counterpart, C2-OH.[9,44,45] This agrees with the results of Garaleh et al.[43] as described above. To change this steric environment, PICD homopolyesters were synthesized using CHDA and ISB through acetylation, substituting the hydroxyl end group with an acetyl group using Ac_2O. This was followed by esterification and polycondensation as illustrated in Scheme 2. The stoichiometric ratio between CHDA and ISB is near unity because of the low volatility of ISB at the reaction temperature, and the steric hindrance of the endo hydroxyl group of ISB is likely decreasing with acetylation. Ac_2O at concentrations of 0−75 mol %, relative to the levels of ISB, was added during the first stage of monomer esterification. The reactivity of ISB with Ac_2O is greater than that with CHDA. The electron-donating substituents of CHDA make its end groups less nucleophilic relative to the hydroxyl end groups of ISB. In accordance with this reasoning, the acetylation reaction with Ac_2O occurs primarily at the ISB subunits.

The nucleophilicity of the hydroxyl oxygen atom in the endoposition of ISB is enhanced by intramolecular hydrogen bonding. This makes the endohydroxyl intrinsically more reactive than the exohydroxyl group.[46] However, higher steric hindrance occurs around the endohydroxyl group. Thus, the acetyl substitution may occur preferentially at the less reactive exohydroxyl. In this work, acetylation of ISB was conducted in an acidic environment, which lowered the effect of hydrogen bonding. Thus, ISB with a monoacetoxy end group was dominant in the exo position as shown Scheme 2. Tamion et al.[47] reported that by varying the parameters for the acetylation reaction (Ac_2O, 120−140 °C vs Ac_2O, PbO, room temp.), both monoesters can be prepared in yields of 70% and 80% for the exo and the endo positions, respectively. Noordover et al.[16,41] prepared polyesters from succinic acid and isosorbide in the presence of titanium(IV) *n*-butoxide. The ratio of terminal hydroxyl groups (endo/exo) was 6:4. This is confirmed in the ^{1}H NMR spectra in Figure 1(A), 5*n* and 5*x* (ratio of 5*n*/5*x* is

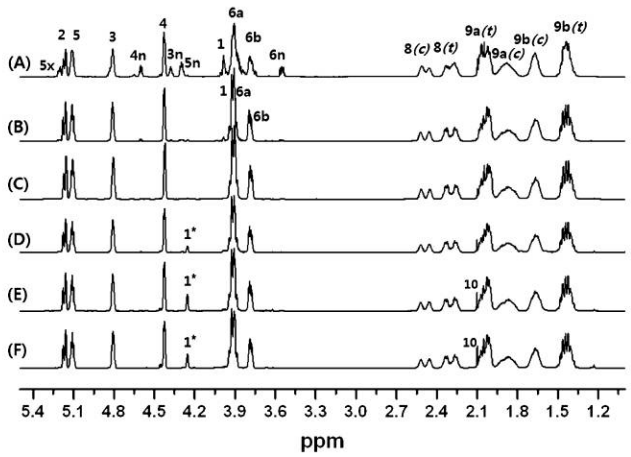


Figure 1. ^{1}H NMR spectra of PICD oligomer and polymers prepared with the various amounts of Ac_2O (a) ^{1}H NMR spectra of P M_w/M_n ICD oligomer, (b) PICD 2, (c) PICD 15, (d) PICD 30, (e) PICD 50, and (f) PICD 75, respectively.

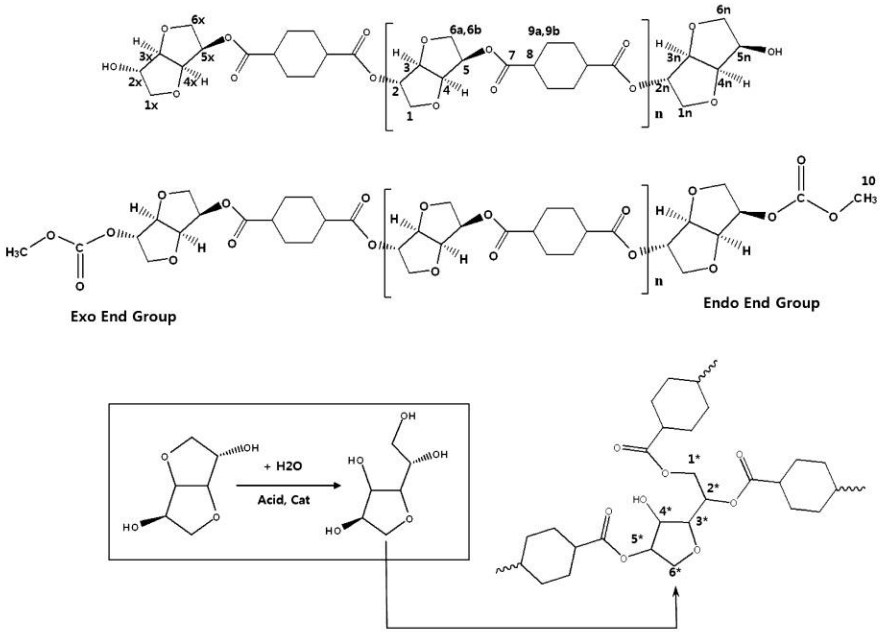
dx.doi.org/10.1021/ma4001435 | Macromolecules 2013, 46, 2930−2940

Table 1. Characteristics of PICD Synthesized with the Various Amount of Ac_2O

sample code[a]	Ac_2O contents (mol %)	IV[b] (°C)	M_n (g/mol)	M_w (g/mol)	M_w/M_n	*trans*-ratio (mol %)	T_g[e] (°C)
PICD-0	0	–	–	–	–	–	–
PICD-1	1	0.40	11 600	26 900	2.3	64.9	116
PICD-2	2	0.61	14 300	71 100	5.0	63.6	131
PICD-15	15	0.74	15 900	94 100	5.9	63.8	131
PICD-30	30	0.65	18 300	84 800	4.6	63.3	128
PICD-50	50	0.73	17 100	95 100	5.6	63.5	124
PICD-75	75	0.48	11 600	53 100	4.6	63.8	119

[a]Sample codes denote the mol % of Ac_2O added relative to ISB. [b]Intrinsic viscosity (dL g^{-1}) measured in *o*-chlorophenol at 30 °C. [c]Number-average molecular weight (M_n) and weight-average molecular weight (M_w) determined by GPC. [d]*Trans* mole fractions of CHDA isomers in the PICD polymers estimated by ^{1}H NMR. [e]Glass transition temperatures measured by DSC.

Scheme 3. Possible Structures of PICD polymer



2:1), which indicate that the endohydroxyl group of ISB is dominant over the exo end group.

Table 1 summarizes the analytical results of various PICD samples as a function of Ac_2O content. The M_n of the samples tended to increase with Ac_2O contents up to 30−50 mol %. In contrast, the M_n of PICD-75 rapidly decreased, presumably due to the reverse reaction induced by the highly acidic atmosphere during polymerization. The values of M_w/M_n (MWD) of PICD-2−PICD-75 are very broad as compared to PICD-1. This phenomenon can be ascribed to the formation of branch structure by reverse reaction of ISB (this will be discussed later in detail).

The chemical structure and composition of PICD were examined by ^{1}H NMR spectra shown in Figure 1. Peak assignments were established by 2D NMR spectroscopy, which provided detailed information about the structure of PICD shown in Scheme 3. Various NMR techniques, including correlation spectroscopy (COSY), heteronuclear single-quantum correlation spectroscopy (HSQC), heteronuclear multiple-bond correlation spectroscopy (HMBC), and distortionless enhancement by polarization transfer (DEPT) were employed to determine the sequence of specific protons and carbon atoms in PICD-50. Peaks in the ^{1}H NMR spectrum of the ISB moiety at δ 3.95, δ 5.13, δ 4.45, δ 4.83, δ 5.18, δ 3.92, and δ 3.82 ppm were assigned to hydrogen atoms 1, 2, 3, 4, 5, 6a, and 6b, respectively. In the ^{1}H NMR spectrum of the CHDA moiety, two methine protons, H8, yielded peaks around 2.31 and 2.51 ppm, indicating the *trans*- and *cis*-isomers, respectively. Both peaks exhibit double splitting, owing to the fact that the end groups of ISB have different steric environments. The methylene protons, H9 of the *trans*-isomer, are identified by peaks at 1.45 and 2.07 ppm. The *cis*-isomer peaks were observed at 1.69 and 1.91 ppm. The ratio of *cis*- to *trans*-isomers in CHDA was determined by integration of the peaks corresponding to H8 (*c*) (2.51 ppm) and H8 (*t*) (2.31 ppm) (see Table 1). As shown in Figure 1, the peak at 4.27 ppm can be conspicuously observed in the NMR spectrum at levels of Ac_2O above 30 mol % (PICD 30). The peak increases with increasing Ac_2O content. This peak also increases with acidity as the result of a reverse reaction (hydrolysis) with ISB. This effect will be discussed in greater detail below.

Using COSY spectra (Figure 2) it was possible to follow the presence of ISB residues bonded at both sides to CHDA (Scheme 3). The presence of ISB fragments was confirmed by correlation signals 1/2, 3/4, 4/5, 5/6a, 5/6b, and 6a/6b in Figure 2. However, because of the V-shaped structure of ISB and its two five-membered rings, correlation signals 2/3 were not detected in the COSY spectrum. On the basis of these

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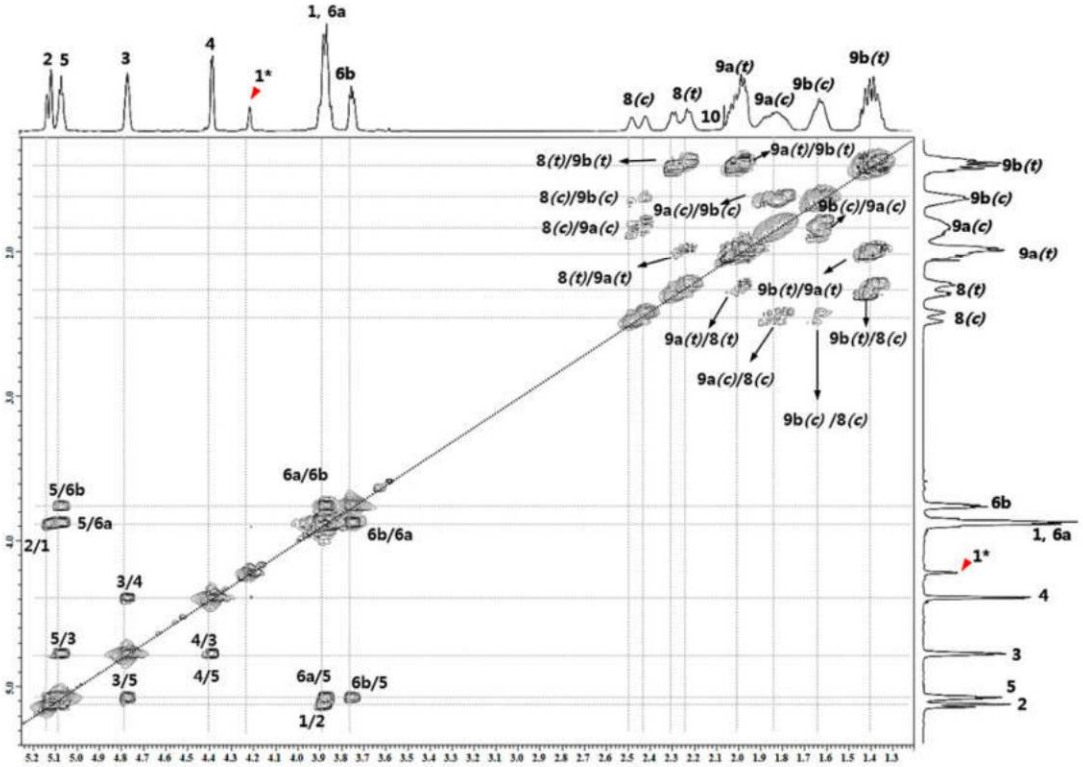


Figure 2. Correlation spectrum (COSY) of PICD 50.

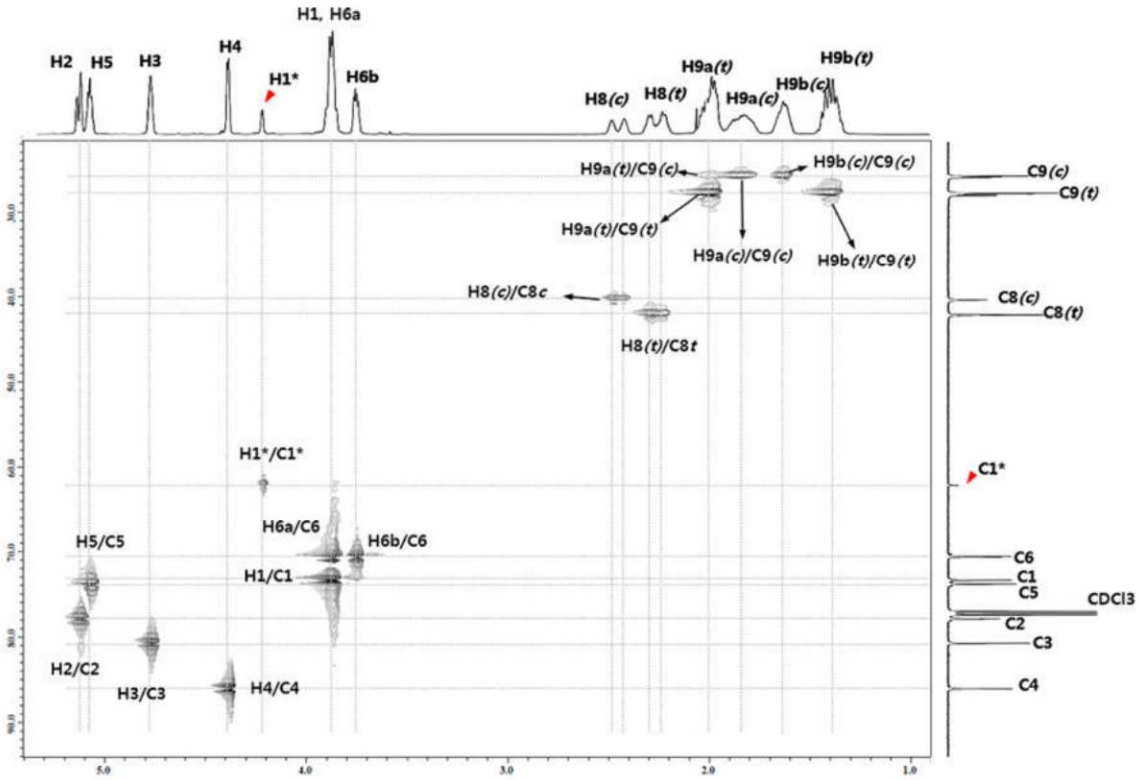


Figure 3. Heteronuclear single-quantum correlation spectrum (HSQC) of PICD 50.

results, proton signals were then assigned to the corresponding ^{13}C signals in the HSQC spectrum shown in Figure 3. The peaks in the ^{13}C NMR spectra of PICD 50 at δ 73.3, δ 77.3, δ 80.7, δ 86.0, δ 73.8, δ 70.6, δ 174.4, δ 40.3, δ 42.2, δ 25.8, and δ 28.0 ppm were assigned to 1, 2, 3, 4, 5, 6, 7, 8 *cis* (C8(c)), 8 *trans* (C8(t)), 9 *cis* (C9(c)), and 9 *trans* (C9(t)) carbon atoms,

dx.doi.org/10.1021/ma4001435 | *Macromolecules* 2013, 46, 2930−2940

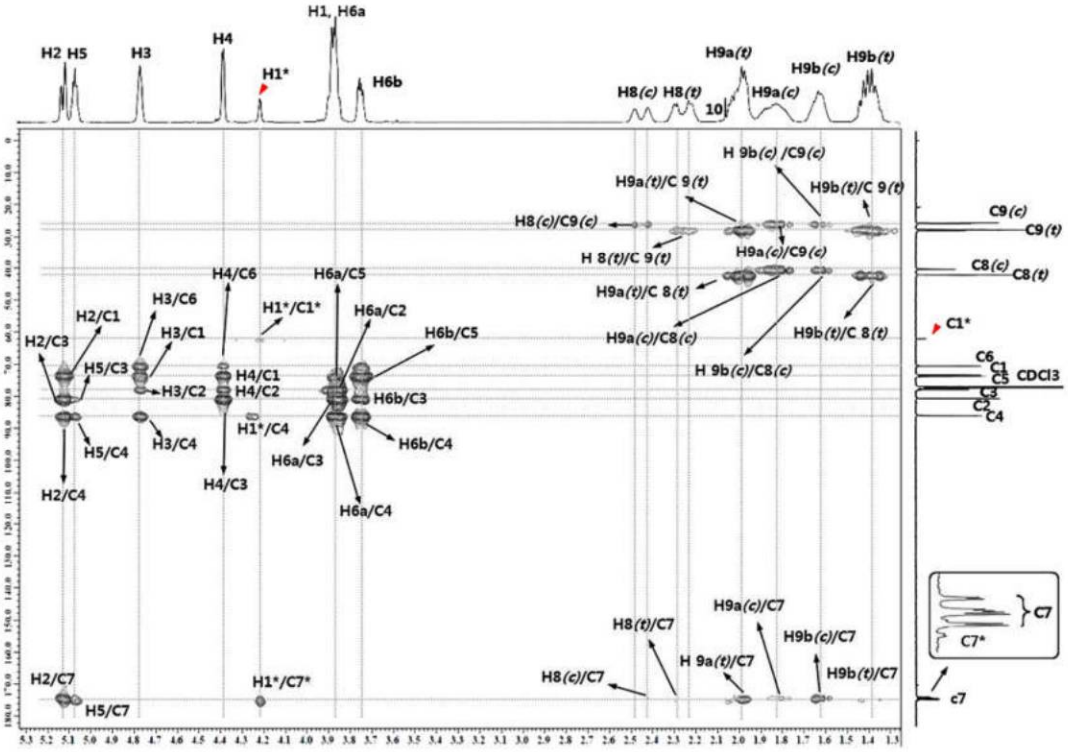


Figure 4. Heteronuclear multiple-bond correlation spectrum (HMBC) of PICD 50.

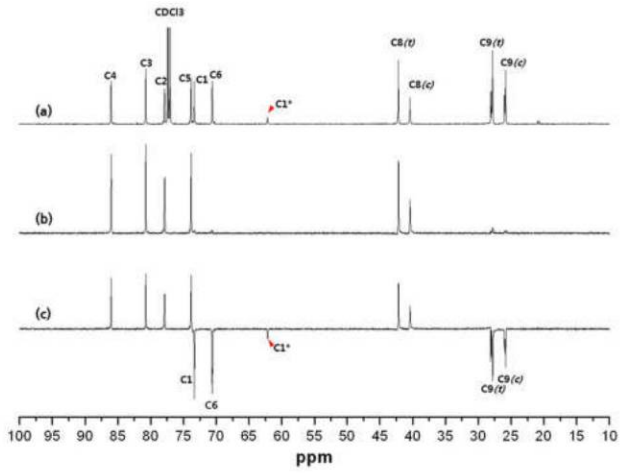


Figure 5. Distortionless enhanced by polarization transfer spectrum (DEPT) of PICD 50 (a) ^{13}C NMR spectra of PICD-50, (b) DEPT(90 angle) of PICD-50, and (c) DEPT (135 angle) of PICD-50.

respectively. These assignments were confirmed by correlation signals H1/C1, H2/C2, H3/C3, H4/C4, H5/C5, H6a/C6, H6b/C6, H8(*c*)/C8(*c*), H8(*t*)/C8(*t*), H9a(*t*)/C9(*c*), H9a(*t*)/C9(*t*), H9a(*c*)/C9(*c*), H9b(*c*)/C9(*c*), and H9b(*c*)/C9(*t*) at 3.95/73.3, 5.13/77.3, 4.45/80.7, 4.83/86.0, 5.18/73.8, 3.92/70.6, 3.82/70.6, 2.51/40.3, 2.31/42.2, 1.45/25.8, 1.45/28.0, 1.69/25.8, 1.91/25.8, and 1.91/28.0 ppm, respectively, in the HSQC spectrum.

ISB is formed by the dehydration of 1,4-sorbitan, an intermediate between ISB and sorbitol, under acidic conditions with a catalyst. Thus, hydration of ISB occurs if the Ac_2O content is high enough during polymerization, forming a branched structure as shown in Scheme 3. In numerous NMR peak assigning programs, the 1* hydrogen of the branched structure of the open-ring ISB moiety appears at around 4.2 ppm in the ^{1}H NMR spectrum. This structure was confirmed with DEPT and HMBC. In Figure 4, analysis of the HMBC spectrum shows correlation signals between H1*/C7* and H1*/C1* (Scheme 3) at 4.27/174.8 and 4.27/62.2 ppm, respectively. Additional evidence for the presence of C1* in open-ring ISB is given in Figure 5. DEPT at an angle of 135° yields all methane and methyl carbon atoms in a phase opposite that of a methylene carbon atom. The C1* peak (62.2 ppm) is a methylene carbon atom because it yields a negative signal as shown in Figure 5C. The H1* and C1* signals likely originate from the open-ring ISB.

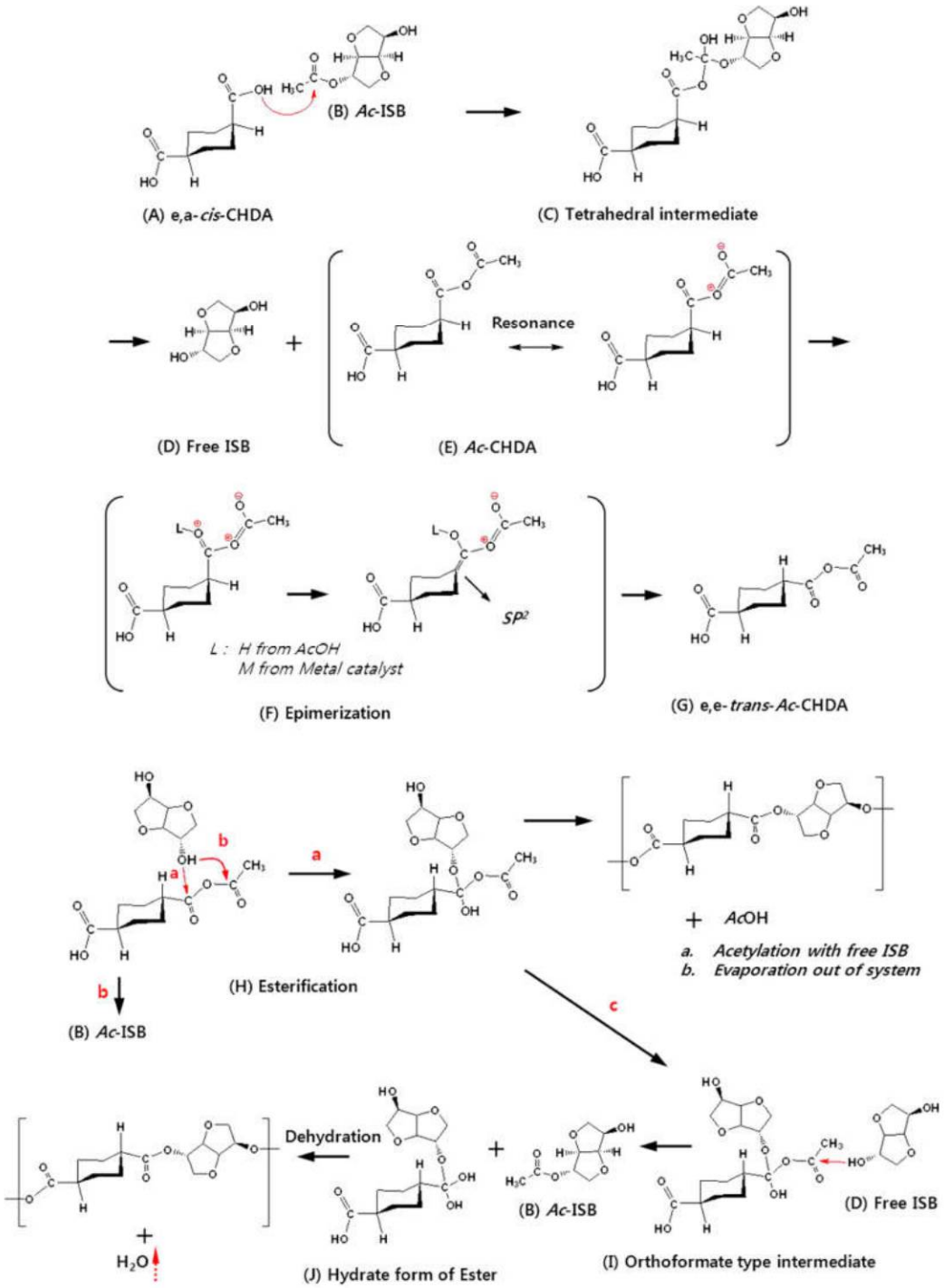
In this experiment, the relative amount of *trans* configurations of the CHDA isomer dramatically increased, regardless of Ac_2O content, from 22 mol % to around 66 mol % (thermal equilibrium) after polymerization.

The *trans* ratio of CHDA changes only slightly during the melt polymerization. Colonna et al.[48] reported on the parameters affecting the polymerization and *cis*/*trans* isomerization of PCCD, which is a homopolyester made from CHDA and 1,4-cyclohexane dimethanol (CHDM). They stated that isomerization of CHDA occurs only slightly toward the thermodynamically stable *trans* ratio (66 mol %) during polymerization. The degree of change in the *trans* ratio was as follows: (1) The ratio of the *trans*-isomer of CHDA changes from 99 to 91 mol % during polymerization at 250 °C, (2) a *trans* ratio of 22 mol % increases to 29 mol % at 250 °C, and (3) a *trans* ratio of 99 mol % decreases to 91, 88, and 85 mol % at polymerization temperatures of 240, 250, and 260 °C, respectively.

As shown in Table 1S (see the Supporting Information), all of the PICD oligomers and polymers exhibited *trans* ratios

dx.doi.org/10.1021/ma4001435 | *Macromolecules* 2013, 46, 2930−2940

Scheme 4. Proposed Mechanism of Acidolysis and Epimerization of PICD Esterification Reaction



above 60 mol % regardless of the concentration of Ac_2O. Epimerization seemed to be activated by an increase in the acidity of the system. However, this explanation is insufficient to explain the results obtained with PICD-1 or PICD-2, which had extremely low amounts of Ac_2O. These phenomena can be explained by the proposed mechanism in Scheme 4. First, a hydroxyl group of e,a *cis*-CHDA (A) attacks the carbonyl carbon atom of Ac-ISB (B), generating a tetrahedral intermediate (C). The resonance stabilized Ac-CHDA (E) is more easily enolized than free CHDA and enol-keto tautomerization occurs, yielding the more stable e,e *trans*-Ac-CHDA. During epimerization (F), as the carbonyl changes back to its original structure, the planar sp^2 hybridized carbon atom eliminates stereoselectivity. The proton reverts to the axial position, which is more thermodynamically stable. This leads to the formation of the more stable e,e *trans*-CHDA (G). Hence, the epimerization of Ac-CHDA can occur at lower temperatures than that of free CHDA. In the esterification reaction (H), the hydroxyl group of ISB can attack two different carbonyl carbon atoms in Ac-CHDA (paths a and b).

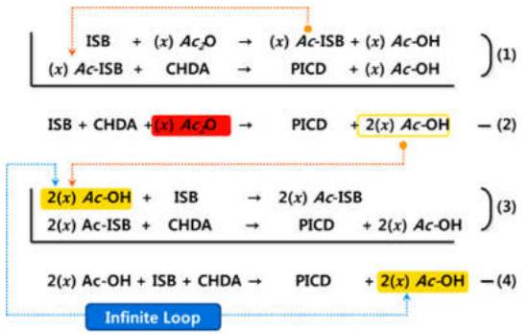
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Table 2. . Comparative *Trans* Ratio of CHDA and Ac-CHDA at Various Temperature

sample code	Ac_2O (mol %)	temperature (°C)	heating time (h)	*trans* contents (monomer)
CHDA[a]	0	–	–	21.5
CHDA-180[b]	0	180	6	10.7
CHDA-200	0	200	6	27.0
CHDA-250	0	250	6	46.7
CHDA-180a1[c]	1	180	6	10.1
CHDA-200a1	1	200	6	20.0
CHDA-250a1	1	250	6	53.2
Ac-CHDA[d]	220	120	1	36.5
Ac-CHDA-180[e]	220	180	1	53.6
Ac-CHDA-200	220	200	1	60.0
Ac-CHDA-250	220	250	1	65.9

[a]CHDA: Neat CHDA. [b]CHDA-180–250: The heat treated CHDA during 6 h at 180, 200, and 250 °C, respectively. [c]CHDA-180a1–250a1: The heat treated CHDA using 1 mol % Ac_2O during 6 h at 180, 200, and 250 °C, respectively. [d]Ac-CHDA: The acetylated CHDA using 220 mol % during 1 h at 120 °C. [e]Ac-CHDA-180–250: The heat treated Ac-CHDA during 1 h at 180, 200, and 250 °C, respectively.

Scheme 5. Infinite Loop of Acetylation Using Ac_2O in the PICD Polymerization Process



The reaction with the acetyl carbonyl carbon atom, which is far from the cyclohexane ring of Ac-CHDA (path b), may occur easily due to less steric hindrance, creating Ac-ISB (B). However, in this reaction, the AcOH byproduct of esterification with the carbonyl carbon atom adjacent to the cyclohexane ring is constantly removed from the system by acetylated free ISB and evaporation, thereby accelerating the forward reaction (path a). In this *in situ* acetylation polymerization, small amount of Ac_2O act very effectively in the acetylation and form high molecular weight polymer. If the AcOH is constantly evaporated out of reaction mixture, the concentration of Ac-ISB(B) will decrease and then the rate of polymerization will also decrease. This phenomenon might indicate the possibility of another reaction (path c) to form the Ac-ISB(B) before the AcOH is removed during the esterification (H). Free ISB(D) attacks orthoformate type intermediate (I) to develope hydrate form of ester(J) and Ac-ISB(B). Then, dehydration reaction occurrs to make PICD oligomer and H_2O.

In Table 2, although Ac-CHDA heated at 200 °C reaches a *trans* ratio of 60 mol % within 1 h, CHDA-180–250 show a much slower isomerization. In addition, both CHDA-250 and CHDA-250a1 did not reach the thermal equilibrium ratio even under identical esterification reaction conditions (temperature and time). The low *trans* ratio indicates that isomerization was not fully activated at 200 °C but proceeded rapidly as the temperature increased to 250 °C. Moreover, the *trans* ratios of CHDA-180–250 and CHDA-180a1–250a1 were similar. Because the acetylation rate of CHDA is lower than that of ISB, the acetylation of CHDA was not sufficient even after 6 h with 1 mol % Ac_2O. Under these circumstances, the epimerization of the CHDA-250a1 series cannot be activated due to the lack of an acetylation reaction. Therefore, the probability of Ac-CHDA acting as an intermediate in Scheme 4 is likely based on the *trans* ratio of oligomer made by adding just 1 mol % of Ac_2O to a PICD esterification, as shown in Table 1S, Supporting Information. In the case of PICD polymerization via *in situ* acetylation, the Ac_2O reacted preferably with ISB directly and not with CHDA (Scheme 4). In addition, AcOH, which is generated as a byproduct, could have proceeded with an acetylation reaction with free ISB. The presence of this AcOH increases the rate of polymerization and has an important effect on the whole polymerization stage.

The suggested reaction process is illustrated in Scheme 5. The x mol of Ac_2O generates $2x$ mol of AcOH via acetylation. If the AcOH is not promptly taken out of system, it can acetylate free ISB, indicating that Ac_2O acts as a catalyst in the polymerization process.

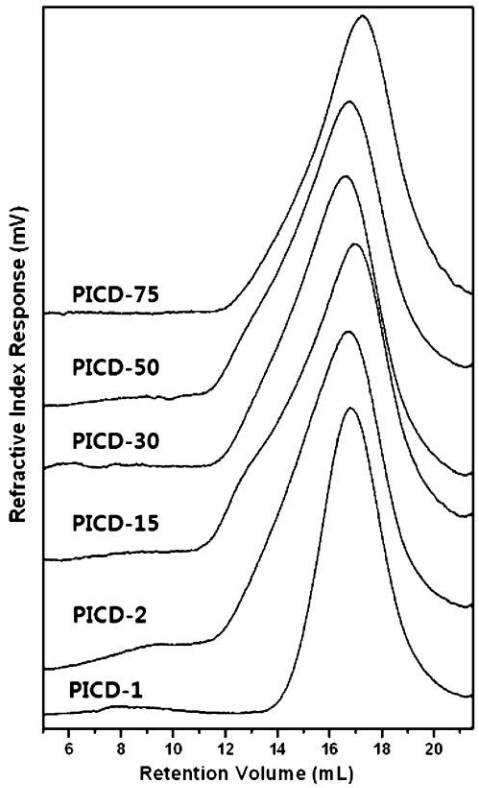
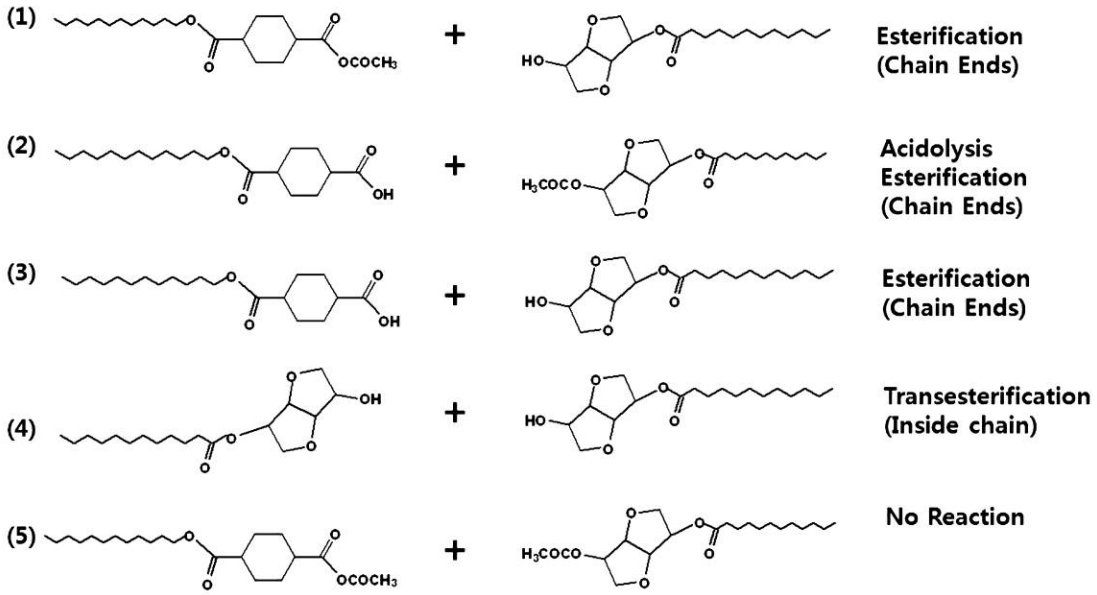


Figure 6. GPC data of PICD polymers.

Properties of PICD Homopolyester. In Figure 6, GPC chromatogram curve of PICD-1 is narrower than other samples (PICD-2–PICD-75) because of having small MWD. Generally, MWD values of polycondensated polyester are about 2–3. In the study of polycondensation of succinic acid and ISB, MWD

dx.doi.org/10.1021/ma4001435 | *Macromolecules* 2013, 46, 2930–2940

Scheme 6. Various Reactions Involved in the Polycondensation of PICD



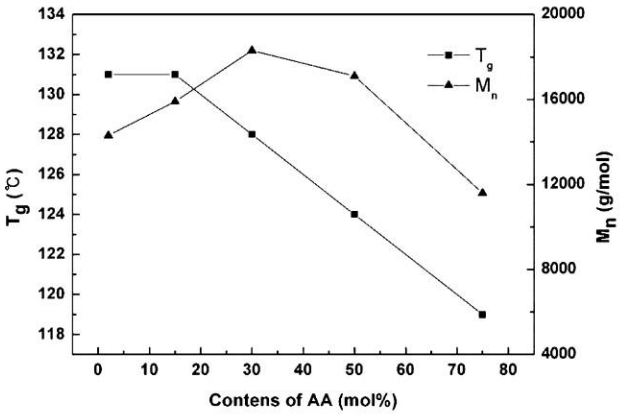


Figure 7. Variation of T_g and M_n as Ac_2O contents.

Table 3. Variation of T_g Against Open-Ring ISB and Mn

sample code	open-ring ISB (mol %)	M_n	T_g
PICD-2	3.8	14 300	131
PICD-15	5.1	15 900	131
PICD-30	14.8	18 300	128
PICD-50	28.0	17 100	124
PICD-75	21.6	11 600	119

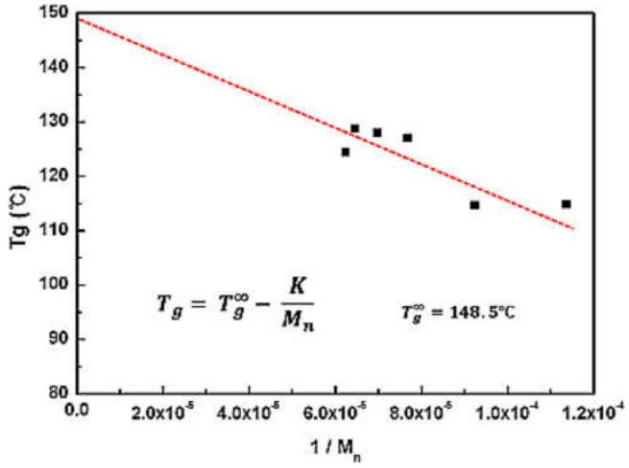


Figure 8. Infinite T_g (T_g^{∞}) of PICD.

is around 2.[17] In case of *in situ* acetylation polymerization, acidity in the system is relatively high enough to form 1,4 sorbitan (open ring structure) by breakage of ISB. This results in the formation of branch structure in the polymer chain and giving broad MWD to PICD polymer. Figure 1S (see the Supporting Information) shows the variation of the η' of PICD-1−PICD-75 at 270 °C from 0.05 rad/s to 600 rad/s. In Figure 1S (Supporting Information), PICD-2−PICD-75 which have broad MWD, shows that the onset shear rate of shear thinning is shorter compared with PICD-1. The shear viscosity at the extremely low shear rate is dependent on the M_w of each sample. Also, the hydrodynamic volume of branched polymer at low shear region in the melt state is relatively higher than that of nonbranched polymer, which means that the branched polymer has higher free volume. This larger free volume enables polymer chain to be compressed at a high shear rate, leading to increase the degree of shear thinning, which is pseudoplasticity. As shown in Figure 1S (Supporting Information), the degree of shear thinning of PICD-1 is lower than that of PICD-2−PICD-75. Degrees of polymerization (M_n) of PICD-1 and PICD-75 are the same in Table 1. However, the amount of branch structure by open-ring ISB of PICD-75 is larger than PICD-1 due to higher AcOH contents in polymerization. The noticeable difference of shear-thinning between PICD-1 and PICD-75 is shown in this melt curve. This may reflect the branch structure leading to high MWD of PICD-2 to PICD-75.

The possible polycondensation of the PICD polymer is shown in reactions 1−5 in Scheme 6. Because the acetyl end group cannot attack carbonyl carbon within the polymer chain, the transesterification reaction of PICD does not occur easily. Although the end hydroxyl group of ISB attacks the carbonyl carbon atom inside chain, the rate of transesterification is slow

dx.doi.org/10.1021/ma4001435 | Macromolecules 2013, 46, 2930−2940

due to its relatively low reactivity, low volatility and large steric hindrance. For such reasons, PICD polycondensation may preferentially occur at the end group. With four possible reactions, the broad MWD can be affected by differences in the rate of chain growth between the more reactive (1) + (2) and the lesser reactive (3) + (4) reactions.

Transition temperature variations can occur from its structurally sensitive characteristics. Steric effects and intra/intermolecular interactions are two main factors, which in this case, correlates to the Ac_2O content, M_n value and amount of opened ring structure of ISB. Before explaining the data, it is important to know that ISB structure, originally rigid, changes to flexible opened ring structure. It is obvious to see that this structural change greatly affects the T_g of PICD.

In Table 1, T_g of PICD-1 is low due to the lowest Ac_2O content, resulting low molecular weight. Normally, T_g increases with the M_n until a critical value is reached. However, as shown in Figure 7. T_g and M_n shows no relation to each other. T_g tends to gradually decrease with increasing contents. (Also, Figures 2S and 3S in the Supporting Information are illustrated for more understanding.)

In Table 3, M_n, T_g and relative proportions of opened-ring structure of ISB by ^1H NMR peaks are compared in order of increasing Ac_2O content. PICD-2 to PICD-30 shows higher T_g due to low amount of flexible opened-ring structure of ISB and relatively high M_n. Whereas PICD-50 shows lower T_g than PICD-30 resulting from almost twice the amount of opened-ring structure of ISB, even though PICD-50 shows higher M_n. For PICD-75, M_n is lowest and the amount of opened-ring structure of ISB has high value resulting in the lowest value for T_g

According to Garaleh et al.,[43] the maximum T_g of PICD, synthesized from dichloride of CHDA and ISB, is 145 °C, which is similar to T_g^∞ calculated using the Fox and Flory equation shown below. From Doolittle's free volume theory and the WLF equation, Fox and Flory presented the relationship between T_g and M_n as eq 1.

$$T_g = T_g^\infty - \frac{K}{M_n} \quad (1)$$

In this equation, T_g^∞ is the glass transition temperature of a polymer with infinite molecular weight and K is a constant related to the thermal expansion coefficients above and below T_g. This equation shows that T_g will increase with the M_n of the polymer, leveling off at certain plateau value (T_g^∞). As shown in Figure 8, we obtained a T_g^∞ of 148.5 °C with a K of 340,062 by plotting T_g against $1/M_n$ using the data in Table 1.

CONCLUSIONS

Important aspects of improving polymerizations involving ISB were discussed. Ac_2O was shown to be an attractive reagent for accelerating the formation of homopolyesters with diols having low reactivity. In addition, small amounts of Ac_2O were considerably effective at increasing the molecular weight of PICD. This suggests that acetylation by Ac_2O can be used in mass production facilities. Ac_2O is easily available and the amount of AcOH byproduct, which can corrode the reactor interior, is negligible. More study is required to determine the best means of controlling and reducing anisotropic reactivity resulting from the heterogeneity of acetylation. However, the acetylation method described herein using Ac_2O was shown to increase the reactivity of other secondary alcohols and rigid glycols.

ASSOCIATED CONTENT

Supporting Information

Comparison results of trans contents of CHDA in PICD oligomer and polymer, rheological data by ARES and T_g variation graphs with M_n and open ring ISB. This material is available free of charge via the Internet at http://pubs.acs.org/.

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Notes

The authors declare no competing financial interest.

REFERENCES

(1) Besset, C.; Pascault, J. P.; Fleury, E.; Drockenmuller, E.; Bernard, J. *Biomacromolecules* **2010**, *11* (10), 2797−2803.
(2) Fletcher, H. G.; Goepp, R. M. *J. Am. Chem. Soc.* **1945**, *67* (6), 1042−1043.
(3) Hockett, R. C.; Fletcher, H. G.; Sheffield, E. L.; Goepp, R. M. *J. Am. Chem. Soc.* **1946**, *68* (6), 927−930.
(4) Hockett, R. C.; Sheffield, E. L. *J. Am. Chem. Soc.* **1946**, *68* (6), 937−939.
(5) Stoss, P.; Hemmer, R. *Adv. Carbohyd. Chem. Biochem.* **1991**, *49*, 93−173.
(6) Yokoe, M.; Aoi, K.; Okada, M. *J. Polym. Sci., Polym. Chem.* **2005**, *43* (17), 3909−3919.
(7) Feng, X. H.; East, A. J.; Hammond, W. B.; Zhang, Y.; Jaffe, M. *Polym. Adv. Technol.* **2011**, *22* (1), 139−150.
(8) Fenouillot, F.; Rousseau, A.; Colomines, G.; Saint-Loup, R.; Pascault, J. P. *Prog. Polym. Sci.* **2010**, *35* (5), 578−622.
(9) Habeych, D. I.; Juhl, P. B.; Pleiss, J.; Vanegas, D.; Eggink, G.; Boeriu, C. G. *J. Mol. Catal. B: Enzymol.* **2011**, *71* (1−2), 1−9.
(10) Quintana, R.; de Ilarduya, A. M.; Alla, A.; Munoz-Guerra, S. *J. Polym. Sci., Polym. Chem.* **2011**, *49* (10), 2252−2260.
(11) Majdoub, M.; Loupy, A.; Fleche, G. *Eur. Polym. J.* **1994**, *30* (12), 1431−1437.
(12) Storbeck, R.; Ballauff, M. *J. Appl. Polym. Sci.* **1996**, *59* (7), 1199−1202.
(13) Kricheldorf, H. R.; Gomourachvili, Z. *Macromol. Chem. Phys.* **1997**, *198* (10), 3149−3160.
(14) Philip, B.; Sreekumar, K. *J. Mater. Sci.* **2003**, *38* (7), 1573−1577.
(15) Chatti, S.; Bortolussi, M.; Bogdal, D.; Blais, J. C.; Loupy, A. *Eur. Polym. J.* **2004**, *40* (3), 561−577.
(16) Chatti, S.; Bortolussi, M.; Bogdal, D.; Blais, J. C.; Loupy, A. *Eur. Polym. J.* **2006**, *42* (2), 410−424.
(17) Noordover, B. A. J.; van Staalduinen, V. G.; Duchateau, R.; Koning, C. E.; van Benthem, R. A. T. M.; Mak, M.; Heise, A.; Frissen, A. E.; van Haveren, J. *Biomacromolecules* **2006**, *7* (12), 3406−3416.
(18) Kricheldorf, H. R.; Behnken, G.; Sell, M. *J. Macromol. Sci. A* **2007**, *44* (7−9), 679−684.
(19) Sablong, R.; Duchateau, R.; Koning, C. E.; de Wit, G.; van Es, D.; Koelewijn, R.; van Haveren, J. *Biomacromolecules* **2008**, *9* (11), 3090−3097.
(20) Gohil, R. M. *Polym. Eng. Sci.* **2009**, *49* (3), 544−553.
(21) Jasinska, L.; Koning, C. E. *J. Polym. Sci., Polym. Chem.* **2010**, *48* (24), 5907−5915.
(22) Bersot, J. C.; Jacquel, N.; Saint-Loup, R.; Fuertes, P.; Rousseau, A.; Pascault, J. P.; Spitz, R.; Fenouillot, F.; Monteil, V. *Macromol. Chem. Phys.* **2011**, *212* (19), 2114−2120.
(23) Tan, L. C.; Chen, Y. W.; Zhou, W. H.; Wei, J. C.; Ye, S. W. *J. Appl. Polym. Sci.* **2011**, *121* (4), 2291−2300.
(24) Quintana, R.; de Ilarduya, A. M.; Alla, A.; Guerra, S. M. *High Perform. Polym.* **2012**, *24* (1), 24−30.

(25) Beldi, M.; Medimagh, R.; Chatti, S.; Marque, S.; Prim, D.; Loupy, A.; Delolme, F. *Eur. Polym. J.* **2007**, *43* (8), 3415−3433.
(26) Lee, C. H.; Takagi, H.; Okamoto, H.; Kato, M.; Usuki, A. *J. Polym. Sci., Polym. Chem.* **2009**, *47* (22), 6025−6031.
(27) Marin, R.; Munoz-Guerra, S. *J. Appl. Polym. Sci.* **2009**, *114* (6), 3723−3736.
(28) Varkey, E. C.; Sreekumar, K. *J. Mater. Sci.* **2010**, *45* (7), 1912−1920.
(29) Marin, R.; Alla, A.; de Ilarduya, A. M.; Munoz-Guerra, S. *J. Appl. Polym. Sci.* **2012**, *123* (2), 986−994.
(30) Chrysanthos, M.; Galy, J.; Pascault, J. P. *Polymer* **2011**, *52* (16), 3611−3620.
(31) Lukaszczyk, J.; Janicki, B.; Kaczmarek, M. *Eur. Polym. J.* **2011**, *47* (8), 1601−1606.
(32) Caouthar, A. A.; Loupy, A.; Bortolussi, M.; Blais, J. C.; Dubreucq, L.; Meddour, A. *J. Polym. Sci., Polym. Chem.* **2005**, *43* (24), 6480−6491.
(33) Caouthar, A.; Roger, P.; Tessier, M.; Chatti, S.; Blais, J. C.; Bortolussi, M. *Eur. Polym. J.* **2007**, *43* (1), 220−230.
(34) Hu, J. S.; Ren, S. C.; Zhang, B. Y.; Chao, C. Y. *J. Appl. Polym. Sci.* **2008**, *109* (4), 2187−2194.
(35) Kricheldorf, H. R.; Berghahn, M.; Probst, N.; Gurau, M.; Schwarz, G. *React. Funct. Polym.* **1996**, *30* (1−3), 173−189.
(36) Lin, Q.; Pasatta, J.; Long, T. E. *J. Polym. Sci., Polym. Chem.* **2003**, *41* (16), 2512−2520.
(37) Sapich, B.; Stumpe, J.; Kricheldorf, H. R.; Fritz, A.; Schonhals, A. *Macromolecules* **2001**, *34* (16), 5694−5701.
(38) Zhang, B. Y.; Hu, J. S.; Wang, B.; Yao, D. S.; Li, H. *Colloid Polym. Sci.* **2007**, *285* (15), 1683−1690.
(39) Jackson, W. J.; Gray, T. F.; Caldwell, J. R. *J. Appl. Polym. Sci.* **1970**, *14* (3), 685−&.
(40) Chen, L. P.; Yee, A. F.; Goetz, J. M.; Schaefer, J. *Macromolecules* **1998**, *31* (16), 5371−5382.
(41) Liu, J. W.; Yee, A. F. *Macromolecules* **1998**, *31* (22), 7865−7870.
(42) Noordover, B. A. J.; Duchateau, R.; van Benthem, R. A. T. M.; Ming, W.; Koning, C. E. *Biomacromolecules* **2007**, *8* (12), 3860−3870.
(43) Garaleh, M.; Yashiro, T.; Kricheldorf, H. R.; Simon, P.; Chatti, S. *Macromol. Chem. Phys.* **2010**, *211* (11), 1206−1214.
(44) Vasquez, T. E.; Bergset, J. M.; Fierman, M. B.; Nelson, A.; Roth, J.; Khan, S. I.; O'Leary, D. J. *J. Am. Chem. Soc.* **2002**, *124* (12), 2931−2938.
(45) Zhu, Y.; Molinier, V.; Durand, M.; Lavergne, A.; Aubry, J. M. *Langmuir* **2009**, *25* (23), 13419−13425.
(46) Stoss, P.; Merrath, P.; Schluter, G. *Synthesis-Stuttgart* **1987**, *2*, 174−176.
(47) Tamion, R.; Marsais, F.; Ribereau, P.; Queguiner, G.; Abenhaim, D.; Loupy, A.; Munnier, L. *Tetrahedron-Asymm.* **1993**, *4* (8), 1879−1890.
(48) Colonna, M.; Berti, C.; Binassi, E.; Celli, A.; Fiorini, M.; Marchese, P.; Messori, M.; Brunelle, D. J. *Polym. Int.* **2011**, *60* (11), 1607−1613.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

ALIGN TECHNOLOGY, INC. *
*
VS. *
*
CLEARCORRECT OPERATING, LLC, ET AL. *

May 27, 2026

* CIVIL ACTION NO. 6:24-CV-187

BEFORE THE HONORABLE ALAN D ALBRIGHT
MOTIONS HEARING (via Zoom)

EXHIBIT D
WITNESS: T. Osswald
Date: July 2, 2026
Reporter: Teri Simons, CCR, RMR, CRR, RDR

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Proceedings recorded by mechanical stenography, transcript produced by computer-aided transcription.

(Hearing begins.)

DEPUTY CLERK: The Court calls the following: 6:24-CV-187, Align Technology, Incorporated versus ClearCorrect Operating, LLC, et al., for a motions hearing.

THE COURT: Starting with plaintiffs, counsel?

MS. DURIE: Good morning, Your Honor. This is Daralyn Durie from Morrison and Foerster. I'm joined by my partners Brian Nash, Rich Hung, and Dan Muino from Morrison and Foerster, and Michael Tubach and Tim Durst from O'Melveny and Myers, as well as various other attorneys from our firm and client representatives who will not be speaking today.

THE COURT: I can't believe there are any attorneys left after all that. That's on -- what a great -- how lucky am I to have all those just on one side.

I get to hear now who's going to be representing the defendant.

MR. UNDERWOOD: Thank you, Your Honor. This is Travis Underwood for ClearCorrect. With me, I have Joe Mueller, Mark Ford, Todd Zubler, Bob Gunther, Jordan Hirsch, Vinita Ferrera, Omar Khan, Marissa Lalli, Holly Ovington, and Tyler Shearer, in addition

to two in-house client representatives, Dave Scannell and David Mlaver. And we are ready to proceed with the hearing.

THE COURT: Well, I appreciate the clients being here. And just -- and I shouldn't even get paid for this next couple of hours just getting to be with such talent. So.

The first issue I have is --

MR. DURST: Your Honor, this is Tim Durst. I might add that we have clients on the line as well from Align Technologies. General counsel Julie Coletti is on the line. Also on the line with us are lawyers in her legal department, Arthur Hirsch -- pardon me, Arthur Hsieh, Reed Willis, and I think James Hemmings may join us, though I don't see him on the call right now. And Kelsey Simmerson is also on the line, Your Honor.

THE COURT: Okay. Thank you for identifying them for the record. And I'm glad they're here too. I always think it's good when clients take the time to attend these.

First up I have is plaintiff's motion for preclusion pursuant to FRCP 37, and I will hear from the movant.

MR. FORD: Good afternoon, Your Honor.

Mark Ford for ClearCorrect. It's good to meet you by Zoom.

THE COURT: I've stopped asking. I didn't think I'd met you, but a week or two ago, I said, have we met before? And they said, yes, Your Honor. I've tried two cases in front of you. So I've stopped saying that. So.

But it is a pleasure to have you here.

MR. FORD: Thank you very much.

So I have some slides. I'm going to ask our hot seater Scott to bring up the Rule 37 slides, if you'll just bear with me for a moment.

But, Your Honor, Judge Gilliland entered an order in this case to prevent Align from using the privilege both as a sword and a shield in its antitrust defense. Align's been trying to circumvent that order ever since.

The sword and shield here relates to a decision Align made to terminate an agreement it had with a scanner company called 3Shape. That agreement had allowed 3Shape users to send scans for Invisalign aligners directly from the 3Shape scanner. They call that the interoperability agreement.

That termination is relevant to our case, because as we'll discuss, especially during the

antitrust summary judgment section, our case is in large part about this policy that Align adopted to not accept from doctors any scan unless it was from Align's own iTero scanner.

I will briefly summarize that on this slide that you see here.

But Align had -- and all these quotes are from internal documents. Align believed the iTero would be "Invisalign's competitive moat." They had a dominant position in Invisalign. They took the position internally that if you want to do Invisalign, quote, you're forced to buy iTero and live with it. That's how they knew they were going to force the iTero on all doctors by refusing to accept anything else.

The iTero then blocks competition. Again, Align internally noted, "The iTero scanner will block competition from gaining business in your accounts." So "an iTero customer is a locked-in Invisalign customer."

But that's just context.

Align, Your Honor, will --

THE COURT: Counsel, if I can ask you a question. I know that I've handled a couple of these cases back when I was a lawyer, and sometimes it's that if you go with one brand, then the equipment only works

with that brand and there's an advantage from that and there's an advantage from getting it in.

I'm taking it what you're saying is -- here is that it's a -- the prohibition against using the other ones was not something -- was something that the customer could have used -- technically used the other ones, they were just being blocked from doing so; is that right?

MR. FORD: They wouldn't be able to order Invisalign, and Invisalign was the dominant scanner.

THE COURT: Okay.

MR. FORD: And so if they use the other ones, they couldn't get Invisalign and they were forced to buy an iTero at a point when Invisalign was the dominant player. And then with the iTero, they couldn't buy competing scanners -- competing aligners. That's how they cemented.

Align -- what's going to happen at trial is Align's going to try to justify this policy and they're going to try to justify their decision to terminate an agreement with 3Shape that was a precursor to this policy.

The real reason --

If you go to the next slide.

The real reason why Align adopted this

policy is because Joe Hogan, the CEO, recognized that if other scanners could go to doctors and say, hey. You can use both Invisalign and other aligner companies, right, those doctors would have an option. They would -- other clear aligner companies would be on a level playing field.

And he wrote, "We have such a huge share of the market, why do we want to give them, doctors, that option?" So this is about taking choice away from doctors. That's the core of the antitrust claim here.

Now, Align has tried to justify this decision to terminate the 3Shape agreement, but the justification is pretext. And more importantly for this motion, Your Honor, it's advice of counsel.

At the motion to dismiss stage, Align said, we terminated 3Shape because we had this patent litigation going and we believed we had to terminate the 3Shape agreement to protect our patent litigation and to protect the validity of our patents because otherwise we may have been vulnerable to a defense that 3Shape might have advanced.

In prior litigation --

If you go to the next slide.

In prior litigation relating to the same 3Shape termination, Align said quite plainly, its

"decision to terminate interoperability was the result of legal advice."

And even in his deposition in that prior case, Your Honor --

If you go to the next slide.

-- Joe Hogan, the CEO, was asked, why did Align accept these TRIOS 3Shape scans for more than a year and then ultimately stop?

And he said again, quite plainly: This was a case where I was advised by my legal team to do so.

We sought discovery -- if you're going to say -- if your justification is going to be I was advised by my legal team, that's putting advice of counsel at issue. We sought discovery. Align refused. And we brought the matter to Judge Gilliland. And we said, Your Honor, this would be advice of counsel. If they want to do that, they need to waive privilege. Judge Gilliland agreed with us.

If you go to the next slide.

Judge Gilliland said at that hearing, Your Honor, that what Align was putting forth sounded like an advice of counsel defense, and so he made a decision, very similar to how it's handled in a lot of patent cases, that Align's going to make an election.

And Align will notify ClearCorrect by November 18th if they're going to continue to do so and waive the attorney-client privilege.

The written order, on the next slide, Your Honor, couldn't be clearer. He ordered that "Align must notify ClearCorrect by November 18th whether, with respect to Align's decision to terminate its interoperability agreement with 3Shape, Align will rely on advice of counsel by presenting evidence that Align's decision to terminate the agreement was motivated by legal considerations related to the patent litigation and, therefore, waive the privilege."

It was crystal clear. If they were to advance this litigation-based defense, that would be advice of counsel and waive privilege.

On November 18th, Align wrote us pursuant to the order. Your Honor, and Align said it "elects not to waive the attorney-client privilege" and it "will not raise an advice of counsel defense."

And so we thought this was crystal clear and we wrote them right back just to confirm. And so a week later, we wrote back and said, we read your letter and we read the order, and our understanding is you will no longer assert this litigation-based justification for the termination of 3Shape because you

decided you wouldn't put legal advice at issue and waive privilege.

And importantly, Your Honor, we said, if you agree with us, let us know by December 1.

We picked that date, Your Honor, because December 1 was the day before Joe Hogan's deposition. Joe Hogan was the CEO of Align. If they were going to waive privilege, we needed to probe it at that deposition.

They did not. In fact, they said nothing in response to this letter for quite sometime.

Then, Your Honor, at the close of fact discovery, it became clear that Align was trying to do an end run around Judge Gilliland's order.

The first thing they did, Your Honor, was they tried to take a deposition of 3Shape out of time. Right? And in the dispute chart seeking to take that deposition late, Align said, quote, it intends to prove at trial that, inter alia, it needed to terminate interoperability with 3Shape to preserve defenses before the ITC.

Basically saying we are going to pursue the very same justification that Judge Gilliland said was advice of counsel would waive privilege. We're just going to try to back door it through 3Shape.

Judge Gilliland agreed again. If you look at the next slide, he asked: How is this not an end run around advice of counsel?

He ultimately denied motion to take leave of -- for -- to take the 3Shape deposition. We thought that was the end of it, Your Honor. But on January 22nd, we finally get a letter responding to my letter from two months earlier.

And in that letter at the end of January, this is a full month after the close of fact discovery, Align says, nope. You got it wrong. We've decided we are going to pursue this litigation-based justification. This will be relevant and without waiving privilege. Just defying the court order. And that's why we brought this motion.

In opposition to this motion, Your Honor, Align is trying to obfuscate. And I'm going to point right to some language in their opposition brief. They say: Align's business decision not to deal with an infringer does not implicate privilege. Right?

So they're trying to reframe it. Not as a legal decision, like Joe Hogan said under oath, like they said to the Court, like they argued to the Court. But now it's a pure business decision.

The problem with that -- and they

02:13 continue -- nevertheless they're continuing to pursue this. Their experts are continuing to pursue the litigation justification. But more importantly, not only have they never disclosed a business decision, it's clear that this business decision is just advice of counsel under another label.

They point in this brief that a comment Joe Hogan made in a prior deposition about some business people expressing the view that they ought to terminate 3Shape.

But let me show you what Joe Hogan says. This is -- this is very important to carefully look at what Joe Hogan said under oath. He said: I didn't want to terminate the agreement but eventually I felt we had to.

The question then, Your Honor, to Joe Hogan was: And why did you feel you had to?

Then he got an instruction. A privilege instruction. And his lawyer says: I do not want you to talk about any communications that you had that caused you to come up with that belief.

So in terms of Joe Hogan now under oath, Your Honor, saying when I made the decision to terminate 3Shape, I felt I had to, when asked about why, they claimed privilege. That's not what you do

when it's a pure business decision.

Second, so he goes on.

Go to the next slide.

Joe Hogan then mentions the legal -- the business people's reaction. So he goes on. He says: So when I made a decision again to move forward with the IP charges, it was my assumption at that point I didn't have to cancel operability -- the operability piece and didn't want to.

Again, this directly refutes the so-called business decision not to deal with an infringer. Said he didn't want to.

He points out that there are emotions in the business. And some business people said, how can you take scans and also sue these guys. But then he responds in the next slide.

He says: My justification was, goodness, they're our customers, right? Forget 3Shape for a second. I didn't want to disenfranchise all the doctors. I didn't want to do it.

So basically he's saying -- by the way, this is all pretext, Your Honor. I showed you the internal document where Joe Hogan said the reason he wants to flood the market with iTeros is to take choice away from doctors. But this is the sword and shield

that Align wants to do in front of the jury.

But Joe Hogan said, I didn't want to do it.

Then -- and this is the critical part, Your Honor. Then, other information was supplied to me that convinced me it was a binary decision, that I didn't have the optionality to maintain the interoperability relationship with 3Shape. Right? So he's saying, I rejected any business decision. Information was supplied to me that said I didn't have a choice.

And then this is a key. This is the sword and shield.

If you go to the next slide.

Mr. Hogan was asked: And who supplied you with that information that told you it was a binary decision?

And the answer -- I'm sorry, the lawyer interjected and said, I'm going to instruct you not to answer on the grounds of the attorney-client privilege.

Did the parties that supplied you with that information give you the reasons?

I'm going to instruct you not to answer.

And so there's no discovery. This is a classic sword/shield, Your Honor. This is exactly what

Judge Gilliland wanted to avoid. This is exactly why Judge Gilliland said, if you're going to advance this defense, this 3Shape litigation defense, you need to notify them right away so that there can be discovery.

Now, we are disadvantaged because we were not able to take discovery into that attorney-client privilege. Perhaps Joe Hogan said to the lawyers, come up with some rationale so I can say I was required by law.

Regardless, Judge Gilliland recognized advancing this argument would be tantamount to putting advice of counsel at issue and waive privilege. If Align did not agree with that determination as a matter of privilege law or antitrust law, it should have objected to the decision and brought it to Your Honor. It did not. So that decision stands.

What Align cannot do now is to try to back door the same sword/shield in by calling it a business decision, a business decision that was never disclosed in fact discovery and a business decision that Joe Hogan says he rejected. Joe Hogan says the only reason he terminated is because he felt he had to, because he was provided legal advice.

They cannot now go and make another argument at trial. They should be foreclosed. That's

what Judge Gilliland intended and we respectfully request, Your Honor, that's what you should enforce. They should be foreclosed. We were deprived of discovery of this attorney-client communications and they should be foreclosed from trying to advance that sword/shield argument at trial.

Unless you have any questions, I'll rest.

THE COURT: Okay. I'll hear a response.

MR. DURST: Good afternoon, Your Honor. Tim Durst for Align Technologies.

Your Honor, there are a couple of preliminary matters that would -- that might be useful for the Court to be focused on as we discuss this request for sanctions against our client.

First, this issue arises only if our motion for summary judgment is denied. This issue is only an antitrust issue and it may be eliminated from the case altogether by Your Honor's ruling on our motion for summary judgment.

The second is, Your Honor, this issue may be eliminated entirely by the Court's ruling on our Motion in Limine No. 1.

The facts related to 3Shape and the decision to terminate interoperability, Your Honor, all arise prior to the relevant time frame for the

antitrust claims. These facts arise in 2018 which is well outside, Your Honor, the damages time frame for antitrust. And we have argued in our first motion in limine that it is irrelevant and prejudicial and should be excluded for those reasons.

The third reason, Your Honor, that this is perhaps easily disposed of by other matters pending or by other issues other than the substance of their sanctions motion, is Judge Gilliland was clear. He was clear with ClearCorrect that if they wanted to take issue with our position on attorney-client privilege, they needed to do so by November 21 of 2025. ClearCorrect did not do so. They missed that deadline and only raised this issue a number of months later.

That's important, Your Honor, because part of -- really the core of ClearCorrect's argument here is not to focus on the language of Judge Gilliland's order but rather to mischaracterize Judge Gilliland's order and then argue that we didn't comply -- we did not comply with the way they've characterized it.

It is a classic strawman argument, Your Honor, where they set up a strawman by saying, this is what Judge Gilliland really meant, even though it's not what he said, and Align has not complied with that

02:21 characterization.

02:21 And one of the things they admitted, and
02:21 it was noticeably absent from Mr. Ford's presentation,
02:21 Your Honor, was that Judge Gilliland set that deadline
02:21 and ClearCorrect did not comply.

02:21 Even the letter that they complain that
02:21 we didn't respond to in a timely fashion, Your Honor,
02:21 that letter from Mr. Ford came days, four days, I
02:21 believe, after Judge Gilliland's deadline for them to
02:21 raise this issue. So this motion can be denied at its
02:21 outset because it has been filed too late.

02:21 Now, this is, Your Honor, fundamentally a
02:21 motion for sanctions. It's a Rule 37 motion for
02:21 sanctions. And sanctions should be denied here, Your
02:21 Honor, because we complied with Judge Gilliland's
02:21 order. Judge Gilliland ordered that we respond by
02:21 November 18th. We did so. He also said to
02:21 ClearCorrect, if you don't like their response, bring
02:21 it back to me by November 21. They did not do that.

02:22 Your Honor, Align has no intention -- and
02:22 we've made this clear in our briefing, we have no
02:22 intention of relying on advice of counsel on these
02:22 issues at trial. We are relying or we will be relying,
02:22 if this claim survives and it avoids the motion in
02:22 limine, we will be relying on the fact that there was

patent litigation. Align has no interest and no duty to do business with a patent infringer.

Align had sued 3Shape for patent infringement at the time of the termination. And the business decision to terminate interoperability turned at least in significant part, Your Honor, on the fact that we believe 3Shape was infringing our patents.

The case law in this area, Your Honor, about injection of legal advice is very clear. There has to be -- in order for there to be waiver, there has to be an affirmative injection of what was the legal advice given?

Here, was there legal advice? Yes. Are we going to rely on that legal advice at trial? No. We will be pointing only to the objective fact that we don't do business with infringers, and we had sued them for patent infringement. There is no sword and shield here. We are not trying to rely on our business advice. We are pointing to the basis -- pointing as a basis to the fact of patent infringement litigation.

And case law says absent an express and explicit injection and reliance, then there is no waiver.

So, Your Honor, again, this is -- the starting point for this analysis is Judge Gilliland's

order about what we were to do. We were required by Judge Gilliland to: Notify ClearCorrect by November 18th whether, with respect to the decision to terminate its interoperability agreement with 3Shape, Align will rely on advice of counsel by presenting evidence that Align's decision to terminate the agreement was motivated by legal considerations related to the patent litigation.

We're not going to do that, Your Honor. We are not going to rely on advice of counsel by presenting evidence that Align's decision to terminate the agreement was motivated by legal considerations. Full stop. We're not going to do that. And we told them that way back in November and they've sat on this issue until now to bring it to Your Honor.

Your Honor, now, this is at its core a sanctions motion and they are asking the Court to sanction us. The Fifth Circuit sets out very clear standards on what circumstance -- what circumstances warrant sanctions, and they have a four -- the Fifth Circuit expresses a four-factor test.

One, was there compliance? As I believe we have demonstrated in our papers and here this afternoon, Your Honor, we complied. We complied with the letter and the spirit of Judge Gilliland's order.

There is no flagrant disregard of the Court's order.

At a minimum there can be no serious doubt that we were attempting to comply, even if somehow through some lens our compliance came up short. But we believe, Your Honor, and I think we did, we fully and fairly complied with Judge Gilliland's order.

Second, there is no unfair prejudice to ClearCorrect. As you've seen, this issue came up a number of times in discovery. They've known of this issue for nine years, Your Honor. We issued a press release when we terminated this interoperability. And we were -- pointed then to the fact of patent infringement litigation. And ClearCorrect's been on notice of that for nine years.

They asked us discovery about it. We responded to discovery. Some of which was assertion of privilege, but we responded to discovery about the facts and circumstances surrounding this.

And ClearCorrect is ready to respond, Your Honor. So they have not been prejudiced, they've not been caught flat footed, and they in fact have designated an expert to bring testimony at trial on this issue if it comes before the jury.

That's the second factor. There is no unfair prejudice.

02:26 And the third factor is --

02:26 THE COURT: Have they -- Mr. Durst, have they provided a report to you from that expert?

02:26 MR. DURST: They have.

02:26 THE COURT: Okay. Thank you.

02:26 MR. DURST: The third factor, Your Honor, is that can the Court correct any prejudice. Because there was no prejudice here, there is no need for correction.

02:26 And then the fourth factor, and this is important, Your Honor, is the importance of this evidence. If these claims survive summary judgment and if this old, out of period activity actually comes into evidence at trial, Align needs to be able to tell the jury that we had a justification for what we did with respect to 3Shape.

02:27 And the law on that, Your Honor, says that, as we've argued, puts us in a position where the fact that we had sued 3Shape for patent infringement litigation, that can be a legitimate business justification for our actions which is a defense to the antitrust claim.

02:27 And it's not just advocacy that brings us to the point that this is important evidence and that that is in fact a viable defense. Your Honor, this

issue's actually already been ruled upon in related litigation.

In the Northern District of California, Judge Chhabria granted us summary judgment that terminating because of patent infringement was a legitimate business judgment. Legitimate business reason for what we did that was alleged to violate antitrust laws.

So, Your Honor, none of the Fifth Circuit's four factors, compliance, unfair prejudice, a need to correct prejudice, or importance of the evidence, none of those factor in support of the motion for sanctions. And, Your Honor, we request that the Court deny the motion for sanctions filed by ClearCorrect.

MR. FORD: Your Honor, may I just respond for a few minutes to some of those points?

THE COURT: Of course.

MR. FORD: So first, interesting that Mr. Durst did not address the testimony from Mr. Hogan. When Mr. Hogan testified under oath that it wasn't a business decision. That it was only because of legal advice. He's making -- this is pretext and it's clear. They're trying to advance an argument that their own CEO foreclosed under oath.

Second, as to the argument advanced in the other case, that they thought was critical, the argument advanced in the other case was not that they terminated 3Shape because they didn't want to deal with an infringer. It was because they felt they needed to in order to avoid defenses. They were advised by legal advice.

In that case, Your Honor, they committed not to presenting subjective evidence of that, that they would only do that through objective evidence. Right? In that case, they did not advance this newly framed it was just a business decision not to deal with an infringer.

Second, they say we've been on notice for a while. Every single time Align described this defense in discovery, they described it in terms of the legal considerations. That they felt they needed to. That they felt they needed to do so to avoid waiver. Not --

THE COURT: Could you give me just one second? I'll be right back.

(Pause in proceedings.)

THE COURT: Okay. If this screws you all up too much, and it might screw me up worse than you all, but before -- I'm good with the arguments I've

heard so far. But Mr. Durst said that the resolution of the motion for summary judgment might obviate the need to rule on this or it might impact it.

So why don't we -- if you're able to -- if we're able to jump to that -- I know -- I think it was farther down the road. But if I can find it -- I think I -- I'll make sure I'm on the right motion. I have -- it's Docket No. 358, the motion for summary judgment, defendants -- let's take that up and argue that and then I'll decide -- I'll rule on that and we'll take up the first motion that y'all have already argued.

MR. TUBACH: Good afternoon, Your Honor. This is Mike Tubach. I represent Align Technology.

THE COURT: Welcome back.

MR. TUBACH: Thank you, sir. And I'll be -- I'll be arguing the motion for summary judgment here.

THE COURT: Okay.

MR. TUBACH: The motion for summary judgment is based on -- it's challenging ClearCorrect and Straumann's claim that Align is a monopolist who engaged in anticompetitive conduct.

Now, to be clear, Straumann did not apparently decide that we were monopolists until after

we had sued them for patent infringement.

The fact is, in the last ten years, the clear aligner business has seen huge growth, many new entrants, lots of product improvements, and perhaps most importantly, lower prices. Those are the hallmarks of a thriving business. And the exact opposite of what you would expect to see if Align were a monopolist engaging in anticompetitive behavior.

The fact is, notwithstanding the dynamic nature of this industry, ClearCorrect has seen its sales decrease substantially since 2020 while its competitors have grown. ClearCorrect is a failing business using our intellectual property, and now they're trying to pin those problems on Align.

As we have shown on our papers, Straumann's antitrust claim is basically a hodgepodge of complaints about how Align runs its business. They complain about our discount programs. They complain about the number of clicks it takes to order a competing aligner from our scanners. They even complain we won't take scans from other companies to make our own product. It sort of reads almost like a bad Yelp review. But nowhere in those lengthy allegations is there an actual antitrust violation.

So let's start, and that's what I want to

02:34 walk the Court through now.

02:34 In order to make out a Section 2 claim, Straumann has to prove both monopoly power in a relevant market and the willful acquisition or maintenance of that power by exclusionary conduct.

02:34 And the same goes for attempted monopolization, they have to show predatory or exclusionary conduct, a specific intent to monopolize, and a dangerous probability that they would succeed.

02:34 Now, in this analysis, the Fifth Circuit and other courts have said you have to take each conduct, each type of conduct and analyze it separately under settled principles of antitrust law. And so when you do that, you have to decide does each conduct that they've alleged violate the antitrust laws? Is it anticompetitive?

02:35 As Judge Rodriguez said in the Doctors Hospital of Laredo case: Adding up instances of such lawful conduct cannot total unlawful conduct. Or maybe put more simply, zero plus zero plus zero equals zero.

02:35 So what are the claims that we have here?

02:35 The four claims that Straumann has brought here relate to our discount loyalty programs, alleged exclusivity provisions, what I'll call scanner interoperability, and then finally a Walker process

claim.

Now, each of these, they have claimed, are exclusive dealing. It's an exclusive dealing claim. To make out an exclusive dealing claim, they have to prove two things. Not surprisingly, they generally have to prove that there's an agreement to deal exclusively.

The second thing they have to show is substantial foreclosure. Substantial foreclosure. And this is true both for the monopolization claim and for the attempted monopolization claim.

Now, they essentially concede that there are no meaningful actual exclusive contracts here that substantially foreclose any part of the market. What they're saying instead is that some of the conduct that Align has engaged in to run its business amounts to what they call de facto exclusive dealing.

And here, where those -- those are the first three buckets there. And then Walker process relates to the patent claim.

Let's talk first about the discount and loyalty programs. I think I'd start with some -- what I think is maybe low-hanging fruit here.

They argue that our discount programs are somehow exclusive. I -- honestly, I just don't

understand this argument. This is a discount program like you get when you go to Starbucks. Or if you fly American Airlines. The more you -- the more you buy a product, the more you get a discount.

These are entirely voluntary. Nobody's required to sign up to get these discounts. And doctors can buy the aligners or not buy the aligners. The more they buy, the more discounts they get. The fewer they buy, the lower the discount is.

This is absolutely commonplace in the economy. Starbucks does it, airlines do it, hotels do it. Straumann does it.

This kind of discount pricing is the exact opposite of an antitrust violation. It is competition by lowering price. The great irony here is that Straumann is literally complaining that our prices are too low.

Now, the only way that Straumann could actually make out a claim for low prices is if they could argue that we were selling our product below cost. That's called predatory pricing. And the Supreme Court has long held that as long as you're selling above cost, there is no liability for discounting for low prices.

But Straumann doesn't even argue that

we're selling below cost. That entire theory doesn't apply here.

So what's their argument? Their argument is that the structure of the discount, the structure of the discount makes it de facto exclusive. And that structure is that every six months, you reset whether you get the discount.

But that makes no sense. This is just like an airline. When you -- however much you fly in one year, the next year determines what your level is. That'll determine all the goodies you get and better pricing and everything else. That's -- it's commonplace.

Now, they can't really argue with that because it's so common. So instead, what they say is, well, there may be instances where a doctor is just about to get to a next tier and so, therefore, he might not buy a ClearCorrect aligner because he's trying to get to that next tier, that next Align tier discount.

But they have no evidence of this. It's just pure speculation. Their expert talked about it for a few paragraphs but didn't offer any data on it. Absolutely nothing. This is not a motion to dismiss here, we're at summary judgment. And they've offered no evidence of this.

And moreover, even if there is a doctor, or two or three who said, you know, this one additional sale, I'm going to give to Align because I want to get to that next tier, that's not a substantial foreclosure of the market. That's a lost sale. So they've made no showing at all that the discounts are anything other than a pure competition on price.

Now, they cite only one case in their brief that they say shows that they should win here. That's the Surescripts case. But the case -- a district court case for the Northern District of Illinois and that involved actual exclusivity where they agreed to buy all of what they were getting from Surescripts. And most importantly, if they decided to buy anybody else's, there was a clawback provision saying they had to pay back all of the discounts.

Nothing like that is here. Absolutely nothing. So this is just pure discounts like you would find anywhere. Absolutely nothing anticompetitive or foreclosing about it. And that part of the claim should be dismissed.

What I want to also focus on here is they have argued that every sale made pursuant to these discounts is a foreclosed sale. That's just wrong as a matter of law. Foreclosure means they never even had a

chance to get in because the door was locked.

Here, there is no such claim that they were locked out of competing for those sales. They just lost those sales.

And the best case I can cite for that, Your Honor, is Eisai out of the Third Circuit. That's 821 F.3d 394. And there, the expert made exactly the same claim. There was a discount program and the expert there said, well, every sale that went to the defendant was a foreclosed sale. And that counts in foreclosure analysis.

And the Court said, no. That's not how foreclosure works. Just because you lost the sale doesn't mean it's a foreclosed sale. They rejected the analysis. They granted summary judgment in favor of the defendant.

So the discount and loyalty programs, that just goes absolutely nowhere, Your Honor.

The next thing they complain about is that Align has certain exclusivity provisions -- what they call exclusivity provisions. And the one that they focus on most is one that tells doctors, you should not divert patients who are prospective Invisalign patients to other companies.

We don't think that's exclusive at all.

That's just saying they come and say they want Invisalign, don't try to sell them an inferior product and maybe not even tell them about it.

But we don't need to win that argument to win this part of the motion. Because there's no foreclosure. The only foreclosure number they offer is one that is below 20 percent. And I'll not say the number, but the Court has that slide. Below 20 percent.

The law's pretty clear that you're under 40 percent, there's no foreclosure. And here, they're not even above 20.

You can look at the Kidd case and Bepco case cited in our brief. They both say that, you know, discounts of 20 percent is virtual safe harbor. 21.5 and 18.5 percent, far short of what's needed to have this foreclosure.

Now, Align offers other contracts also. For example, you can -- if you don't want to just buy your iTero, your scanner from us outright, you could buy it outright or you can go finance it with a bank. But if you want -- if you want to get a financing program with us, then for that 12-month period, then you -- some contracts say you can only sell Invisalign.

They can't even argue that that's

foreclosure because it's very short and they've done absolutely no analysis of the percent of the foreclosure over the entire period of the claim that they're arguing. None of those provisions that actually have an exclusivity clause in them are in any way foreclosing any meaningful part of the market. And most importantly, their expert doesn't have any analysis saying otherwise. So it's undisputed.

So as I said, the only claim -- the only data they show at all to show foreclosure for these alleged exclusivity provisions, that are really the anti bait and switch provisions, is this number under 20 percent. And so they can't make out a claim for those alleged exclusivity provisions.

And just to be clear, they're perfectly lawful unless they foreclose a substantial part of the market.

Let me talk about scanner interoperability. Here, what they're claiming is really two different things. First, that it's -- that we won't accept scans from other people's scanners to build our own product. That's what we're calling inbound.

Now, they also complain that we made it too difficult, there are too many clicks to take a scan

from our scanner and buy somebody else's aligners.

And we think, just as a matter of basic principle, we don't have a duty to deal with other businesses. We can decide who we want to do business with. If we don't want to take other people's scanners, that's our business. Other people's scans, that's our business. And if we don't want to design our product to help other people sell their scanners, that's our business. We have no duty to deal with them. We have no duty to deal with ClearCorrect at all.

We also say even if we take their framing of it, well, these are all exclusive dealings, Straumann still loses.

Let's talk about inbound interoperability. So this is one where some other scanner has scanned a patient, and ClearCorrect is complaining, Straumann's complaining that they can't send that scan to us to make Invisalign. We have absolutely no duty to accept somebody else's scans. This is our business. We can say we'll accept scans from our scanner and not from any else's.

In fact, it's not really even exclusive. You can still do what's called PVS, the goop, that -- where you can make a physical impression and send it

in. We still allow that.

The only way that they could try to attach liability for this inbound interoperability is if they could show this very limited exception under a Supreme Court case called Aspen Skiing, where there's a prior course of dealing and then you cut it off and you lose money by cutting it off in the short term. And Straumann hasn't even tried to make that showing.

So that very limited exception to the basic rule that you would expect, which is that businesses get to decide who they're going to do business with does not apply here.

And then finally, it's a very odd argument. What they're saying is that here this doctor has done this scan. It's, okay. Now, who can I send this scan to? And we say, well, if it didn't come from an iTero, we don't want it because we want to make sure we're getting the scan from a scanner that we know and trust.

ClearCorrect has suffered no injury if we won't take that scan. Exactly the opposite, if anything, it enhances their chance of making a sale. So there's absolutely no injury that they've suffered whatsoever on inbound --

THE COURT: Explain that to me. Why does

it enhance their --

MR. TUBACH: Because if the doctor's trying to decide who he's going to buy an aligner from -- who he's going to buy the aligners from and we're saying, well, you can't buy it from us, he's more likely to turn to them.

He might turn to somebody else, but if we take our sales out of the running, and they are, you know, pick a number, I'll just randomly say there are five, six, seven, eight aligner companies out there and we say, no. Well, that increases his -- that increases their chances of making that sale.

THE COURT: Okay.

MR. TUBACH: So that's inbound. Let's talk about outbound.

Again, as I've mentioned before, we have no duty to make it easy for our product to sell somebody else's product. We generally have no duty to deal with competitors.

And here, they make an exclusivity dealing argument. But to be clear, there's no exclusivity agreement here. Doctors can use the scanners to order companies' aligners. That is what makes this case fundamentally different than the other cases on which Straumann relies. In particular, Google

and Microsoft.

There, there were actually contracts with third parties that were exclusivity contracts. Google said, you have to -- to various phone makers, for example, you have to preload Google Search on the phone. Exclusively. Nobody else's, just Google.

And the Microsoft case, they said you have to preload Microsoft Internet Explorer to the various computer manufacturers.

And then the question is, what was the consequences of those exclusive contracts? We don't have any exclusive contracts here.

What they're claiming is that -- it's a little convoluted. Honestly. They spend many pages talking about how we tied Invisalign sales to purchases of the iTero. But then you get to end of those six or seven pages, and they say, well, actually we're not making a tying claim. No tying claim at all. Nor could they.

Because in order to make a tying claim, they have to show that we use the tying product, which is here Invisalign, to somehow harm the tied product, which is the scanner market. They have not even attempted to show that there's any harm in the tied market. And so they don't have a tying claim. It's a

complete red herring, that argument.

What they're really saying is that it just takes too many clicks from when you scan on an iTero to buy a competing aligner. But the fact is the iTero is used to order competing aligners.

And here, we've redacted the specific numbers so we don't have an issue about sealing, but the Court has the unredacted version and we've sent that to opposing counsel also.

The -- it's clear that the iTero is used to order competing scanners and quite a bit, including for ClearCorrect aligners. And so there is no foreclosure. Their only estimate of foreclosure is wrong as a matter of law. And it's like -- it's what I said before, a fore -- a lost sale is not a foreclosed sale.

Here, what they're saying is foreclosure is every sale, every sale that went to Align. And that's not how you calculate foreclosure. Foreclosure is were you -- were you barred from making a sale in some way. And we know that's not the case because we know the iTero is -- we know the iTero is used to buy competing aligners. So there isn't actually foreclosure at all.

And so their only estimate of foreclosure

is this everything that went to Align is a foreclosed sale. That's barred by the Eisai case that I cited and discussed earlier.

I want to just ask, does the Court have those slides with the actual numbers in them? I think we e-mailed them.

THE COURT: Yes. My clerks do. Yeah.

MR. TUBACH: Wonderful. Thank you very much, Your Honor.

So their only argument of foreclosure is just wrong as a matter of law.

So for their entirety of what they're arguing truly about in the antitrust sphere, there are no exclusivity provisions that matter. We don't have a duty. They haven't shown exclusivity. And they certainly haven't shown the kind of foreclosure they have to show in order to make out an antitrust claim.

And the last thing that they argue is this Walker process argument, that we -- that we procured the patent by fraud. And I'm sure the Court is quite aware of those kinds of allegations.

And here, with the Court's permission, because it's related to the patents, we're going to have a lawyer from Morrison & Foerster argue that because, as I'm sure the Court is well aware, the

Walker process counterclaim rises and falls with the inequitable conduct defense.

And so with the Court's permission, I will turn this over to Mr. Hung from Morrison & Foerster unless the Court has questions about any of the points that I've made today.

THE COURT: I will on rebuttal, but I don't now.

MR. TUBACH: Thank you very much, Your Honor.

MR. HUNG: If I could take control of the slides.

Your Honor, Richard Hung of Morrison & Foerster. Good afternoon.

THE COURT: Welcome.

MR. HUNG: I'm sure Your Honor is very familiar with inequitable conduct. Inequitable conduct really focuses on the --

THE COURT: Not personally, I'm not.

(Laughter.)

MR. HUNG: Well, Your Honor, you're familiar with the doctrine and the Therasense --

THE COURT: I am. I am.

MR. HUNG: -- case from way back in 2011. And you remember that the case was groundbreaking

because Judge Rader talked about the scourge and the plague of inequitable conduct allegations and how they needed to reset the standard for this.

And so in the en banc decision, they said you have to have both elements, intent and materiality, separately by clear and convincing evidence. So there's no sliding scale. You can't point to just materiality and say the intent exists or vice verse.

Here, we have a problem with both elements, intent and materiality. If we look at what their main claim is, their main claim is that the Li inventor of the materials patents, Chunhua Li, Dr. Li, that she lied in declarations -- in a declaration -- in the 2019 declaration to the Patent Office. And their basic argument is that she knew that Zendura existed, she amended her claims, and the declaration that she submitted in support is basically a lie.

They're trying to benefit from a narrow exception in the Therasense case that says for an unmistakably false declaration, they can, in their view, forego but-for materiality.

This isn't an unmistakably false case. We know that because unmistakably false case involved cases like the Intellect Wireless case that they cite in which no one's disputing that there were lies in the

declaration.

Here, our expert Maureen Reitman explains at length why Dr. Li told the truth, why her declaration was accurate, and why the positions that she took were consistent with the data that she had done -- the experiments that she and her co-inventor had done.

Moving into but-for, the issue is, well, can they show any but-for materiality? And simply can't. The reason is that Align submitted this declaration by Dr. Li in connection with then pending claims, and the Patent Office responded by rejecting the claims.

And you see this right here at Docket 358, Document 8:249. There's an Office Action in which they say they're just rejecting all the claims relating to the declaration that Dr. Li submitted.

And so fast-forward, Align amends the claims, narrows them, and then again, the Patent Office rejects the claims yet again. Finds those claims not patentable.

And so Align amends the claims yet again to arrive at the current claims that we have. The claims require three or more polymer layers, a hard polymer layer, a soft polymer layer with very specific

characteristics.

It is only then that the Patent Office allows the claims. And when you see why the Patent Office allows the claims, the notice of allowance, they say, look. The main prior art reference that we've been relying upon doesn't teach the limitations that you've amended.

So the Patent Office wasn't relying upon the declaration. There is no but-for materiality. The main prior art reference just didn't disclose the claims as then twice amended after that declaration.

Straumann's going to come and say, well, no. In the notice of allowability, you will see that there's a reference to finding the applicant's affidavit persuasive.

But if you look carefully at what the Patent Office actually said, first, they say it's also persuasive. Meaning there's no but-for. They'd already determined that the claims were patentable.

And secondly, if you look at what they're actually pointing to, they point to statements that Straumann is not contesting are false. They're pointing to statements in the declaration where they say this invention is great because in clinical studies, it really improves teeth movement, stress

relaxation, things like that.

And in fact, those are true. That is true. Align conducted a clinical study and the results are discussed in the specification. It was very good at improving the movement of teeth over the prior EX30 product. So there's just no but-for materiality. The Patent Office rejected the amend -- even the amended claims before finally allowing them.

That brings us to the issue of intent, Your Honor. As you know from the Therasense case, intent has to be the single most reasonable inference. Also in Therasense, there's no sliding scale. You can't rely upon the evidence relating to materiality to show intent. You just can't say because there's -- it references material, the person intended to deceive. Or the opposite. It has to be the single most reasonable inference that you can find from the evidence.

We also know from the Exergen case that you have to identify a who. So you can't just say Align's a bad actor. You have to point to someone at Align specifically that is a bad person, that committed fraud on the Patent Office. And in this case, that person they're pointing to is Dr. Li.

But then you look at the evidence that

they offer to support. In support, their first four exhibits don't involve Dr. Li at all. They point to a press release announcing the accused product in this case. They point to three e-mails between Joe Hogan and Srini Kaza and Raj Pudipeddi, two other individuals who aren't Dr. Li and who also aren't inventors on the patent.

The only thing that they point to relating to Dr. Li is the fact that she was aware of Zendura FLX itself. They say that it's wrong because she was trying to get claims to cover Zendura FLX, therefore, you can assume inequitable conduct. You can assume intent.

And that doesn't work because, again, intent must be the single most reasonable inference. And when you look in this case, Kingsdown Medical, it's a pretty old case but it's still good law. It says that it's okay to amend claims to cover the accused infringer's product. There's nothing -- absolutely nothing wrong with that. The case makes very clear the fact that someone wants to do that is irrelevant and cannot of itself evidence deceitful intent.

Which then brings us to the other things that they try and throw up to try and justify intent.

The only other things they point to is

they say, hey. There were other pending applications and Align did not specifically disclose those to the Patent Office as relating to rejections of other applications, ergo, Dr. Li is a bad person.

What they're missing is, number one, they concede this. This is from Page 33 of their own brief, their opposition brief at Note 20. And they say: To be sure, Align listed on an IDS the two pending applications.

So it's undisputed that the Patent Office actually had these applications and could have looked them up themselves if they wanted to to find those rejections that they say were withheld.

But more importantly, there is zero evidence in the record, there's zero testimony that Dr. Li knew anything about any of these things, that she was involved in the submission of these specific IDSes or intended to conceal to withhold.

Therasense also again is very clear on this, if you're going to argue that someone withheld something, you have to show that that person, the who, in this case Dr. Li, knew of the reference, knew it was material, and made a deliberate decision to withhold it.

If you look at their brief, Your Honor,

you'll see that there is a single cite, just one cite in the entire brief to testimony by Dr. Li. In fact, it's only eight lines. And it's the following:

They asked her: Did you review testing results before you prepared your declaration?

She says: Yeah. I normally do that.

And is that what you did?

She says: Yes.

This is the sum total of the testimony that they have on intent from Dr. Li, the lead inventor, the person that they're accusing of inequitable conduct and intent, intent to deceive. Instead, they're pointing to people, Joe Hogan, Raj Pudipeddi, Srini Kaza, all of these other individuals that have nothing to do with Dr. Li.

And, therefore, there's just a -- simply an absence of evidence on intent. Much less intent that goes to the single most reasonable inference for such a powerful, what Judge Rader calls an atomic bomb of trying to kill all these patents based on inequitable conduct.

Thank you, Your Honor.

THE COURT: A reply?

MR. MUELLER: Yes, Your Honor. Joe Mueller on behalf of ClearCorrect and the other

defendants. Good to see Your Honor.

THE COURT: Good to see you again.

MR. MUELLER: And before I jump in, Your Honor, if I could just give a minute or so on the big picture and then take it down to the level of the antitrust motion and more specifically the Walker process issues that Mr. Hung just concluded with.

And then we'll also address and my colleague Mr. Ford will take on some of the legal arguments on the competition issues.

So, Your Honor, at a high level, this is a case between competitors. The plaintiff Align is the dominant supplier of clear aligners.

And, Your Honor, I'm not going to pull it up because there's some confidential information, but I don't know if you have Slide 4 of our deck in front of you. It has some market share information on a diagram. And I won't -- again, I won't pull it up because it includes some third-party confidential information that the respective client representatives are not privy to.

But this is a chart prepared by our economic expert for this case, Dr. Perryman. And as you can see, Your Honor, in the unredacted version of this, the share held by the Invisalign product supplied

by the plaintiff Align is by far and away the dominant product in this market.

And this type of product, clear aligners, relate to other technologies that are used in tandem with clear aligners. And in particular, scanners are used to scan patients' mouths to get, you know, imaging of the teeth and the topography of the teeth, that in turn allows for planning or developing a plan for the use of these clear aligners in a patient's mouth.

So we have scanners, and you've already heard about those today, that are used to create plans for the application of these clear aligners. And Align, again, the plaintiff, is the dominant supplier in this marketplace.

ClearCorrect, you can see towards the bottom, clustered with some of the other incipient competitors in this market. And this is a case that involves interlocking and overlapping intellectual property and competition claims.

And to make that a little bit more vivid, we prepared a Venn diagram of sorts. This is Slide 2 of our deck.

And if we could pull that up.

Here, Your Honor, we have the claims in the case or our best attempt to depict the claims in

the case. And I'll actually start on the right-hand side just to clear the brush here a bit.

There's two patents on the right-hand side, one in a triangle, one in a square. The '936 patent which relates to a particular type of scanner technology, and the '444 patent which relates to a particular type of treatment planning system.

Your Honor, you'll hear more about those later today in the context of the Section 101 summary judgment motion that Your Honor has asked to hear about today.

I'll just note that there's literally no damages claim being made at this point on those patents. There's been no damages expert opinion offered by the plaintiff in this case. We've actually sent multiple Octane letters asking Align to drop those patents. But for today, the issue is Section 101.

The core of the case, though, really is on the left-hand side. And here, we have the other patent claims, so the other patents in the case which relate to very particular types of configurations of the materials used within certain clear aligners.

We have Align's infringement claims. Of course we dispute those.

We have invalidity claims, including for

lack of written description and enablement. And in a bit, we'll discuss the written description issues.

And then relatedly, we have antitrust claims, a Walker process, as you just heard, and some inequitable conduct claims and defenses.

In addition to all of that -- so our position is the assertion of these patents is itself -- is itself a form of attempt to suppress competition from ClearCorrect. So part of the antitrust conduct at issue are the patent claims.

And early on today, you heard that there's been no complaint by ClearCorrect on these antitrust issues until this complaint was filed. Well, that's part of the complaint. Our complaint, from a competitive standpoint, is the assertion of having claims that we believe are based on patents procured by inequitable conduct and misleading statements to the Patent Office.

But that's not all. There's also marketplace conduct which works in tandem, again, with the improper patent claims to attempt to suppress competition from ClearCorrect.

This scanner lock-in dynamic, you've heard a bit about that in the context of the Rule 37 motion. And that's an attempt by Align to use its

scanner technology to lock in dentists for using Invisalign.

Restrictive contracts and an improper use of loyalty programs.

So that's the case, Your Honor, at a high level, is we have these material patent claim assertions, we have defenses to those claims, some of which we believe. Also -- we don't believe. Some of which also form predicates for our antitrust claims. And then we have marketplace conduct in addition to that.

We greatly appreciate -- and this is maybe getting ahead of the issues that we'll take up towards the end. But we greatly appreciate Your Honor's willingness to give us some additional trial time for the trial, and we are extremely confident that we can provide a full factual record on all these issues within the time that you are proposing to give us.

And we think that factual record is going to reveal --

THE COURT: I only did that because I have such enormous respect for the lawyers in this case. So.

MR. MUELLER: We really appreciate that.

THE COURT: It'll be my benefit to have the extra hours.

MR. MUELLER: We really appreciate it, Your Honor.

And we think it's going to be good for the case because it'll allow us to ventilate these issues which are factually intensive in a variety of ways and to provide Your Honor with the most robust record possible on both the patent and the antitrust issues.

So let me turn to the Walker process which not only is relevant to the Walker process per se, but I think will also give you a window into the factual story that brings us here today and that brings us to this case.

So if we go to Slide 5, I want to take you through a bit of a timeline here, Your Honor.

So in October of 2012, Align launched a version of its Invisalign product using something called SmartTrack materials. And these are the actual materials in the aligner. And it had what we call a -- and not just what we call, what they call a soft-hard-soft design, meaning the layer that would contact your gum and your cheek is soft, soft on the inside, soft on the outside. And there was a harder

layer of material within those two soft layers. Soft-hard-soft.

Now, over the next few years --

And if you go to the next slide, please, Slide 6.

-- between 2012 and 2017, Align secured patents on its soft-hard-soft design or aspects of its soft-hard-soft design. And we'll take you through some of the back-and-forth they had with the Patent Office in that time period, Your Honor, which is we think revealing as to what they actually had developed in that time period.

And I'll make one note here, Your Honor, which we'll pick up as we go through this. This is not a so-called predictable art in terms of developing these clear aligners. The particular research and development process required to develop an efficacious clear aligner is very complicated and frankly very unpredictable. And it takes a lot of experimentation to develop an efficacious clear aligner that will function for its purpose of straightening teeth that will be safe, that will be sufficiently comfortable, sufficiently stain resistant. This takes an enormous amount of work to develop these types of aligners.

And what Align had developed in this time

period was a soft-hard-soft design. And they had represented to the Patent Office that this soft-hard-soft design had, in their own words, "surprisingly superior properties."

And so if we go to Slide 7.

Here is a declaration from Align's lead inventor, Dr. Li, who you heard about from Mr. Hung. We understand that she will testify at trial in this case. And she stated in her declaration to the Patent Office that this is a field that involves technology that is not predictable, not predictable.

That's very relevant to the written description and also our enablement defenses, which we'll talk about a bit later today. Written description at least.

But it's also relevant here in terms of whether Dr. Li was forthcoming to the Patent Office years later.

But back in this time period, she was telling the Patent Office that the field is not predictable, and moreover, that: SmartTrack, the soft-hard-soft material, had surprisingly superior properties of modulus of elasticity, elongation, time stress-relaxation, durability, and thermoform ability.

And she also said: In the course of

developing the ST, SmartTrack, 30 material, we evaluated numerous multi-layer material combinations and determined that merely combining the materials into multiple layers was insufficient to improve performance.

And that's a critical point, Your Honor. The representation at that time, at that time was this is an unpredictable field. Merely coming up with a multi-layer composition of materials is not enough, is not enough, insufficient to improve performance. And that they had arrived at a particularly efficacious combination that had, in their own words, "surprisingly superior properties."

And based on these representations and then other materials that were submitted by Align, Align received multiple patents on this soft-hard-soft design.

Now, if you go back to the timeline and go to Slide 8, in November of 2018, Bay Materials, which is now today a subsidiary of defendant Straumann, launched another type of material that could be used in applications like clear aligners called Zendura FLX, Zendura FLX.

This had a very different design based on Bay Materials' own hard work and innovation over many

years. It had a hard-soft-hard configuration.

So again, if you think about this in a -- inside a patient's mouth, that means hard layer on the outside, hard layer on the inside, including in contact with the teeth and gums, and a softer layer in the interior. So it's the exact opposite of SmartTrack, which is soft-hard-soft. Zendura FLX was hard-soft-hard. Again, based on Bay Materials' own hard work and innovation. And at trial, we intend to show exactly how that was created and all of the work and ingenuity that went into it.

Now, when this hit the market, within days, within days Align was concerned.

And if we go to the next slide, please.

This is Joe Hogan. And as my colleague Mr. Ford mentioned earlier, CEO of Align. He's asking the head of research and development of Align, Srini Kaza, in November of 2018, that -- he asked the question, quote: Do you think we have any IP at all we could hit them with?

We could hit them with. Meaning Zendura FLX.

If we go to the next slide, please, Slide 10.

Here, in January of 2019, a couple months

later, second sentence from Mr. Hogan to, again, his head of R&D. He's "really worried about marginalizing ST," meaning his own product SmartTrack.

And so we have Align expressing concern about the effective competitive impact of this new product, Zendura FLX. Again, we understand Mr. Kaza will be a witness at trial as well.

If we go to the next slide, we can see his words.

He said: Unless we can stop with IP, they will keep coming. In other words, unless we can stop with IP, there's going to be competition. Competition for SmartTrack, and more importantly, competition for Invisalign which was using SmartTrack. And they were concerned about the possibility of clear aligners using this new material, Zendura FLX.

Now, Align studied Zendura FLX at a very detailed level and there's nothing wrong with reverse engineering, there's nothing wrong with studying your product out in the marketplace. But it speaks to their, here, their attentiveness to this new product.

And if we go to Slide 12.

Here, we have Dr. Li again. I'm sorry. Here, we have a reference to some work that Dr. Li had done in terms of -- we have the wrong one here.

Give me one moment, Your Honor.

Yeah. Go to the next slide, actually. I'm sorry.

So here, we have Align identifying Zendura FLX as a "big threat," a big threat to SmartTrack which is consistent with the e-mails between Mr. Hogan and Mr. Kaza in the months after this was released to the marketplace.

And if you look at the second highlighted bullet point, Your Honor, towards the bottom of this document here, it says: Bay Materials hard-soft-hard structure big threat to superiority of SmartTrack.

Again, Bay Materials, their Zendura FLX hard-soft-hard structure big threat to superiority of SmartTrack.

If we go to Slide 14.

Here, we have Mr. Hogan to various colleagues at Align. Here, Mr. Pudipeddi. And he said in the highlighted sentence here, Your Honor: I just wanted to get this asset off the market.

And so this is the backdrop for what happened next in the Patent Office. We have a very clear set of internal materials within Align demonstrating acute concern over the competitive impact of this new competitive product, the Zendura FLX

material, and clear aligners that could be based on that material.

Those are exactly the types of aligners that are accused of infringement in this case, Your Honor. The accused products are the types of aligners that Align was concerned about after Zendura FLX, the underlying material, was launched to the market.

And if we go back to the timeline in Slide 15.

Against that backdrop, Align began to amend pending claims in the patent family that had originally been filed on soft-hard-soft in an attempt to eliminate requirements that are idiosyncratic to soft-hard-soft.

Now, I want to be very clear about one point right now, Your Honor, which is we don't think that they succeeded in eliminating all of the requirements that would have been -- that would have needed to have been eliminated to have a viable infringement claim against Zendura FLX or against the ClearCorrect clear aligners that use that type of material in their aligners. There's no infringement and we very much intend to prove that at trial.

But our point for now or for present purposes is that there was a concerted effort to try to

get there to suppress competition from ClearCorrect.

And so the claims were amended. And if we go to Slide 16, we can see an example of this.

We see Align deleting language stating that a hard polymer layer was, quote, disposed between a first soft polymer layer and a second soft polymer layer. So they're deleting language about the hard layer being disposed between two soft layers. And the obvious reason for that was Zendura FLX is the opposite. Zendura FLX is hard-soft-hard, not soft-hard-soft.

And so they're trying to amend their claims to eliminate requirements that explicitly require that hard layers be disposed between soft layers.

If we go to Slide 17.

I showed you earlier the -- a portion of Dr. Li's declarations to the Patent Office back in the earlier original applications on soft-hard-soft. Well, Dr. Li at this point, as part of this new campaign to try to get broader claims that could be used against Zendura FLX and products like what's ultimately accused in this case, the ClearCorrect aligners, essentially red lined the declaration or changed it in very significant ways that made it false and misleading in

critical respects for the Patent Office.

So here, you can see some of the changes that were made, Your Honor. References, for example, to SmartTrack were eliminated. References to SmartTrack were eliminated. And there's language about testing which we'll come to shortly that were not true. And moreover, there was some language that was meant to demonstrate possession and -- for other issues that -- we also have enablement issues in this case, Your Honor, although they're not before you today.

But there's representations about Dr. Li, quote, expecting or I would expect the presence of only two such layers, i.e., a hard polymer layer and a soft polymer layer according to the current claims, would also provide beneficial and surprisingly superior properties.

Well, if you look at that language, it's very carefully written. I would expect that these two such layers would provide, as opposed to saying I have seen this done. I have testing to prove it. In fact, she didn't.

Years before she had told the Patent Office that this is an unpredictable field, and now she's making statements about what would be expected that are contrary to the representations of

unpredictability that had been made previously.

If we go to the next slide, Slide 18. I'm sorry. The next one, the timeline.

Here we go.

So we have the amendment of the pleading to try to eliminate the soft-hard-soft, and then at some point, the '613 patent, which is one of the patents that had pending claims when Align began this campaign to try to eliminate requirements that were idiosyncratic to soft-hard-soft, issued.

That conduct continued, however. It continued while Align pursued other patents, three more continuation patents based on amended claims like the ones that we just looked at.

And if we go to Slide 20.

After having mounted this campaign to try to get broader patent coverage to cover the hard-soft-hard aligners, a campaign that wasn't ultimately successful, we don't infringe, but was based on misrepresentations to the Patent Office, they had patents which they then unveiled in court and brought in this lawsuit.

So in April of 2024, Align sued ClearCorrect and its parent company for its use of Zendura FLX in its aligners.

Now, let me just pause here, Your Honor.

So under Therasense, the question isn't whether Align can offer some alternative explanation for what they told the Patent Office -- and we're going to go into some more detail on what was said to the Patent Office in this time period very shortly -- it's whether any reasonable juror can find that intent to deceive is the most reasonable inference.

I'll note, Your Honor, we, for our part, the defendants' part, are not suggesting that the jury would receive an inequitable conduct instruction. There's a dispute between the parties on that issue.

Jury would receive, however, an instruction on fraud --

THE COURT: They won't receive one.

MR. MUELLER: Right. We understood that Your Honor would be taking that up yourself.

THE COURT: Right.

MR. MUELLER: But the trial record would give you all of the factual information needed to fully assess whether or not the representations made to the Patent Office were in fact false, were in fact material to these patents that are at issue in this case being granted by the Patent Office.

And again, the issue for today is just

could any reasonable fact finder find that the pattern of facts suffices to meet the inequitable conduct standard, relatedly the fraud standard for the Walker process antitrust claim. So even though inequitable conduct would not go to the jury, the Walker process antitrust claim would. And the full trial record would help both the jury on the antitrust claims and Your Honor on the inequitable conduct claims.

And we think that full picture, the events that were occurring in the marketplace, the claim amendments based on the motivation expressed from the CEO on down to knock out a competitive upstart product, and the false declaration plainly would permit at least a reasonable fact finder from finding inequitable conduct and from finding the necessary predicate for a Walker process antitrust claim.

So if we go to Slide 22.

So again, it's legal background.

Slide 21, we'll just hit briefly.

As legal backdrop -- and this is in our briefing as well, Your Honor -- the Federal Circuit has held that the requisite intent can be proven by indirect and circumstantial evidence. The bar is unquestionably a significant bar, and as Mr. Hung said, the Therasense case set the bar.

THE COURT: I don't need -- I'm good on the law.

MR. MUELLER: Understood. So we'll go here to the particulars, Your Honor.

So we have here that Align and Dr. Li engaged in a pattern of lack of candor with the Patent Office.

And if you go to the next slide, please.

They misrepresented what materials had surprisingly superior properties beyond the soft-hard-soft configuration used in SmartTrack.

They misrepresented what materials met Align's own development criteria. Again, the unpredictability of this art relates to what will be efficacious for these types of products. And Align and other similar companies have development criteria that set milestones for what would be a truly efficacious composition of materials for this type of product. And there were misrepresentations made about which materials would meet those criteria.

And then finally, there's a failure to disclose all of the technical data that was relevant to the issues that were being considered by the Patent Office.

Go to the next slide, please.

So here, Dr. Li in the later declaration, not the earlier one from the applications that led to early patents on soft-hard-soft, rather than just saying that -- as she did in her original declaration that the resulting orthodontic appliances, meaning clear aligners, incorporating the SmartTrack material had surprisingly superior properties, they excised the language or Dr. Li excised the language of incorporating the SmartTrack material and said: We found that materials with both hard and soft polymer layers according to the current claims in orthodontic appliances had surprisingly superior properties.

So there's now representation being made that something greater than SmartTrack had these surprisingly superior properties. And that wasn't true.

In the course of discovery, we received access to the data that Align had collected on all of the materials with, quote, with both hard and soft polymer layers that it had tested. And our technical expert, who you would hear from at trial, Dr. Stephen Spiegelberg, he's a material scientist, reviewed that data and assessed whether this was correct, whether it was true or false in terms of the characterization being made to the Patent Office about the data.

And if we go to the next slide, please.

Dr. Spiegelberg concluded it was not true. He first identified the materials identified by Align that had both hard and soft polymer layers according to the current claims, using the infringement theory articulated in this case. There were 23 of them.

He then compared the properties of those 23 materials to the properties of an earlier available material called EX30. And he did this for the four metrics identified in Dr. Li's declaration. And those are elongation, time-stress relaxation, durability, and thermoform ability.

And he found that not a single material of those 23 outperformed the earlier EX30 material on those metrics, Dr. Li's own metrics. In fact, he found that many of those 23 materials were worse than EX30 with respect to one or more of those metrics. And there were even a few that were worse on every single metric for which we were provided data in discovery.

And this is a classic example, Your Honor, of a factually intensive issue that would benefit from a full trial record to demonstrate whether or not what was said to the Patent Office was in fact false.

If we go to the next slide, please.

Here's a chart --

THE COURT: If you could hold on one second. I'll be right back.

MR. MUELLER: Sure.

(Pause in proceedings.)

THE COURT: Okay. Here's what I'm going to do, Mr. Mueller. I typically handle inequitable conduct claims at the end of the trial and have the evidence put on while the jury is out waiting because it's just going to come before me.

Now, you have to remember whatever your time limit is on both sides. If you were to run out of time, let's say the minute before you did your closing arguments, then there will be no inequitable conduct. So you have to reserve time for it.

But that -- I'm going to sever out the inequitable conduct claim here and I'll take that up at the end of the trial. I will say -- I won't say it.

But is there anything else you wanted to say with respect to just the motion for summary judgment?

MR. MUELLER: No, Your Honor. That's helpful. And that's consistent with what we expected in terms of the trial structure.

I will note that much of this evidence will be relevant for the Walker process antitrust claim. It doesn't have the same -- exact same legal requirements as inequitable conduct, but some of the facts here will be relevant there as well.

THE COURT: No. And that's why I didn't interrupt y'all earlier and make the suggestion because I thought it might -- I thought there might be overlap there and it was worth me hearing all of it. So.

But I felt like you were kind of getting towards the end and I thought I would let you know now. So.

MR. MUELLER: That's very helpful, Your Honor.

So I'll just briefly take you through the facts because these facts are relevant to the antitrust claims as well. But just -- I can take you through it relatively quickly.

So here, we have, Your Honor, again, a chart from -- we have a chart from the other side's expert Dr. Reitman, and it lists the 23 materials identified by Dr. Spiegelberg. For each material, it includes the material's properties across the four metrics that I discussed a moment ago from Dr. Li's declaration.

One of the material's property exceeded the standard of care based on the preexisting EX30 material. Dr. Reitman colored the box green. So this is their expert's own coloring. And as you can see, there's not a single row that's all green, meaning there's not a single material that beat EX30 on each of the other four metrics that Dr. Li called out.

So again, this is an example of factually intensive evidence about the accuracy or inaccuracy of statements made to the Patent Office.

To take you through a couple additional ones, if we go to Slide 26? 28, I'm sorry.

Yeah. Here, we have, again, a portion from the declaration -- the later declaration of Dr. Li. Before learning of Zendura FLX, the competitive product that's at issue in this case, Dr. Li had told the Patent Office, if you read the original source material kind of behind the red lines: Only the material of the instant claims. That was the original language in the original declaration.

The claims at that time expressly required soft-hard-soft, which means in the original declaration, Dr. Li told the Patent Office that only soft-hard-soft met the criteria. But then in the red line, the changes were an attempt to broaden that out

to change it from the soft-hard-soft claims to something broader. And again, the underlying test data did not support that.

If we go to the next slide.

When we asked Align's -- one of Align's experts about this shift in Dr. Li's representation to the examiner, he conceded this "was unfortunate" and imprecise. And we think it was more than that, but again, this goes to the factual record that is going to be relevant to the antitrust claims, also relevant to inequitable conduct.

If we go to Slide 30.

Final point here, Your Honor. There was a failure to disclose relevant technical data and other examiner rejections. This was data that was available. She -- Dr. Li and a colleague, another inventor Ms. Chin, had compiled test results in a single Excel spreadsheet that could have been shared with the examiner. Dr. Li also did not disclose that she had submitted similar declarations in other patent applications filed in 2019 and 2020.

So we think the underlying data would have been relevant to the Patent Office's assessment of whether the new claims, the amended claims were based on accurate and full information, including the

characterizations of the surprisingly superior performance results and what types of materials those were based on.

And then finally, Your Honor, and this goes to the but-for materiality, which I won't spend too much time on. It is certainly something Your Honor can take up when you take up inequitable conduct after having a full record.

But there's no requirement that there be only one but-for materiality clause. And I think Mr. Hung may have been suggesting there needs to be a cause, and that here, there could be multiple causes of the claims issuing, including amendments that had been made by Align before the issuance of the final claims.

There's no such requirement. You can have two but-for causes for the same thing, and of course there's many examples in both the patent world and real life. I'm starting a fire with a match. The match is one but-for cause of the fire and my own striking of the match to light it is another but-for cause. They're both but-for causes. In the absence of either one of them, there would be no fire.

And here, in the absence of Dr. Li's statements, we believe these claims would not have issued.

And one way to see that, Your Honor, is if we go to Slide 34.

The examiner in the notice of allowance for the '613 patent noted that the examiner found persuasive the applicant's affidavit. That's the one that had been changed as compared to the one earlier, that was submitted years earlier. And notes explicitly the "unexpectedly positive results."

Well, those unexpectedly positive results were not true. And we believe that the full trial record will show that they are not true.

So again, Your Honor, we think this is a record that shows a lack of candor and false statements to the Patent Office. Part of this will be for Your Honor in the inequitable conduct request that we'll make to you on the full record. But then part of it is for the antitrust claim.

And at this point, Your Honor, I'll turn it over to Mr. Ford, who can explain how this ties in with that broader pattern of conduct that was designed to suppress competition from ClearCorrect. It includes this, this is part of it, the attempt to get IP claims to stop -- to stop the new product, as we saw in the CEO e-mails. But it goes beyond that as well.

And I'll turn it over to Mr. Ford to give

03:41 the fuller picture and the law that shows that we have
03:41 a tenable claim that should go to the jury.
03:41 MR. FORD: Thank you. Good afternoon
03:41 again, Your Honor.
03:41 I'm going to address the arguments that
03:41 Mr. Tubach made sometime ago concerning the marketplace
03:41 conduct. And so if we can pull up the slides for
03:41 antitrust summary judgment portion.
03:41 He mentioned there were three sort of
03:41 buckets of activity that we, ClearCorrect, identified
03:41 as having an effect of locking doctors in exclusively
03:41 to Invisalign.
03:41 The first bucket he called
03:41 interoperability. I'll call it the iTero moat. And
03:41 the reason why I'll call it the iTero moat is because
03:41 that's what Align calls it. You'll find over the next
03:41 20 minutes what Align says about its conduct is a far
03:41 cry from what Mr. Tubach says about it.
03:41 The second is loyalty pricing. Not
03:41 discounts, loyalty pricing that creates penalties
03:42 exactly of the type the Surescripts case mentioned.
03:42 And not only a few contracts, but literally tens of
03:42 thousands of contracts that locked doctors in.
03:42 If we could jump to Slide 7, I want to
03:42 talk about the iTero moat.

I'm sorry, Slide 8.

Around the time, and this is around 2017, 2018, that Align began anticipating the entry of new clear aligner competitors, it decided it wanted to create what it called a competitive moat around Invisalign. You see here a presentation where they literally say it's time to "build a moat around your business." The business was Invisalign. The moat was the iTero.

Go to the next slide.

You don't have to take my word for what "moat" meant. The speaker notes, as part of that presentation, Your Honor, literally says: The iTero scanner will block competition from gaining business in your account.

They knew the iTero scanner would block competition.

In fact, Align's senior director of strategy --

If you go to the next slide.

-- noted some years before internally: As we're preparing for serious competition in the next three to five years, an iTero customer is a locked-in Invisalign customer.

We should be locking in every Invisalign

customer into the iTero now.

Your Honor, Mr. Tubach went through the elements of a monopolization claim. And he implicitly noted they're not challenging on this motion that Invisalign has monopoly power. They do. You saw the slide that Mr. Mueller showed you.

What they're challenging is anticompetitive conduct. Anticompetitive conduct, under the Fifth Circuit law, is conduct that tends to impair the opportunities of rivals. And the most common form, what the Fifth Circuit said is the quintessential form of anticompetitive conduct, is foreclosing access to customers. What the Fifth Circuit's called barricading access to markets.

This internal document from Align is a confession, Your Honor. It's a confession of the anticompetitive nature of their conduct. An iTero customer is a locked-in Invisalign customer.

And the reason --

If you go to the next slide.

The reason why an iTero customer's a locked-in Invisalign customer is not because, as Mr. Tubach says, there's a couple more clicks. Far from it. When a doctor has an iTero, they can order Invisalign at the click of a button. But to get a scan

from the iTero to send to a competing aligner, it's a 15- to 18-step process across three different platforms. It's incredibly complicated and time consuming.

In fact, that is exactly what Align noticed.

Go to the next slide.

When Joe Hogan took over as CEO, he actually asked: Can the iTero really be used to order a competing aligner?

And the answer he got I think is quite revealing. The answer was: Whilst customers could potentially use the iTero for submitting a scan to any company today, the workflow is not simple and we would of course not support it.

Right? It's possible but it's difficult and we're not going to make it any easier.

If you look at the next slide.

Align's director of product design, the person who's literally responsible at Align for designing products that work well, he confessed internally that the STL export process, that process of trying to get a scan off the iTero to send to a competing aligner company, "is highly manual, time consuming and thus will never be widely adopted."

And the reason is, Your Honor, we'll bring an expert, a former orthodontist from Waco, to testify that in this industry, doctors' time is money. Anything that causes a few more minutes across 80 patients a day is going to undermine not only their patients' satisfaction but their profitability. Align knew that.

Go to the next slide.

This is another statement from a senior director at Align. He said to Joe Hogan: I don't think we are ever going to cross the threshold of allowing iTero to scan for other aligners in any meaningful way.

That is another confession.

Mr. Tubach will say, well, they do actually send some scans. ClearCorrect does get some scans from the iTero. The problem is they're microscopically few. And there's the admission internally. They knew the iTero would not scan for competing aligners in any meaningful way. That's why they're locked in.

And so Mr. Hogan --

If you look at the next slide.

Mr. Hogan took this information and that's when he decided, I'm going to force every

Invisalign doctor to get an iTero. The reason why is I know that if a doctor has another scanner where it's just as easy to buy Invisalign as another aligner, that puts us on a level playing field with competitors. He didn't want that.

He said, why would we allow other scanners to work with Invisalign? They, the competing scanner companies, can say to docs you can do Invisalign or other clear aligners. We have such a huge share of the market, why do we want to give them, doctors, that choice?

This answers the question you asked Mr. Tubach. Mr. Tubach said why would it -- it would benefit ClearCorrect if other scanners didn't work with Invisalign. Right? That is completely false and Align knew it.

The reason why is that this policy, once you force doctors to buy an iTero, means that the iTero will dominate the market for scanners among doctors doing clear aligners. It's not there will be many doctors have other scanners. The policy forces doctors to buy scanners from Align and that iTero doesn't work in any meaningful way with other clear aligner companies.

I said the word "force." That's not my

word. That's Align's word.

If you look at the next slide.

This is -- this is the silver bullet, so to speak, in a monopolization case. Invisalign is a monopoly product. That's what we have to assume under this motion. And they write internally: If you want to do Invisalign, you're forced to buy an iTero and live with it. That's what they say. That, Your Honor, creates the moat around an Invisalign.

If you go to the next slide.

It locks doctors in. Doctors want to offer Invisalign because it is the 90 plus percent market share. They need to be able to offer that, at least some of it. They're then forced to buy an iTero. And so as a result of that, 75 percent plus of the clear aligner prescribing volume in the U.S. is an iTero. And that iTero blocks competition.

This is a summary judgment motion. We have admissions from Align. Admissions that they have a huge share of the market. Admissions that they force doctors to buy an iTero. Admissions that they do so to deprive those doctors of choice. Admissions that it's a time consuming, complex process and will never widely be used. Admissions that it won't ever work for competing aligners in any meaningful way. Admissions

that an iTero customer is a locked-in Invisalign customer.

They can try to throw data. That's just a disputed fact. We have by far enough to get that question to a jury.

And so what Align then pivots to is they try to give you legal arguments for disposing the claim despite this damning factual evidence from their own documents. Evidence that is clearly monopolistic.

But here's the problem, Your Honor. And this is important. Every single rule Mr. Tubach provided you is not a rule that applies to monopolization claims. This is important. He is providing you antitrust rules that don't apply to this statute.

There are, as you may know --

If you go to the next slide.

-- two principle statutes that the antitrust law has. There's Section 1 of the Sherman Act which deals with contracts, combinations or conspiracies and restraint of trade. And there's Section 2, monopolization, which is what -- it's what we're dealing with here.

Section 1 requires there to be an agreement among market participants. And Section 1

only requires mere market power. That is not the statute we're bringing a claim under.

Section 2 is about monopolization. Monopolization reaches unilateral conduct. No agreement is required. It does require more power. Instead of mere market power, it requires us to show monopoly power which is an extreme form of market power.

Now, they have conceded on summary judgment that we get to the jury on that question. But because Section 2 requires more power, the cases recognize they have more ability to harm competition. And so the type of conduct that can violate Section 2 is, as the Seventh Circuit in Viamedia said, broader and less categorical in its definition than conduct under Section 1.

I tee this up because I want to point you to the first legal argument that Mr. Tubach presented you. And that's this.

If you go to the next slide.

He argued that exclusive dealing requires a contract, an agreement. Right? He said the Google case had an agreement in it. The Microsoft case had an agreement in it. And at least with respect to the iTero moat, he says there's no agreement.

Let's put aside the fact that there is an agreement. There's an agreement to sell every one of these scanners and there's a subscription agreement. So this argument is factually flawed. But it's legally flawed in a significant way.

Your Honor, they cite one case for this proposition, ZF Meritor. And they cite in the brief what's quoted on the left, this proposition that: Generally, a prerequisite to any exclusive dealing claim is an agreement to deal exclusively.

They quote that to you.

They ignore the footnote. The footnote says everything. The footnote says: Evidence of an agreement is expressly required under Section 1 of the Sherman Act and Section 3 of the Clayton Act. However, an agreement is not necessarily required under Section 2 of the Sherman Act, which can provide a vehicle for challenging a dominant firm's unilateral imposition of exclusive dealing on consumers -- on customers.

The one and only case they cited for Mr. Tubach's proposition that we needed a contract says 180 degrees the opposite.

In fact, if you go to the next slide, I have an excerpt from a treatise by a Professor Areeda

and Professor Hovenkamp.

The Areeda treatise is the leading treatise on antitrust law. It's been cited by over 20 Fifth Circuit cases. It is the source of the monopolization standard that you, Your Honor, endorse by accepting Judge Gilliland's report and recommendation.

Areeda says the following: Section 2 is also properly brought to bear when a defendant is a monopolist. Indeed, as we point out later, Section 2 may be better suited for the task, given that exclusive dealing is best considered as a unilateral exclusionary practice rather than an agreement between a manufacturer and its dealers.

An occasional practice may have exclusive-dealing-like effects, not satisfy the agreement requirement and raise concerns under Section 2.

Align offers no evidence or case law to the contrary. So that one legal principle they offered to try to get rid of the iTero moat is flawed and flawed according to their own theory.

Now, the next thing they say in their reply brief is that we have not offered a case where technical impediments constitute any competitive

conduct absent an agreement. That's false. Microsoft does.

Microsoft, Your Honor, this is the U.S. v. Microsoft case. It is the seminal monopolization case of this century. In a lot of ways, is one of the most cited monopolization cases.

Now, there was contracts at issue, just like there's contracts at issue in this case. But the DC circuit in Microsoft separately analyzed as standalone anticompetitive conduct the technical impediments Microsoft inserted. Microsoft had the dominant operating system platforms in the Windows -- in Windows. And they tied it to Internet Explorer. And their hope was to block browsers that would come in the market.

And one of the things Microsoft did is they took and they made it really hard for OEMs to take Explorer off the computer, out of Windows. They deleted the Explorer from the add/remove program. They commingled the code. And what the Court said is that this made it difficult for OEMs to take Explorer out and provided a disincentive to add Netscape, other competing browser. Right? Because it's difficult.

That in turn provided a deterrence to consumers who would have to go out and load Netscape.

And few did.

These were technical impediments that restrained competition by locking in customers to Explorer. And they were actionable in and of themselves, if you look at that opinion. That section had nothing to do with any agreement.

You go on. This type of choice friction, next step, next slide.

This type of choice friction is most certainly actionable to show substantial foreclosure. Align's own expert, Your Honor, acknowledged that one of the ways monopolists can achieve substantial foreclosure is by imposing what he called operational frictions that materially impede customers' ability to access competing options.

That is exactly what Align has done here. They force the iTero on most of the clear aligning prescribing population in the U.S., and those technical frictions make it hard and almost impossible for those doctors to use anything else.

If you go to the next slide.

Many of the leading cases -- I'll just move quickly here. But many of the leading cases impose monopolization liability based on this type of friction. Right?

The Google Play case is very much on par with our case. There, Google Play tied the Android operating system to the Google Play Store in devices like phones.

Now, it was possible to load in another app store, but it was a 14-step process that was very complicated, and the evidence showed that few would. Right? So this choice friction is exactly what underlies a lot of the most significant antitrust verdicts.

If you go to Slide 25, I want to talk about the next fundamental error in law that Mr. Tubach pitched you.

They talk about the tie. And it's true, we argued and alleged that Align tied Invisalign to the iTero. And this is the depiction of a tie. Doctors wanted the Invisalign and so they must buy an iTero. That's the policy. That's exactly what Align wanted.

And so in this case, Align was the -- Invisalign's a tying product and the iTero's the tied product. And you may have heard Mr. Tubach said -- say that this tying theory doesn't make any sense because we are using this tie to demonstrate how Align insulated its Invisalign monopoly in the tying market.

And he told you that a tie to the

03:59 actionable must foreclose competition in the tied
03:59 market. Right? In the iTero market. That's not what
03:59 we do. He's 100 percent false.
03:59 If you go to the next slide.
03:59 He is again applying Section 1 principles
04:00 to a Section 2 case. Right? Align says tying only
04:00 matters if you prove monopolization of a tied market.
04:00 The leading authority says: The
04:00 principal difference between ties addressed under
04:00 Section 2 and those considered under Section 1 are,
04:00 among other things, the competitive harm must result
04:00 from unreasonable exclusion in a market in which the
04:00 defendant has or threatens to have monopoly power.
04:00 Thus, the harm can result in either the tying or tied
04:00 market. Right?
04:00 He goes on to say at the bottom: The law
04:00 of monopolization generally looks for anticompetitive
04:00 effects in the market being monopolized, which is
04:00 usually the tying market.
04:00 And so once again, Align has urged you to
04:00 throw this case out based on a principle of law that
04:00 applies to an entirely different statute in the Sherman
04:00 Act. And that is crystal clear it doesn't apply to a
04:01 Section 2 claim.
04:01 We pointed out in our brief that the

Microsoft case is very much a model for this Court's decision here and for thinking about this case. In Microsoft --

If you go to the next slide.

Microsoft had a dominant position in Windows. OEMs wanted Windows and they were forced to take Explorer. So Windows was the tying product. And Internet Explorer was the tied product. Right?

The reason why this tying worked to protect the Windows operating system monopoly was because Windows was concerned that if Netscape became very popular as a browser, app developers could develop apps that would work on Netscape and, therefore, OEMs wouldn't have to use Windows in order to have a platform for applications.

So the tie was about protecting and insulating the tying market. And Microsoft court found that to be monopolization.

Now, if you go to the next slide.

Align says that in Microsoft, the Court required showing of the essential elements of a tying claim, including harm in the tied product market. Once again, they improperly conflate Section 1 and Section 2. They -- Microsoft had an entire section on Section 2, an entire section on Section 1.

They pointed you to the section on Section 1. Overlooking the fact that the exact same tying allegations were part of the monopolization claim and found to be part -- a valid part of the claim in which Microsoft was found to have monopolized the Windows market in the tying market.

If you go to the next slide.

Again, Your Honor, you don't have to take my word for it. Let's look at the leading treatise. The leading treatise says: The law of monopolization generally looks for anticompetitive effects in the market being monopolized, which is usually the tying market.

Again, that's what we're doing here. Because this is a monopolization case, not a Section 1 case.

For example, one analyzing Microsoft's tying of its Windows operating system to Internet Explorer under tying doctrine of Section 1 would likely look for impairments of competition in the tied market, the browser market. By contrast, one analyzing the same tying as unlawful monopolization under Section 2 would likely look at the tie's propensity to maintain or extend power in the tying market.

And so that argument that Mr. Tubach made

that we can't have a tying claim here that's based on maintaining monopolization in the Invisalign market is dead wrong. Dead wrong.

The next thing I'll -- point he makes is that they have no duty to deal. He frames this all as a duty to deal. Align doesn't have a duty to deal with any competitors. Your Honor, you already rejected that argument in this case by adopting Judge Gilliland's report and recommendation.

If you go to the next slide.

Judge Gilliland explained that Aspen Skiing -- remember the Aspen Skiing case that Mr. Tubach referenced -- did not involve conduct directed at customers such as here, where the customers were allegedly forced to accept any competitive conditions. And he cites Chase Manufacturing. And you adopted this. Right?

They're trying to get you to reverse course now. Duty to deal is implicated when a monopolist is selling to or entering a joint venture with or otherwise contracting with a competitor. That's not at all what we're dealing with here.

They don't need to contract with any competitor to accept from doctors scans that doctors take with another aligner. Every other aligner company

in the world just allows doctors to upload scans from wherever they get it. They just have to deal with their customers.

And you want to know why we know you don't need a contract to accept scans? Because Mr. Tubach said to you that the iTero can be used to order competing aligners. Well, Align doesn't have any contract with any competing aligner companies. Those aligner companies just accept from their doctors scans. We're not asking to do any deal.

And so if you go to the next slide.

The case law here is clear. You and Judge Gilliland were right and you're in really good company. The Court in Google, a recent decision, said: Courts have contrasted the refusal to deal doctrine from a monopolist's more direct interference with rivals, such as limiting ability of third parties to deal with rivals, exclusive dealing like we do here, requiring third parties to purchase a bundle of goods rather than just ones they really want, tying, as here.

You may have heard of the recent Live Nation monopolization decision. The Court there said the same thing. To the extent plaintiffs can make out a claim that Live Nation is engaged in tying --

THE COURT: Counsel, can you give me just

a couple minutes? I'll be right back.

(Pause in proceedings.)

THE COURT: My understanding is Kristie's back.

I'm going to deny the motion for summary judgment.

With respect to the first motion we took up, the motion for preclusion pursuant to Rule 37, the Court is going to grant that.

What I have up next is Align's partial motion for summary judgment of validity. I'll take that up next.

MR. NASH: Good afternoon, Your Honor.

THE COURT: Good afternoon, Mr. Nash.

MR. NASH: Can you hear me okay?

THE COURT: Yes.

MR. NASH: It's good to see you, Your Honor.

Give me one moment to get the slides set up, if that's all right.

THE COURT: I don't know how to stop you.

(Laughter.)

MR. NASH: Well, I appreciate your patience, Your Honor.

I think I have the wrong screen, Your

Honor. Hold on. I apologize.

Okay. Your Honor, are you able to see my slides?

THE COURT: Yes.

MR. NASH: I don't know how helpful these are frankly going to be, Your Honor. I think this is actually a pretty open-and-shut issue. So I'm just going to start pretty quick.

I think you've heard a lot about sort of what we call the materials patents. And at a high level, there's four of them. They refer to the material that's being used in these aligner devices or appliances, if you will.

And this is one that's representative, if you can see it up on my screen, Your Honor. It's got the -- it's called the '613 patent. And I'm going to use this to illustrate the issues that we've been talking about with respect to this.

But you've heard a lot about soft-hard-soft, soft-hard-soft, the various configuration of these layers. And I don't think that's a fair characterization of what these claims necessarily cover.

So if you look at the claim language we see here, we're talking about a method of making a

dental appliance for positioning a patient's teeth. I've highlighted in the green that it must be a multi-layer material. That multi-layer material has three polymer layers.

In blue, I've highlighted that one of those polymer layers needs to be a hard layer. And specifically the material type for that hard layer is a co-polyester. And the particular co-polyester must have a physical property of a flexural modulus greater than about 150 PSI (sic). So that's highlighted in blue.

Then highlighted in pink on my screen, Your Honor, is another layer requirement for that multi-layer material. Another layer must be a soft polymer layer that comprises a thermoplastic polyurethane elastomer, TPU, Your Honor. That's the material type. And then there's also physical properties associated with that TPU layer. It has to have an elongation of break at 200 percent or greater. It has to have a hardness from about 60 A to 85 D. That's on the Shore Hardness Scale, Your Honor.

And so it's a specific multi-layer configuration, but it's configured according to the layer types and the physical properties associated with that layer.

It also continues with two other limitations which I don't think are really at issue today. There has to be a positive model for the patient's teeth. And then you fabricate an appliance on a negative of that positive model.

What's important, though, about what these claims require is more what they do not require. There is nothing specific in this claim that requires a particular order or arrangement of the multi-layer materials as to how that soft and hard layer are arranged according to each other. There's nothing that says it has to be a soft-hard-soft arrangement, a hard-soft, soft-hard-soft, or hard-soft-hard, or any configurations thereof. It's a multi-layer material and it requires those specific structural features that are described there.

Now, the reason why we've brought this partial motion for summary judgment is because the entirety of ClearCorrect's written description theory is premised not on comparing this claim to the specification, it's premised on comparing the specification to their accused product.

And you heard a lot already in Mr. Mueller's upfront discussion about the history involving these two parties and their competing

products.

And one thing I think that they've tried to make and what I see in their slides is ample discussion about their Zendura FLX material. And they do that because their Zendura FLX material, they contend, has their hard layers on the outside, whereas what is disclosed in the specification as one embodiment, Your Honor, just one embodiment. It's never limited to that embodiment, but is a configuration with effectively the same materials but soft is on the outside rather than hard.

And so what they've argued in this case and what their expert's argued over the course of his expert report and in deposition is a position that because the specification doesn't disclose that configuration in the accused product, then there's a problem with the written description.

Now, they contend or argue that that's a full scope argument or they try to argue it as a genus-species, as you've seen, Your Honor. Frankly, I think they're already starting with the wrong framework, the wrong inquiry.

The inquiry is what is disclosed in this claim, or what's claimed by the claims, and is that supported in the spec. And that's a pretty simple

inquiry, Your Honor.

In fact, the reason why this I think is amenable to summary judgment is because when you look at the spec, it's obviously disclosed, each of these layers, and specifically the materials, and the materials having those physical properties are disclosed. And their expert kind of concedes that these are there.

The expert's only qualification on those concessions is, ah, yes. But it's in the context of a soft-hard-soft arrangement. Yes, but it's in the context of soft-hard-soft. And he's making that qualification, Your Honor, because he's tried to effectively import that into the claim language, like that's something that needs to be shown as well. It's a back door to either rewrite the claim language or it's a back door noninfringement position.

And I think effectively what their expert's trying to do and what ClearCorrect's trying to do in this case is when it says in this green limitation you see in front of you, Your Honor, a sheet comprising three or more polymer layers, I think they want to import a requirement with soft on the outside. That's effectively what they're trying to argue. That's obviously not existent in this claim language.

So to illustrate just quickly, Your Honor, because I did make these color-coded slides and they're kind of fun.

That first limitation, multi-layer material. We see that more than adequately disclosed in the specification. Here's one example from Column 3, Lines 46 to 54. It discusses having a sheet comprising a hard polymer layer disposed between two soft polymer layers. So three layers. It's a multi-layer sheet.

And their expert, as we saw during deposition, conceded, yes. That is disclosed in the specification.

Does it disclose three polymer layers?

He says: Yes, in a soft-hard-soft configuration.

Well, Your Honor, there's nothing requires a specific configuration. The concession that there are three polymer layers, no material dispute of fact.

Similarly on the blue, Your Honor, that's the hard layer. Now, remember, the hard layer has structural features associated with it. It has to have a material type. It's a co-polyester. There's other types of hard polymer layers disclosed in the spec, but

one of them is a co-polyester.

Has to have a flexural modulus greater than 150 PSI (sic). And that's disclosed as we see in the specification right here. This comes from Column 5, Lines 62 to Column 6, Line 1, and from Column 6, Lines 34 to 39. You see that it's a hard polymer layer of one type of material, e.g., a co-polyester. That's your material type.

And then we see specific properties that are associated with that hard polymer layer. Among the physical properties that are disclosed is a flexural modulus greater than 150 PSI (sic).

Expert also conceded this point in deposition: You're not disputing, sir, that the specification discloses a hard polymer layer comprised of a co-polyester?

He said: No. I'm not disputing that. But it's soft-hard-soft configuration.

Again, the hard polymer layer is -- has a flexural modulus greater than 150 disclosed in the spec, right?

He says: The hard polymer layer in the hard -- soft-hard-soft discussed in this application, meaning the spec, has a flexural modulus greater than 150. So again, he's qualifying it --

(Clarification by Reporter.)

MR. NASH: So again, we see him importing this soft-hard-soft aspect into the claim language when it doesn't exist.

And then similarly with the soft layers, Your Honor, we see that it's disclosed in the specification. This is Column 6, Lines 23 to 28 -- sorry, Kristie -- and Column 6, Line 34 to 39.

And we see there a discussion in the specification of soft polymer layers of thermoplastic polyurethane, TPU. That's the material type. And then we have a disclosure of the specific properties. Several different options, but among those, Your Honor, are the specific ones that are claimed in the claims.

We have a property of at least hardness between 60 A to about 85 D. We also have a property with an elongation of break greater than about 200 percent. Both of those are fully disclosed in the specification and both of those, the expert concedes, are disclosed there.

So again in deposition, we see, as Dr. Spiegelberg testified: Specification discloses a soft polymer layer that is comprised of a thermoplastic polyurethane elastomer, correct?

He says: Yeah, it's describing a soft

04:22 layer is a polyurethane elastomer with specific
04:22 properties.
04:22 Then he adds: But it's on the outside of
04:22 a hard layer.
04:22 It's not anywhere required in the spec or
04:22 required in the claims, Your Honor.
04:22 Then he says again: Well, so the spec,
04:22 sir, discloses a soft polymer layer having an
04:22 elongation at break. That's one of the properties for
10 the soft layer.
04:23 11 And he says: Yes. It's describing a
04:23 12 multiple soft polymer layer. So he puts his qualifier
04:23 13 in there. And the soft polymer layers have the
04:23 14 properties of an elongation of break greater than 200
04:23 15 and a hardness of 60 A to 85 D.
04:23 16 So in each of these instances, Your
04:23 17 Honor, he's conceding what is in the claims is in the
04:23 18 specification and is described there.
04:23 19 What he wants to do with these qualifiers
04:23 20 and what ClearCorrect is advancing as part of their
04:23 21 written description argument, though, is an attempt to
04:23 22 try and either import a soft-hard-soft requirement into
04:23 23 the claims or try to convince the jury to be looking
04:23 24 for the accused product somewhere in the specification
04:23 25 and then argue it's not there.

04:23 We see that borne out in his expert
04:23 report. Here's Paragraph 18, Your Honor. Sorry, 810,
04:23 Your Honor.
04:24 He says: It's my opinion that the
04:24 written description describes only one configuration of
04:24 the so-called hard and soft polymer layers. That
04:24 configuration, he says, is soft-hard-soft.
04:24 And then he says it doesn't disclose
04:24 other configurations, in particular the hard-soft-hard
04:24 configuration used in the Zendura FLX material, accused
04:24 product, and is the opposite of the soft-hard-soft
04:24 configuration described.
04:24 So he's advancing a position on written
04:24 description that's going to ask the jury to compare the
04:24 accused product to the spec when that's not the right
04:24 inquiry. The right inquiry is to compare the claim
04:24 language to the specification.
04:24 Similar discussion in his report at
04:24 Paragraph 962. In that paragraph, he says: The
04:24 specification fails to disclose any other configuration
04:24 than soft-hard-soft. And then he compares it again to
04:24 ClearCorrect's own aligners. He says that because
04:25 Align asserts that the asserted claims cover the
04:25 ClearCorrect aligners, which uses a hard-soft-hard
04:25 arrangement, a person of skill in the art would not

04:25 know how to compare that -- or sorry, would not know
04:25 how to modify from soft-hard-soft to hard-soft-hard.
04:25 Your Honor, again, we're comparing, in
04:25 the context of written description, the specification
04:25 to the accused product. And that's legally improper.
04:25 So from a legal perspective, I realize
04:25 that written description is a question of fact, but
04:25 there is no dispute between the parties that what is
04:25 claimed is what is disclosed. What their expert is
04:25 advancing and what ClearCorrect's trying to advance is
04:25 an improper legal analysis that compares accused
04:25 product to the spec.
04:25 And this I think is most apparent in this
04:25 question from the deposition that is up on the screen,
04:25 Your Honor.
04:25 So in the context of asking about the
04:26 positions on noninfringement, we asked, do you intend
04:26 to offer any opinion on noninfringement, that Zendura
04:26 FLX does not infringe other than this one that they
04:26 believe on the elongation of break.
04:26 And then your response, Your Honor, you
04:26 see this right here at Lines 21 to 25 of what I'm
04:26 showing on the screen, the expert says: Well, taking
04:26 into account the entire patent, which only describes
04:26 soft-hard-soft configuration, and the fact that the

accused product, Zendura FLX, only has a hard-soft-hard configuration, it's outside the scope of the claims.

That's a noninfringement position that their expert testified to.

And to clarify, we said: Well, that's your written description argument, correct, sir?

He says: Oh, it is.

So that's the problem, Your Honor. I think what we're seeing is if it was a position by ClearCorrect that the claims required soft-hard-soft, as their expert testifies to here in deposition, if that was a requirement, they should have brought that up in the context of claim construction. Because it's not anywhere in the claims. What they want to do is try and limit this to a specific embodiment, and that's not -- that's not proper, Your Honor.

So I think they want to try and turn this into a genus-species debate, Your Honor. I don't think that's the proper legal analysis. I think in a typical genus-species case, Your Honor, you've got a claim that covers a broad class of things, you have a specification that only discloses like a member or two within that broad class, and the big dispute is over whether the handful of species within that broad class represent the broader class.

And it's often done in functional terms. And that's exactly what we see in this case that they rely on, this Brita in the briefing case. The functional terms would be like anything of this sort of genus that achieves blank. So it's like a functional result-based claim mechanism. And the big issue is how do you identify all of the members of that genus?

That's not I think what we have here. We've got specific layers. We have a specific description of what those required layers comprise. They have a specific type of polymer, specific type of properties. There's not a dispute over like this order arrangement because it's frankly just not part of the claim language.

So there isn't this issue of what's the sort of members of this sort of species because the species is already defined and identified by the claim language itself.

I think even if you were to engage in a genus-species debate, I think they've framed the genus in an improper or incorrect way. I do not believe that it is simply a debate over soft-hard-soft. I think they want to talk about this arrangement. They've said it's a vast broad genus. And I saw some pictures from their slides that are -- just have Ss and Hs. That's

not the correct analysis, Your Honor.

When we looked at the claim, and we can go back, but in each of these sort of layers that are required by the claims, it's a specific TPU, it's a specific co-polyester, and each of those have properties associated with them.

So if you do an Areeda-type analysis -- and again, I don't think that's really the right framework for it, but if you do an Areeda-type analysis, Areeda, if you remember, says there's sufficient written description support either if there's a representative number of species or whether there's specific structural requirements that would give a skilled artisan a vision of what the scope is.

And here, with the specific properties we've identified associated with the specific material types, that absolutely meets that requirement.

I'm happy to talk more about some of the cases, Your Honor. I think this is a lot more like In Re Ernesto and some of the district court cases we've cited out of California, Texas, where what we really have is someone trying to bring in under the guise of written description what is effectively a noninfringement or claim construction position, and that's legally improper, Your Honor.

04:30 THE COURT: A response?

04:30 MR. MUELLER: Yes, Your Honor.

04:30 So maybe I'll start at the big picture level and then go to the details of the arguments that my friend Mr. Nash made.

04:30 First, at a big picture level, Your Honor, if we look at the timeline that we showed you earlier, this is Slide 15. We have this chronology.

04:30 We have this chronology where there was an earlier set of Align patents that were expressly limited to soft-hard-soft, a hard layer disposed between two soft layers. And then we have these later patents in the same family for which amendments were made. And we believe what the record will show is an attempt to broaden out claims to use against Zendura FLX material and the ClearCorrect aligners more specifically in this case.

04:31 And so the question is, are these later claims for which there was a manifest attempt to have broader claim scope supported by the written description? And the more specific question for today is, would every reasonable juror find that the written description suffices to support the claim scope?

04:31 There's two ways of looking at the claim scope and our expert has analyzed it under both. One

is under the claim scope, according to the requirements that are expressly recited in the claim itself. Mr. Nash showed you those.

Second, we are also analyzing and our expert has analyzed the sufficiency of the written description under their infringement theory, which we believe rests on an overextension of those claims to cover material that's outside the boundaries of the claims.

So I'm going to address it from both perspectives, Your Honor, because our expert has done the same. And I'll just start with the very simple analogy, Your Honor, which I think shows the logic of what we're trying to argue in this case and the clash between the parties.

If I had a patent that said I claim a blue truck with an electric engine and a sunroof, and I file a claim on that basis, and it's described in the patent, blue truck, electric engine, sunroof, and my claim requirements in my original patent application say blue truck, electric engine, and sunroof, and I get a patent with that claim language, I'd of course be limited to blue trucks that also have a sunroof and an electric engine.

If I then years later eliminated the

words "electric engine" and "sunroof," I've now changed the scope of the claims to cover the genus of blue trucks, all blue trucks, regardless of engine and regardless of roof.

And so I would need to show in my example that my written description has a sufficient number of trucks, blue trucks in particular, to support the broader genus of all blue trucks as distinct from the narrower genus of just blue trucks that have an electric engine and a sunroof.

And here, we have something similar going on. We have claims that originally said soft-hard-soft where requirements are being excised, the declaration is being modified by the inventor in support of these new amended claims, and the scope is changing.

Now, we think the expanded scope still does not reach the accused products. There's no infringement. But there clearly was an attempt to extend out the coverage of the claims in the later applications.

And so the question is not, do these words appear in the patent? The same would be true in my example, blue truck appears in the patent. But the question is, in my example, is there a representative number of species to support the claiming of all blue

04:33 1 trucks? And here, the question is, is there a
04:33 2 sufficient number of representative species to support
04:34 3 the claims as amended in the later applications?
04:34 4 And the briefing on this issue, Your
04:34 5 Honor, to Your Honor was quite terse. The opening
04:34 6 brief was about a page and a half on these issues in
04:34 7 Align's summary judgment motion.
04:34 8 Just to give you some sense of the extent
04:34 9 of the analysis, if we could pull up the table of
04:34 10 contents from our expert's report on these issues. And
04:34 11 this will just take a second, Your Honor. I just want
04:34 12 to show you the table of contents.
04:34 13 This starts at Page 254, if we go to
04:34 14 Section 15. And the page number is 254 for the section
04:34 15 of the report -- no, I'm sorry. Go back to the table
04:34 16 of contents. Which is Section 15.
04:34 17 One more page here. And one more after
04:34 18 that.
04:34 19 Okay. So, Your Honor, you see here a
04:34 20 little bit down from the top of the page, the asserted
04:35 21 claims are invalid for insufficient written
04:35 22 description. There is about 100 pages of analysis by
04:35 23 our expert Dr. Spiegelberg with respect to this genus
04:35 24 issue, with respect to this species issue. It's done
04:35 25 under the proper scope of the claims, including the

explicit requirements that Mr. Nash showed you. It's also done under Align's application of the claims in their infringement theory.

And there's a variety of technological issues that fall within the rubric of this written description section of the report. As I mentioned earlier, Your Honor, Dr. Li, the inventor, one of the inventors in this patent family, herself told the Patent Office years ago, this is an unpredictable science. That's what she said years ago to the Patent Office.

And that was right. I mean, that was in fact correct. This is an unpredictable field for which experimentation is required to determine if particular compositions of materials are efficacious in terms of arriving at teeth distributions that the dentists want to achieve within a mouth of a patient, safety, stain resistance, comfort, on and on. And those customer or patient-facing characteristics rest on technological characteristics that are hard to achieve.

Dr. Li had it right in her original declaration when she said that this is an unpredictable science.

So it's an unpredictable science for which we believe the trial record will show in great

04:36 detail by our expert, by our own engineers, material
04:36 scientists who worked on the accused technology, we
04:36 believe by their witnesses, that the amount of work
04:36 required to arrive at an efficacious aligner is
04:36 immense. This is hard to do and it is analogous, Your
04:36 Honor, to some of the biotech cases for which the
04:36 species-genus issues often come up. There's a similar
04:36 degree of unpredictability.
04:37 And so that's important here because in
04:37 the particular patent specification for the patents at
04:37 issue, there is not a description of representative
04:37 species commensurate with the scope of either the
04:37 claims as written or especially the infringement theory
04:37 that's being articulated by Align in this case.
04:37 If we go to Slide 21.
04:37 The patents only disclose, only disclose,
04:37 only disclose a soft-hard-soft configuration in the
04:37 body of the patents. The specification talks about a
04:37 hard polymer layer disposed between two soft polymer
04:37 layers. There's no description of the inverse.
04:37 There's no description of a hard -- a soft polymer
04:37 layer disposed between two hard polymer layers. Zero.
04:37 None.
04:37 Now, even just a soft -- a hard polymer
04:37 layer disposed between the soft interior and exterior

embraces a broad genus of species, and I'll come to that in just a moment. But the genus-species problem is exacerbated and amplified by the infringement theory in this case.

Now, Mr. Nash said a few times that you can't just do a written description analysis by comparing something in the specification to the accused product, and that's 100 percent correct. And that's not all we would be doing, not all that Dr. Spiegelberg did in his nearly 100 pages of analysis in his report.

But it is 100 percent relevant to the analysis what is being accused. Because for the infringement theory to be tenable, the boundaries of the claims would need to embrace what's being accused and, therefore, those boundaries would require a sufficient written description.

The written description needs to support the full boundaries of the claims. We don't think the written description is sufficient either under a proper application of the claims for which we believe there's no infringement, but it is certainly not sufficient to support the expansive infringement theory which, as a logical matter, embraces hard-soft-hard. That's the accused product.

So for the infringement theory to be

tenable, the boundaries of the claims would need to reach hard-soft-hard and, therefore, the boundaries of the claims would need to describe a sufficient number of species to support a hard-soft-hard genus coverage. That's the issue.

So the issue is, whether you look at the claims as written, which we believe of course is the only way to do it, and under which we believe there's no infringement if you apply the requirements of the accused products, there's a written description problem even there, that the written description problem is exacerbated by the more expansive infringement theory that Align is articulating in this case.

And if we go to the next slide.

If we look beyond what I just showed Your Honor, there's only just the boilerplate language, any combination of the above described elements is contemplated. And that's, you know, the sort of language that we see in many patent applications. But that is not enough under the case law to describe representative species. That would support either the genus as written in the asserted claims or the infringement theory which overextends those claims.

If we go to Figure 4, for example, in the specification, it doesn't provide any example of a

hard-soft-hard multi-layer sheet.

So there's this very limited disclosure in the specification which is expressly directed to soft-hard-soft, and that makes good sense. What they were working on at the time was soft-hard-soft, that SmartTrack product for which Dr. Li said there were surprisingly superior performance characteristics. And then tried to change her declaration years and years later.

There's no description at all, top to bottom, front to back in these patents of anything other than that in terms of a species and, therefore, at least a reasonable fact finder could find, which is the only question for present purposes, that there's insufficient written description.

If you go to the next slide.

Even under --

Or Slide 25, actually. One more.

If we look at different ways of considering the potential genus coverage here, Mr. Nash said the only requirements are the ones that are written in the claims. And those requirements alone, we believe, are not met by the accused products.

But if you think about what the infringement theory is as being articulated in this

04:41 case, they are saying these claims are not limited to
04:41 soft-hard-soft. That's that dark shaded region towards
04:41 the bottom of this Venn diagram. And what that means
04:41 is it could cover things like hard-soft,
04:41 hard-soft-hard, hard-soft-soft. And so on and so
04:41 forth. And the mathematical implications of this are
04:42 profound.

04:42 If you go to the next slide.

04:42 Even with respect to soft-hard-soft,
04:42 there are -- and the record at trial would show -- over
04:42 50 options for the thermoplastic polyurethane layers
04:42 and over 50 plus options that would be practically
04:42 available to material scientists in this area. 250
04:42 plus options for co-polyesters.

04:42 So if you have the softer TPU layer and
04:42 the harder co-polyesters, if you just do the math, 50
04:42 plus times 250 plus times 50 plus, that's 625,000
04:42 combinations only within a soft-hard-soft subgenus.
04:42 And if you expand that out to include other types of
04:42 combinations, hard-soft-hard and on and on, the math
04:42 only becomes more daunting.

04:42 And in theory, they could have broad
04:42 coverage of a broad genus but they need a sufficient
04:42 number of representative species to support such a
04:43 claim, especially so in an area of technology that's

unpredictable.

And here, the named inventor, Dr. Li, expressly represented to the Patent Office in the early applications that this is an unpredictable science that requires experimentation.

I'll also note, Your Honor, they did not move for summary judgment on enablement, so the jury is going to need to hear in any event about whether there's undue experimentation required to arrive at the claimed configurations.

And that fits hand in glove with the evidence that would go to written description. And we think that evidence is more than sufficient to allow a reasonable juror to find a lack of written description support.

And just a couple final pieces of evidence to show illustrations of what the trial record would make abundantly clear.

If we go to Slide 25, please.

I'm sorry, 28.

So here, we have Align concluding that layer configuration impacts properties of materials, and if you have certain configurations, you're going to result in problems like a deformation or deformation and cracks, which obviously can't be suitable for a

04:44 device to be used in a patient's mouth.

04:44 And it takes trial and error, experimentation, years of hard work to arrive at something that's not going to suffer from problems like this or staining or a level of discomfort that patients would find (audio distortion).

04:44 If we go to the next slide.

04:44 Dr. Li conceded at her deposition that it requires a lot of tests, and not only a lot of tests, they worked with a lot of chemical companies to try to find the right chemical compositions that would meet their own development criteria, including the criteria that we went through, Your Honor, earlier in the context of the representations made in the (audio distortion).

04:44 So we have admissions by the inventors that this is an unpredictable and complex art.

04:45 There's more on Slide 31.

04:45 Here, we have two inventors, Dr. Li and Dr. Pelhert, admitting the development of these materials is complex, takes years.

04:45 And as we've talked about a few times today, if we go to the next slide, unpredictability.

04:45 (Clarification by Reporter.)

04:45 MR. MUELLER: But the inventor Dr. Li

represented the -- that a hallmark of this area of technology is lack of predictability.

So, Your Honor, in sum, this is a situation where we believe the literal language of the claims lack sufficient written description report. Moreover, the overly extended or stretched scope of the claims under the infringement theory would be a exacerbating factor on this written description issue and make the written description problem even more pronounced.

This is a type of invalidity argument. The one I just mentioned that has been endorsed by the Federal Circuit, this conditional argument, in cases like 01 Communique, where the Court has held that if you take infringement theory -- or you can take infringement theory and assess the validity implications of it.

So either under the claims as written or the infringement theory as applied, there's insufficient written description support because these are claims intended to capture a broader genus than the species that are actually described in the body of the claims.

We think the evidence from the plaintiff will show that, the evidence from our own material

scientists will show that, and the evidence from Dr. Spiegelberg will show it. And all of it suffices to allow at least a reasonable juror to find in our favor on this issue.

So unless Your Honor has any further questions, I will rest there.

THE COURT: Mr. Nash, if you want to address the issue about -- Mr. Mueller's made points that I should let this go to the jury. Why shouldn't I?

MR. NASH: I disagree, Your Honor, because I think that's the improper legal analysis that would be applied. I think that would be problematic for the Court from a sort of written description perspective.

I think the test on written description is comparing the claim language to what's disclosed in the specification.

I think what Mr. Mueller was trying to argue here when he's talking about overly stretching the claims, frankly, Your Honor, I don't understand that because this is like -- there is no sort of issue of claim interpretation. There is no requirement in the claim language for a specific arrangement of these layers.

It requires that there be at least three. It requires that one be hard with a specific material type and property. It requires that one be soft with a particular material type and properties associated with that. And that's it, Your Honor.

If you were to go --

THE COURT: If you'll hold on one second. I'll be right back.

MR. NASH: Of course. Sorry, Your Honor.

(Pause in proceedings.)

THE COURT: With regard to the Docket No. 354, the partial motion for summary judgment of validity, the Court is going to grant that.

Given the time of day, I'm happy to go past 5:00, but with respect to defendants' motions for summary judgment of invalidity under Section 101 -- give me one second, please.

I'm going to deny the motion with respect to the '936 patent. But I would like to hear argument on the '444 patent.

MR. MUELLER: My colleague Mr. Zubler will address that issue.

THE COURT: Okay.

MR. ZUBLER: Good afternoon, Your Honor. Todd Zubler from WilmerHale on behalf of ClearCorrect

and Straumann.

Your Honor, as Mr. Mueller mentioned --

If we could go to Slide 2.

-- these two patents -- and I realize I'm not going to argue the '936 patent right now. But these two -- these patents in general have been sort of patents that have been off to the side in this case. They involve different technology from the materials patents that we've heard so much about today.

And furthermore, Your Honor, there's -- they're sort of odd patents in this case. There's no damages claim from the -- from Align in this case.

THE COURT: Counsel, we have very limited time. So if you'll focus us and -- and to give my cards away, if you'll tell me why you think Claim 1 is invalid under Section 101, that would help me a lot.

MR. ZUBLER: Yes. Absolutely, Your Honor. I will move forward quickly on that.

If we can just go to Slide 3 real quick.

THE COURT: I mean, I'm going to want to hear both 1 and 2 -- Claims 1 and 2, but starting with Claim 1.

MR. ZUBLER: Sure. Yes, Your Honor.

We could then turn to -- let's see here. If we could go to Slide 17, please.

04:54 So let me just give you a slight brief introduction to the '444 patent to give -- set the context for Claim 1, Your Honor.

04:55 The '444 patent is directed to an abstract idea of planning a sequence of tooth movements to straighten teeth. The prior art was clear that you would have some computer implemented techniques that would be used to design and simulate the orthodontic treatment plan.

04:55 And what the '444 patent says is our goal here, our objective here is to increase automation of that process. And that's a telltale sign, Your Honor, of invalidity under Section 101 because what we're talking about is automation of existing processes, as shown to you by the title of the patent, Automated Treatment Staging For Teeth.

04:55 Now, let's dive in a little more closely now to Claim 1 and the process that is discussed.

04:55 If we could go to Slide 18.

04:55 Slide 18 summarizes Claim 1. And what we're talking about here is a very high level results-oriented functional process where there is no technological improvement, which is what the Federal Circuit has focused on from the -- in many cases. And

04:56 instead, all that Claim 1 talks about, Your Honor, are

04:56 abstract functional result-oriented processes.

Let's just look at it.

Step 1 of Claim 1 talks about receiving the initial tooth positions of a patient. That's just the starting point for the patient's treatment.

Step 2 says the computer should receive desired final tooth positions. In other words, where do you want the teeth to end up to have a beautiful smile? Those are just givens that come into the computer.

And then finally, Step 3 says the computer should determine an order of movement to avoid collisions. And it's sort of a black box. It says computer should determine an order of movement to avoid collisions. And it says instead of having a human do it, the computer should do it. That's pure automation.

And as the slide notes, the patent admits that this type of treatment planning and avoiding collisions was something that was always done manually on a computer but by technicians who would do that avoiding of collisions. It was often necessary to manually manipulate the digital or physical models of a patient's teeth to plan the movements.

And this -- Align's own brief confirms, this patent is directed to automated treatment of

staging for teeth.

If we go to Slide 19.

Credit Acceptance Corp versus Westlake Services is right on point. The mere automation of manual processes using generic computers, and it's all that's involved here. There's no special software algorithm. There's no hardware that's discussed. That does not constitute a patentable improvement in computer technology. That's the core of our case.

Now, what do they point to? What does Align point to as being special in Claim 1 that might avoid this?

If we go to Slide 20.

There are two limitations in Claim 1 that Align focuses on. They focus on the fact that the claim mentions that the computer, when it's determining an order of movement to avoid collisions, it could use staggering or it could use round tripping.

But what are staggering and round tripping? Those are just further abstract functional concepts that entirely fail the Federal Circuit's clear jurisprudence about what kind of steps can constitute eligible subject matter.

"Staggering" simply means that you're delaying a planned tooth movement to prevent a

collision. That is an abstract concept. There's no technological improvement. It's a result. There's no specificity about how you do that or when you do that.

Similarly, round tripping is talking about moving one tooth out of the way while another passes. Again, what you have to do when you design a treatment plan is if the mouth is very crowded, you have to move teeth around, all that's being discussed here, Your Honor, is a very generic result-oriented functional analysis of saying, you know what, the computer should just abstractly figure out how this happens without any discussion or detail as to how this would improve technology -- improve technology.

And if I could go to the next slide. I think Slide 21.

The USAA versus PNC Bank case from just last year. It's very clear that if you just add an abstract functional sub step, such as staggering or round tripping, that's just another abstract idea without -- and if you have -- if you lack any clear description of how those processes are performed or specificity concerning what these -- if there's a technological improvement, that's ineligible, Your Honor.

And if I could just return briefly to --

05:00 going back to Slide 3. I skipped over this earlier, Your Honor.

These are four telltale signs that the Federal Circuit has identified as signs of abstractness. And you can see that this patent checks off all four of those.

Generic data steps are well-settled indicators of abstractness according to the Federal Circuit. That's all we're talking about here is general manipulation of data, receiving data, calculating data.

Result-focused functional language. That's all that's talked about here. The claim just says computer should do it. Instead of having an individual technician do it, the computer gets to do it.

Third point, no technological improvement. And as the Federal Circuit has said, whether the issue is raised at Step 1 or Step 2, increased speed and efficiency resulting from use of computers with no improved computer techniques, that does not create eligibility.

And that's Align's main argument, Your Honor. Their brief is replete with descriptions of how much faster and how much more efficient the process can

be done by a computer. That is categorically insufficient under the case law.

And as I mentioned before, the fourth touchstone of abstractness here is on the automation of a manual process. Credit Acceptance Corp. from the Federal Circuit says that is insufficient.

And now finally, Your Honor, to return back to Claim 2, which I believe you mentioned you wanted to hear argument on.

If we could jump to Slide 22.

The dependent claims are no better than Claim 1 in this situation. What does Claim 2 add? Claim 2 adds a requirement that the computer calculate a route over which the teeth will move from their initial position to their final position. The -- Claim 2 says the computer should calculate a distance the tooth moves and calculate -- and should determine the rate at which the teeth move.

Those are not technological improvements. Those are not specifying any algorithm, any software, any hardware. They are result-oriented steps that are going to be part of planning any sequence.

THE COURT: What tooth movement? With Claim 2, what impact does it have that there are considerations of route, distance, and rate?

MR. ZUBLER: I'm sorry. Could you repeat the question, Your Honor?

THE COURT: Yes, of course.

With regard to Claim 2, what about the fact that it includes considerations of route, distance, and rate, what does -- how does that affect the 101 analysis?

MR. ZUBLER: Sure. Well, Your Honor, you know, the route, the distance, and rate are inherent parts of any treatment plan. There's going to be a determination of a route any time you --

THE COURT: I think -- did you say -- I'm sorry. Did you say "any treatment plan"?

MR. ZUBLER: Any treatment plan. Yes.

THE COURT: Okay. Got it.

MR. ZUBLER: Yes, Your Honor.

So, you know, these are like the -- the most basic elements of any treatment plan. You have to calculate a route. A tooth has to move from Point A to Point B. There's going to be a distance that that tooth moves. And there's going to be a rate at which that tooth can move.

Nothing about that is nonabstract. There's nothing technical about that. It's a result too. It says calculate a route. Doesn't say how you

calculate the route. It doesn't say how you calculate the distance or determine a rate. It's just abstract functional language.

THE COURT: Okay. And Claims 11 and 39, what about the inclusion of a midline shift pattern?

MR. ZUBLER: Yeah. So the midline shift pattern, again, it adds nothing that is nonabstract to these claims.

So what is a midline shift pattern? So the midline of your mouth is where the middle of your teeth, between your two incisors right in the front. And sometimes that's misaligned. It might be miss -- your top jaw might be misaligned with your bottom jaw or both of them might be misaligned with the center of your face. So often what needs to be done is teeth need to be shifted to correct that midline, to move your teeth one way or the other to correct it.

All that the patent claim says is, is that it describes how you should do a sequential movement of teeth to correct that. It doesn't discuss when you do that. It doesn't discuss how you do that. It simply says implement a midline shift pattern. Have the computer implement that. That's not an inventive concept. It's not -- it's an abstract concept. Again, nothing technical about it.

And to the extent that Align has argued that this is some kind of new thing or something that could be claimed as inventive, during claim construction, this was a term that was up for claim construction. We argued for a specific claim construction. Align came in and said, no, no, no. This claim does not need construction. Plain and ordinary meaning.

Because their Dr. Kuo, K-u-o, submitted a declaration, said it can be given just the ordinary meaning that it has in the orthodontic field.

So there's nothing special about midline shift pattern, and they should be held to that. They won that claim construction fight before Judge Gilliland. And for them to come in now and argue that, oh, this could be some inventive concept I think is unsupported.

And again, there's no specificity in the patent about how you -- you know, in the claims about when you do this, how you do it. It's a pure functional result-oriented step.

THE COURT: That's all I had for you.

Could I hear a response?

MR. MUINO: Yes, Your Honor. Good afternoon. Daniel Muino of Morrison Foerster for

Align.

Your Honor, if I can put up my slides here.

Your Honor, counsel is dismissive of the specific movement techniques that are disclosed in the '444 patent. As was the focus of the argument, the patents claim specific techniques, staggering, round tripping and midline shift. The midline shift coming up in the dependent claims.

It is not simply a matter of automating the preparation of a treatment plan with the movement of teeth. It is using those particular techniques in order to move the teeth.

Now, the theory that they floated is that these things, staggering and round tripping and midline shift, were in fact done by human technicians using software before the patent. They haven't actually shown that, though. There's no evidence, Your Honor, in the record that any of these techniques here, staggering, round tripping, midline shifts, were actually used by human technicians for treatment planning before the '444 patent.

And the admissions that they claim to have gotten from Dr. Valley were in fact not admissions to the effect.

As I mentioned, Your Honor, the presentation that counsel provided was dismissive of what's disclosed here. The patent actually does disclose details about these various techniques.

With respect to staggering, for example, in addition to providing a very clear definition of what staggering is, which is the definition that the parties have embraced for purposes of the case, there are figures and there's portions of the specification that show what staggering is and how that specific type of movement can help to avoid collisions in treatment plans.

And so here's Figure 8, Your Honor. It has an example from the patent that shows a pattern where the two teeth in the middle, the two central incisors, this would be Teeth 8 and 9, would ordinarily move from the start of the case from Stage 1.

In this circumstance, because the system has determined that they would collide with other teeth, with the adjacent teeth, it staggers, it delays the movement of those teeth until Stages 2 and 3. And so this is an example of how staggering addresses collisions in these treatment plans.

Round tripping also is disclosed in the figures and in the specification. Figure 9 here gives

us a specific example of round tripping.

And so what we see here in Figure 9 is Tooth No. 7 and Tooth No. 10 are teeth that are moved initially in the opposite direction out of the way of other teeth to allow other teeth to pass by. Once those other teeth have sufficiently moved past Tooth No. 7 and 10, 7 and 10 start moving back into their original position and then move on ultimately to their final position.

So contrary to what counsel seemed to indicate, the patent does provide a fair amount of specificity as to the benefits and the nature of the staggering and round tripping techniques.

As I mentioned, Your Honor, they incorporated into their briefing some admissions from -- some testimony from Dr. Valley, who is an orthodontist retained by Align in this case.

What Dr. Valley was discussing, though, and what she was acknowledging was the nature of these movement techniques as used in braces, in traditional braces in the past. She said, when asked specifically about the use of staggering or round tripping in connection with clear aligner treatment, is that she didn't know that that was the -- those techniques were ever actually used in clear aligner planning in the

past.

And apart from those -- the testimony they've pointed to from Dr. Valley, they've offered nothing else to support the idea that these techniques, staggering or round tripping, were actually known and being used for clear aligner treatment before the '444 patent.

Counsel alluded to and Your Honor alluded to the midline shift pattern in the '444 patent in Claim 11. This is a very specific pattern that addresses, as counsel indicated, the problem of the teeth being skewed in one direction or another relative to the midline of the face.

And here too, Your Honor, the patent discloses specifics of what midline shift patterns look like, what their purpose is, what the benefits are of midline shift patterns.

Figures 6A and 6B are two examples of that. We see midline shift patterns executed from one side of the mouth to the other to shift the teeth in one direction. And then 6B shifts it in the opposite direction. So the patent provides a fair amount of disclosure, Your Honor, and quite a bit of detail on these various techniques.

And again, I think as is most important,

Your Honor, to the pending motion and is -- and a reason for denying it is they don't actually have evidence that this was being used, that this was well-known or conventional in the area of treatment planning for aligners before the patent.

That's the basis of their argument is to sort of wave their hands and say, well, yeah. This is -- this is just abstract and surely, you know, technicians were doing this manually before the patents. But they don't have evidence that that's the case.

With respect to the midline shift pattern, Dr. Valley testified that that phrase, "midline shift pattern," or the idea of having a pattern for addressing midline discrepancies was actually not part of the language of orthodontics in her experience, and up until she had read the patent, that was a new phrase to her.

Using a pattern to accomplish a midline correction, she said, was not something that orthodontists did prior to the '444 patent.

Your Honor, we think that the applicable case here might be the McRO case from the Federal Circuit, where the Court, looking at this, looked at a patent that was directed to a software method, but a

software method that had specific rules that were being applied, specific rules that were not necessarily conventional in the field. And because it was applying specific unconventional rules in this software method, it was patent eligible.

And we think similarly, Your Honor, in this circumstance, there are specific movement techniques and specific movement patterns that the patent applies that make this patent eligible.

And with that, Your Honor, I will stop.

THE COURT: A response?

MR. ZUBLER: Yeah. Very briefly, Your Honor.

I think the key to focus on here is to start with the threshold question of abstractness and whether the ideas being described here are abstract.

Mr. Muino very accurately showed a description or a figure of what staggering might look like or what round tripping might look like in a case. That's a definition or it's an example of it. But that doesn't change whether it's abstract or not.

Abstraction relates to whether or not, you know, that the -- whether or not the patent is describing just a functional result. Do staggering, you know, achieve staggering without any description of

how it's done or any technological improvement, which, again, is the touchstone of Federal Circuit jurisprudence on this issue. So that's Point No. 1, Your Honor.

Point No. 2, if I could go to -- if I could ask Slide 35 to be pulled up from our presentation.

Slide 35, please.

The hour's late. I'll keep moving along.

What Slide 35 would show and I don't know if you have access to it, Your Honor, separately, but these were concessions by Align's experts about the ideas of staggering, slowing, and round tripping.

And Dr. Valley, one of their experts, said: In the field of orthodontics, staggering was a technique that we practiced with braces and wires; and therefore, it was general knowledge in the field of orthodontics.

Now it's available on the screen.

Similarly, what Dr. Singh said was: A skilled artisan would have recognized that staggering, slowing, and round tripping were methods of collision avoidance.

Now, what Mr. Muino just said was one of that counts, you can't use those concessions against

Align because those must have been made in the context of braces, not aligners.

But look at the claims in this case, Your Honor. None of them require aligners. All of these claims could apply to braces. So the idea that they can -- that they've -- you know, that they can kind of artificially create a field of use restriction on these patents, it's just not in the claims and, therefore, the -- and Mr. Muino's point is not a rebuttal to the concession that was made here.

And in his own last point, Your Honor --

Slide No. 23, if you could go to that.

This is Align's own brief, again, where they're emphasizing that the key to the '444 patent is automation, automation of what had previously existed.

And just read what they say here: Align's invention provides automated staging of teeth by scheduling movement using specialized movement patterns, routes, rates, distances, including tooth staggering, round tripping, midline shift patterns.

The next sentence: Automation of these techniques, as in the '444 patent, helped reduce the time required to prepare treatment plans and improved the precision and consistency of the applied movement patterns.

That's Align implicitly recognizing that what their -- what this patent is about is about automating techniques that have always been done. And what they really want to focus on in this case is just, oh, it would have been hard to do this without the computer. It would have been -- the computer makes it more efficient. But that by itself is clearly insufficient under Federal Circuit case law.

THE COURT: I'll be back in a few seconds.

(Pause in proceedings.)

THE COURT: If we can go back on the record, please.

With respect to the '444 patent, the Court is going to grant the motion with respect to all the claims that were raised.

With regard to plaintiff's motion for summary judgment, Docket 358, and the various points that were raised, the Court is going to deny all of that motion. I'm denying the motion for summary judgment of plaintiff in its entirety.

So if you all will give me another second, I'm going to huddle with my clerks and see when we can next get together. I think we're planning on Monday, but I'll be right back.

(Pause in proceedings.)

THE COURT: Okay. Thank you all for that.

We have a hearing set on Monday at 10:00, which still works for me at the moment. If you all -- if everyone can plan to be a little bit flexible, because I do want to get as much done as I can on Monday morning. We may -- we may either move the hearing up to an earlier time -- sorry for the people in California. Or if we start at 10:00, we may plan on going till probably 1 o'clock. So I'm going to do my best to get through as much of the motions as I can on Monday. So.

Mr. Nash, you're in my screen so I'll ask you first. Is there anything else for your client?

MR. NASH: Nothing from plaintiff at the time, Your Honor.

THE COURT: Anything, Mr. Durst?

MR. DURST: No, Your Honor.

THE COURT: Okay. Thank you all for the arguments. I look forward to seeing you on Monday morning either at 10:00 or a little earlier if necessary. Take care.

(Hearing adjourned.)

UNITED STATES DISTRICT COURT)
WESTERN DISTRICT OF TEXAS)

I, Kristie M. Davis, Official Court Reporter for the United States District Court, Western District of Texas, do certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

I certify that the transcript fees and format comply with those prescribed by the Court and Judicial Conference of the United States.

Certified to by me this 29th day of May 2026.

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

EXHIBIT E
WITNESS: T. Osswald
Date: July 2, 2026
Reporter: Teri Simons, CCR, RMR, CRR, RDR

ALIGN TECHNOLOGY, INC. *
*
VS. *
*
CLEARCORRECT OPERATING, *
LLC, ET AL. *

June 24, 2026

* CIVIL ACTION NO. 6:24-CV-187

BEFORE THE HONORABLE ALAN D ALBRIGHT
JURY TRIAL PROCEEDINGS
Volume 3 of ^

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Proceedings recorded by mechanical stenography, transcript produced by computer-aided transcription.

08:57

09:07 (Hearing begins.)

09:07 THE BAILIFF: All rise.

09:07 THE COURT: Please remain standing for the jury.

09:07 (Jury entered the courtroom.)

09:08 THE COURT: Thank you. You may be seated.

09:08 MR. MUELLER: Good morning Your Honor, and good morning, ladies and gentlemen.

09:08 Your Honor, for our next witness, we call Dr. Stephen Spiegelberg, and Mr. Zubler will conduct the examination.

09:08 THE COURT: Very nice. Thank you, sir.

09:08 (The witness was sworn.)

09:08 DIRECT EXAMINATION

09:08 BY MR. ZUBLER:

09:09 Q. Good morning, Dr. Spiegelberg. Could you please introduce yourself to the jury?

09:09 A. Good morning. My name is Stephen Spiegelberg.

09:09 Q. Where do you live, Dr. Spiegelberg?

09:09 A. I live in Winchester, Massachusetts.

09:09 Q. And can you describe briefly your family?

09:09 A. I live with my wife of many years and my two small dogs.

09:09 Q. What do you like to do in your spare time,

Dr. Spiegelberg?

A. My wife and I are amateur musicians, and we've developed a home concert series over the past couple of years where we invite professional musicians in to play in our living room, basically.

Q. What kind of music do you play?

A. I like to play blues and bluegrass.

Q. Dr. Spiegelberg, what is -- where do you work, sir?

A. I work at a company called Cambridge Polymer Group.

Q. And what is the Cambridge Polymer Group?

A. Cambridge Polymer Group is a research laboratory that specializes in polymeric materials.

Q. Have you prepared some slides to assist your testimony today, sir?

A. Yes. I have.

Q. If we could turn to the first slide.

Dr. Spiegelberg, what have you been asked to do in this case?

A. I was asked do two main things: One, to assess whether or not the ClearCorrect products infringe the materials patents of Align and whether or not the Align patents are valid.

Q. Okay. Before we go into your conclusions on

those issues, I'd like to ask you some questions about your background.

Sir, what educational degrees have you received?

A. I have a bachelor's of science in chemical engineering from the University of Wisconsin-Madison and a Ph.D. in chemical engineering from the Massachusetts Institute of Technology or MIT.

Q. When did you get your Ph.D., sir?

A. In 1993.

Q. And what was the focus of your research in getting your Ph.D.?

A. Both my Ph.D. and my undergraduate degree focused on polymer science.

Q. And what did you do after your got your Ph.D.?

A. After my Ph.D., I became a research associate at Harvard University, and then that job translated over to MIT, when the professor I was working for took a job at MIT. And there we developed materials for characterizing polymer solutions in a zero-g environment.

Q. When did you start working at your current position, the Cambridge Polymer Group?

A. I'm one of the cofounders of Cambridge Polymer Group which we started in 1996, and I currently serve

as the chief scientific officer.

Q. And what kind of work does the Cambridge Polymer Group do?

A. We do a lot of testing for clients according to standards and ones that we develop inhouse. We develop new materials for different products. We help companies develop new products and also get them through the regulatory pathway.

Q. Have you ever worked with polymers for biological uses?

A. Yes. About 75 percent of our work involves polymers used in medical applications.

Q. If we could go to the next slide.

Have you received any recognitions, sir, for your work?

A. Yes. I have over 40 patents, both in the United States and ex-U.S, and then I have over 75 published articles, book chapters, conference presentations. And because of my heavy involvement with ASTM, they've made me an ASTM fellow.

Q. Okay. Let's pause for a second on ASTM. The jury has heard about that already.

What is ASTM?

A. ASTM is what's called a consensus standards organization where we develop standards to help any

09:12 laboratory around the world know how to properly test
09:12 materials.
09:12 Q. And what's the -- what does ASTM stand for?
09:12 A. It used to stand for the American Society for
09:12 Testing Materials. Now it just stands for ASTM.
09:13 Q. And where is the ASTM organization based?
09:13 A. Oh, it's international. So they have
09:13 headquarters in New Jersey, but they're everywhere.
09:13 Q. All right. And if I could ask you,
09:13 Dr. Spiegelberg, perhaps just to get a little closer to
09:13 the microphone just to make sure the jury and lawyers
09:13 can hear your voice.
09:13 A. Of course.
09:13 Q. Now, on your slide here, it refers to the ASTM
09:13 Committee D20 on Plastics. What is that?
09:13 A. That's the committee that's in charge of
09:13 standards associated with testing polymer materials.
09:13 Q. Now, the jury has heard evidence regarding an
09:13 ASTM standard known as D638.
09:13 Are you familiar with that standard, sir?
09:13 A. Yes. I am.
09:13 Q. Does the ASTM Committee D20 on Plastics, of
09:13 which you're a part, have anything to do with the D638
09:13 standard?
09:13 A. Yes. Committee D20 is in charge of standard

09:13 D638, which means we maintain it, we make sure it's up
09:14 to date, and we were the original drafters of it.
09:14 MR. ZUBLER: Your Honor, ClearCorrect
09:14 offers Dr. Spiegelberg as an expert in the field of
09:14 polymer science.
09:14 MR. HUNG: No objection.
09:14 THE COURT: I missed what instrument you
09:14 played.
09:14 THE WITNESS: I play the mandolin and
09:14 piano.
09:14 THE COURT: Okay. Sorry. Sorry.
09:14 I've been sitting here waiting for you to
09:14 finish, because I heard what you did, but I missed what
09:14 you played. So thank you for that.
09:14 THE WITNESS: Happy to do a concert later
09:14 on if you want.
09:14 THE COURT: I will accept him as an
09:14 expert.
09:14 BY MR. ZUBLER:
09:14 Q. If we could go to the next slide.
09:14 You said you've analyzed Zendura FLX's
09:14 infringement allegations. What did you conclude? Do
09:14 aligners made by ClearCorrect using Zendura FLX
09:14 infringe Align's patents?
09:14 A. No. They do not.

09:14 Q. At a high level, why did you conclude that, sir?

09:14 A. They don't have all the properties required in the Align patents.

09:14 Q. And you also said that you evaluated whether the asserted claims in this case are valid.

09:15 What did you conclude about whether or not the asserted claims of Align are valid?

09:15 A. If the Align claims are stretched to include a hard-soft-hard configuration, then they are not valid.

09:15 Q. Now, before we dive into your conclusions, I wanted to ask you -- if we could go to the next slide -- what -- in doing your analysis, what definition of a person of ordinary skill in the art did you apply in analyzing the facts in this case?

09:15 A. I applied the definition of a person of ordinary skill in the art as one who has a four-year undergraduate degree in polymer science or materials science or related field, about two years of experience in the field of design and manufacturing of films and thermoforming.

09:15 Q. Do you qualify as a person of ordinary skill in the art today and also back in 2010?

09:16 A. Yes. I do.

09:16 Q. Now, again, before we dive into your

09:16 conclusions, I'd like to ask just a few brief questions about the technology in this case. The jury has heard a lot about two different types of polymers, TPUs and copolyesters.

Have you heard some of that testimony so far?

A. Yes. I have.

Q. Did Align invent TPUs?

A. No. They did not.

Q. Are all TPUs the same?

A. No. They're quite varied.

Q. How many different types of TPUs are there?

A. There are hundreds to thousands of types of TPUs.

Q. Now, copolyesters, did Align invent copolyesters?

A. They did not.

Q. Are all copolyesters the same?

A. No. They are not.

Q. And how many copolyesters are there available today?

A. Hundreds, hundreds.

Q. Now, let's talk about polymers in the context of dental care. When were polymers first used for dental aligners?

A. In the 1940s.

09:16 Q. Was Align the first to use polymers for dental aligners?
09:17 A. They were not.
09:17 Q. When were clear aligners first developed for repositioning teeth?
09:17 A. Around 1993.
09:17 Q. Was Align the first to develop a clear aligner for repositioning the teeth?
09:17 A. No. They were not.
09:17 Q. Was Align the first to use a multi-layer dental aligner?
09:17 A. No. They were not.
09:17 Q. If we could go to the next slide.
09:17 If I could ask you, Dr. Spiegelberg, what does this slide show?
09:17 A. This is showing two multi-layer aligners that were introduced in 2009 and 2010.
09:17 Q. And which ones are you referring to there, sir?
09:17 A. I'm referring to NuBrace and Durasoft.
09:17 Q. And what were the characteristics of those two aligners?
09:17 A. They --
09:17 Q. Aligner materials, I should say.
09:17 A. Sure. They both had a hard layer and a soft

layer.

Q. And the dates, 2009 and 2010 shown on your slide here, how does -- how do those dates relate to the dates of Align's claimed invention of the SmartTrack material?

A. They are before Align's claimed date of invention of SmartTrack.

Q. All right. Let's go to the next slide.

I'd like to ask you some questions about the patent background in this case. We just saw that multi-layer aligner materials existed back in 2009 and 2010. So what did Align say that it invented in its application for patents that it started filing in 2012?

A. A multi-layer film that had a soft-hard-soft configuration.

Q. If we could go to the next slide which shows a portion of the '613 patent called the Abstract.

Could you describe, sir, what's being described in this slide?

A. This is the abstract from Align's '613 patent.

Q. And what is the abstract discussing or saying about the '613 patent?

A. It's describing the invention being a dental appliance that includes a hard polymer layer that's disposed between two soft layers.

09:19 Q. Now, did you review the entire '613 patent, sir?
09:19 A. Yes. I did.
09:19 Q. How many times does the specification refer to a soft-hard-soft configuration?
09:19 A. 13 times.
09:19 MR. HUNG: Your Honor, objection. May we approach?
09:19 THE COURT: Sure.
09:19 (Bench conference.)
09:19 MR. HUNG: Your Honor, there's a lot of characterization of the claims as "if stretched to cover hard-soft-hard." There's no debate in this case the claims cover hard-soft-hard. He's trying to revive the written description argument and also make a claim construction argument that the claims as stated don't cover hard-soft-hard. He can make his enablement argument. He can't say the claims are stretched to cover hard-soft-hard or the like.
09:19 THE COURT: Overruled.
09:19 (Bench conference concludes.)
09:20 BY MR. ZUBLER:
09:20 Q. I believe, just to make sure I caught your answer on the last question, you said that the specification refers to soft-hard-soft configuration 13

09:20 times. Was that your answer, sir?
A. That's correct.
Q. And if the ladies and gentlemen of the jury were to take a look at the patents, would they find any other configurations described in the '613 patent?
A. They would not.
Q. And we're talking here about the '613 patent. There's three other patents at issue in this case with respect to materials.
Are the specifications in those patents the same or different than the specification of the '613 patent that we're looking at right now?
A. They are the same.
MR. ZUBLER: Now, if we could pull up DTX-462, which has already been entered into evidence.
BY MR. ZUBLER:
Q. What is this, sir?
A. This a declaration from Dr. Li submitted to the Patent Office.
Q. And this was -- we discussed this a little bit earlier this week.
MR. ZUBLER: And if we could go to the last page of this declaration.
BY MR. ZUBLER:
Q. When was this declaration submitted by Align

to the Patent Office?

A. In November 2016.

Q. Did Align submit this declaration before or after Bay Materials launched Zendura FLX?

A. This was before.

MR. ZUBLER: Let's go to Page 3 of this declaration from 2016.

BY MR. ZUBLER:

Q. And there's a section entitled Not Predictable.

Do you see that, sir?

A. Yes. I do.

Q. At a high level, what is Align describing in this declaration, in this paragraph or section of the declaration?

A. Dr. Li's informing the Patent Office that the development of dental aligners was not predictable.

Q. What evidence does Dr. Li cite to support the proposition that the development of clear aligners is unpredictable?

A. She indicates that it took them over seven years and looking at over 250 different materials to arrive at a solution.

Q. Now, if we go to Paragraph 4 where we are and we go about halfway down, there's a sentence that

09:22 begins "We found."

09:22 MR. ZUBLER: If we could have that highlighted, please.

09:22 And the sentence -- yeah. There we go.

BY MR. ZUBLER:

09:22 Q. The sentence states: We found that the resulting orthodontic appliances incorporating the SmartTrack material had surprisingly superior properties of modulus, of elasticity, elongation, time stress relaxation, durability, and thermoform ability.

09:22 For a layperson, Dr. Spiegelberg, what does that mean?

09:22 A. Dr. Li's informing the Patent Office of all the different materials they looked at, only the SmartTrack material had superior properties in these four categories over the previous technology.

09:23 Q. What material is she referring to here, sir?

09:23 A. SmartTrack.

09:23 Q. What's the configuration of hard and soft layers of SmartTrack, sir?

09:23 A. It's a soft-hard-soft configuration.

09:23 Q. Now, let's look at Paragraph 5 which Mr. Mueller discussed yesterday with Dr. Reitman.

09:23 There's a sentence here that says -- it begins "During": During evaluation of the over 250 materials,

only the materials of the instant claims met Align's development criteria.

Do you see that sentence, sir?

A. Yes. I do.

Q. And again, for a layperson, what does that mean?

A. Of all the materials that they examined, the 250, only the soft-hard-soft configuration met their design criteria.

Q. And I want to focus on the language that says "only the materials of the instant claims."

What is that referring to? What were the instant claims?

A. The instant claims in this document were soft-hard-soft.

Q. Now, have you reviewed the entire '613 patent, sir?

A. Yes.

Q. And I believe you testified before that -- well, I'll ask you the question.

What types of configurations are described in the '613 patent?

A. Soft-hard-soft.

Q. Is the statement here in Paragraph 5 consistent or inconsistent with the specification of

09:24 the '613 patent?
A. It's consistent.
Q. I'm sorry. Could you repeat that?
A. It is consistent.
Q. Thank you.
Now, when do you understand that Align first learned about Zendura FLX? Was that before or after this declaration?
A. It was after.
Q. And how did Align executives react to the announcement of Zendura FLX?
A. They sounded concerned.
Q. All right.
MR. ZUBLER: Could we look at DTX-200, which has already been admitted?
BY MR. ZUBLER:
Q. And what is DTX-200, sir?
A. This is an e-mail exchange between Joe Hogan, the CEO of Align, and Srini Kaza, the VP of research at Align.
Q. Now, if we could go to bottom of Page 3 of DTX-200, and you see there's an e-mail from Joe Hogan to Srini Kaza dated January 18, 2019.
Do you see that, sir?
A. Yes. I do.

09:25 Q. Who is Joe Hogan?
09:25 A. CEO of Align.
09:25 Q. Who's Srini Kaza?
09:25 A. The VP of research at Align.
09:25 Q. Now, the e-mail begins: Hi Srini. Chunhua sent a previous note to me on the material so I know it will be better than EX30.
09:25 Do you see that?
09:25 A. Yes. I do.
09:25 Q. Who's Chunhua?
09:25 A. That's Dr. Li.
09:25 Q. And what is the material being discussed here?
09:25 A. Zendura FLX.
09:25 Q. Now, Mr. Hogan goes on: I am really worried about marginalizing ST.
09:25 What is ST?
09:25 A. SmartTrack.
09:25 Q. Now, let's look at Mr. Kaza's response to this e-mail. And if we could go to the sentence that begins "I hope we will."
09:26 It says: I hope we will find -- actually, let's -- I hope we will find -- there we go.
09:26 It's the sentence that begins: I hope we will find some good points of differentiation, but my concern is that this has clearly been on people's minds

for a few years now, and unless we can stop with IP, they will keep coming.

Do you see that, sir?

A. Yes.

Q. What do you understand IP to mean in that sentence?

A. IP means intellectual property; in other words, patents.

Q. Based on the evidence you've seen, what did Align do next with respect to Zendura FLX and Bay Materials?

A. They filed some more patents.

Q. And when you file -- when they filed for more patents, did they submit further declarations to the Patent Office?

A. Yes. They did.

MR. ZUBLER: Let's look at DTX-84, which has already been admitted.

BY MR. ZUBLER:

Q. This is entitled Declaration of Chunhua Li under 37 CFR 1.132.

What is this document, sir?

A. This is the second declaration that Dr. Li submitted to the Patent Office.

Q. And we looked at this previously with

Mr. Mueller and Dr. Li. When was this declaration submitted, before or after Align learned about Zendura FLX?

A. After.

Q. And approximately how long after they learned it?

A. I think it was about eight months after.

Q. Now, did you prepare anything to help identify the differences between the original declaration that Align submitted and the revised declaration?

A. Yes. I did.

Q. If I could ask you to look at Tab 11 of your binder, sir. DTX-422.

Do you see it, sir?

A. I do.

Q. What is this?

A. This is a redline comparison between the first declaration and the second declaration.

MR. ZUBLER: Your Honor, we move the admission of DTX-422.

MR. HUNG: No objection.

THE COURT: Admitted.

BY MR. ZUBLER:

Q. So now let's look at the redline. And what is the purpose of a redline, sir?

09:28 A. It allows one to quickly see what changes were made between two documents.

09:28 Q. Now, previously we looked at two different statements, one in Paragraph 4, one in Paragraph 5 of the original declaration. Let's look at each of those statements now in order.

09:28 So let's look at your redline, starting at Paragraph 4, and we'll focus in again on the sentence that begins "We found."

09:28 And the sentence now reads: We found that the materials with both hard and soft polymer layers according to the current claims in orthodontic appliances had surprisingly superior properties.

09:28 Do you see that, sir?

09:28 A. Yes. I do.

09:28 Q. Now, you testified that in the prior declaration, Align was referring here to the SmartTrack soft-hard-soft configuration.

09:29 What configuration or configurations is Align discussing now?

09:29 A. They're indicating that not just SmartTrack but a variety of hard-soft-hard configurations meet their design criteria.

09:29 Q. Dr. Spiegelberg, have you analyzed, from a scientific perspective, whether this revised statement

to the Patent Office was accurate?

A. Yes. I have.

Q. How did you do that?

A. I looked at Dr. Li's actual testing data of the different multi-layer films she examined.

Q. Did Align submit that testing data to the Patent Office?

A. They did not.

Q. Was that data published publicly so the Patent Office or the public could review it?

A. No.

Q. So then how were you able to look at that data?

A. It was produced in this litigation.

Q. Now, having reviewed the actual testing data that wasn't submitted to the Patent Office, what, if anything, did you conclude about the accuracy of the statement we're looking at in the revised declaration?

A. It is not accurate.

Q. And what are the reasons it's not accurate?

A. The various materials do not have superior properties over the previous material.

MR. ZUBLER: Okay. Let's look now at JTX-077, which is already admitted.

BY MR. ZUBLER:

09:30 Q. All right. Can you see this document, sir?
09:30 A. Yes. I can.
09:30 Q. A lot of numbers here. What is this?
09:30 A. This is the testing data that was provided by Align showing all the different materials they considered, demonstrating that the -- the data from their testing.
09:30 Q. Okay. So what's on each row of this spreadsheet, sir?
09:30 A. Well, we see tensile data, durability data, stress relaxation, flexural modulus, et cetera.
09:30 Q. Actually, let me just ask the question.
09:30 What's shown on each row of this spreadsheet?
09:30 A. Oh, each row is a different formulation that they considered, different set of films, basically.
09:30 Q. And then what's shown on the columns?
09:30 A. The columns are the actual testing data.
09:30 Q. Now, going back to the declaration, how many materials from this testing data was Align referring to in its revised declaration?
09:31 A. 23.
09:31 Q. And of those 23 materials that Align was referring to in the declaration, how many of those were superior to EX30 based on the four characteristics that Align mentioned in its revised declaration?

09:31 A. None of them.
09:31 Q. Can you describe what you mean by that?
09:31 A. None of the 23 multi-layer films that meet the specifications in the claims had superior properties over the EX30 in all four categories.
09:31 Q. Now, did Align's expert, Dr. Reitman, did she do her own analysis of Align's testing data?
09:31 A. Yes. She did.
09:31 Q. What materials, if any, did Dr. Reitman find that were better than EX30 along each of the four metrics that Align listed in its declaration?
09:31 A. None.
09:31 MR. ZUBLER: So let's go back to Paragraph 4 of the redline DTX-422, in the sentence that begins "We found," if we could highlight that again.
BY MR. ZUBLER:
09:32 Q. Was that statement in Align's revised declaration true or false?
09:32 A. It was false.
09:32 Q. All right. Let's look at the second statement in Paragraph 5 that we looked at before.
09:32 This was the sentence --
09:32 MR. ZUBLER: We can pull it up. And it says: During evaluation of the over 250 materials. If

we could highlight that sentence.

BY MR. ZUBLER:

Q. Now, in this sentence, there's a change in the text. So it previously said "only the materials of the instant claims met Align's development criteria," and now it says "only the claims according to the current" -- "only the materials according to the current claims met Align's development criteria."

Do you see that, sir?

A. Yes. I do.

Q. Now, at the time of the revised declaration, what was the scope of the current claims as listed here in the declaration?

A. The current claims are much broader, and they consider materials beyond a soft-hard-soft configuration.

MR. ZUBLER: If we could look at the next slide in your presentation, DDX-7.12.

BY MR. ZUBLER:

Q. I'd ask you to focus first on the left side of this demonstrative. What's shown there, sir?

A. Dr. Li's original declaration to the Patent Office only considered a soft-hard-soft configuration as a material that met their design -- or original Align's development criteria.

09:33 Q. And what's shown on the right side of the slide, sir?

09:33 A. This is the materials that Dr. Li is now saying meets their development criteria in the revised declaration.

09:33 Q. Let me see if I understand that. There's a lot of letters on here, HSSS, HHSS, and so forth.

09:33 What are you talking -- what you showing there?

09:33 A. S refers to a soft layer. H refers to a hard layer. And in original declaration, Dr. Li only considered soft-hard-soft as meeting their development criteria. In the revised declaration, multiple configurations now meet their development criteria.

09:34 Q. Now, is the statement that Dr. Li made in the revised declaration, is that based on the same or different data than the data she used in the original declaration?

09:34 A. It's based on the same data.

09:34 Q. How do you know that?

09:34 A. No other data was produced.

09:34 Q. So if the data didn't change, how could Align first state in the original declaration that only the soft-hard-soft material met Align's development criteria and then later state, based on the same data,

that a larger set of material configurations met Align's development criteria?

A. I don't know. It doesn't make any sense.

Q. Can you think of any technical or scientific reason that would justify that change?

A. No.

MR. ZUBLER: I'd like to now ask you -- or show JTX-79, which has already been admitted. We could look at Sheet 2.

BY MR. ZUBLER:

Q. Dr. Spiegelberg, what being shown here in JTX-79?

A. This is another spreadsheet that Align produced in this litigation that describes the various materials they considered and the composition and the reasons that they rejected them.

Q. Okay. What's shown on each row of this spreadsheet?

A. Each row is a different formulation that was considered.

Q. What's shown on each column of -- or not each column, but what is shown generally on the columns in the spreadsheet?

A. The columns indicate the materials, the orientation of the materials, in other words, like a

09:35 soft-hard-soft configuration, and the reasons that they
09:35 rejected these based on testing.
09:35 Q. What is Column G, sir?
09:35 A. Column G is the reasons that Align rejected
09:35 these materials from further consideration.
09:35 Q. Now, of all the materials that are included in
09:36 this testing data, how many were multi-layer materials?
09:36 A. Around 68.
09:36 Q. And of the materials on this list that were
09:36 multi-layer materials, how many did Align reject?
09:36 A. All but three.
09:36 Q. What were the materials that Align didn't
09:36 reject?
09:36 A. The three were the precursors to SmartTrack.
09:36 Q. And what was the configuration of these three
09:36 materials that Align didn't reject?
09:36 A. Soft-hard-soft configuration.
09:36 Q. Did Align ever tell the Patent Office that it
09:36 had rejected all materials except soft-hard-soft
09:36 materials?
09:36 A. No.
09:36 Q. So going back now to the statement in
09:36 Paragraph 5 that we looked at in the revised
09:36 declaration, the statement that begins "During
09:36 evaluation of the over 250 materials, only the

materials according to the current claims met Align's development criteria," is that statement in the revised declaration true or false?

A. It is false.

Q. Now, based on your evaluation, sir, of the records of the patent prosecution in the '613 patent at the Patent Office, is there any evidence regarding whether Align's false statements were material to the issuance of the patent claims?

A. Yes.

Q. What's the basis for your statement?

A. The notice of allowance for the patent.

Q. All right.

MR. ZUBLER: Let's look at DTX-323. This has not been admitted, actually. So if we could, that's in your binder at Tab 14.

BY MR. ZUBLER:

Q. What is this, sir?

A. This is the notice of allowance the Patent Office sent to Align.

MR. ZUBLER: Your Honor, we move the admission of DTX-323.

MR. HUNG: No objection.

THE COURT: Admitted.

MR. ZUBLER: If we could publish that to

the jury.

BY MR. ZUBLER:

Q. What is a notice of allowance at the United States Patent and Trademark Office, sir?

A. It's an official document where the Patent Office informs the inventor that their patent is going to be allowed.

Q. And if we could go to the heading "Allowable Subject Matter" on Page 6 of the PDF, Page 2 of the document, I believe.

What is this section "Allowable Subject Matter" describing?

A. This is the narration from the patent examiner explaining why they gave the allowance of the patent.

Q. And if we could now go to the next page, and there's a sentence that begins "The applicant's affidavit."

Do you see that sir?

A. Yes.

Q. And it states: The applicant's affidavit was also found persuasive, in particular attention to the statement of the appliances recited in the claims of the '665 application exhibit unexpectedly positive results over previously known applications (sic).

Do you see that?

09:39 A. Yes, sir.
09:39 Q. What is the affidavit described in that
09:39 sentence?
09:39 A. This is Dr. Li's declaration.
09:39 Q. And what is the examiner saying about Dr. Li's
09:39 declaration?
09:39 A. She is saying that she found it persuasive.
09:39 Q. When the examiner made this statement and
09:39 allowed the claims, did she have access to Align's
09:39 testing data or not?
09:39 A. She did not.
09:39 Q. What actual material testing data about
09:39 Align's materials did Align submit to the Patent
09:39 Office?
09:39 A. No data was submitted.
09:39 Q. What, if anything, could the Patent Office
09:39 have done if it had received that data?
09:39 A. They could have done the same thing that I
09:39 did.
09:39 Q. Now, yesterday in court were you here when
09:39 Mr. Hung showed -- and actually it might have -- I'm
09:39 not sure which day it was. But Mr. Hung showed Dr. Li
09:39 Figures 5 through 8 of the '613 patent.
09:39 Do you recall that, sir?
09:39 A. Yes. I do.

09:39 Q. And Mr. Hung suggested this was evidence that Align had submitted data to the Patent Office in the -- in the patent.

09:39 Do you recall that?

09:40 A. Yes.

09:40 MR. ZUBLER: And let's pull up Figure 7 of the '613 patent, JTX-002.

BY MR. ZUBLER:

09:40 Q. This one of the figures that Mr. Hung showed Dr. Li.

09:40 Does this figure, sir, provide any data to the Patent Office regarding Align's alleged invention?

09:40 A. It does not.

09:40 Q. Why do you say that?

09:40 A. There's no description of what Material 1 or Material 2 is anywhere in patent. So there's no information about that other than Material 2 is a multi-layer film but a generic one.

09:40 The force plot here shows no data. There's no numbers on it, so a person of ordinary skill has no idea what kind of forces are being applied. And there's no information on what this X-axis is.

09:40 So this just a drawing. It's not data.

09:40 Q. Does the patent provide any numerical data about the nature or performance of what are called

09:40 Materials 1 and Material 2?
09:40 A. They do not.
09:40 Q. This is one of the four figures that Mr. Hung showed Dr. Li. I'm not going to go through them all.
09:41 Do the other figures that Mr. Hung showed Dr. Li provide any data regarding Align's alleged invention?
09:41 A. No. There's no useful data there.
09:41 Q. Now, we've talked a lot about the '613 patent and the prosecution at the Patent Office of the '613 patent. But there are three other materials patents in this case, the '384 patent, the '090, and the '091 patent. How do those patents relate to the '613 patent?
09:41 A. Those are all continuations of the '613 patent.
09:41 Q. What's a continuation of the '613 patent?
09:41 A. It has the same specifications, just some modifications to the claims.
09:41 Q. Are the claims of those other three patents similar or dissimilar to the claims of the '613 patent?
09:41 A. They're similar.
09:41 Q. Now, when Align was applying for these other three patents after the '613, did it ever modify or correct the representations that it made to the Patent

09:41 Office in its declarations that we looked at previously?

09:42 A. No. They did not.

09:42 Q. And if we could go to Slide 7.11, DDX-7.11.

09:42 So to conclude, sir, what did you conclude based on your analysis of the revised Align declaration in 2019?

09:42 A. That it contained at least two false statements.

09:42 Q. Were you here yesterday for the testimony of Mr. John Lahlouh?

09:42 A. I was.

09:42 Q. And are you aware that Align has accused Mr. Lahlouh of copying Align's SmartTrack material and patents?

09:42 A. I am.

09:42 Q. Now, based on your analysis in this case, including the examination that you witnessed yesterday of Mr. Lahlouh, are you aware of any evidence that Mr. Lahlouh or ClearCorrect copied Align's SmartTrack material or patents?

09:42 A. No. I'm not.

09:42 Q. Is Zendura FLX a copy of SmartTrack?

09:42 A. It is not.

09:43 MR. ZUBLER: Your Honor, we'd like to use

09:43 a demonstrative slide now that contains some
09:43 confidential information. I don't think we need to
09:43 seal the courtroom because I'm not planning to elicit
09:43 that orally, but I would ask if we could turn any
09:43 public gallery video monitor off so the information
09:43 remains confidential.
09:43 THE COURT: Sure.
09:43 BY MR. ZUBLER:
09:43 Q. Dr. Spiegelberg, with respect to this slide
09:43 that you prepared, what are you generally at a high
09:43 level trying to show with this slide?
09:43 A. This is showing the differences between
09:43 ClearCorrect's Zendura FLX material and Invisalign's
09:43 SmartTrack material.
09:43 Q. Okay. Let's look at the middle column
09:43 entitled Patient Experience Differences.
09:43 How, if at all, is Zendura FLX different from
09:43 SmartTrack with respect to the patient experiences?
09:43 A. Because of the configurations, Zendura FLX
09:43 will be more stain resistant and have a greater ability
09:43 to move teeth, whereas SmartTrack will initially be
09:44 more comfortable with the soft layer on the outside and
09:44 has easier removal and insertion forces.
09:44 Q. Now, let's look on the far column on the
09:44 right, physical differences. And you've listed some

various items there, some of which again I will not state and I'll ask you not to state in public in court for confidentiality reasons.

Let's start with the first line, configuration. How are the configurations of ClearCorrect Zendura FLX and Invisalign SmartTrack the same or different?

A. Zendura FLX has a hard-soft-hard configuration. SmartTrack has a soft-hard-soft configuration. So the opposite.

Q. And with respect to the next item, layer thickness, how do the layer thicknesses in Zendura FLX compare to SmartTrack?

A. Zendura FLX has the same thickness for all three layers, whereas SmartTrack has a much thicker inner layer and thinner outer layers.

Q. Now, I want to ask you about the next two items which are the TPUs and the copolyesters that are in both products. And here is the place, sir, where I don't want you to mention any of the specific item names or numbers there, sir.

How do the TPUs and copolyesters in Zendura FLX and SmartTrack compare to each other? Are they the same or are they different?

A. They are using different TPUs and

09:45 copolyesters.

Q. Last item, the manufacturing method. How do the manufacturing methods for Zendura FLX and SmartTrack compare to each other? Are they similar or dissimilar?

A. They are different manufacturing processes.

Q. One last question, sir, about the Patent Office examination that we were discussing earlier in the prosecution of these patents.

Were you here for Align's opening statement, sir?

A. Yes. I was.

Q. And do you recall that Ms. Durie stated in her opening statement, and I quote: And if you see that someone else is using your invention, you're allowed under the rules to go back to the Patent Office and say that's actually using our invention.

Do you recall that statement, sir?

A. Yes. I do.

Q. Based on all of your analysis in this case, including your examination of the prosecution records at the Patent Office, have you seen any evidence that Align ever went to the Patent Office and told the Patent Office that Zendura FLX was using Align's invention?

09:46 A. No. I did not.

09:46 MR. ZUBLER: Now, if we could go to DDX-7.13.

BY MR. ZUBLER:

09:46 Q. Let's move from the patent background to the infringement analysis. What has Align alleged with respect to infringement in this case?

09:46 A. They are alleging that Zendura FLX infringes their patents.

09:46 Q. All right. If we could go to Slide -- the next slide, DDX-7.14.

09:47 This shows '613 patent, Claim 1. There's some highlighting on here in yellow. What are you highlighting, sir?

09:47 A. One of the elements of the claim requires a soft polymer layer having an elongation at break greater than 200 percent.

09:47 Q. Which asserted claims across all of the asserted patents have this elongation at break requirement?

09:47 A. All of them.

09:47 Q. And what is your conclusion that we'll come to as to whether the elongation at break requirement is met by Zendura FLX?

09:47 A. It is not met by Zendura FLX.

09:47 Q. And what do you understand Align has to show in order to prove infringement against my client ClearCorrect?

09:47 A. Align has to show that every element of the claim is met by Zendura FLX.

09:47 Q. What if Align fails to prove even one element of a claim such as the elongation at break element?

09:47 A. Then Zendura FLX does not infringe.

09:47 Q. Now, at a high level, what did you conclude about whether there's infringement of the elongation at break limitation here, sir?

09:48 A. I concluded that Zendura FLX does not infringe.

09:48 Q. All right. Now, what is elongation at break?

09:48 A. Elongation at break is basically how far you can stretch a material before it breaks.

09:48 Q. Now, were you in here in court yesterday when Dr. Reitman said that the proper way to analyze and apply these claims for infringement in this case is to look at the individual polymers before they are incorporated into the multi-layer Zendura FLX material?

09:48 Do you recall that testimony?

09:48 A. Yes. I do.

09:48 Q. Do you agree with her testimony?

09:48 A. No. I disagree.

09:48 Q. Why not?
09:48 A. Because the important property is the material in its final configuration, in other words, in a multi-layer film, not before it's made into the film.
09:48 Q. Okay. Let's look at the '613 patent, Claim 1, and particularly DDX-7.17.
09:49 Sir, and '613 patent, Claim 1, begins "A method of making."
09:49 Do you see that language?
09:49 A. Yes. I do.
09:49 Q. This claim describes a method for making what?
09:49 A. A dental appliance.
09:49 Q. And what kind -- a dental appliance for what purpose?
09:49 A. For positioning teeth.
09:49 Q. And what is the dental appliance comprised of?
09:49 A. It's comprised of providing a sheet that has three or more polymer layers.
09:49 Q. Okay. The word "sheet," I'm not sure that's been discussed in this trial very much.
09:49 What's a sheet? Is that a piece of paper?
09:49 A. No. It's like a polymer film, basically.
09:49 Q. And as described in the '613 patent, Claim 1, what is the sheet comprised of?
09:49 A. It is comprised of a hard polymer layer with

multiple -- or with certain properties and a soft polymer layer with certain properties.

Q. Does this claim describe making a sheet?

A. No. The sheet's already made at this point.

Q. Where does the sheet come from for this claim?

A. From a manufacturer.

Q. Now, sir, as a person of ordinary skill in the art, do you understand this claim language should be applied to the characteristics of the individual polymers before they are included in a multi-layer sheet or after they are included in a multi-layer sheet?

A. After.

Q. And what claim language informs that opinion of yours, sir?

A. The fact that the sheet is already in existence. So the hard polymer layer and the soft polymer layer already have these properties at this point.

Q. Let's look again at the claim language at the beginning of this claim: A method for making a dental appliance for positioning a patient's teeth.

For a dental appliance for positioning a patient's teeth, what is relevant, the characteristics of individual polymers before they're included in a

multi-layer sheet or after they're included in a multi-layer sheet?

A. Since the properties influence how the dental appliance is effective at moving teeth, it has to be after it's incorporated into the multi-layer films, the properties after it's been manufactured.

Q. Let's now talk about how you measure the characteristics of the layers within a multi-layer material.

Can you measure the elongation at break of each layer in a multi-layer material?

A. Yes.

Q. How?

A. By doing tensile testing.

Q. And what is tensile testing at a high level, sir?

A. Tensile testing is taking a sample and pulling it apart and see how far it can stretch before it breaks.

Q. Now, did you hear Dr. Reitman say that you can't measure the elongation at break of individual layers within a multi-layer material?

A. Yes. I did.

Q. And do you agree with her or not?

A. I do not.

09:51 Q. Why not?
09:51 A. Because by testing a multi-layer -- tensile
09:52 testing a multi-layer film, you are testing each layer.
09:52 Q. Did you perform testing of Zendura FLX in this
09:52 case, sir?
09:52 A. Yes.
09:52 Q. Okay. We're going to come back to that
09:52 testing in more detail later, but in this case, were
09:52 you able to measure the elongation at break of
09:52 individual layers within the Zendura FLX multi-layer
09:52 material?
09:52 A. Yes.
09:52 Q. Now, when you're testing, when did the
09:52 individual layers break relative to each other?
09:52 A. For four of the specimens, they tested -- they
09:52 broke almost at the same time. One of the specimens,
09:52 the TPU layer broke about three seconds later, after
09:52 the copolyester layer is broken.
09:52 Q. Now, if all we know -- if you're doing this
09:52 testing or pulling of the Zendura FLX material, if all
09:52 we know is that the entire material breaks at a certain
09:52 elongation at break, what does that tell you about the
09:52 elongation of break of one of the layers, such as the
09:52 middle soft layer?
09:52 A. It shows that's the highest elongation of

break it could have. It may be a bit lower than that, but that's the highest value it could have.

Q. Now, in this case did either Align or Bay Materials conduct any testing of the elongation at break of Zendura FLX before this litigation?

A. Yes. Both companies did.

MR. ZUBLER: If we could pull up DTX-417, which has already been admitted into evidence.

BY MR. ZUBLER:

Q. What is this document, sir?

A. This is a testing report from Align materials on Zendura FLX.

Q. And when did Align perform this testing?

A. This was before the litigation.

Q. And what protocol did Align use to do this testing?

A. They used ASTM D638.

Q. All right.

MR. ZUBLER: If we could go to DDX-7.18 which excerpts some of that document.

BY MR. ZUBLER:

Q. What were the results of Align's testing as shown here?

A. The results from Zendura FLX, which are shown by the orange bars on this plot, indicate that Zendura

09:54 FLX had a elongation of a break between 123.7 percent
09:54 up to 139.6 percent.
09:54 Q. And what does this testing indicate about the
09:54 elongation at break of the TPU layer within Zendura
09:54 FLX?
09:54 A. That it has a elongation of break well below
09:54 200 percent.
09:54 Q. Now, let me make sure I understand. You said
09:54 this testing occurred -- well, I'll ask you this
09:54 question: When did this testing occur, before or after
09:54 Align sued ClearCorrect?
09:54 A. This was before.
09:54 Q. And Align, I believe you said, testified --
09:54 strike that.
09:54 Align -- you testified that Align found that
09:54 the elongation at break of Zendura FLX was greater than
09:54 or less than 200 percent?
09:54 A. Much less than 200 percent.
09:54 Q. But if Align's own testing showed that the
09:54 elongation at break was less than 200 percent, how can
09:55 Align accuse ClearCorrect of infringing Align's patents
09:55 which require an elongation at break greater than
09:55 200 percent?
09:55 A. I don't know. Doesn't make any sense.
09:55 Q. Now let's turn to Bay Materials' testing.

09:55 MR. ZUBLER: If we could pull up DDX-7.19.

BY MR. ZUBLER:

Q. What is this showing, sir?

A. This shows the test configuration that Bay Materials used to test the Zendura FLX.

Q. And what protocol did Bay Materials use for this testing?

A. They also did D638.

Q. And when did this testing occur?

A. This was before litigation.

MR. ZUBLER: And if we could go to DDX-7.20.

BY MR. ZUBLER:

Q. What were the results of this testing?

A. Bay Materials found that Zendura FLX had an elongation of break around 102 percent.

Q. And what does this testing indicate was the elongation at break of the TPU soft layer within Zendura FLX?

A. The TPU layer would have an elongation of break around 102 percent, much less than 200 percent.

Q. Was this testing by Bay Materials done before or after Align sued ClearCorrect?

A. This was done before.

09:56 Q. Now, Dr. Spiegelberg, have you done testing on Zendura FLX?

09:56 A. I have.

09:56 Q. And what protocol did you apply, sir?

09:56 A. I also did D638.

09:56 MR. ZUBLER: If we could go to DDX-7.21.

BY MR. ZUBLER:

09:56 Q. I want to ask you, how did you perform your testing? What is shown in this figure?

09:56 A. This is a photo from my laboratory. This shows a load frame which is used to do tensile testing on polymers. And the sample, which is cut into what's called a dog bone, is placed between two grips, a stationary grip on the bottom and then a moving grip on top. The moving grip separates the sample at a known rate. And then you measure how long it takes for it to break.

09:57 Q. If we could turn now to Tab 18 of your binder, Dr. Spiegelberg.

09:57 And we're going to look at -- behind Tab 18 of your binder is DTX-2190.

09:57 Do you see that, sir?

09:57 A. Yes. I do.

09:57 Q. What is DTX-2190?

09:57 A. These are the testing results from my testing

of Zendura FLX.

MR. ZUBLER: Your Honor, we move admission of DTX-2190.

MR. HUNG: Your Honor, we're fine with displaying to the jury, but it's a demonstrative. It's not a -- it's an expert-created piece of evidence.

THE COURT: I agree that it should be a demonstrative.

MR. ZUBLER: Okay. May we publish it to the jury, Your Honor?

THE COURT: Yes. Yes.

You're okay with it being a demonstrative?

MR. HUNG: I am, Your Honor.

THE COURT: Okay. Yes.

BY MR. ZUBLER:

Q. Looking at DTX-2190, sir --

MR. ZUBLER: And if we could zoom in a little bit more on the screen to make the data bigger. Thank you.

BY MR. ZUBLER:

Q. Will you please walk the jury through what's shown on this slide?

A. Yes. This is the test configuration and testing results from our tensile testing of Zendura

09:58 FLX. I show the testing speed conducted at 2 inches per minute or 50 millimeters per minute.

We looked at five different specimens per ASTM D638, and then the testing results indicated as elongation of break at the TPU layer is shown for the five specimens. And you can see we had a range between 145 percent up to 151 percent.

Q. And just to do some basic math, is an average of 148 greater than or less than 200 percent?

A. It is less than 200 percent.

Q. What did you conclude based on your testing?

A. That the TPU layer in the Zendura FLX has an elongation of break much less than 200 percent.

Q. And what is your opinion, based on this data, regarding whether or not ClearCorrect aligners made with Zendura FLX infringe the four asserted materials patents?

A. It does not infringe.

Q. Now, were you here for Dr. Reitman's testimony yesterday?

A. I was.

Q. And did you hear her testify that she ran tests on Zendura FLX?

A. Yes.

Q. Did Dr. Reitman's test results that you heard

09:59 yesterday cause you to reconsider your conclusion that
09:59 you drew from your testing?
09:59 A. No.
09:59 Q. Why not?
09:59 A. Dr. Reitman used a testing configuration that
09:59 was not in compliance with ASTM D638.
09:59 Q. Why was it not in compliance?
09:59 A. She used the wrong testing speed.
09:59 Q. Testing speed. What do you mean by "testing
09:59 speed"?
09:59 A. Basically, how quickly are you pulling the
09:59 sample apart.
09:59 Q. What pulling speed did she use?
09:59 A. She used 10 millimeters per minute or about a
09:59 factor of 5 less than what the standard requires.
09:59 Q. Which standard are you comparing that to?
10:00 A. ASTM D638.
10:00 Q. So just to be clear, was Dr. Reitman's pulling
10:00 speed slower or faster than what the standard requires?
10:00 A. Slower.
10:00 Q. And how does a slower pulling speed affect the
10:00 results you get when you're doing a measurement of
10:00 elongation at break?
10:00 A. It can result in a higher elongation at break.
10:00 Q. Is there a way to demonstrate this to the

10:00 jury, Dr. Spiegelberg?

A. Yes. There is.

Q. I believe you have with you DPX-38, which is an exhibit we made available for an inspection to the other side. Could you pull it out and show to it the jury, please?

What is it, sir?

A. This is Silly Putty. You can tell there's a polymer scientist in the crowd when they're carrying around Silly Putty because it's a great way of demonstrating the response of materials to deformation rate.

Q. Is Silly Putty a polymer, sir?

A. Yes. It is.

Q. Please go ahead.

A. Okay. So when you're doing a stretching experiment with Silly Putty, you can do it at different rates and you get different responses. If I do a faster rate, you can see that the material breaks at a fairly low strain.

I take the same material now and I do a much slower stretching rate, you can see I can take it to a much longer stretch before it even breaks, if it even breaks at all.

So what's happening is the polymer chains are

10:01 having a lot more time to respond and flow so that they
10:01 don't break.
10:01 Q. Now, to obtain her results, for how long of a
10:01 period of time did Dr. Reitman pull her samples?
10:01 A. She had some experiments that went over ten
10:01 minutes.
10:01 Q. And when you say her experiments ran for more
10:01 than ten minutes, what do you mean?
10:01 A. That the sample didn't break within ten
10:01 minutes. It went longer than that.
10:01 Q. And does that comply or not comply with the
10:01 ASTM standard?
10:01 A. It does not comply with it.
10:01 Q. How so?
10:01 A. The ASTM standard is fairly prescriptive in
10:01 that you should have a break between half a minute to
10:01 five minutes. And if you go longer than five minutes,
10:02 then you're at the wrong speed.
10:02 Q. Now, you said you were here for Dr. Reitman's
10:02 testimony yesterday. And do you recall she testified
10:02 about the manufacturer's technical data sheets?
10:02 A. Yes.
10:02 Q. And Dr. Reitman concluded that the data sheet
10:02 for a raw polymer such as the TPU used in Zendura FLX
10:02 was evidence of infringement, the data on this data

sheet.

Do you recall that, sir?

A. Yes.

Q. Do you agree with her?

A. I do not.

Q. Why not?

A. Because manufacturing changes polymers' behavior.

Q. And do you recall, sir, that Dr. Reitman also testified about her testing of the individual polymers used within Zendura FLX?

Do you recall that testimony?

A. Yes.

Q. And she testified that her testing of the individual polymers by themselves was evidence of infringement. Do you agree with that?

A. I do not.

Q. Why not?

A. The materials that she manufactured used a different manufacturing process than what's used in Zendura FLX. So it's not replicative of what's happening in Zendura FLX manufacturing, so therefore are different properties.

Q. Let's talk about the manner in which Zendura FLX manufactured. What is the process for

10:03 manufacturing Zendura FLX?
10:03 A. It's a process called extrusion lamination.
10:03 Q. Okay. Let's break that down, extrusion lamination. What's extrusion?
10:03 A. Extrusion is the process by which you can take polymer pellets and get them into a melt or molten state so then you can process them into other conditions. It's kind of like taking a stick of chewing gum and chewing it up so it's much more pliable and flexible.
10:03 Q. Okay. That's extrusion. What's lamination?
10:03 A. Lamination is taking preexisting sheets and bonding them together in some way.
10:03 Q. Have you prepared an animation, sir, to explain this process?
10:03 A. I have.
10:03 Q. If we could start the animation and you could explain what the first step is here in the extrusion lamination process.
10:04 A. This is a cartoon of an extruder. And you can see a hopper that contains the copolyester pellets shown in blue.
10:04 The pellets are introduced into the extruder, and then it begins to be heated and then conveyed by the screw, which acts as a shearing action to help make

10:04 the polymer pellets all molten.

10:04 They're conveyed to the end, and it goes through a die and is formed into a sheet.

10:04 Q. If we could pause right there for a second. What temperature is being applied during this process, sir?

10:04 A. There's a high elevated temperature in the hundreds of degrees and then also shearing forces which create a great amount of temperature too.

10:04 Q. What do you mean by "shearing forces"?

10:04 A. It's a -- basically a screw that's kind of grinding up the material, kind of like your teeth chewing up gum and, you know, grinding it back and forth.

10:04 Q. Let's go to the next step in the animation, please.

10:04 And please describe it, Dr. Spiegelberg.

10:04 A. So we do the same process now with the TPU layer. Now we have the pink pellets representing the TPU pellets.

10:05 Those go into the extruder and are heated up and -- at 385 to 425 degrees Fahrenheit. And then the screw conveys them along a shearing action as well, and they're extruded out the die. But this time they're going to go between two preexisting rolls of the

copolyester layer. So now you're creating a three-layer film.

Q. And then what's shown at the right with the blue, pink, blue on the right there, sir, what is that end product?

A. This is the -- a hard-soft-hard configuration like Zendura FLX.

Q. Now, how, if at all, does this process that we just saw in the animation, extrusion lamination, how does that affect the properties of the soft middle layer, the TPU layer within Zendura FLX?

A. When polymers are subjected to high temperatures and that shearing action, the polymer chains, these long floppy chains, can be snipped into smaller bits which change their mechanical properties.

Q. Now, can you give the jury an analogy to understand why the characteristics of the original polymer as described in the technical data sheets do not reflect the ultimate properties of the polymer when it -- after extrusion lamination?

A. Sure. If there are any bakers in the room and if you've made pie crusts, when you first make the pie crust before baking, it's very flexible. You can mold it into the pie tin, you can stretch it to some degree, you can roll it out. It's very, very pliable.

10:06 Once you bake it, it goes through a chemical reaction and the material is -- the pie crust is now much more brittle, hopefully a bit flaky. But if you try to break it or pull it, it will break at a much lower strain.

Q. Does a baked pie crust have an elongation of break greater than or less than 200 percent?

A. I haven't tested it, but it seems like it would.

Q. Greater than or less than?

A. Less than.

Q. All right.

MR. ZUBLER: Your Honor, if I could approach the witness. We have a placard we'd like him to use.

And, Your Honor, if I could ask permission for the witness to step down from the witness stand.

THE COURT: As long as he has a mic.

MR. ZUBLER: Yes.

BY MR. ZUBLER:

Q. Dr. Spiegelberg, and if you could maybe stand a little bit to your left, to the right, just to make sure the jury and the attorneys from Align can see your -- your demonstrative there.

10:08 Sir, what is shown here at a high level?
10:08 A. This is showing the elongation of break from
10:08 the tensile testing that was conducted at various
10:08 facilities.
10:08 Q. All right.
10:08 A. Zendura FLX.
10:08 Q. All right. And let's start with the testing
10:08 results in the left, the lower left, the bars that are
10:08 above "Align prelitigation." What are those numbers,
10:08 sir?
10:08 A. These results here are the testing on Zendura
10:08 FLX conducted by Align before the litigation where they
10:08 found results between 124 and 140 percent.
10:09 Q. And are those above or below 200 percent, sir?
10:09 A. I show 200 percent with the dashed line here.
10:09 So these are below.
10:09 Q. Let's look at the next set of data, the data
10:09 that's above the words "Bay Materials prelitigation."
10:09 What does that show?
10:09 A. This is the testing on Zendura FLX conducted
10:09 by Bay Materials. They found values between 94 percent
10:09 up to 110 percent. So on average all below
10:09 200 percent.
10:09 Q. Now, if I could ask you to use your marker,
10:09 sir. If you could draw a line on the demonstrative

10:09 separating the data that was created before this
10:09 litigation ever began from the data that was then
10:09 created as part of this litigation.
10:09 A. (Witness draws.)
10:09 Q. All right. Now, let's look at the data that
10:09 was created as part of the litigation in this case.
10:09 Let's -- what are the green bars above the
10:10 text "Dr. Spiegelberg testing"?
10:10 A. These are the results from my testing
10:10 laboratory on Zendura FLX, and we found an elongation
10:10 of break that range between 145 percent up to
10:10 151 percent.
10:10 Q. And now finally let's look at the last set of
10:10 data, the orange and brown bars above the text
10:10 "Dr. Reitman testing."
10:10 What do those show, sir?
10:10 A. These results show two sets of data basically.
10:10 Dr. Reitman found three specimens that had elongation
10:10 of breaks below 200 percent and then two that were
10:10 above.
10:10 Q. Is this the same data that Dr. Reitman
10:10 referred to in her testimony yesterday?
10:10 A. It was.
10:10 Q. Dr. Reitman found that three of the samples
10:10 were below 200 percent, you testified, and then there's

10:10 two with much larger values.

10:10 What do you conclude, based on your expert experience and knowledge, about the variability of those results?

10:10 A. Well, you can see all these other tests that were conducted at the right rate had a very tight grouping of the data. Dr. Reitman, because she used the wrong testing speed, had a lot of variability in her results.

10:11 Q. Does that make her results more reliable or less reliable, sir?

10:11 A. They are less reliable.

10:11 Q. All right. Thank you, Dr. Spiegelberg. And you can return to the witness stand.

10:11 Dr. Spiegelberg, we talked about the extrusion lamination process and how it affects elongation at break.

10:11 Are there any other impacts from the manufacturing process that you observed in a multi-layer material?

10:11 A. Yes.

10:11 Q. And what kind of effects are those?

10:11 A. There can be inner diffusion between the layers during the manufacturing process.

10:11 Q. Okay. Inner diffusion between the layers.

10:12 Let's talk a little bit about that.

10:12 Have you prepared a demonstrative to explain that concept?

10:12 A. Yes.

10:12 MR. ZUBLER: All right. If we could go to DDX-7.28.

BY MR. ZUBLER:

10:12 Q. What does this show, sir?

10:12 A. This was showing the three layers in Zendura FLX. The blue layer is representing the copolyester layers, the red/pink layer representing TPU layer. And at the interface, between the two -- the three layers there's mixing of the polymers which occurs when the polymers are still in a slightly molten state.

10:12 Q. And are there benefits or drawbacks from this mixing that occurs?

10:12 A. There's a bit of both. The mixing helps ensure good bonding between the two layers, the three layers in this case. So it's harder to delaminate them or pull them apart.

10:12 But you can also see a reduction in some of the properties because of, for instance, the mixing of the copolyester into the TPU layer, that will probably drop the elongation at break a bit.

10:13 Q. Have you done any testing relating to this

10:13 phenomenon and whether or not it occurs with Zendura FLX?

A. I have.

Q. What kind of testing did you do?

A. I did a technique called infrared spectroscopy.

Q. What is infrared spectroscopy?

A. It's a really useful technique for looking at the presence of different materials, such as different polymers, in a specific area of a sample.

Q. If you could go back to your binder for a moment, please, sir, and look at Tab 20, which is DTX-2187, Tab 20.

What is Tab 20, DTX-2187?

A. This is the raw data from my infrared spectroscopy testing of Zendura FLX.

MR. ZUBLER: Any objection to publishing this as a demonstrative?

MR. HUNG: No objection.

MR. ZUBLER: If we could publish DTX-2187.

BY MR. ZUBLER:

Q. There's a lot of graphs on here, Dr. Spiegelberg. What does this show?

A. This shows the infrared spectroscopy signature

10:14 of the elements in Zendura FLX, the copolyester layers and the TPU layers.

Q. And what does this show with respect to whether there is or isn't the diffusion you talked about previously?

A. I found mixing between the layers as a result of this testing.

Q. Has Align or its experts performed any testing to determine whether there's this diffusion of layers in Zendura FLX?

A. Although Dr. Reitman did do infrared spectroscopy as well on Zendura FLX, she did not do the same type of infrared that I did, where we're stepping across the sample in very small steps. So you see the change in the mixing as you move across the sample.

Q. What effect, if any, does this testing, the infrared spectroscopy testing, have on your analysis of the infringement issue?

A. It demonstrates that the film layers are not made of individual polymers but are mixes.

Q. Okay. Let's look -- strike that.

And how is that relevant to infringement or noninfringement of the patents in this case?

A. It demonstrates noninfringement.

Q. With respect to which patents, sir?

10:15 A. The '090 and the '091 patents.
10:15 Q. Let's look briefly, if we could, at the '090 patent, Claim 1. This is the text of the '090 patent.
10:15 What does this refer to, or what have you highlighted on the screen, sir?
10:15 A. This shows in green that the first layer consists of a single material copolyester and that the second layer consists of a single material, a thermoplastic polyurethane elastomer.
10:15 Q. And which patents have this type of requirement, sir?
10:15 A. The '090 and '091 patents.
10:15 Q. And with these requirements about the composition of a first layer and second layer, what is your conclusion about whether clear aligner -- ClearCorrect aligners using Zendura FLX infringe the '090 and '091 patents?
10:16 A. They do not.
10:16 Q. All right. Let's turn now to the last issue, if we could, in DDX-7.35.
10:16 There's a point here on your slide that says: If the claims are stretched, they are invalid for lack of enablement.
10:16 Sir, what is your conclusion with respect to validity or invalidity?

10:16 A. If the claims are stretched to include a hard-soft-hard configuration, then they are invalid for lack of enablement.

Q. Lack of enablement. We haven't heard much about that in this trial yet. What is lack of enablement?

A. Enablement is basically is there enough information in the patent for a person of ordinary skill in the art to be able to practice the patent and know that they're going to get a reasonable result at the end.

MR. ZUBLER: Okay. If we could pull up PDX-1.39, which was from opening statement of Align in this case.

BY MR. ZUBLER:

Q. Do you remember that Ms. Durie used this slide during her opening statement?

A. Yes.

Q. And she explained that when you have a new idea, you have two options. You can keep it secret, or in her words, you have the option -- and I quote: You have the option to go to the United States Patent Office and make your invention public, add to the sum of human knowledge, and in exchange for that disclosure, you are awarded a patent that gives you the

10:17 exclusive right to that invention for a period of time.
10:17 Do you recall her saying that?
10:17 A. Yes. I do.
10:17 Q. Does that have any relationship to the
10:17 enablement requirement?
10:17 A. Yes.
10:17 Q. How so?
10:17 A. The deal is that the Patent Office will give
10:17 you exclusivity on your patent for a period of time if
10:17 you provide sufficient information in the patent to
10:18 understand, for a person of ordinary skill, what is the
10:18 patent and how I do practice it.
10:18 Q. So that was the enablement requirement, but
10:18 you also mentioned something that you said: If the
10:18 patents are stretched to cover HSH, then they would not
10:18 be enabled.
10:18 What do you mean by that, sir?
10:18 A. That there's insufficient information in the
10:18 patent to enable someone, a person of ordinary skill,
10:18 to practice the art if they include a hard-soft-hard
10:18 configuration.
10:18 MR. ZUBLER: All right. If we could go
10:18 to PDX-1.40. This is another slide from Align's
10:18 opening statement.
BY MR. ZUBLER:

10:18 Q. And do you recall this from the opening statement, sir?
10:18 A. Yes.
10:18 Q. And Ms. Durie, if I recall correctly, used this slide. And she analogized Align's patent claims to a fence around a house.
10:18 Is that what your recollection is, sir?
10:18 A. Yes.
10:18 MR. ZUBLER: Your Honor, if I could use a microphone to do a brief illustration.
10:19 BY MR. ZUBLER:
10:19 Q. So I want to give you a hypothetical, Dr. Spiegelberg. Let's suppose that Align's patent claims have a scope, a proper scope, as properly applied, of a fence, approximately in this area in front of me here, if you can kind of see -- if you can see my hands.
10:19 And if that is the scope of Align's patent claims, a fence of this approximate area, what is your conclusion about whether Zendura FLX would fall within this scope of Align's claims?
10:19 A. With the proper scope, it would not fall within those.
10:19 Q. And what's the basis for your conclusion there?

10:19 A. Because the properties in the Zendura FLX do not meet the scope, and it's only describing a soft-hard-soft configuration.

10:19 Q. All right. In this hypothetical, where would Zendura FLX be if it's not in this box?

10:19 A. Somewhere over there.

10:20 Q. All right. So let's suppose, as part of this hypothetical, that Align's fence, Align's patents are applied more broadly to cover not just this box here but all of this area over here.

10:20 Do you follow me, sir?

10:20 A. Yes.

10:20 Q. If Align's patent fence is drawn all the way around here, what is the consequence for validity or invalidity of these claims?

10:20 A. It's invalid.

10:20 Q. Why would it be invalid if these claims are broader?

10:20 A. Because it doesn't enable a person of ordinary skill to practice the patent.

10:20 Q. All right. So if the claims are broad, the fence goes all the way over here, you've testified the claims are not valid; is that right?

10:20 A. That's correct.

10:20 Q. But if we go back over here and the claims are

given the proper application as you understand it, the claims, are they infringed or not infringed?

A. Not infringed.

Q. Is there any place along this continuum, from here or all the way over there, where Align's claims are both infringed and valid?

A. No.

Q. Let's talk about enablement and the legal test for enablement.

MR. ZUBLER: If we could go to DDX-7.36.

BY MR. ZUBLER:

Q. What is shown here, sir?

A. These are some of the factors I considered when assessing whether or not Align's patents had adequate enablement.

Q. And where do these factors come from?

A. These are standard ones. Wands factors, they're called.

Q. What did you conclude in analyzing these factors?

A. That they did not meet the criteria.

Q. Okay. We're going to through each one of these four factors. We'll move through them as promptly as we can. Let's start with breadth of claims.

10:22 MR. ZUBLER: And if we could go to the next slide.

BY MR. ZUBLER:

10:22 Q. Sir, what is shown on this slide regarding breadth?

10:22 A. This demonstrates the various features of the claims that are very broad under Align's theory.

10:22 Q. Okay. The first item here refers to the number of layers or configuration. Under Align's application, its proposed application of its claims under its theory, do Align's patents contain any limitation on the number of layers or configuration of those layers?

10:22 A. No. They do not.

10:22 MR. ZUBLER: Let's go to the next slide.

BY MR. ZUBLER:

10:22 Q. You have a slide here that has two circles, a big one and a small one.

10:22 Do you see that, sir?

10:22 A. Yes.

10:22 Q. What's the small one?

10:22 A. The small one represents the soft-hard -- soft-hard-soft configuration which was the original patent that Align has.

10:22 Q. And what is the larger circle?

10:22 A. The larger circle represents all the -- some
10:22 of the possible combinations that are anticipated in
10:23 Align's interpretation of the claims where again
10:23 hard -- or H indicates the hard layer, S indicates a
10:23 soft layer. So you could have various combinations of
10:23 hard-hard-soft-soft, hard-hard-hard-soft.
10:23 Q. So under Align's theory, what, with respect to
10:23 this figure, is the scope of the claims, again, under
10:23 Align's theory?
10:23 A. There's no limit on the number of possible
10:23 combinations.
10:23 Q. And let's go back to your list. We're talking
10:23 about thickness of layers now. Under Align's theory,
10:23 are there any limits on the thickness of layers of the
10:23 multi-layer material?
10:23 A. No. There are not.
10:23 Q. The next two items out of your list are the
10:23 TPUs and copolyesters. Under Align's theory, are there
10:23 any limits on the TPUs or copolyesters that could be
10:23 used?
10:23 A. No. There are not.
10:23 Q. Next on your list is manufacturing methods.
10:23 Under Align's theory, are there any limits on the
10:24 manufacturing methods that can be used to make the
10:24 multi-layer material?

10:24 A. No. There are not.
10:24 Q. Are there different types of manufacturing methods that could be used?
10:24 A. Yes. There's co-extrusion. There's extrusion lamination. There's simple adhesive lamination, compression molding. Many options.
10:24 Q. Last item on your list, thermoforming method. Under Align's theory, are there any limits on the thermoforming method that would be used to make a dental appliance that's the result of the claims in this case?
10:24 A. No. There are no limits.
10:24 Q. Are there different methods of thermoforming?
10:24 A. There's different conditions, different temperatures, pressures, times.
10:24 Q. Now, are there any limits in Align's claims regarding the breadth of their scope?
10:24 A. There are some.
10:24 MR. ZUBLER: All right. If we could go to the next slide, DDX, I believe it's 7.43.
10:24 45. Strike that.
BY MR. ZUBLER:
10:24 Q. With respect to this Exhibit DDX-7.45, what are you showing with the highlighting here?
10:25 A. I'm showing some of the limits that are

established within the claim.

The first one indicates the requirement that you make a dental aligner that's effective in repositioning a patient's teeth.

Q. And what is -- that's in yellow, sir?

A. That's in yellow.

Q. What's in the purple-ish color?

A. Purple then indicates the properties of the formed layers in the first layer, the hard layer and the soft layer.

Q. And what's shown in green?

A. The green is a requirement that the multi-layer sheet be thermoformable.

Q. So these are all limitations, you said, on the claims. How would one determine whether a multi-layer material satisfies these requirements?

A. You have to test them.

Q. And how does that -- well, strike that.

What would be the quantity of testing required to determine that?

A. It would be a lot of testing.

Q. And how does that impact your analysis of enablement in this case?

A. It demonstrates no enablement.

Q. We're going to come back to the testing issue

in a moment.

Now, let's go back to the four key enablement factors that we looked at earlier.

The next factor is existence of working examples and amount of direction provided.

What does this factor refer to, sir?

A. How much information is in the patent that shows actual examples of the claim -- or the inventor has done.

Q. Why is that relevant to enablement?

A. It demonstrates to a person of ordinary skill in the art what types of materials the inventor tried and found successful.

Q. Okay. Now, do Align's patents provide working examples or guidance for how to make the materials that Align says are covered by the patent?

A. No.

Q. Do Align's patents identify by commercial name any specific polymers?

A. They do not.

Q. Do Align's patents describe the specific thickness of any layer in a multi-layer material?

A. No specific thickness.

Q. Do Align's patents describe the manufacturing parameters that should be used to make the material,

such as temperatures or pressures or speeds?

A. No.

Q. Now, yesterday -- we talked earlier about Mr. Hung walking through Figures 5 through 8 of the '613 patent, those various figures of Material 1 and Material 2 that we looked at today a little bit.

Do any of those figures provide a working example or guidance as to how to make the claimed materials under Align's theory of the scope of the claims?

A. No. They do not.

Q. The next item on your list is the level of predicability in the art.

Do you see that, sir?

A. Yes. I do.

Q. What does that refer to as a factor relevant to enablement?

A. Whether or not a person of ordinary skill in the art would know what kind of outcome they can expect from practicing the invention.

Q. Does this factor, the level of predicability in the art, have any relationship to the concept of trial and error?

A. It does.

Q. How so?

10:27 A. The same thing.
10:27 Q. And if you -- if you need a lot of trial and error, does that make a -- an art -- a field predictable or unpredictable?
10:28 A. No. A lot of trial and error means it's unpredictable.
10:28 Q. Now, is making a multi-layer material for use in a dental aligner, is that predictable or unpredictable?
10:28 A. It is unpredictable.
10:28 Q. Is there any dispute in this case about that, sir?
10:28 A. No. There doesn't appear be.
10:28 MR. ZUBLER: All right. And if we could just go back to DDX-7.43.
BY MR. ZUBLER:
10:28 Q. What do we see here, sir?
10:28 A. This is an excerpt from the declaration that Dr. Li provided to the Patent Office.
10:28 Q. And what did she conclude?
10:28 A. She concluded that dental aligners and making thereof is -- lacks predicability.
10:28 Q. And what was the basis for her opinion or her statement that there's a lack of predicability in this area?

10:28 A. She had to do a lot of testing.
10:28 Q. And finally let's go to final factor for enablement, quantity of experimentation needed to practice the full scope of the claims.
10:29 What does this factor relate to?
10:29 A. It relates to how much experimental work a person of ordinary skill would have to employ in order to practice the scope of the claims.
10:29 Q. And how does this factor affect your conclusions about enablement in this case?
10:29 A. It demonstrates that it -- it's not enabled.
10:29 MR. ZUBLER: All right. If we could go to the next slide, DDX-7.44.
BY MR. ZUBLER:
10:29 Q. What's shown here with respect to quantity of experimentation?
10:29 A. It shows Align's development pathway for SmartTrack which took eight years. They evaluated over 260 materials. They had 19 companies involved in the development, and that was all to get to one material, SmartTrack, which is a soft-hard-soft configuration.
10:29 Bay Materials had a different path. It took 15 years. They looked at over 850 different formulations with fewer engineers, and they arrived at Zendura FLX, a hard-soft-hard configuration.

10:29 So those are just one material for each
10:30 company with all this development time.
10:30 Q. Now, let me ask you a question. If claims are
10:30 as broad as Align's theory would suggest, how much
10:30 experimentation would be required to practice that full
10:30 scope of Align's claimed invention?
10:30 A. I can't even estimate it because of the great
10:30 number of possibilities.
10:30 Q. So we've been through all of those four
10:30 factors of enablement, what you called the Wands
10:30 factors. Dr. Spiegelberg, based on your analysis, if
10:30 Align's patent claims are as broad under Align's theory
10:30 as they say, what is your conclusion about whether or
10:30 not the patents enable a person of skill in the art to
10:30 practice the full scope of the claims?
10:30 A. They do not enable them.
10:30 Q. All right. Thank you, Dr. Spiegelberg. Let's
10:30 conclude it.
10:30 Let's go back to my hypothetical about the
10:30 fence.
10:30 Do you recall that, sir?
10:30 A. Yes.
10:30 Q. If the fence of Align's patents is given a
10:30 proper scope and the claims are applied properly, do
10:31 ClearCorrect aligners that use Zendura FLX infringe

10:31 Align's claims?
10:31 A. They do not.
10:31 Q. If Align's fence is broadened, it's stretched to cover a hard-soft-hard material like Zendura FLX, are the claims valid?
10:31 A. They are not valid.
10:31 Q. Is there any circumstance in which Align's patent claims are both infringed and valid?
10:31 A. No.
10:31 Q. Thank you. Thank you very much.
10:31 MR. ZUBLER: I pass witness.
10:31 THE COURT: Ladies and gentlemen of the jury, we're going to take our morning recess. If you would please remember my instructions not to discuss the case. We'll be back in about 10 or 15 minutes.
10:31 (Jury exited the courtroom.)
10:32 THE COURT: You may be seated. You may step down, sir.
10:32 Is there anything we need to take up?
10:32 MS. DURIE: Good morning, Your Honor. I would like to lodge an objection to the continuing reference to the claims being stretched to cover --
10:32 THE COURT: I've already done that.
10:32 MS. DURIE: Sorry?
10:32 THE COURT: It was raised and I've dealt

10:32 with that. Your co-counsel raised that at the bench,
10:32 that specific objection. And I -- and I overruled it.
10:32 MS. DURIE: Thank you, Your Honor.
10:33 THE COURT: Anything else?
10:33 MR. MUELLER: Your Honor, just a brief
10:33 scheduling note. So after Dr. Spiegelberg testifies,
10:33 we're going to call Mr. Julien Marbach. He's the fact
10:33 witness that we mentioned yesterday, the remaining
10:33 piece of the scan patent evidence. After he concludes,
10:33 we will move for JMOL on the scan patent, the '936.
10:33 THE COURT: Okay.
10:33 MR. MUELLER: It might be a good time to
10:33 do it right before lunch.
10:33 THE COURT: You just let me know.
10:33 MR. MUELLER: Okay. Understood. Thank
10:33 you, Your Honor.
10:33 That's all we have.
10:33 THE COURT: Anything else?
10:33 MS. DURIE: No, Your Honor.
10:33 THE BAILIFF: All rise.
10:33 (Recess taken.)
10:50 THE BAILIFF: All rise.
10:50 THE COURT: Please remain standing for
10:50 the jury.
10:50 (Jury entered the courtroom.)

10:50 THE COURT: Thank you. You may be seated.

10:50 I'm sorry. If we can get the witness back up here.

10:51 CROSS-EXAMINATION

10:51 BY MR. HUNG:

10:51 Q. Dr. Spiegelberg, good to see you again.

10:51 A. You too.

10:51 Q. Okay. I want to table set to kick us off. Before this case, you had never heard of Bay Materials, fair?

10:51 A. That's correct.

10:51 Q. But you had heard of Align?

10:51 A. I had.

10:51 Q. And you knew that Align is very well-known for its products?

10:51 A. I've heard of their products.

10:51 Q. And you agree that Align has a good reputation?

10:52 A. I've heard good things.

10:52 Q. You've also heard and worked with Maureen Reitman before, correct?

10:52 A. I have.

10:52 Q. And you believe and know she is a good and competent polymer scientist?

10:52 A. She is.
10:52 Q. Now, let's talk about the first SmartTrack patent.
10:52 MR. HUNG: And let's pull up PTX-1876 at Page 19, already admitted.
10:52 BY MR. HUNG:
10:52 Q. And if you look at this, sir, this is the first SmartTrack that issued in 2017, correct, sir?
10:52 A. Yes.
10:52 Q. You are not disputing that this patent covers SmartTrack, are you?
10:52 A. I am not.
10:52 Q. And, sir, if you look at this, you are not disputing that these claims cover hard-soft-hard, correct? You see the words hard-soft -- sorry.
10:52 You're not disputing that these claims cover soft-hard-soft?
10:52 A. I'm not.
10:53 Q. And, sir, you know this patent -- this first SmartTrack patent is not asserted in this case. You know that, right?
10:53 A. Yes. I do.
10:53 Q. So this patent is not relevant to the infringement analysis, fair?
10:53 A. I did not look at this in my infringement

10:53 analysis.
10:53 Q. Okay. Now, let's look at -- let's look at
10:53 something else. You heard Mr. Lahlouh who testified.
10:53 He mentioned that he has his own patents, right?
10:53 A. Yes.
10:53 Q. In fact, sir, you read some of those patents,
10:53 right?
10:53 A. I skimmed over them.
10:53 Q. You skimmed over them.
10:53 And in fact, you are offering -- or you
10:53 offered opinions on litigation settlement involving Bay
10:53 Materials to support Mr. Perryman's opinions who have
10:53 appeared, correct?
10:53 A. Yes.
10:53 Q. And, sir, but you know that whether
10:53 Mr. Lahlouh has patents is completely irrelevant to the
10:53 infringement inquiry, fair?
10:53 A. I think that's fair.
10:53 Q. You understand -- you've heard of an
10:53 improvement patent, right? You know what that is?
10:53 A. I've heard of that.
10:53 Q. So if I have a patent on a chair with four
10:54 legs and you obtained a patent with a chair with four
10:54 legs that's red, you still infringe my patent, right?
10:54 A. It depends.

10:54 Q. Now, sir, let's go to the only patents that are at issue in this case. Those are the four asserted materials patents, for the materials case, fair, right?

A. Yes.

Q. You're not disputing that the Patent Office issued those patents after doing a full examination, correct?

A. Those patents were issued.

Q. And you agree --

MR. HUNG: And let's put this up. Let's just put up the '613, JTX-2 at Page 20, already admitted.

BY MR. HUNG:

Q. You agree that these claims do not require soft-hard-soft, correct?

A. Correct.

Q. And you agree that these claims cover hard-soft-hard, correct?

A. Debatable.

10:55 Q. Sir, there's nothing in these claims that require that that third layer be soft?

A. Not quite.

Q. And, sir, again, you're not disputing that SmartTrack practices these patents, are you, sir?

A. No.

10:55 Q. And, sir, you're not challenging the adequacy of something called the written description in this case, correct?

10:55 A. Correct.

10:55 Q. You're offering no opinions that the written description in this case doesn't support the claims as issued, fair?

10:55 A. I'm not opining on written description.

10:55 Q. And to be crystal clear, there is no claim in this case that the claims of the materials patents that we are asserting do not cover hard-soft-hard?

10:55 A. Not quite.

10:55 Q. Sir, but to be crystal clear, you aren't challenging written description, that is, whether the inventors as of the filing date, the priority date here, were in possession of the inventions as claimed.

10:56 You aren't offering that opinion, are you?

10:56 A. I'm not challenging written description.

10:56 Q. All right, sir.

10:56 MR. HUNG: Let's turn to JTX at 2 -- let's pull it up at Page 26, the claims.

BY MR. HUNG:

10:56 Q. Actually, we have it. We have it right here.

10:56 Sir, if you look at this, you will see that it refers to a soft polymer layer comprising a TPU

elastomer.

MR. HUNG: Back up.

BY MR. HUNG:

Q. And that there -- it has to have an elongation at break greater than 200 percent.

You see that, sir?

A. Yes.

Q. And that is of the layer. The layer must have an elongation at break of greater than 200 percent, correct?

A. Yes.

Q. It's not of the whole sheet. This claim does not say: Providing a sheet where the sheet has an elongation at break of over 200 percent. Right?

A. Correct.

Q. And, sir, to be crystal clear, you never tested elongation at break for just the TPU soft layer, the sheet itself, right, sir?

A. I did.

Q. You never just took a sheet of Texin and performed your tensile testing, did you, sir?

A. No.

Q. And you're not disputing -- if I look at that Texin TPU sheet, if I look at the sheet that defendants used, I will see in the data sheet that it reports an

10:57 elongation at break of 480 percent for the Texin material itself, correct?

A. Premanufacturing, yes.

Q. And you're not disputing that if I look in Bay Materials' documents, it will report an elongation at break for that material of 500 percent or so, fair?

A. Premanufacturing, yes.

Q. What you disagree with, Dr. Spiegelberg, is whether it's appropriate to rely upon data sheets, right?

A. Correct.

Q. Now, sir, we covered this to start. You've opined to support Mr. Perryman on a litigation settlement between Bay Materials on the one hand and 3M on the other hand, right, sir?

A. Yes.

Q. And that litigation settlement that you offered opinions on involved Bay Materials asserting its own patents against 3M, right?

A. That's what I recall.

(Bench conference.)

MR. ZUBLER: Your Honor, he's venturing -- Dr. Spiegelberg did opine regarding a 3M agreement but not -- he's getting into the litigation itself and not the nature of the actual patents in the

10:59 comparability analysis that is in his opinion, which goes against the MILs in your case.

MR. MUELLER: He also didn't offer the opinion.

10:59 THE COURT: Yeah.

10:59 MR. HUNG: Your Honor, No. 1, Mr. Perryman's relying upon it.

10:59 No. 2, he relies upon the litigation settlement between Bay Materials and 3M.

10:59 No. 3, he read those patents. He took -- Mr. Lahlouh talked about the patents.

10:59 And No. 4, if you read those patents, it says "a layer with properties," and that expert in that case that he's relying upon, the litigation settlement in that patent, says you look at the data sheet. I should be able to impeach him on that.

10:59 THE COURT: You want to impeach him on patents in another case?

10:59 MR. HUNG: On a patent that he testified on that Mr. Lahlouh presented as his own patent to show independent of element and says that that patent is comparable to our patent. And when you look at that patent, it uses the same language as ours --

10:59 THE COURT: So how are you trying to impeach him here? I just don't see how you're going to

11:00 do this.

MR. HUNG: He knows Mr. Perryman. Sorry. He knows -- he knows the expert. He's familiar with the litigation. He selectively read materials from that case. He's offering the settlement.

Mr. Perryman's going to discuss the settlement. That's not fair. He's going to discuss the patents. He's ready to discuss the patents, and I can't --

THE COURT: What is it you want to cross him about?

MR. HUNG: I want to show him the declaration that the -- Bay Materials' own expert submitted in the case directly contradicting his position that you shouldn't look at a data sheet.

THE COURT: You want to use an expert opinion from a different case to impeach him and -- to impeach -- that is not impeachment.

MR. HUNG: No. But, Your Honor, it's Bay Materials and Bay Materials. It's a patent that he offered, he's read, he's talked about. And this patent is -- it's relating to the interpretation of the patent that he says is comparable to our patent.

THE COURT: I understand. But you want an expert from a different -- I don't -- I understand

what you're saying. I don't understand how it's admissible, and I'm not going to allow it.

MR. HUNG: Okay.

(Bench conference concludes.)

BY MR. HUNG:

Q. Sir, you think it's wrong to look at the data sheets, right? I think you just said that, right?

And you think that one should be looking at the property of the sheet, of the layer once it's in the sheet, right, sir?

A. Yes.

Q. Now, you've read the '613 patent multiple times at this point probably, right?

A. That's correct.

MR. HUNG: All right. Can we pull up JTX-2, the patent itself at Column 6?

BY MR. HUNG:

Q. And, sir, read along with me. Now, you read the written description of the patent, correct?

A. Yes.

Q. And you've read the discussions in this patent describing the properties of the materials in the layers, right, sir?

A. The properties of the layers.

Q. Okay. Read along with me.

11:02 In some embodiments, the soft polymer layers of the appliances -- are you following me?

A. Yes.

Q. Can independently, independently have a physical property.

Do you see that, sir?

A. Yes.

Q. Of at least one of.

Do you see that?

A. Yes.

Q. And then it continues: An elongation at break of greater than about 200 percent.

Do you see that language, sir?

A. Yes.

Q. And what this is discussing is that one is not looking at the property of the multi sheet. One is looking at the prop -- multi-layer sheet. One is looking at the prop -- the independent property of the layer and its elongation at break, fair?

A. I don't think so.

Q. You don't think so?

A. No.

Q. One more time, sir.

In some embodiments, this states, the soft polymer layers of the appliances can independently have

an elongation at break of greater than about 200 percent.

Did I read that correctly?

A. Paraphrasing, yes.

Q. Yeah. This sentence is not referring to the multi-layer sheet itself having an elongation at break of greater than 200 percent, true?

A. I'm sorry. Say that again, please.

Q. This sentence from the specification of the patent that you've read multiple times is not saying that it -- the property of the multi-layer sheet that has an elongation at break greater than 200 percent.

This sentence, just this sentence, sir.

A. This sentence doesn't mention the multi-layer.

Q. At all.

A. Actually, it does.

Q. Now, sir, you showed testing results that you ran, right, on the multi -- on the multi-layer sheet. If we were to run that test, you showed the jury the testing results that you ran, right, sir?

A. Yes.

Q. And you showed one chart, one chart from your report, right?

A. Yes.

Q. Do you believe that it's important to show the

11:04 jury the full -- to give the jury a full understanding
11:04 of the tests that you ran?
11:04 A. Yes. All the valid results.
11:04 Q. Of course, right, sir.
11:04 Let's -- let's pull up Slide 29 and see if you
11:04 recognize this. This is a table from your report.
11:04 You didn't show the show jury this table, did
11:05 you, sir?
11:05 A. No. I did not.
11:05 Q. Now, help me understand this, sir. This is a
11:05 test that you ran on the multi-layer sheet, correct?
11:05 A. Yes. Using Dr. Reitman's rate.
11:05 Q. You ran this test yourself, right, sir?
11:05 A. Yes.
11:05 Q. Help me understand this for a second.
11:05 Actually, can you read the jury the results for
11:05 elongation at break at the inner TPU layer as run on
11:05 the multi-layer sheet? Just read the results including
11:05 4.4.7.
11:05 A. The average was 338 percent.
11:05 Q. Now, sir, I think --
11:05 MR. HUNG: We can take this down. Thank
11:05 you.
11:05 BY MR. HUNG:
11:05 Q. I think we've established in your view that

11:05 Align practices its own SmartTrack patents, the '691, the first one, and all the others, correct, sir?

You're not disputing that?

A. Say that again, please.

Q. You aren't disputing that Align practices the first SmartTrack patent, the soft-hard-soft, and all of the asserted materials patents in this case?

11:06 A. I'm not opining on that.

Q. Well, sir, let's look at Slide 11. I think this is the one you showed on the whiteboard.

Do you recall discussing this whiteboard with the jury, sir?

A. Yes. I do.

Q. Okay. Let's look at the elongation at break. If you take the whole SmartTrack sheet, the whole sheet and you stretch it, what's the elongation at break value, sir? Pick the middle one.

A. It is 135.6.

Q. And so, sir, under your theory, under your theory that you have to test the whole sheet, it's the case that SmartTrack itself wouldn't practice its own patents, fair?

A. I don't know.

Q. You don't know? You don't know?

A. I didn't test it.

11:06 Q. Sir, you're offering testimony about copying, anticopying. You say that Mr. Lahlouh didn't copy, did all this work independently, correct?

11:07 A. Correct.

11:07 Q. But you know that the man who created the Zendura A, which was the clone of EX30 that they made for Align or sold to Align for a period, you know that aligners -- he was supplying other companies with that material.

11:07 You know that, right, Zendura A?

11:07 A. I think I learned that.

11:07 Q. You knew that. He certainly was doing so in 2014, right? Companies like ClearCorrect, Ormco, et cetera, were buying Zendura A in 2014, right, sir?

11:07 A. I believe so.

11:07 Q. But you know that Mr. Lahlouh's own daughter, when she needed aligners, got a SmartTrack aligner. You know that, right, sir?

11:07 A. I heard him say that.

11:07 Q. And you know that he obtained the data sheet, he testified, to make sure that it was safe for his daughter. That's why he pulled the technical data sheet off the website indicating the materials that were in that aligner. You know that, right?

11:08 A. I heard him testify about the data sheets.

11:08 Q. And you know he created simulates, right, sir?
11:08 A. Yes.
11:08 Q. And you know he made those simulates in one week. It took him just one week to make those simulates. You know that, right?
11:08 A. I don't remember that.
11:08 Q. You don't remember that?
11:08 You read his deposition in this case, right, sir?
11:08 A. Possibly.
11:08 Q. Let me see if I can help you with this.
11:08 I'll come back to it when we discuss enablement.
11:08 Now, sir, independent development, I want to be crystal clear, you're telling the jury your opinion as an expert is that Bay Materials independently developed this, okay? That's what you think, right?
11:08 A. Yes.
11:08 Q. Okay. Were you here when Dr. Li put up that presentation where she talked about LE30?
11:08 Do you recall that, sir?
11:08 A. Vaguely. Yes.
11:09 Q. You do vaguely remember that.
11:09 And do you remember that that was an internal secret code name for SmartTrack at Align? Did you hear

that?

A. Yes.

Q. And you also know, sir, don't you, that in January 1st of 2013, Align released SmartTrack? You know that, right?

A. Yes.

Q. Okay. You have before you -- when you saw 21 notebooks, you discussed those with Mr. Lahlouh, right?

A. Yes.

Q. Full opportunity to ask him what was in those notebooks, right?

A. Yes.

Q. If we can turn to DTX-811 in your binder.

Do you recognize that notebook, sir, as one of his notebooks?

A. Yes.

MR. HUNG: We'd offer this.

MR. ZUBLER: No objection.

THE COURT: Admitted.

BY MR. HUNG:

Q. Please turn to Page 105.

MR. HUNG: And let's publish it, and let's highlight it.

Next slide.

BY MR. HUNG:

11:10 Q. Now, sir, did you see -- if you look at this, this is a slide --

MR. HUNG: Can we go back a slide? Can you publish my Slide 12?

BY MR. HUNG:

Q. While you're looking, sir, you see that that is a notebook page that Mr. Lahlouh -- from his own notebook in January of 2013. You see that, right, sir?

A. I'm sorry. I'm on Page 105, but I don't see that.

Q. You look at the bottom, sir, do you see that? Right here. It's on the screen, sir. Look at the screen.

That page is January 2nd, 2013, one day after SmartTrack was available to the world and orthodontists.

Do you see that?

A. Oh, so Page 98?

Q. Sure. You see that, sir? And you see his name on that page? He signed it?

A. Yes.

Q. And do you see competitive analysis?

A. Yes. I do.

MR. HUNG: Okay. Let's blow this up. Let's go to the next slide, same page.

BY MR. HUNG:

Q. Now, read along with me, sir: Competitive analysis. Six Invisalign aligners made with LE30 material, three upper and three lower, were chopped and dried in a vac.

Do you see that, sir?

A. Yes. I do.

Q. Do you see the following language: Two dried chopped aligners LE30 were placed in the 2-by-2 frame and pressed into a sheet at 420 degrees Fahrenheit in a Carver press.

Do you see that, sir?

A. Yes. I do.

Q. This is one day after SmartTrack comes out, sir, correct?

A. Looks like it.

Q. Do you stand by your opinion that he independently developed Zendura FLX?

A. Yes. I do.

Q. All right. Sir, let's just touch upon the consisting of limitation very briefly. Let's go to my Slide 30, which was your DDX-7.27.

This is a cartoon that you showed the jury, right? This is a cartoon image, fair?

A. Correct.

11:12 MR. HUNG: Now, let's go to the next slide, which was PTX-1666 admitted.

BY MR. HUNG:

Q. Now, sir, if you look at this -- now, you may disagree -- but her microscope, Dr. Reitman's microscope picture shows three layers, right?

You see that, right?

A. Yes.

Q. And now let's add some lines.

And your theory is that there's blending between these layers, the hard and the soft, right, sir?

A. That's correct.

Q. Okay. Let's add the lines.

MR. HUNG: Next slide.

BY MR. HUNG:

Q. But your own analysis showed that the blending doesn't go all the way through. In the middle, there's this pure layer of TPU elastomer that isn't blended in, fair?

A. That's correct.

Q. Also, sir --

MR. HUNG: Let's go to my Slides 3.43 which is the '613 patent. My Slide 3.

BY MR. HUNG:

11:13 Q. This argument that you made doesn't even apply to all the patents, does it, sir?
11:13 A. No.
11:13 Q. It doesn't apply to the '613, right?
11:13 A. No.
11:13 Q. Next slide, Slide 4. Doesn't apply to the '384, does it, sir?
11:13 A. No.
11:13 Q. Next slide. It doesn't apply to the '090, Claim 1, does it, sir?
11:13 You see the word "containing," sir? That's not "consisting of," right?
11:13 A. "Consisting" is not in that phrase.
11:13 Q. And, sir, so it's true that your argument that you made about this blending doesn't even apply to all the claims, right?
11:14 A. It only applies to some of them.
11:14 Q. Let's talk about Dr. Li for a second, who's in the gallery today.
11:14 It's your opinion that she misrepresented herself, that's what you think, to the Patent Office, right?
11:14 A. That's correct.
11:14 Q. But, sir, you are not offering an opinion -- you are not offering an opinion that Dr. Chunhua Li

intended to defraud the Patent Office, are you, sir?

A. I'm not offering an opinion.

Q. And, sir, let's pull up their DTX --

MR. HUNG: Actually, I have it. If we can switch to the ELMO.

BY MR. HUNG:

Q. This was -- this was your DTX-2189.

You recall seeing this before, correct, sir?

A. Yes.

Q. And I can slide it through. It's a little hard to see here, but I'll slide it through to help you.

If you look at this, we talked a lot in this case about stress relaxation, right?

A. I talked a little bit about stress relaxation.

Q. You've heard other witnesses talk about stress relaxation, correct?

A. Correct.

Q. And that is a big benefit of the multi-layer materials, a combination of the TPU elastomer, and the hard copolyester, true?

A. True.

Q. And, sir, if you look at this exhibit that you created, DTX-2189, do you see that for every material listed for which they ran this test, stress relaxation

11:15 is better, sometimes 5, 9, 10 times better, fair?
A. Than?
Q. Fair?
A. Than what?
Q. Than EX30.
A. Yes.
Q. And, sir, also --
MR. HUNG: Let's pull up JTX-79.
BY MR. HUNG:
Q. Now, you want to be fair to Dr. Li, right?
A. Of course.
Q. Okay.
MR. HUNG: Let's pull up JTX-79 as an exhibit. And let's go to the top of this.
BY MR. HUNG:
Q. And you told the jury that the reason why she rejected this was because those were bad materials.
Do you recall discussing that?
A. I didn't say "bad materials."
Q. Sir, did you read Dr. Li's deposition in this case?
A. I believe so.
Q. And were you here when she testified?
A. I was.
Q. Did you hear her testify that "reasons to

reject" means that this is a summary of her comparisons against SmartTrack? Do you understand that, that this sheet is a comparison against SmartTrack? Do you understand that?

A. I heard her say that.

Q. And "reason to reject" means she's explaining after the fact why she thought these were not as good as SmartTrack.

Do you recall that testimony?

A. I heard her say that.

MR. HUNG: Let's pull up the declaration, which is the last exhibit.

BY MR. HUNG:

Q. Now, sir, you've read this declaration probably many times now, right?

A. Yes.

Q. And do you know that this declaration -- I just counted -- has 90 -- I think about 90 sentences, correct, sir?

A. I haven't counted.

Q. You don't know. 12 pages?

A. Sounds right.

Q. And you aren't disputing that the vast majority of this declaration, Dr. Li told the truth? All of those statements are true. You're not disputing

that, are you, sir?

A. I've only focused on those certain parts.

Q. You've only focused on two sentences out of a 90-sentence, 12-page declaration, fair, sir?

A. I focused on those.

Q. And, sir, when you told the jury that the Patent Office found this declaration persuasive, you know that even after Dr. Li submitted this, the Patent Office rejected her application twice after that.

You know that, right?

A. I recall that.

Q. And she had to amend her claims, right, sir?

A. Yes.

MR. HUNG: And if we pull up the notice of allowance, let's pull that up, Mr. Smith.

And let's go to the reasons for allowance.

Keep on going.

Keep on going.

Right there.

Let's blow up the second sentence involving DeSimone. "DeSimone fails to teach."

BY MR. HUNG:

Q. Now, you were here when Ms. Li explained that what was occurring here is people were telling -- the

Patent Office was telling her, hey. DeSimone, your colleague, and Yan Chen, your co-inventor, it's obvious to make in the light of this, right?

You understood that, right, sir?

A. I heard that.

Q. And you see in this next sentence right after this that the Patent Office was persuaded that DeSimone fails to teach, suggest, or disclose a sheet comprising three or more polymer layers with all of these limitations that we see in the SmartTrack patents. Correct?

A. I see those words.

MR. HUNG: Actually, while we're at it, can we pull up JTX-2? And let's go to the cover. You can use Slide 2.

BY MR. HUNG:

Q. And I think there's some confusion here, sir.

MR. HUNG: If we can blow up the left side, "filed."

BY MR. HUNG:

Q. It's really small. You can kind of see it.

This is the '613 patent, correct, sir?

A. Yes.

Q. This claims priority to the original application filed in 2012, right?

11:19 A. Yes.
11:19 Q. And if you look under -- this specific application, sir, was filed on March 31st, 2017.
11:19 Do you see that right there, sir?
11:19 A. Yes.
11:19 Q. For the jury's benefit, was that before or after Zendura FLX was released?
11:19 A. That was after.
11:19 Q. May 31st --
11:19 A. I'm sorry. Zendura FLX. It says before.
11:19 Q. This application, the '613 application, was filed before Zendura came on the market, true or false, sir?
11:20 A. That's true.
11:20 Q. Basic question, sir, back to stress relaxation. You agree that the material properties improve stress relaxation for Zendura FLX, right?
11:20 A. I'm sorry. Say that again, please.
11:20 Q. You agree that the properties and the materials in Zendura FLX improve stress relaxation, right?
11:20 A. Yes.
11:20 Q. And you agree that that allows aligners to treat complex cases more effectively, correct?
11:20 A. I imagine so.

11:20 Q. You don't know?
11:20 A. I'm not a dentist.
11:20 Q. You're not a dentist. You never made an aligner material for an aligner, have you, sir?
11:20 A. That's correct.
11:20 Q. You never thermoformed an aligner?
11:20 A. I have.
11:20 Q. All right. All right, sir. Enablement. It's your testimony that one of skill in the art such as yourself could not make this material, right?
11:20 A. Which material?
11:20 Q. Could not make a material, according to the claims, the four SmartTrack patents without undue experimentation. That's what you're saying, right, sir?
11:21 A. That's correct.
11:21 Q. But again, I want to be crystal clear. We just established that Mr. Lahlouh, one or two days after SmartTrack comes out, buys the material and chops it up.
11:21 We saw that, right, sir?
11:21 A. I saw that.
11:21 Q. We know that rather than get his daughter his own material, he gets his daughter Invisalign SmartTrack.

11:21 We know that, right?
11:21 A. I heard that.
11:21 Q. We know that he gets the material data sheet and looks at the polymers on that sheet.
11:21 We know that, right, sir?
11:21 A. I heard him say that.
11:21 Q. And finally, we know that he makes simulates of the material, right, sir?
11:21 A. Yes.
11:21 Q. And what you'd forgotten is how hard that was, whether it took him a week or a year or four years, right?
11:21 A. Correct.
11:21 Q. Let me show you some deposition testimony. You read Mr. Lahlouh's deposition testimony, right?
11:21 A. I think so.
11:21 Q. Let me show it to you and see if this helps you remember.
11:22 MR. HUNG: Let's go to Slide 35.
BY MR. HUNG:
11:22 Q. This is Lahlouh's transcript at Line 202.
11:22 And I'm going to show it to you.
11:22 MR. HUNG: Slide 35. Thank you, Mr. Smith.
BY MR. HUNG:

11:22 Q. Now, read along with me.

How much time did you spend preparing the simulates, sir?

Did I read that correctly?

A. Yes.

Q. To prepare the simulates, it takes standard time, at least a week of work.

Do you see that, sir?

A. Yes.

Q. Do you stand by your testimony that it requires undue experimentation to make the materials according to the claims?

A. Yes.

Q. All right, sir. Let's talk about ASTM D638. In your binder is PTX-394.

MR. HUNG: I raised it yesterday, but I just forgot to introduce it. PTX-394.

Mr. Zubler, I'm going to offer it also.

MR. ZUBLER: No objection.

THE COURT: Admitted.

BY MR. HUNG:

Q. And let's --

MR. HUNG: Let's put that up. Sir, let's put up Slide 26.

BY MR. HUNG:

11:23 Q. This is the ASTM D638 standard, correct, sir?
11:23 A. That's correct.
11:23 Q. Now, let's take a step back. Dr. Reitman applied Type 5 specimens, right?
11:23 A. That's correct.
11:23 Q. For the multi-layer sheet?
11:23 A. Yes.
11:23 Q. She didn't think she should run that test, but she did, right?
11:23 A. I'm sorry. Say that again.
11:23 Q. Dr. Reitman did not think running the test on the whole sheet was appropriate. You heard her say that, right?
11:23 A. Yes.
11:23 Q. But when she ran the test, she applied an ASTM D638 standard, right?
11:23 A. She -- yes. She used this procedure.
11:23 Q. And she did a Type 5 specimen, right, V, 5?
11:23 A. Yes.
11:23 Q. And you did a Type 4 specimen, right?
11:23 A. Correct.
11:23 Q. And you did it because in your view, a sheet of Zendura FLX is nonrigid, right, sir?
11:24 A. That's one of the reasons.
11:24 Q. That's one of the reasons, right, sir?

11:24 And but you know, as a man who sits on the standards committee for the ASTM, that D638 refers to D883.

You know that, right?

A. Yes. It does.

Q. And let's go to the D883 standard at Slide 27.

Read along with me, sir. This is from PTX-412: A nonrigid plastic is one that has a flexural modulus of not over 70,000 megapascals or 10,000 PSI.

And then you see a reference to the D638 standard, correct, sir?

A. Yes.

Q. And now, sir, you know, right, that the -- you know that the flexural modulus of Zendura FLX altogether as a sheet is 213,000 PSI, right?

A. That sounds right.

Q. The flexural modulus with Zendura FLX is 20 times more -- it's 20 times this value right here, right, sir, for a nonrigid plastic?

A. That sounds about right.

Q. That's right, sir?

Actually, let's -- let's show the jury. Let's go to -- in your binder it's PTX-292.

Do you recognize this, sir, the tests that were done by Bay Materials?

11:25 A. Yes.
11:25 MR. HUNG: I'd like to offer this.
11:25 MR. ZUBLER: No objection.
11:25 THE COURT: Admitted.
11:25 BY MR. HUNG:
11:25 Q. And, sir, if you look at Page 6 of this, you will see a table. And in that table we will see that Zendura FLX, the entire sheet has a tested value of 208,000 PSI.
11:25 Do you see that, sir? It's also on your screen, sir.
11:26 A. Yes. I see that.
11:26 Q. And that is 20 times 10,000 PSI, correct?
11:26 A. That's correct.
11:26 Q. And nonrigid in D883, the definition, refers to 10,000, correct?
11:26 A. Yes. As a general.
11:26 Q. Now, sir, the reason why you thought that Zendura FLX is nonrigid, why you ran a Type 4 specimen, and you say she was wrong, is because you bent it in your hands, right, sir?
11:26 A. That's one evaluation.
11:26 Q. Can you tell the jury what the ASTM standard is for assessing materials based on hand bending?
11:26 A. There isn't one. It's years of practice.

11:26 Q. Well, sir, are you aware of any peer-reviewed publication that endorses manual bending as a method of classifying rigidity?

11:26 A. No. It's best practices.

11:26 Q. You're not aware of one, though, right, sir?

11:26 A. No. It's best practices.

11:26 Q. In fact, sir, you've never looked to see if there's an ASTM standard, of which you sit on the committee, to see whether there is a manual bending standard, correct?

11:27 A. That's correct.

11:27 Q. I want to close with one thing, sir.

11:27 MR. HUNG: Let's go to my Slide 6 listing the four patents.

BY MR. HUNG:

11:27 Q. Now, sir, you agree that three different examiners, and I had to look into this, Ms. Beha presumably changed her surname. But three different examiners reviewed the materials patents, correct, sir?

11:27 A. I see that.

11:27 Q. And you agree that all three of them determined that the patents should issue and in fact issued them, the ones before you, correct, sir?

11:27 A. That's correct.

11:27 Q. And as part of their examination, sir, they

had to assess whether the claims of this patent are enabled, correct, sir?

A. I believe so.

Q. They have to do that under the Manual of Patents Examining Procedure, right, sir? The MPEP, right?

A. I believe so.

Q. And they did, right, sir? You're not denying they did?

A. I'm not denying that.

Q. And they allowed all four patents to issue, right?

A. They did.

Q. And, sir, it's your view that they were wrong, right, sir?

A. Yes.

Q. And that they made a mistake, right, sir?

A. They didn't have full information.

Q. Three different examiners, right? Right?

A. Yes.

MR. HUNG: I pass the witness.

REDIRECT EXAMINATION

BY MR. ZUBLER:

Q. Dr. Spiegelberg, let's start where Mr. Hung just finished.

He was asking about other patents that were granted, and you stated that the examiners for those other patents didn't have full information. What did you mean?

A. They didn't have the data that Dr. Li assessed on all the various materials she considered.

Q. And did Dr. Li or Align submit any of that data in any of their applications?

A. No.

Q. Let me ask you a few more questions as well about some issues that Mr. Hung raised.

Let me start, if I could, to look at some data from your report that Mr. Hung showed you with some testing data.

MR. ZUBLER: If we could pull up Spiegelberg rebuttal report, Paragraph 361, in the data that Mr. Hung showed.

BY MR. ZUBLER:

Q. Do you recall looking at this data with Mr. Hung?

A. Yes.

Q. And Mr. Hung pointed in particular to the number 1096.

Do you recall that?

A. Yes. I do.

11:29 Q. For this testing that you're putting in this
11:29 chart in your report, what were the circumstances or
11:30 testing procedures you used to come up with this data?
11:30 A. This test was done not in compliance with D638
11:30 but was rather following what Dr. Reitman had conducted
11:30 in her test at the lower rate to see what the effects
11:30 of the lower rate out of compliance with D638 would be.
11:30 Q. I'm sorry. We're having a little trouble
11:30 hearing you. Could you just state that again, maybe
11:30 get a little closer to the microphone, Dr. Spiegelberg?
11:30 A. I'll try to get even closer.
11:30 Yes. This testing was done to replicate what
11:30 Dr. Reitman had done in her laboratory using the slower
11:30 rate of stretching and to understand why she was
11:30 getting the results that she got.
11:30 Q. Do you believe this is the proper testing
11:30 protocol, sir?
11:30 A. No. It's out of compliance with ASTM D638.
11:30 Q. Now, I notice here on this data there are five
11:30 reported sample numbers, four of which are under 200,
11:30 one of which is much larger.
11:30 How does that compare? Is that similar or
11:30 dissimilar to the bar chart you previously showed us
11:31 where you showed Dr. Reitman's data?
11:31 A. It's similar to what Dr. Reitman found where

there was a large variation in test results.

Q. And is it your opinion that Dr. Reitman's protocol affected her test results?

A. It did.

Q. Mr. Hung also asked you a number of questions about whether you applied for your testing that we looked at earlier, whether you applied the proper testing protocol.

Did anything that Mr. Hung asked you about or showed you cause you to have any questions or doubts about whether you applied the proper testing protocol?

A. No. I applied the proper testing protocol.

Q. Sir, how many years have you been on the ASTM Committee D20 on Plastics that maintains the D638 standard?

A. I think about 20 years.

Q. Mr. Hung also asked you some questions and he -- about Align patents. And he showed you some testing data that show that the SmartTrack material, in at least some testing data that I think you hadn't seen, had an elongation at break below 200 percent.

Do you recall seeing that?

A. Yes. I do.

Q. And Mr. Hung was suggesting that SmartTrack wouldn't be covered by Align's own patents. Was

that -- was that your understanding, sir?

A. I believe so. Yes.

MR. ZUBLER: If we could pull up the '691 patent, particularly Claim 1, and -- of -- this is Align's original SmartTrack patent.

BY MR. ZUBLER:

Q. We looked at this claim with Mr. Hung. This is the original claim for SmartTrack. Does this claim require any particular elongation at break?

A. It does not.

Q. Would this claim cover Align's SmartTrack patent?

A. Yes.

Q. Let me strike that question.

Would this claim cover Align's SmartTrack material?

A. Yes.

Q. Now, Mr. Hung also asked you questions about the declaration of Dr. Chunhua Li, and in particular we talked about -- he talked about the accuracy of her statement regarding the surprisingly superior performance of certain materials.

Do you recall that, sir?

A. Yes. I do.

Q. And Mr. Hung suggested that Dr. Li's data did

show and was consistent with her statement.

What was Dr. Li's statement and how did it compare to the data regarding the properties that were surprisingly -- allegedly surprisingly superior?

A. Dr. Li told the Patent Office that the properties were surprisingly superior on four metrics, not just stress relaxation, but four other -- or three other properties.

Q. And did Dr. Li's data show any materials that were surprisingly superior on those four properties?

A. They did not.

Q. From a scientific -- from a scientific perspective, were the statements in the 2019 declaration true or false?

A. They are false.

Q. Mr. Hung also asked you some questions about the patents that were -- or strike that.

Mr. Hung asked you questions about the fact that after the original declaration of -- I'm sorry, after the original declaration that Dr. Li submitted, actually the revised declaration that Dr. Li submitted, Mr. Hung said that the claims were then rejected on a -- provisionally by the patent examiner and only then later allowed.

Do you recall that?

11:35 A. Yes. I do.
11:35 Q. But let's focus, if we could, on the notice of allowance, the final reason why the claims were allowed in this same patent prosecution.
11:35 What did that notice of allowance say with respect to the revised declaration that Dr. Li submitted?
11:35 A. The patent examiner stated that she was persuaded by Dr. Li's declaration.
11:35 Q. Now, Mr. Hung also asked you some questions about Mr. Lahlouh's notebooks.
11:36 Do you recall those -- that testimony?
11:36 A. I do.
11:36 Q. And he showed you some pages from one of the notebooks dating to 2012, I believe.
11:36 A. Yes.
11:36 Q. Did Mr. Hung or anyone from Align ask Mr. Lahlouh about those pages from Mr. Lahlouh's own notebooks yesterday?
11:36 A. Not that I heard.
11:36 Q. Do you know why he asked you about those pages and didn't ask Mr. Lahlouh?
11:36 A. I don't know.
11:36 Q. Now, those pages talked about competitive analysis, I believe was the word.

11:36 Do you recall seeing that as the heading on that page?

A. I do.

Q. Did you hear Mr. Lahlouh yesterday talk about benchmarking?

A. Yes. I did.

Q. Are you familiar with the concept of benchmarking?

A. Yeah. We do it in our lab.

Q. Is benchmarking a common or uncommon practice in the industry?

A. It's very common.

Q. Looking at the pages that you did see from Mr. Lahlouh's notebooks today, the pages they didn't show Mr. Lahlouh, what is your understanding of whether or not Mr. Lahlouh was doing benchmarking on those pages?

A. It looked like he was doing benchmarking.

Q. Mr. Hung also asked you a few questions about the original patent that was filed for the SmartTrack material in this case.

Do you recall those questions?

A. Yes.

Q. When the statements that we focused on in the revised declaration were made by Dr. Li and Align, were

11:37 the claims at issue then the same or different than the
11:38 claims that were made in the original patent?
11:38 A. They were different.
11:38 Q. And did those changes in the claims, the
11:38 amendments to the claims, did those occur before or
11:38 after the e-mails we looked at from 2018, when Align
11:38 executives were concerned about Zendura FLX?
11:38 A. They came after the e-mails.
11:38 Q. Mr. Hung also asked you some questions about
11:38 whether you should test the raw ingredient for a
11:38 multi-layer product or the final multi-layer product.
11:38 Do you remember those questions?
11:38 A. Yes.
11:38 Q. Why did you test the multi-layer product?
11:38 A. Because it's important to assess the
11:38 properties in the final finished device because that's
11:38 what's going to impact the patient.
11:39 Q. And from the perspective of the claim language
11:39 that you looked at, how should the claim language --
11:39 and speaking as a person of skill in the art, how
11:39 should the claim language be applied regarding that
11:39 testing?
11:39 A. The claim language is clear that they're
11:39 talking about the properties of the films in the
11:39 multi-layer film -- of the layers in the multi-layer

11:39 film.

11:39 Q. What did Align test before the case began? Did they test the raw ingredient, or did they test the multi-layer product?

11:39 A. They tested the multi-layer product.

11:39 Q. What about Bay Materials? Before this litigation began, what did they test, the raw material or the multi-layer product?

11:39 A. The multi-layer product.

11:39 Q. If the jury focuses on and applies the claim language as you suggest based on your position as a person of skill in the art and analyzes the claim language so that the multi-layer product is the relevant point of analysis, is there any basis for a finding of infringement?

11:40 A. No.

11:40 Q. Let's go back, if we could, one final time, Dr. Spiegelberg, to the analogy of the fence. If the fence is properly drawn of Align's patents to cover the proper scope of Align's claims, does the hard-soft-hard configuration of Zendura FLX fall within that fence?

11:40 A. It does not.

11:40 Q. If the patent claims are stretched, if the fence is stretched, as we did earlier over here, to cover the hard-soft-hard configuration of Zendura FLX,

11:41 is -- are the Align patents enabled?
11:41 A. They are not.
11:41 Q. And if they're not enabled, are they valid or invalid?
11:41 A. They're invalid.
11:41 Q. Is there any location in this entire space where the Align patents are both infringed and valid?
11:41 A. No.
11:41 MR. ZUBLER: No further questions.
11:41 RECROSS-EXAMINATION
11:41 BY MR. HUNG:
11:41 Q. Dr. Spiegelberg, you spoke with Mr. Lahlouh, correct?
11:41 A. Briefly.
11:41 Q. Briefly?
11:41 To prepare your opinions on this case that the man didn't copy, you spoke with him briefly; is that right?
11:41 A. About half an hour.
11:41 Q. Half an hour in total?
11:41 A. I think that's right.
11:41 Q. Now, you saw his 21 notebooks, right, sir?
11:41 A. Yes.
11:42 Q. Did you discuss those with him?
11:42 A. Yes.

11:42 MR. HUNG: And actually, since it was raised on redirect, let's put that notebook back up, if we could. That's my Slide 12. It's DTX-811, now admitted.

11:42 And let's go to the next slide.

BY MR. HUNG:

11:42 Q. Now, sir, it's actually 2013. I was wrong. It's one day after orthodontists start getting SmartTrack.

11:42 Do you see that?

11:42 A. Yes.

11:42 Q. Now, sir, you're not disputing, based on what Ms. Li said, Dr. Li, that LE30 is a confidential internal code name for SmartTrack? No dispute about that, right, sir?

11:42 A. I don't know.

11:42 Q. You don't know? Did you attend her testimony, sir?

11:42 A. Yes.

11:42 Q. Did you have occasion to ask Mr. Lahlouh how he obtained the code name LE30 and obtained aligners one day after the commercial launch to test them? Did you ask him that, sir?

11:43 A. I did not.

11:43 Q. Now, sir, you did -- I think you said you did

11:43 look at Mr. Lahlouh's patents, correct, sir?
11:43 A. I briefly looked at them.
11:43 Q. Did you look to see whether he submitted all
11:43 of those notebooks to the Patent Office to support his
11:43 patents and obtaining them?
11:43 A. I don't know.
11:43 Q. But yet you stand by your opinion, don't you,
11:43 that Dr. Li, who's obtained all these patents, 100 from
11:43 the U.S. Patent Office during her time at Align, should
11:43 have submitted two summary charts? Is that your
11:43 opinion?
11:43 A. Yes.
11:43 MR. HUNG: Your Honor, can I approach and
11:43 put the pedestal back up, the board back up?
11:43 THE COURT: Yes.
11:43 MR. HUNG: Thank you.
11:44 BY MR. HUNG:
11:44 Q. Now, Dr. Spiegelberg, you were asked about
11:44 this -- this exhibit, DDX-20.
11:44 And you created this, right?
11:44 A. Yes.
11:44 Q. And if you'll -- sorry. Too close.
11:44 And if you look at this, you will see you
11:44 pointed out all the prelitigation Align testing and all
11:44 the prelitigation Bay Materials testing, right?

11:44 A. Correct.
11:44 Q. Were those tests performed on the whole sheet, or were those performed on an individual layer?
11:44 A. They were done on the whole sheets.
11:44 Q. Now, Dr. Reitman's testing, afterwards, also done on the whole sheet, right, sir?
11:44 A. That's correct.
11:44 Q. And you can see that she's getting values that are well in excess of 200 percent, sir, right?
11:44 A. For two of the specimens.
11:44 Q. You see that, right?
11:44 And that's because after that outer layer broke, the rubber, the elastomer kept on stretching, right?
11:44 A. At the wrong rate.
11:45 Q. But to be crystal clear for the jury so there's no confusion, those are all tests on the elongation at break of the whole sheet before litigation. That's what you're saying, right, sir? Right?
11:45 A. Some testing was after litigation.
11:45 Q. And, sir, we know the properties of Desmopan or of Texin because we can read those on the data sheet, right?
11:45 A. Before manufacturing.

11:45 Q. A person of skill in the art like you refers to those data sheets all time, sir, right?
11:45 A. As a general rule.
11:45 Q. So if I want to know how stretchy Texin or Desmopan are, I don't got to run a test on the whole sheet; I can just look at the data sheet, fair?
11:45 A. That's wrong.
11:45 Q. Sir, you mentioned that you have been a person who's involved with ASTM, I think you said, for 20 years, right, sir?
11:46 A. Yes.
11:46 Q. And we talked about rigidity, correct, sir?
11:46 A. Yes.
11:46 Q. And you understand the importance of the scientific method, correct, sir?
11:46 A. Yes.
11:46 Q. You learned about those in undergrad, high school, at Wisconsin, right, sir?
11:46 A. That's correct.
11:46 Q. And part of the reason why you did your tests that you said is better than Dr. Reitman's test is because you think that Zendura FLX, the whole sheet is nonrigid. That's part of the reason, right, sir?
11:46 A. The TPU layer is definitely nonrigid.
11:46 Q. And, sir, you still can't point me to a single

ASTM standard on the American Society of -- I think it's Testing Methods, a single ASTM standard that refers to manual bending to define that test, can you, sir?

A. That's correct.

Q. Thank you.

Oh, I'm sorry. I forgot something.

MR. HUNG: Thank you, Ms. Durie.

Can we put up the '691 patent, which is DTX-72?

BY MR. HUNG:

Q. I think there was an implication, sir, that this patent doesn't cover elongation at break of a layer more than -- less than 200 percent -- more than 200 percent.

Do you recall discussing that?

A. I do.

Q. Okay. Help me here. Read along with me.

MR. HUNG: Let's go to Claim 12 on Page 19.

And, Your Honor, I'd also like to admit this. I forgot to admit it.

MR. ZUBLER: No objection.

BY MR. HUNG:

Q. Okay. You see Claim 12, sir?

11:47 A. Yes. I do.
11:47 Q. Now, sir, we are looking at the first SmartTrack patent, correct?
11:47 A. I believe so.
11:47 Q. And you were shown this first SmartTrack patent and shown that it had a soft-hard-soft configuration, correct?
11:47 A. That's correct.
11:47 Q. And it was implied that this patent doesn't require, have claims that require an elongation at break of greater -- of greater than about 200 percent, right?
11:48 A. That's correct.
11:48 Q. And you see that Claim 12 refers to an appliance, an aligner, right, sir?
11:48 A. Yes.
11:48 Q. Now, read along with me. It says that "the second soft outer polymer layer," and then it continues, "each independently comprise," and it continues, "an elongation at break of greater than about 200 percent."
11:48 Do you see that, sir?
11:48 A. Yes. I do.
11:48 Q. Thank you.
11:48 MR. ZUBLER: Your Honor, very briefly.

11:48 THE COURT: Of course.

11:48 MR. ZUBLER: If we could just go back to the '691 patent, the patent that Mr. Hung just had up, and Claim 1.

11:48 FURTHER REDIRECT EXAMINATION

11:48 BY MR. ZUBLER:

11:48 Q. This is the claim we looked at previously, Dr. Spiegelberg. And does this claim have an elongation at break requirement, sir?

11:48 A. It does not.

11:48 Q. Can you practice a patent without practicing every single claim in the patent?

11:49 A. Of course.

11:49 Q. Does Align's SmartTrack material practice Claim 1 without any elongation at break requirement?

11:49 A. It does.

11:49 Q. Let me ask you just a handful more questions about the copying allegations in this case which Mr. Hung brought up again.

11:49 You were here for Dr. Reitman's testimony, weren't you, sir?

11:49 A. Yes. I was.

11:49 Q. She didn't testify that Mr. Lahlouh copied, did she?

11:49 A. I didn't hear her say that.

11:49 Q. What do you think? Do you think, based on your analysis of the evidence, that Mr. Lahlouh copied the SmartTrack patent or the SmartTrack material?

A. I do not.

Q. And what did Mr. Lahlouh say in court and under oath regarding whether he copied the SmartTrack patent or material?

A. He said he did not.

MR. ZUBLER: No further questions.

MR. HUNG: No questions.

Thank you, Your Honor.

THE COURT: Thank you, sir. You may step down.

MR. MUELLER: Is Dr. Balakrishnan in the courtroom?

I'm sorry, Your Honor.

THE COURT: Is the next witness -- is the next witness --

MR. MUELLER: He's a fact witness, Your Honor. Mr. Marbach.

THE COURT: Why don't we go ahead and get that done, and then we'll go to lunch.

MR. MUELLER: That would be great, Your Honor. Thank you.

At this point, Your Honor --

THE COURT: I'm sorry. Is that okay with y'all?

MR. MUELLER: May I proceed, Your Honor?

At this point, we call Julien Marbach, and Ms. Ferrera will conduct the examination.

(The witness was sworn.)

DIRECT EXAMINATION

BY MS. FERRERA:

Q. Good morning, sir. Could you please introduce yourself?

A. I'm Julien Marbach.

Q. And where did you grow up, Mr. Marbach?

A. I grew up in France.

Q. Where do you currently work?

A. I currently work at Dental Wings in Montreal, Canada.

Q. What is Dental Wings?

A. Dental Wings is a company that develops and sells scanners, dental scanners and software, yeah, for the dental field.

Q. And what is the relationship between Dental Wings and Straumann?

A. Dental Wings is a company that is in support of the Straumann Group.

Q. What's your current job title?

11:52 A. My current job title is principal software developer.

11:52 Q. I'd like to just ask you a few questions about your background.

11:52 First, can you tell us about your education and your work history?

11:52 A. Sure. I attended a French engineering school where I obtained a master's degree in computer science, and then I moved to Canada where I've worked at a few companies as a software developer before joining Dental Wings.

11:52 Q. And when did you join Dental Wings?

11:52 A. I joined Dental Wings in 2007.

11:52 Q. What have your responsibilities been at Dental Wings?

11:53 A. I've been a software developer, a technical lead, then a manager, and now I'm more helping on the strategy.

11:53 Q. So all told, Mr. Marbach, how long have you now worked in the field of dental scanning technology?

11:53 A. About 20 years.

11:53 Q. So fair to say that dental scanning has been around for several decades; is that correct?

11:53 A. That's correct.

11:53 Q. Now, Mr. Marbach, were you here earlier in the

11:53 week on Monday for the parties' opening statements?
A. Yes. I was.
MS. FERRERA: I'd like to pull up DDX-1.62.
BY MS. FERRERA:
11:53 Q. And you should be able to see it on the screen there.
11:53 Do you recall seeing this slide on Monday?
11:53 A. Yes. I do.
11:53 Q. And you see there's a reference on this slide to DWOS?
11:53 A. I see that.
11:53 Q. Have you heard that term?
11:53 A. Yes. It's stands for Dental Wings Open System which is an ecosystem of software and scanners that our user can use and pull scans from and share those scans with anybody they may want to.
11:54 Q. So that's the software that's used on the scanners; is that right?
11:54 A. Exactly. DWOS is the software.
11:54 Q. And why is it called the Dental Wings Open System?
11:54 A. Open system because the users have the choice to export the data they capture with the scanner to any third party.

11:54 Q. How long has Dental Wings had an open system?
11:54 A. Since the very beginning. It was like really the mission of the company to offer such a system on the market.
11:54 Q. And have all the dental scanners that Dental Wings has developed been open systems?
11:54 A. Yes. All of them.
11:54 Q. Now, you mentioned a moment ago that Dental Wings is now part of the Straumann family; is that right?
11:54 A. That's right.
11:54 Q. And has that open system philosophy continued under Straumann?
11:54 A. Yes. It does.
11:54 Q. So do Dental Wings scanners show any kind of a preference for sending scans to ClearCorrect as opposed to other clear aligner manufacturers?
11:55 A. No. It doesn't.
11:55 Q. And do Dental Wings scanners limit users' ability to export files to other -- to other manufacturers besides ClearCorrect?
11:55 A. No. It doesn't.
11:55 Q. Why has Dental Wings continued to maintain or to use this open system philosophy?
11:55 A. Because we believe our users should have the

choice to work with whoever they want.

Q. I just have one last question, Mr. Marbach.

Are you proud of work that you've done at Dental Wings?

A. Yes. I am. Because we were the pioneers at introducing open system in the dental field, and we've always been a small company, a small engineering team, facing competition from bigger corporation. And despite that, we've had great success with our product.

So yeah, I'm proud of it.

Q. Thank you, Mr. Marbach.

MS. FERRERA: Pass the witness.

CROSS-EXAMINATION

BY MR. NASH:

Q. Hello, Mr. Marbach.

A. Hello.

Q. We haven't met yet. My name's Brian Nash.

A. Nice to meet you.

Q. Nice to meet you too.

Before we start, you're aware of the iTero?

A. Yes. I am.

Q. Intraoral scanner, right?

A. An intraoral scanner. Yeah.

Q. By my client Align?

A. Yes.

11:56 Q. You're familiar with that device. You've seen it before?
11:56 A. I've seen it before.
11:56 Q. Do you know whether iTero allows you to export an STL file to order any competitive product?
11:57 A. I'm not sure about that.
11:57 Q. You're not sure about that?
11:57 A. That's right.
11:57 Q. You don't look at other scanners?
11:57 A. I do.
11:57 Q. How long have you been in the scanner business?
11:57 A. For 20 years.
11:57 Q. 20 years. You've never determined whether or not the iTero scanner can export STL files?
11:57 A. I've done that on other scanners but not on the iTero specifically.
11:57 Q. Isn't the iTero scanner one of your competitor scanners?
11:57 A. It's one of them.
11:57 Q. And you haven't determined whether it can export a standard STL file?
11:57 A. No. Not specifically.
11:57 Q. I'd like to talk to you a little bit about Virtuo Vivo and the SIRIOS scanners.

11:57 A. Right.
11:57 Q. You're familiar with those, right?
11:57 A. I do.
11:57 Q. You know how they work?
11:57 A. Yes.
11:57 Q. And you talked to defendants' expert about how they operate; is that right?
11:57 A. Can you say that again, please?
11:58 Q. Defendants' expert Dr. Balakrishnan, you talked with him about how they work, right?
11:58 A. That's correct.
11:58 Q. Okay. And you gave him information about these products so that he could arrive at his opinions in this case?
11:58 A. I did.
11:58 Q. I want to talk to you about that information so that the jury can hear about it directly from you. Okay?
11:58 A. Can you say that again, please?
11:58 Q. I would like to talk to you about the information about how these devices operate so the jury can hear it from you; is that okay?
11:58 A. That's fair.
11:58 Q. Okay. I'd like to start to see if we agree on a few things.

Both of them have a handheld scanner, right?
A. That's right.
Q. Okay. The scanner is intraoral, right?
A. It is.
Q. It means you can put it in your mouth. That's intraoral?
A. That's fair.
Q. Okay. And each is used with software?
A. Yes.
Q. Software is used to scan a patient's teeth, right?
A. That's right.
Q. Okay. And I want you to follow along with me, tell me if you disagree, but let's say we want to do an initial scan. I want to do the workflow, okay?
A. Okay.
Q. Okay. Scanner's placed inside the mouth?
A. Right.
Q. Okay. Intraoral cavity, right?
A. Correct.
Q. You take the scanner, you rock it back and forth over the teeth, right?
A. Yeah.
Q. All the way around the dental arch?
A. Yes.

11:59 Q. Now, that scanner, it gathers data, right?
11:59 A. It does.
11:59 Q. Okay. That data is about the teeth, right?
11:59 A. Yes. It is point cloud data.
11:59 Q. I'm sorry, what?
11:59 A. Point cloud data. Yes.
11:59 Q. The data that is being gathered by the scanner is about the teeth; is that correct?
11:59 A. That's correct.
11:59 Q. And that data includes data about the surface of the teeth, correct?
11:59 A. It does.
11:59 Q. It's not the inside of the teeth?
12:00 A. Sorry. Say that again.
12:00 Q. It is not the inside of the teeth?
12:00 A. No. It's not.
12:00 Q. It's the surface, right?
12:00 A. No. It's not the surface.
12:00 Q. It's data about the surface, correct?
12:00 A. Correct.
12:00 Q. The computer receives that data; isn't that fair?
12:00 A. It does.
12:00 Q. Now, that data is then used to provide a 3D rendering to the doctor, fair?

12:00 A. That's fair.
12:00 Q. The doctor can see something on his monitor; is that true?
12:00 A. Yes, after processing.
12:00 Q. I'm sorry?
12:00 A. After processing. Yes.
12:00 Q. Isn't it true that the doctor can see something on his monitor, his display?
12:00 A. It is true.
12:00 Q. It's three-dimensional?
12:00 A. Yes. It is.
12:00 Q. It's rendering, right?
12:00 A. Yes.
12:00 Q. Now, the doctor can remove some of that data, right?
12:01 A. That's right.
12:01 Q. It's the lasso tool or the cut tool. We heard all about it yesterday.
12:01 A. That's right.
12:01 Q. Okay. Delete it, it's gone, that data, off the -- off the rendering, true?
12:01 A. That's true.
12:01 Q. Now, next, the doctor can change something on a tooth, right?
12:01 A. Correct.

12:01 Q. Okay. Like for a crown prep, for example. You're familiar with a crown prep?
12:01 A. Yes.
12:01 Q. And if it's a little too high on one of the teeth, you can trim a little bit more off, right?
12:01 A. That's right.
12:01 Q. Okay. And then the doctor would want to go and scan back over that area, true?
12:01 A. Yes.
12:01 Q. He uses the scanner again, right?
12:01 A. It does.
12:01 Q. That scanner captures new data, true?
12:01 A. True.
12:01 Q. The data includes data about the surface?
12:01 A. Point cloud data. Yes.
12:01 Q. It includes data about the surface, true?
12:02 A. True.
12:02 Q. And specifically, that data is about the surface where the doctor made a change, true?
12:02 A. It can be. Yes.
12:02 Q. He went back over the area where the crown was adjusted, fair?
12:02 A. Fair.
12:02 Q. Okay. And he scanned that area, received some data. That data is about an area that has changed,

12:02 correct?
12:02 A. That's correct.
12:02 Q. Changed on the surface, correct?
12:02 A. Can you say that again?
12:02 Q. The data that has been captured by the scanner is -- includes data about an area on the surface that has changed, correct?
12:02 A. Correct.
12:02 Q. Now, this new scan data, it's received by the computer, right?
12:02 A. It is.
12:02 Q. And it is used to update what the doctor sees, correct?
12:02 A. Not immediately.
12:03 Q. But it is used by the computer to update what the doctor sees, right?
12:03 A. It is.
12:03 Q. Okay. The doctor deleted some data. This data's being used to replace what got deleted, correct?
12:03 A. Correct.
12:03 Q. And that data, it gets registered onto what the doctor sees; isn't that true?
12:03 A. Point cloud data. Yes.
12:03 Q. That data gets registered into what the doctor sees, correct?

12:03 A. No. It doesn't.
12:03 Q. The rescan data would be registered with what was existing, the existing scan data; is that correct?
12:03 A. That's correct.
12:03 Q. And that's true in the Virtuo Vivo, correct?
12:03 A. Yes.
12:03 Q. And it's true in the SIRIOS, correct?
12:03 A. Correct.
12:03 Q. And what he sees on his monitor has been updated, correct?
12:04 A. Yes.
12:04 Q. Now, Virtuo Vivo first launched in 2019, right?
12:04 A. That's correct.
12:04 Q. It had significant problems, didn't it?
12:04 A. I won't agree with that.
12:04 Q. It was pulled from the market shortly thereafter, wasn't it?
12:04 A. Say again.
12:04 Q. It was pulled from the market shortly thereafter, wasn't it?
12:04 A. Temporarily in the United States, yes.
12:04 Q. A few years later, Straumann bought a different scanner company called AlliedStar; is that right?

12:04 A. That is right.
12:04 Q. And now Straumann has an entirely different scanner called SIRIOS, fair?
12:04 A. That's fair.
12:04 Q. And Virtuo Vivo isn't being sold at all right now, right?
12:04 A. That's correct.
12:04 Q. So I want to talk about how -- what the doctor sees, okay?
12:04 A. Okay.
12:04 Q. And you mentioned point cloud.
12:05 A. Sorry?
12:05 Q. You mentioned point cloud earlier, right?
12:05 A. I did.
12:05 Q. And I think what it's fair to say is your position is that it looks like a bunch of points if you zoom in; is that fair? Do I understand what that means?
12:05 A. I won't put it like that.
12:05 Q. It's a rendering that's based on point cloud data?
12:05 A. It is.
12:05 Q. Okay. So I'm going to use an example. I have an apple, just for demonstrative purposes. I won't be eating it. I'm going to scan the apple. We're going

12:05 to pretend the apple's the tooth.

Go over the apple, right?

A. Uh-huh. Right.

Q. It would show an apple on the display, true?

A. No. I won't say that.

Q. I think you would say it would show a rendering of an apple on this display, correct?

A. That's correct.

MR. NASH: Okay. Let's pull up PDX-27.1.

BY MR. NASH:

Q. All right. Do we have our digital rendering of the apple? Let's do a scan. Thank you.

Fair representation?

A. Fair representation of what? Sorry.

Q. Of how this would operate. Looks like a digital rendering of an apple, correct?

A. I'm sorry. I didn't hear you. It looks like a what?

Q. A digital rendering of an apple, correct?

A. Yes. I agree.

Q. And those dots, those points, each one of them, right, you see those?

A. I do.

Q. That'd be based on the point cloud, correct?

A. That's a point cloud.

12:07 Q. That's a point cloud. It's data, right?
12:07 A. It is.
12:07 Q. Each one of those dots is data?
12:07 A. Yes.
12:07 Q. That data came from the scan of the surface of the apple, correct?
12:07 A. That's correct.
12:07 Q. Now, we have a change. We're going to take a bite out of our apple. I shouldn't bite it. No eating in court. All right. So we've changed our apple.
12:07 The surface of the apple is different, right?
12:07 A. It is.
12:07 Q. So you can delete the data that's associated with that area where it changed, right? Lasso tool, cut tool, you can delete it, fair?
12:07 A. Correct.
12:07 Q. Okay. We're going to use our lasso tool.
12:07 Now, you can rescan that area where it was changed, right?
12:08 A. Yes.
12:08 Q. The second scan you take involves capturing data about that changed portion, doesn't it?
12:08 A. It does.
12:08 Q. The bite area, correct?
12:08 A. Correct.

12:08 Q. Where it changed, true?
12:08 A. True.
12:08 Q. And the software uses that new scan data to update what the doctor sees, true?
12:08 A. True.
12:08 Q. And we see that there on the right, right?
12:08 A. Yes. We do.
12:08 Q. What the doctor sees has been updated?
12:08 A. Correct.
12:08 Q. It uses that new scan data to replace the part that was removed, correct?
12:08 A. That's correct.
12:08 Q. All right. So let's talk about what the doctor sees.
He sees an apple with a bite out of it, right?
12:08 A. It is.
12:08 Q. And that part with the bite, the creamy yellow part, right there on the right.
You see that?
12:08 A. I do.
12:08 Q. Okay. The information for that area, it came from second scan, correct?
12:09 A. Yes. Correct.
12:09 Q. That second scan had data, true?
12:09 A. True.

12:09 Q. That data was used to update what the doctor sees, right?
12:09 A. That's correct.
12:09 Q. And that data was gathered by scanning the surface, true?
12:09 A. That's correct.
12:09 Q. And each of those dots represents data, fair?
12:09 A. That's fair.
12:09 Q. All of those yellow and cream dots that came from the data that was scanned in from the surface, correct?
12:09 A. Sorry. Can you say that again?
12:09 Q. Each of those yellow and cream dots came from data that was scanned in from the surface of that bite, correct?
12:09 A. Correct.
12:09 Q. That data is data that came in from the surface of the tooth, true?
12:09 A. I won't put it like that.
12:09 Q. The data didn't come from the inside of the tooth, right?
12:09 A. No.
12:09 Q. It came from the surface of the tooth, right?
12:10 A. Generated from the surface of the tooth. Yes.
12:10 MR. NASH: Pass the witness, Your Honor.

REDIRECT EXAMINATION

BY MS. FERRERA:

Q. Mr. Marbach, counsel just asked you a number of questions about the data that Virtuo Vivo and SIRIOS use after a second scan where there's been a physical change.

Do you recall that?

A. Yes. I do.

Q. What kind of data do the Virtuo Vivo and SIRIOS use at that step?

A. They use point cloud data.

Q. And as a factual matter in the world of 3D modeling, what is point cloud data?

A. It's a discrete set of individual points in the 3D space.

Q. And as a factual matter in the world of 3D modeling, what's the difference between point cloud data and surface data?

A. Surface data is continuous and connected and form the outer skin of an object; whereas, point cloud data are not connected. They are individual dots in a 3D space. There's no interconnection and continuity; whereas, surface data has it.

Q. And once again, which of those two types of data do the Virtuo Vivo and SIRIOS use at the replacing

12:11 step in the rescanning process?
12:11 A. Point cloud data.
12:11 Q. Last question, Mr. Marbach.
12:11 Can you just remind us again, are the Virtuo Vivo and SIRIOS open systems or closed systems?
12:11 A. They are open systems.
12:11 MS. FERRERA: Thank you. Pass the witness.
12:11 MR. NASH: No further questions, Your Honor.
12:11 Thank you, Mr. Marbach.
12:11 THE WITNESS: Thank you.
12:11 THE COURT: Thank you, sir.
12:11 May he be excused?
12:11 MR. MUELLER: Yes, Your Honor.
12:11 THE COURT: Thank you.
12:11 Could I have counsel up here for a second?
12:11 (Bench conference.)
12:12 THE COURT: So if I'm following along, you now want to --
12:12 MR. MUELLER: We move for JMOL now.
12:12 THE COURT: So let's do this. I tell the jury to be back at 1:45, and we will get back at -- is it 12:30? Yeah. Why don't we get back at 1:30, and

12:12 we'll take that Rule 50 motion up.

12:12 MR. MUELLER: Thank you, Your Honor.

12:12 MR. NASH: Thank you, Your Honor.

12:12 (Bench conference concludes.)

12:12 THE COURT: Ladies and gentlemen of the jury, we're going to take our lunch recess. If you'd please be back and ready to go by 1:45, we'll start then.

12:12 Please remember my instructions not to discuss the case, and I will see you then.

12:12 THE BAILIFF: All rise.

12:12 (Jury exited the courtroom.)

12:13 THE COURT: Thank you. You may be seated.

12:13 Counsel, if you'll be back here at 1:30, we'll take up the motions, the renewed motion under Rule 50. Is there anything I need to take up besides that?

12:13 MR. MUELLER: Nothing further for defendants, Your Honor. Thank you.

12:13 MS. DURIE: No, Your Honor.

12:13 THE COURT: Thank you.

12:13 (Recess taken.)

01:27 THE BAILIFF: All rise.

01:27 THE COURT: Thank you. You may be

seated.

I'm happy to take up the Rule 50 motion.

MR. MUELLER: Thank you, Your Honor. May I proceed?

THE COURT: Please.

MR. MUELLER: Your Honor, there's a number of reasons why we believe and would respectfully request that judgment as a matter of law enter on the '936 patent, and I'll go through the secondary reasons in a moment.

But the high level primary reason why we believe JMOL is appropriate is that there was a failure of proof. And when the witnesses -- expert witnesses for the plaintiff testified to present the infringement case, neither of the two experts, Dr. Valley nor Dr. Singh, addressed all of the requirements of the claims.

And, Your Honor, may I just pass out the slides they used?

THE COURT: Sure.

MR. MUELLER: This is Dr. Valley. And this is Dr. Singh.

THE COURT: Okay.

MR. MUELLER: And, Your Honor, I'll just take you, if I could, to the key slides that were

01:29 presented. These are their demonstratives.

01:29 In the Valley deck, it's Slide 3.11. And as you can see, Your Honor, on this slide -- and I can put it on the ELMO too. It says: Replace at least -- this is Dr. Valley -- replace at least a portion of the removed surface portion of the model using the received second scan data.

01:29 That's the highlighted portion.

01:29 But the requirement continues. The requirement continues. It's not just scan data. It also requires of the patient's teeth including, including surface data of a physically changed portion of the patient's intraoral cavity.

01:30 And so the claim requires the receipt -- receive second scan data, and that scan data needs to include surface data. And we know those are two different things because there's two different terms in the claim. It's scan data including surface data.

01:30 And Dr. Valley never addressed the surface data. Dr. Valley didn't have the expertise to do so. She is not a computer scientist. She's not an expert on 3D graphics modeling. And she did not address that issue in any way, shape, or form in her testimony on the stand on Monday.

01:30 Now, for Dr. Singh's part, in this deck,

Your Honor, the one with the Avatar photo on the cover, if we go to Slide 4.6. So here, again, the highlighted portion for which an opinion was offered, it is to replace at least a portion of the removed surface portion of the model using the received second scan data.

So again, what needs to be received is second scan data, but that's not all. The second scan data in the portion that continues but was not addressed by Dr. Singh requires that the scan data include surface data for a physically changed portion of the intraoral cavity.

Again, this is different than scan data, two different terms. And surface data, our position has been in this case, is not the same thing as point cloud data. Points are different than surfaces.

And neither Dr. Valley nor Dr. Singh offered any opinion to this jury explaining how point cloud data could be surface data to meet the requirements of the claim.

And Dr. Singh acknowledged when cross-examined by Ms. Ferrera that he had not addressed that portion of the case.

On redirect, on redirect, there was an attempt to have some sort of opinion offered by

01:32 Dr. Singh, and this is at the trial transcript on
01:32 Page 261. But even then, even then, on redirect, after
01:32 Ms. Ferrera had extracted a concession that he did not
01:32 offer any opinion -- and let me read her question and
01:32 answer.
01:32 Question: You didn't give any opinion
01:32 about the second portion of the claim limitation during
01:32 your direct testimony, did you?
01:32 Answer: I did not.
01:32 That's the trial testimony at Page 259,
01:32 two pages earlier, Lines 13 through 14.
01:32 You didn't give any opinion about the
01:33 second portion of the claim limitation during your
01:33 direct testimony, did you?
01:33 I did not.
01:33 On redirect, again, on redirect on
01:33 Page 261, there was an attempt to have Dr. Singh offer
01:33 that opinion. And he didn't do it even then. He made
01:33 a passing reference to the entire phrase, the first
01:33 line of his answer on Line 11 of the transcript.
01:33 But even that conclusory reference said
01:33 nothing about surface data and focused on the words
01:33 "physically changed portion of the person's intraoral
01:33 cavity."
01:33 So we have a clear failure of proof.

Neither expert addressed a requirement of the claim language. Neither expert even attempted to explain how the point cloud data used in the accused scanners could satisfy the surface data requirement of the claims.

And then today, Your Honor, we called a fact witness. And I'll note parenthetically, our understanding had been the reason why Align was leaving their case open for that fact witness was that the fact witness might provide some testimony that could assist their indirect infringement claims vis-à-vis encouragement of customers to use scanners and instructions for how to do it.

Nonetheless, we called that fact witness, Mr. Marbach, and he was not asked a question during cross-examination about surface data. He was asked questions about data about the surface, but wasn't asked about the claim term "surface data."

The only question to Mr. Marbach about surface data was from Ms. Ferrera on redirect. And in response, Mr. Marbach explained, no, that the scanners use point cloud data, not surface data.

So what we have here, Your Honor, is a record where the two experts who are offered by Align failed to address a claim requirement. Neither one addressed one of the requirements that needs to be

satisfied for infringement. We offered a fact witness who denied, who denied that that technical element was met in the accused scanners.

Now, we didn't show him the claim language. He was here as a fact witness. But he denied that the point cloud data was surface data.

So we have a fact witness denial. We have two experts failing to meet requirement in any form or fashion. That's a failure of proof. And that failure of proof means no reasonable juror could find infringement of this patent.

On top of that, the only claim that's actually pleaded in the complaint is an indirect infringement claim, not direct, indirect infringement claim.

And here, mere knowledge of the patent is not enough. Of course as Your Honor knows, knowledge of infringement would be required. There's no evidence, none, that ClearCorrect or the other defendants knew about any infringement of the '936 patent before the lawsuit was filed.

After the suit was filed, we have asserted reasonable defenses showing no intent to infringe. At best --

THE COURT: And there's no -- and there's

no marking issue with that patent?

MR. MUELLER: Correct. And even if there were marking, Your Honor, the marking would not suffice to show that we had knowledge of infringement.

On top of that, there's no specific act of direct infringement that's been shown.

Dr. Singh, in addition to the failure of proof that I mentioned earlier, testified only about how the software worked, but Align put on no evidence of any use in the United States.

On top of that, there's no expert opinion on damages for this patent, and Your Honor has previously suggested that you might not instruct on or have the jury render a verdict on damages for this patent even if it were to go to the jury on infringement.

So this is a patent for which there's no damages claim, no damages opinion by Mr. Lasinski, no evidence of indirect infringement, no predicate act of direct infringement in the United States, no evidence of intent, and no opinion by the experts on a claim requirement for each of the asserted claims.

All we have in this record, Your Honor, on requirements that need to be shown is a fact witness saying it doesn't happen. So we have a fact witness

saying it doesn't happen, two experts failing to say it does happen, and on that record, no reasonable juror could find infringement.

THE COURT: A response?

MR. NASH: Your Honor, with apologies, I do have a couple of slides, but I wasn't able to get those printed out in advance. Would it be okay for me to use those on the screen?

THE COURT: Of course.

MR. NASH: Okay.

Mr. Smith, if you don't mind.

THE COURT: Has opposing counsel seen them?

MR. NASH: No.

(Conference between counsel.)

MR. NASH: Your Honor, I heard opposing counsel up here arguing on this Rule 50. I should start out by saying there is substantial evidence in the record on every single limitation. It was brought in both by our experts and by a percipient fact witness that we called from defendants, but what I heard from opposing counsel was effectively a claim construction that is contrary to the plain and ordinary meaning.

Your Honor actually addressed this term or the context of this limitation in his -- in your

Markman order. The portion that we're talking about today was not construed and, therefore, has its plain and ordinary meaning.

Both experts applied that meaning, and then the percipient fact witness confirmed that surface data is present in the data that's being displayed to the doctor.

So with the Court's permission, I'd like to walk through the claim construction, what our experts did, and then what the percipient witness just conceded.

So as we see up here, Your Honor, this is the Court's construction. The "receive second data" is the preceding limitation. I think that's important, Your Honor, because this is where this term first comes up. This term was never construed.

So we have been talking today about the second scan. That's when the surface of the tooth has been modified. You go back in, you scan again, and then that second scan includes surface data.

Surface data is just data of the surface, data about the surface. It's of the physically changed portion of the patient's intraoral cavity.

That portion I've highlighted in orange, Your Honor, is the portion that the Court construed.

01:39 Now, that construction did have a computer science element to it. It was to require that replace be registering, "registering" meaning aligning that data up with the existing model and then attaching it.

01:39 But the rest of it, Your Honor, does not have a computer science-type definition. It is a plain and ordinary definition. That's what our two experts applied. And they approached this as one of ordinary skill in the art.

01:39 So here's the Court's construction on that orange portion. I don't believe the orange portion is in dispute. Register the second data -- again, that's the data from the rescan -- after removing the second data of the removed second portion.

01:40 Your Honor, this part from the specification confirms that this plain and ordinary meaning is intended to be broad. So this comes from Column 3, Lines 41 to 60, Your Honor. And it's referring to the intake of that data.

01:40 It says: The term "scanning" and its analogs refer to any procedure directed to obtaining 3D topographic data of a surface.

01:40 So in the context of this patent, it is adopting the plain and ordinary meaning wherein scan

01:40 data is any data of a surface, any data of a surface.
01:40 And that's exactly what our experts addressed.
01:40 So Dr. Valley walked through each of the
01:40 limitations. In the context of this limitation,
01:40 Your Honor, which is the replace limitation, as I've
01:40 highlighted here in green, Your Honor, it's referring
01:40 to the including surface data of the physically changed
01:40 portion of the patient's intraoral cavity.
01:40 And then she addressed this specifically
01:40 with both a demonstrative, record evidence, which was
01:41 PTX-1798.21.
01:41 And she was asked: Now, about this
01:41 limitation, replace at least a portion of the removed
01:41 surface portion of the model using the second received
01:41 second scan data including surface data of the
01:41 physically changed portion of the patient's intraoral
01:41 cavity.
01:41 That's a mouthful. What does that mean?
01:41 It means that when I went in for the
01:41 second time -- she's referring to her testing -- and I
01:41 was scanning the surface of the tooth that I had
01:41 previously removed from the display and the scanner's
01:41 picking up the surface of the tooth, the data from
01:41 that -- "from that," meaning the surface -- and that is
01:41 being projected now onto the display screen.

So she is offering her expert opinion that data from the surface of the tooth has been scanned in as part of the second scan.

Dr. Balakrishnan addressed the exact same thing, and in fact, he referred broadly to what it is that constitutes scan data.

He says: When you're using scanners, it's light reflecting off points on the surface of an object. Those points can be called a point cloud. That's a digital model. It's a 3D model that's in the computer of the physical object surface.

So Dr. Singh's opinion is that a point cloud, Your Honor, is how data is input from a 3D model, and that itself is a model of the physical object's surface.

He continues.

He was asked: Do all three of these types of models, meaning the point cloud, the mesh, and the grid, do these represent the surface of the tooth.

He says: Absolutely. All three -- all three are 3D digital models of the physical surface of the tooth.

He continues.

Well, before you go into your analysis --

And by the way, Your Honor, we confirmed

with Dr. Singh that that was his understanding, and that understanding was consistent with the '936 patent. I have the citation for that as well.

Well, before we go into your analysis, I want to ask, what's the point of this definition?

And now he's talking about that "registration" definition that the Court provided.

He said: The point of this is really something we've actually already seen with Mr. Kopelman, Dr. Valley. They talked about it, and I just mentioned you have a model. A portion of it's removed. What's left is the retained portion. Then you get some new data. You align it and combine it.

So now he's applying the computer science context to the data, but the data itself was second scan data. And as Dr. Valley testified to, that second scan data relates to the surface of the tooth.

He continues.

After going through the source code, he recited the different functions, which ones were referring to functions that created the retained portion of the model, Your Honor.

Then he also walks through the source code and talks about the functionality that's used to add new data.

01:43 And when asked how that operated, he said: So as I've said before, once the second scan data is passed to the MatchAndInsertFrame function, that data gets matched with the retained model, and it gets inserted or combined with the model. It gets registered.

01:44 Finally, Your Honor, when he was asked by opposing counsel in cross, he actually clarified this.

She said: My question was, surface data is one type of data, one type of scan data in the context of the '936 patent.

He said: It is the scan data in the context of the '936 patent. Yes.

Because scanners can take in lots of different types of data, but in the context of the '936 patent, Your Honor, the scan data is surface data.

And on redirect, Your Honor, it is -- he did clarify that his opinion was that the phrase was met, the entirety of it. And as he -- he referenced Dr. Valley again.

The second scan data we've been talking about, that has been shown prior by Dr. Valley with toothpaste on there. By a conversation with Mr. Kopelman, it refers to a physically changed portion that is being scanned.

So you had a surface there before. It's a different surface. So all this portion in red is saying -- and that's the additional portion that's now in green, Your Honor -- it's just saying you can't scan something that existed before. You must include in that same some portions of a surface that is actually physically changed on the surface of the tooth.

And, Your Honor, counsel referred to part of the cross-examination but left out -- sorry, Your Honor. I'm looking for a citation that's not on a slide.

So opposing counsel asked again -- I'm not sure what -- oh. She was asking about what Dr. Balakrishnan was going to testify to.

She said: You don't give any of that testimony here to the jury today, right, with respect to the second portion of the limitation?

He said: I actually did.

Which is why I asked for his clarification on redirect, because he did testify to that, Your Honor. He testified to the second scan data, what happened to it from a computer science perspective. And that second scan data is data from the surface of the tooth. It's data of the tooth. It's data about the surface of the tooth, Your Honor.

01:46 Leaving aside that our experts established substantial evidence on their own, we also got that confirmed by the percipient witness today.

01:46 And, Your Honor, as we see in Ironburg versus Valve, 64 F.4th 1274, it's not necessary to have expert testimony when there is an easy to establish infringement where the jury can reach its own decision on infringement by ignoring all the expert testimony and focusing exclusively on the patent and the accused device.

01:46 They're allowed to make a factual determination, Your Honor, and we had a factual witness that testified to that. His name was Julien Marbach. He is knowledgeable about the accused devices and, Your Honor, he confirmed that every single limitation was met.

01:46 So I'm here on Slide 13, Your Honor, systems for scanning handheld intraoral scanner. He confirmed that both of these systems had that. Receive first scan data, the patient's teeth. He confirmed that both of those had that just moments ago, Your Honor. Same with displaying it. Based on a received first scan data, receiving user input defining a portion of the model to be removed. Remove -- a surface portion to be removed.

Deleted. Gone.

Receive second scan data of the patient's teeth. And, Your Honor, this is where he's confirming that it's receiving that second data.

And then importantly, the portion that we're talking about, Your Honor, this is where the percipient fact witness confirmed that the data that's being shown to the doctor is from the second scan, and it's data about the surface.

That's the plain and ordinary meaning of surface data, Your Honor. Plain and ordinary meaning of the surface data is data about the surface. And that's where the doctor made a change, and he said: It can be. Yes.

He also confirmed that that data, the second scan data, which is surface data of the changed portion, Your Honor, was registered. According to the Court's construction, it was registered with the existing scan in both the Virtuo Vivo and the SIRIOS devices.

And so he's confirmed on each of these that this was area on the surface that has changed. All that's an output to the display.

Your Honor, if you were to grant this motion, it would be injecting a claim construction

argument that hadn't been made prior to this. It hasn't been adopted by the Court. And this has been confirmed under a plain and ordinary meaning by both the experts and Mr. Marbach, Your Honor.

MR. MUELLER: May I respond briefly?

THE COURT: Are there any of the slides you'd like to respond to?

MR. MUELLER: Very, very briefly, Your Honor.

THE COURT: I'm saying is there any specific slide you'd like to have Mr. Nash put up so that he --

MR. NASH: He has my slides.

MR. MUELLER: Yes. I have them, Your Honor.

MR. NASH: Sorry.

MR. MUELLER: May I proceed, Your Honor?

THE COURT: Please.

MR. MUELLER: Your Honor, first of all, even if everything Mr. Nash said were correct, and I respectfully disagree with my friend Mr. Nash on several points, there was no rebuttal to the failure of proof on indirect infringement. That's the only claim pleaded in the complaint for this patent. There was no proof of the requirements for indirect infringement

01:49 with respect to intent, with respect to predicate acts
01:49 in the United States, with respect to knowledge of
01:49 infringement, the requisite intent.
01:49 So even if all that were right, there
01:49 would still be grounds for JMOL insofar as the pleaded
01:49 claim is indirect infringement and there's nothing in
01:49 the record to remotely support an indirect infringement
01:49 claim. There's also nothing in the record to support
01:49 damages as we've discussed.
01:49 But on the points that Mr. Nash raised,
01:49 let me --
01:49 THE COURT: Because I'll have Mr. Nash
01:49 come back up, if I need to. But your position is no
01:50 evidence of intent, no evidence of knowledge of the
01:50 patent?
01:50 MR. MUELLER: No -- no evidence of a
01:50 predicate act in the United States, Your Honor, as
01:50 well, a predicate act of direct infringement that's
01:50 been encouraged by the defendants.
01:50 THE COURT: Okay. Let me hear from
01:50 Mr. Nash. And all I need from Mr. Nash is a citation
01:50 anywhere in the record where it shows the elements of
01:50 intent, knowledge of the patent or evidence of a
01:50 predicate act.
01:50 MR. NASH: We have record evidence of the

user manuals, Your Honor. We have record evidence that these devices are used.

But leaving aside that, Your Honor, if I may, on the direct infringement point, this is a system claim. We absolutely pled direct infringement in our complaint, and this is a system claim so its very sale is an infringing act.

THE COURT: Let's stick with the issue of indirect infringement.

MR. NASH: Yes, Your Honor.

THE COURT: Are you conceding that there's not evidence of indirect infringement?

MR. NASH: I'm not conceding that. I don't happen to have a citation in the transcript for you handy.

THE COURT: You don't have a citation that would establish intent, knowledge of the patent, or evidence of a predicate act in the United States?

MR. NASH: Not at this moment, Your Honor. But we do have instruction manuals which would constitute instructing customers to also take direct infringing steps. But, again, the system itself is an infringing.

(Conference between counsel.)

MR. NASH: That's true. Dr. Valley

tested this in the United States, and that would have been a -- constitute indirect infringement, Your Honor.

THE COURT: I'm not going to find that.

MR. HUNG: Your Honor?

THE COURT: Okay.

MR. NASH: We also read into the record an interrogatory response where they confirmed their knowledge of the patents.

THE COURT: Okay. Now, getting back to your evidence, what evidence -- give me a summary so Mr. Mueller can respond directly to it, a summary of the evidence you have of direct infringement.

MR. NASH: A summary of the evidence of direct infringement, Your Honor?

THE COURT: Uh-huh.

MR. NASH: The entirety of Dr. Valley and Dr. Singh's testimony, along with the percipient witness, Mr. Marbach, who I just walked through on each one of the limitations.

THE COURT: Okay.

MR. NASH: And there are -- the accused sales have been confirmed too. Those sales constitute direct infringement in the United States.

THE COURT: Okay. Mr. Mueller, do you want to take up direct infringement?

01:52 MR. MUELLER: Yes, Your Honor.

01:52 So just in terms of the act of infringement, to finish the discussion of that, there's no specific act of direct infringement that's been introduced.

01:52 Dr. Singh testified about how the software worked. The patent owner must show evidence of specific instances of direct infringement. That's the Fujitsu case, 6:20 F.3d 1321 in the Federal Circuit. There was no attempt to meet that burden, no evidence of any use in the United States.

01:53 You heard the reference to Dr. Valley's inspection. An expert inspection for litigation is not use by the defendants that would satisfy the requirement of a predicate act.

01:53 And on top of all of that, Your Honor, if we go back to the theory, the theory and the question of whether the theory advanced by the plaintiff in this case is legally sufficient, I would respectfully submit -- Mr. Lee, if you can put up those two slides, this is PDX-4.6 and 3.11.

01:53 If the experts that Align offered for the jury's consideration were meeting and addressing the requirement of the surface data of a physically changed portion of the patient's intraoral cavity, they would

have said so. They would have highlighted that portion of the claim language in their testimony at some point.

I didn't pick slides that omitted that when other slides address it. No slide addresses it.

Mr. Nash showed you various portions of the testimony of Dr. Singh. And if you look carefully at the page cites for all but the redirect, for all but the redirect, they came before the following. If you go to Page 259, all of the transcript cites that Mr. Nash showed you, other than redirect, came before the following from Page 259, Line 1.

And this is Ms. Ferrera: And you highlighted just the first portion of that limitation, ending with the words "received scan data."

Do you see that?

Answer: Yes.

Question: You didn't highlight the rest of the claim, right, or the claim limitation?

Answer: Yes.

And in your direct testimony, you didn't talk about the second portion of the claim limitation, did you, Dr. Singh?

Answer: I did analyze it.

Question: You didn't give any opinion about the second portion of the claim limitation during

your direct testimony, did you?

Answer: I did not.

So Dr. Singh, when asked on the stand whether any of what you were just shown was an opinion addressing the second portion of a claim limitation, he said it was not.

THE COURT: And I'm not sure I completely followed it. But with respect to one of the witnesses who was not one skilled in the art, this was part and parcel of that, right?

MR. MUELLER: Correct. Dr. Valley did not address this either and lacked the expertise to do so. She's an orthodontist, not a computer scientist.

So neither one addressed it, neither Dr. Valley nor Dr. Singh.

And the last thing I'll say, Your Honor, is the attempt to turn the fact testimony today into a cure for that expert failure of proof rests on a mistaken interpretation of the claims. And it doesn't require a Markman hearing to understand that.

The claim limitation speaks of scan data received, received. Scan data received, and that scan data has to include surface data. The claim itself distinguishes between the scan data and the surface data included within that scan data. It has to be

received.

And so the device that would meet these claims would need to receive scan data including surface data, not transform point cloud data into surface representations but to receive scan data that includes surface data as a subset.

Here, there's no expert opinion from anyone that the devices at issue receive scan data that includes the surface data. And the only testimony is from a fact witness who said it doesn't do that. Instead, it receives point cloud data, not scan data.

So we have an expert -- a fact witness saying it doesn't happen and two experts failing to say it does happen.

And on that record, there can be no reasonable juror who could find infringement. And that's without even getting to the failure to allege the predicates for indirect infringement, the only claim pleaded in the complaint, or the failure to present a damages opinion.

This is not a patent that should go to the jury. We respectfully request JMOL.

THE COURT: Mr. Nash, anything else?

MR. NASH: Two final points, Your Honor.

There were direct infringement based on

01:57 sales. This is an accused system. The system
01:57 comprises a handheld scanner plus computer readable
01:57 medium with the software. Those systems were sold.
01:57 That was confirmed and factual testimony came in to
01:57 that point.
01:57 With respect to what counsel just
01:57 mentioned, he's stepping beyond a plain and ordinary
01:57 meaning, because literally the words that he just
01:57 recited was "scan data including surface data." That
01:57 means it can be more than surface data. We're not
01:57 saying they're necessarily coextensive. It has to
01:57 include surface data. That's what both of our experts
01:57 testified to.
01:57 And Dr. Valley was there to confirm it
01:57 was a surface of a tooth, Your Honor. And Dr. Singh
01:57 was there to testify as to what happens with that data
01:58 once it's being processed and added to the
01:58 representation that's on the screen, Your Honor.
01:58 It's blackletter law that scan data
01:58 including surface data is not saying these are two
01:58 different things. It's saying that the surface data is
01:58 included in the scan data.
01:58 And that was confirmed by both of our
01:58 experts and by Mr. Marbach, who was asked repeatedly if
01:58 the data we were seeing represented on the screen

included data that came from the surface, Your Honor. Plain and ordinary meaning, surface data.

THE COURT: Anything else, Mr. Mueller?

MR. MUELLER: Again, the only thing I'd add, there's still no evidence of indirect infringement, which is the only claim pleaded in the complaint. So we think this fails at every level.

THE COURT: Thank you.

Okay. Thank you for the arguments. The Court is going to grant the motion, Rule 50 motion.

What does that do with respect to who the next witness is?

MR. MUELLER: Yes, Your Honor. We're going to call Ms. Sterling as our next witness, and we should be able to finish her today before your conference, Your Honor.

THE COURT: Oh, great.

MR. MUELLER: Thank you, Your Honor.

THE COURT: Okay. Perfect. And if -- I don't want you all pushing -- the trial's important and I have to do the other hearing. Let's get this person done however you all need to, and they can wait on the pretrial conference --

MR. MUELLER: We appreciate it, Your Honor.

02:00 THE COURT: -- until we get this witness done. I don't want anyone feeling like they've got to meet a 3:00 p.m. deadline. So.

02:00 MR. MUELLER: We appreciate it. Thank you, Your Honor.

02:00 THE COURT: Sure.

02:00 THE BAILIFF: All rise.

02:03 (Recess taken.)

02:03 THE BAILIFF: All rise.

02:03 THE COURT: Please remain standing for the jury.

02:03 (Jury entered the courtroom.)

02:04 THE COURT: You may be seated, counsel.

02:04 MR. MUELLER: Thank you, Your Honor. May we call our next witness?

02:04 THE COURT: Please.

02:04 MR. MUELLER: We will call Ms. Laura Sterling, and Mr. Underwood will conduct the examination.

02:04 THE COURT: Lovely.

02:04 (The witness was sworn.)

02:04 DIRECT EXAMINATION

02:04 BY MR. UNDERWOOD:

02:04 Q. Good afternoon, Ms. Sterling. How are you doing?

02:05

02:05 A. I'm okay.
02:05 Q. Can you please introduce yourself to the ladies and gentlemen of the jury?
02:05 A. Yes. My name is Laura Sterling. And I am the vice president and global head of marketing and growth enablement for ClearCorrect at Straumann Group.
02:05 Q. And where do you live, Ms. Sterling?
02:05 A. I live in Basel, Switzerland.
02:05 Q. Do you have a family?
02:05 A. I do. I have a husband, Eric, and two sons, Austin, who's 12, and Jack, who's 9.
02:05 Q. Does your family live with you in Basel?
02:05 A. They do.
02:05 Q. And how long have y'all lived there?
02:05 A. We moved in December 2024.
02:05 Q. What took y'all to Basel?
02:05 A. So in 2024, I received a promotion and an incredible opportunity to relocate to Basel, Switzerland, which is the headquarters of Straumann Group. And it was a great opportunity for me professionally but also to have the kids be able to experience a different country for a few years, it was an opportunity I couldn't refuse.
02:05 Q. Where'd you grow up?
02:06 A. I grew up in Rochester, New York.

Q. Did you attend college?
A. Yes.
Q. Where at?
A. I attended Indiana University Kelley School of Business in Indiana.
Q. Did you graduate?
A. I did, with a bachelor's of science in business with a major in marketing.
Q. What'd you do after graduating?
A. I -- sorry -- started my career. I moved to Dallas, Texas.
Q. And what'd you do in Dallas?
A. I worked for a company called St. Jude Medical, and I worked as a marketing specialist for patient programs.
Q. How'd you become interested in marketing?
A. Yeah. So when I was originally looking for a university, I talked to my mom, and she suggested marketing as a career path.

So I studied that in college. And between my junior and senior year of college, I had an opportunity to work in marketing at St. Jude Medical. And that's when I found that you can apply marketing in the medical device space, and I just fell in love with it.

Q. Why'd you fall in love with it?

02:07 A. I mean, for me, you know, when you think about marketing, you think about consumer goods, hair care products, and I was able to apply what I learned to helping people's lives. It was just incredible.

02:07 Q. And have you done any other coursework related to marketing after graduating from Indiana University?

02:07 A. Yes. I've taken some advanced courses at Kellogg and as well as an international school in Switzerland.

02:07 Q. What's Kellogg?

02:07 A. It's a university.

02:07 Q. And how long did you work at St. Jude?

02:07 A. I worked at St. Jude Medical for about nine years.

02:07 Q. And were you always in the Dallas office of St. Jude?

02:07 A. No. I relocated from Dallas to Austin, Texas, in around 2013.

02:07 Q. Scoot a little back from the microphone. All right. Thank you very much.

02:07 And what did you do after leaving St. Jude?

02:08 A. So St. Jude Medical was actually acquired by a company called Abbott. So I remained working in the medical devices space, remained working for the company for another three to four years.

Q. And then what?

A. So in 2021, I left Abbott and joined Straumann Group.

Q. Why did you join Straumann Group?

A. So I had been in the same industry for 13, 14 years, neuromodulation, and I was looking for something different. I really wanted to get to something a bit more entrepreneurial where I could have a direct impact with the work that I did.

I was also looking for a company that really valued corporate culture, and I found both of those in Straumann.

Q. Where were you based when you first joined Straumann?

A. Round Rock, Texas.

Q. And what position did you hold when you first joined Straumann?

A. I was the head of global marketing and education for ClearCorrect.

Q. And what products were you responsible in that role?

A. The clear aligner products.

Q. What were your day-to-day responsibilities with respect to those products?

A. So ultimately, my job is -- was, you know,

there's personnel management, but ultimately I was responsible for upstream and downstream product marketing, so working on new product development with our software engineers and also talking to customers, understanding their current needs, working with the sales representatives around the world.

Q. And sitting here today, what products are you responsible for?

A. I'm still responsible for clear aligner products, but I recently was given the opportunity to also be marketing SIRIOS, which is our intraoral scanner, specifically to the clear aligner customers.

Q. And what do you do with respect to those products?

A. I'm responsible for marketing, which is in general raising awareness of our brand, our products. I still talk to customers on a weekly basis. We do host events, a variety of things.

Q. How many people do you have reporting to you?

A. So I have 16 direct reports and about 30 to 35 in my department.

Q. And as the VP of global marketing, what's your involvement with marketing of clear aligners here in the United States?

A. Yeah. So part of my team, I am responsible

for local country marketing as well in addition to global marketing. So I have a team of four that is specifically dedicated to the United States.

Q. Do you have an opportunity in your role to talk with ClearCorrect's customers?

A. Yes. On a weekly basis.

Q. Now, as the VP of global marketing, are you personally familiar with the market for ClearCorrect's clear aligners?

A. Yes. Absolutely. As part of being responsible for marketing, it's my responsibility to understand the market. We conduct third-party market research. We look at independent analysts reports. We talk to customers in a variety of ways to try to understand the current landscape.

Q. As a factual matter, when you think about the market in which ClearCorrect competes, what products does that include?

A. Clear aligner products.

Q. Did we get you a binder? Is that a binder for you?

A. Yes.

Q. All right. Can you turn to Tab 2 in that binder, please? And let me know when you're there.

A. Yes. I'm here.

Q. That is PTX-75. If you need to take a second to look at it, please do so. But do you recognize this document?

A. I do.

Q. What is that document?

A. So this is the launch binder for ClearQuartz, specifically our North America go-to-market strategy.

Q. And what's the date?

A. August 2020.

MR. UNDERWOOD: Your Honor, we offer PTX-75.

MR. DURST: No objection, Your Honor.

THE COURT: Admitted.

BY MR. UNDERWOOD:

Q. All right. And is this document on the screen the one you're looking at in your binder?

A. Yes. It is.

Q. All right. Let's turn to Page 5, please.

What's the title of this slide?

A. It's Market Opportunity.

Q. And what market is ClearCorrect describing here in this document?

A. The clear aligner market.

Q. And now let's go to the next page, Page 6, please.

What's the title of this slide?

A. Market Trend: Clear Aligner Global Market Share (sic).

Q. Clear Aligner Global Market Share?

A. Yes.

Q. And let's go to the right-hand side of the page.

Do you see those bullet points there under the title Market Trend?

A. Yes. I do.

Q. Can you read the first bullet point, please?

A. Clear aligner global market size, 1.87 billion, 2018.

Q. Now, if you go back to the left-hand side of this slide under North America, what portion of that 1.8 billion was from North American in 2018?

A. 940 million.

Q. All right. All right. So now let's go back --

MR. UNDERWOOD: I apologize, Mr. Lee. I'm making you work.

BY MR. UNDERWOOD:

Q. If we can go back to those bullet points on the right-hand side and go down to the fourth bullet point.

Do you see where I am?

A. Yes.

Q. All right. Can you read that, please?

A. NAM, which is North America Market, is the largest market and is expected to remain with 50 percent of the business.

Q. Which market is the largest market?

A. North America.

Q. That includes the United States of course?

A. Absolutely.

Q. Let's go to --

THE COURT: Counsel, could I have y'all up here for just one second?

MR. UNDERWOOD: Absolutely.

THE COURT: I just need you and Mr. Durst.

(Bench conference.)

(Off-the-record bench conference.)

MR. UNDERWOOD: All right. Can we go to Slide 7, please?

BY MR. UNDERWOOD:

Q. All right. And what's the title of this slide, Ms. Sterling?

A. Market Trend: Market Size and Market Share Percent.

02:14 Q. MS percent, that stands for market share percent?
02:14 A. Correct.
02:14 Q. All right. And if we go down to the bottom left-hand corner, do you see it says "market opportunity"?
02:14 A. Yes.
02:14 Q. Can you read those two bullet points to the jury, please?
02:14 A. Adult population represents about 75 percent of total clear aligner market. Adolescents are expected to grow at a faster rate; however, the adult segment will remain as the largest one.
02:15 Q. All right. Now, I want to ask you a question about that first bullet point, okay?
02:15 Do you see where it says "clear aligner market"?
02:15 A. Yes.
02:15 Q. Is that term consistent with how ClearCorrect views the market for its products?
02:15 A. Yes.
02:15 Q. And if you go to the second bullet point where it discusses the populations, is that statement consistent with how ClearCorrect views the populations in the clear aligner market?

02:15 A. Yes.

02:15 MR. UNDERWOOD: Let's go to Page 14, please, Mr. Lee.

02:15 BY MR. UNDERWOOD:

02:15 Q. All right. What's the title of this slide?

02:15 A. Customer Target Group.

02:15 Q. And do you see where it says "patients"?

02:15 A. Yes.

02:15 Q. What's it say under the patients category?

02:15 A. Adolescents and adults with mild-to-moderate cases of malocclusion that don't want a fixed and painful brace experience but instead are looking for a more convenient and more comfortable treatment.

02:16 Q. Is this drawing a distinction between wire and bracket braces on one hand and clear aligners on the other?

02:16 A. Yes.

02:16 Q. And is this statement consistent with your experience and your understanding of these products?

02:16 A. Yes.

02:16 Q. Are braces and clear aligners different?

02:16 A. Yes.

02:16 Q. How so?

02:16 A. So braces are fixed appliances that are glued to a patient's teeth; whereas, clear aligners are

02:16 removable which allow for better oral hygiene.
02:16 Q. Does ClearCorrect compete with wire and
02:16 bracket braces?
02:16 A. No.
02:16 Q. What does ClearCorrect compete with?
02:16 A. Other aligner brands.
02:16 Q. Such as?
02:16 A. Invisalign, Spark, Dentsply, SureSmile,
02:16 Angelalign, and there are a variety of other brands.
02:17 Q. And who does ClearCorrect consider to be its
02:17 primary competitor in the clear aligner market?
02:17 A. Invisalign.
02:17 Q. What's ClearCorrect's understanding regarding
02:17 Align's market share in the clear aligner market?
02:17 A. No. We've looked at a variety of sources, but
02:17 I've seen 80 to 90 percent.
02:17 MR. UNDERWOOD: Can we go to Page 7 of
02:17 this deck, please?
02:17 BY MR. UNDERWOOD:
02:17 Q. All right. And do you see on the right-hand
02:17 side there's that big blue circle?
02:17 A. Yes.
02:17 Q. What is this chart showing?
02:17 A. This is showing the clear aligner market share
02:17 by company.

02:17 Q. And who has 90.4 percent of the clear aligner market share?
02:17 A. Align Technology or Invisalign.
02:17 Q. And what percentage does Straumann have?
02:17 A. 3.6 percent.
02:17 MR. UNDERWOOD: You can take that down, Mr. Lee.
02:17 BY MR. UNDERWOOD:
02:17 Q. Can you go to Tab 3 in your binder, please?
02:17 A. Yes.
02:17 Q. And let me know when you're there.
02:18 A. I'm there.
02:18 Q. Oh, you're there. All right.
02:18 Do you see a document labeled DTX-2236?
02:18 A. Yes.
02:18 Q. Do you recognize this document?
02:18 A. I do.
02:18 MR. UNDERWOOD: Your Honor, we offer DTX-2236.
02:18 MR. DURST: No objection, Your Honor.
02:18 THE COURT: Admitted.
02:18 BY MR. UNDERWOOD:
02:18 Q. What's the title of this document?
02:18 A. It's the ClearCorrect 2020 North America Strategy.

MR. UNDERWOOD: Can we turn to Page 2, Mr. Lee?

BY MR. UNDERWOOD:

Q. All right. What's the title of this slide?

A. North America Market Overview Current Situation.

Q. And when this document uses the term "market overview," what market is it talking about?

A. The clear aligner market.

Q. If you go down, do you see the bullet point beginning 1.3 billion?

A. Yes.

Q. Can you read that, please?

A. 1.3 billion of revenue in the North America market with a leader controlling 93 percent of market share, ClearCorrect less than 5 percent market share.

Q. And who's the leader controlling 93 percent of that market share?

A. Invisalign.

Q. And when it says "ClearCorrect less than 5 percent market share," what market is it talking about?

A. The clear aligner market.

MR. UNDERWOOD: Let's go to Page 5, please, Mr. Lee.

BY MR. UNDERWOOD:

Q. All right. Do you see the pie chart there?

A. Yes.

Q. And I should apologize, Ms. Sterling. If you need to take a second to look at the document, please do so.

A. Okay.

Q. What companies are shown on this pie chart?

A. Align Technology, Straumann Group, 3M, Danaher, Henry Schein, and Dentsply Sirona.

Q. And again, which company has the overwhelming share of the market?

A. Align Technology.

Q. And is that consistent with how ClearCorrect views the competitive landscape?

A. Yes.

MR. UNDERWOOD: We can pull that down, Mr. Lee.

BY MR. UNDERWOOD:

Q. Who does ClearCorrect actually sell its products to?

A. We sell our products to doctors. So specifically orthodontists, general practitioners, providers in dental service organizations or DSOs, or orthodontic service organizations, OSOs.

02:20 Q. Now, of those different categories of doctors, which one uses clear aligners the most in your experience?

02:20 A. I mean, there are some high volume general practitioners, but predominantly it's orthodontists.

02:20 Q. And who's the person that plays the most significant role in determining what brand of clear aligner a patient gets?

02:20 A. The doctor.

02:20 MR. DURST: Objection, Your Honor. That is --

02:20 THE COURT: I'm sorry?

02:20 MR. DURST: Objection, Your Honor. That is outside the zone of her knowledge.

02:20 THE COURT: If you want to lay a foundation for her to answer, you can.

02:20 BY MR. UNDERWOOD:

02:20 Q. Ms. Sterling, earlier you talked about some of the market research you do. What does that market research involve?

02:20 A. We research -- or we speak with doctors as well as patients to understand how they select products, what their current experience with them is, and a variety of other things.

02:21 Q. And how often do you do that?

02:21 A. We do market researches annually.
02:21 Q. And based on that experience doing market research and talking to folks in the field, who is the person who plays the most significant role in determining which brand of clear aligners a patient gets?
02:21 MR. DURST: Objection, Your Honor. We laid a foundation for hearsay. That -- he plainly said --
02:21 THE COURT: I don't think he asked what anyone said.
02:21 MR. UNDERWOOD: I didn't.
02:21 THE COURT: I think the question was what person plays the role.
02:21 MR. DURST: Based on?
02:21 THE COURT: Well, I understand they have to get it from somewhere, but she's not -- it's not hearsay. I mean, he's not asking her to -- at any rate, overruled.
BY MR. UNDERWOOD:
02:21 Q. Do I need to repeat the question, Ms. Sterling?
02:21 A. No. The doctor plays the role.
02:21 Q. And how important is the doctor's choice in terms of competition between clear aligner companies?

02:21 A. I mean, it's extremely important. I mean, the
02:21 doctor is the one that selects the brand and is
02:22 ultimately the one that prescribes the treatment.
02:22 Q. What's the relationship between doctor choice
02:22 and the concept that the jury's heard about of a closed
02:22 system?
02:22 A. Yeah. I mean, if the doctor has a closed
02:22 system and doesn't have the options to choose other
02:22 systems, then they're locked in to choosing the brand
02:22 that they have the closed system of.
02:22 Q. Does ClearCorrect use a closed or an open
02:22 system?
02:22 A. ClearCorrect has an open system.
02:22 Q. What about Straumann? Does Straumann use a
02:22 closed or an open system?
02:22 A. No. Straumann has an open system.
02:22 Q. Can I ask you some questions about the
02:22 ClearCorrect clear aligners and the Straumann scanners?
02:22 A. Yes.
02:22 Q. If a doctor wants to prescribe a ClearCorrect
02:22 clear aligner, does ClearCorrect or does Straumann
02:22 require them to purchase a Straumann scanner?
02:22 A. No.
02:22 Q. Can a Straumann scanner be used to order clear
02:23 aligners from any clear aligner company?

02:23 A. Yes.
02:23 Q. And is that a simple or a difficult process in your experience?
02:23 A. My experience, it's a simple process.
02:23 Q. How does ClearCorrect try to reach doctors for marketing and sales purposes?
02:23 A. Yeah. So we have a direct sales force, so reps that are in the field. We also participate in scientific congresses and events. We do education. We also do marketing efforts, so digital marketing, social media.
02:23 Q. Now, of the categories of doctors that you identified earlier who are involved with clear aligners, which of those categories of doctors does ClearCorrect focus its marketing efforts on?
02:23 A. Yeah. So overall, we try to focus our efforts on all customers, but what we found, especially in the United States, that we are locked out of the orthodontist customers. And so we have chosen to divert our resources to the general practitioner.
02:24 Q. And approximately how much money does ClearCorrect spend on marketing for its clear aligners in the United States?
02:24 A. We spend $2 million.
02:24 Q. To your knowledge, how does that compare to

Align?

A. While sitting in the opening statements in the room, I saw 1.4 billion.

Q. So I'm curious. Why is ClearCorrect's marketing budget so much lower than Align's?

A. I mean, ultimately, the marketing budget is set as a percent of sales. So whatever we bring in is what we can spend. And so if we're not making the sales, then our marketing budget is going to be lower.

Q. Based on the ClearCorrect research and marketing efforts you described moments ago, what characteristics do doctors consider when selecting a clear aligner brand?

A. I mean, ultimately doctors select a variety of characteristics.

Q. Such as?

A. So the product plays a role in it, but also what's really important, what I've seen in my experience and then also in the market research, is service and support is really important, so the support that they're getting, the partnership that they're getting from the company. In addition, it's important for them to have options.

Q. In your experience, what are the physical differences between the ClearCorrect aligners and the

Align aligners?

A. Yeah. So there are a couple differences, but the two main ones are the material. So you've heard a lot about that. The ClearCorrect material is a hard-soft-hard material. It's a three-layer material.

But we also have a high and flat trim line. So it goes straight across the gums.

With Invisalign, they have a soft-hard-soft material, and they have a scalloped trim line. So it follows the shape of the teeth.

Q. And what impact do those differences you've just described have for the patient experience?

A. I mean, one of the main reasons is -- the main differences is stain resistance. So because we have a hard outer layer on our aligner, it stains less, which is important, as you've heard, because the whole point of a clear aligner is that it's aesthetic.

In addition, it tears -- the ClearCorrect aligner tears less.

Q. Now, besides the physical differences in the aligners you just described, are there any differences between ClearCorrect's approach to business and Align's?

A. I mean, we fundamentally take a different approach to the way that we conduct business. I mean,

for us, it's very much about partnership and really being alongside our customers, understanding their clinical needs, and working with them to support them.

Q. And what has been the response in the market to ClearCorrect's approach?

A. Yeah. I mean, for the doctors who use us, we hear a lot of amazing things. They really appreciate that. And it's definitely generated a lot of interest in the customers that are locked out.

Q. You mentioned locked out.

Has ClearCorrect encountered any obstacles in the marketplace?

A. Yeah. I mean, we would expect any obstacles, right, with competition, but especially in the United States, we're experiencing something a bit different.

Specifically with Invisalign, they are -- they require their customers to purchase an iTero scanner in order to do business with Invisalign.

In addition, it's really difficult to get the files off of that scanner to use with another aligner company.

In -- on top of that, they also require customers to purchase -- or to do a certain number of cases in order to receive a certain price, and if they don't hit that price, or they don't hit that volume,

then they get penalized and have a higher cost in the following six months.

Q. And why are these policies a problem for ClearCorrect?

A. I mean, ultimately, what it does is locks us out of that account, because they don't want to pay a higher price, and time is money.

So if it's difficult to get the files off of the scanner, then they're going to continue to do with what they have in their practice. The --

Q. Now -- oh. I'm sorry. Go ahead.

A. Sorry.

And the scanner itself is a really expensive piece of capital equipment. I mean, it's thousands of dollars. So they have -- they use what they've already purchased.

Q. Now, other than scanners themselves, is there any other mechanism for a doctor to place an order for a clear aligner?

A. I mean, so industry standard is using a scanner.

Q. Is there any other option, even if it's not the industry standard?

A. Yeah. So I think we've heard a little bit about this over the past couple of days. You know,

there's an older method which is the PVS impression, which is where you put the putty in the tray, you hold it in the patient's mouth for a few minutes, but the quality of that and the patient experience, really the market and the industry has gone to digital impressions.

Q. How commonly is PVS used today in your experience?

A. Not very common.

Q. Let's go to -- can you open Tab 4, please? And let me know when you get there.

A. Yes.

Q. Do you recognize the document you're looking at?

A. I do.

Q. What is it?

A. It is a spreadsheet of submissions to ClearCorrect from 2017 to Q2 of 2024 and the method it was submitted to ClearCorrect.

MR. UNDERWOOD: Your Honor, we offer JTX-60.

MR. DURST: No objection, Your Honor.

THE COURT: Admitted.

BY MR. UNDERWOOD:

Q. All right. Can you describe again at a high

level, Ms. Sterling, what this is showing now that the jury can see the document?

A. Yeah. So these are submissions of cases. It can be a unique case or a case that may already be in progress, from 2017 to 2024 Q2, specifically in the United States.

And what -- on the left-hand side, what you see is the method of which these were submitted to ClearCorrect.

Q. And what does this document show about the number of cases that ClearCorrect receives from PVS in 2017 versus 2024?

A. So as you can see, in 2017 we had 68,000 cases that were submitted using PVS, but by -- in Q2 of 2024, we only had 8,800.

Q. And what about iTero? Is that shown on this chart?

A. It is.

Q. What does this show about iTero over this time period?

A. When you look at the total number of cases that are submitted, so let's just use 2023 as an example, we had 169,000 cases that were submitted and only 9,297 were from an iTero.

Q. Now, in your experience, if a doctor has an

iTero scanner, is it easy to use that scanner to send cases to a competitor like ClearCorrect?

A. From what I -- what I experience is that it's difficult.

Q. How so?

A. It requires multiple steps, right? It's not a seamless integration.

Q. Now, based upon this data, what is your best estimate of how many ClearCorrect submissions come from iTero scanners?

A. Very few.

Q. About 3 to 5 percent?

A. Yes.

MR. UNDERWOOD: Can we get PDX-1.76, Mr. Lee?

BY MR. UNDERWOOD:

Q. Now, you have been sitting at counsel table this whole trial, right?

A. Uh-huh. Yes.

Q. And did you see the parties' opening statements?

A. Yes.

Q. Do you recall the plaintiffs using this slide?

A. Yes. I do.

Q. And they were suggesting that one of every

five ClearCorrect orders comes from an iTero, right?

A. Yes.

Q. Is this correct?

A. It's not what we see.

Q. Again, based on data that we just looked at, what is the correct number?

A. 3 to 5 percent.

MR. UNDERWOOD: You can pull that down, Mr. Lee.

BY MR. UNDERWOOD:

Q. What, if anything, has ClearCorrect done to attempt to compete more successfully against Align in the United States?

A. We've done a lot. First, it's important for us to continually improve, continually innovate. So that's one of things we do is constantly evolve and advance our product.

We've invested in marketing. We've invested in education. We attend congresses. We've even changed personnel. We've tried a lot.

Q. Has ClearCorrect attempted to increase its sales or its marketing efforts?

A. I mean, as I said before, at the end of the day, the marketing budget is a percent of sales. So we haven't drastically increased our budget.

02:33 Q. Has ClearCorrect done anything to make its products more attractive to customers?

02:33 A. Absolutely. It's important for us to continually improve and innovate.

02:33 Q. I want to ask you some questions about the market in the United States versus the rest of the world. Okay?

02:33 A. Yes.

02:33 Q. All right. Since the time ClearCorrect became a part of Straumann, how would you describe ClearCorrect's performance in the United States versus the performance in the rest of the world?

02:34 A. I mean, the acquisition of ClearCorrect by Straumann has definitely helped overall the ClearCorrect process and infrastructure and just kind of grown us up a little bit.

But when you look at the sales in the United States, we've remained flat or declined; whereas, outside of the United States, like Latin America, Europe, and even Canada, we've grown.

02:34 Q. So outside the United States, growing?

02:34 A. Yes.

02:34 Q. Inside of the United States, not growing?

02:34 A. Correct.

02:34 Q. Is the product that ClearCorrect sells any

different outside the United States versus inside the United States?

A. No. It's exactly the same.

Q. Are the marketing approaches different outside of the United States versus inside the United States?

A. No. They're the same.

Q. Are there any product issues relating to quality or anything else that are different outside the United States versus inside the United States?

A. No. We see the same things.

Q. So if the product is the same, the marketing is the same, and the quality is the same outside the United States and inside the United States, what accounts for the difference and the growth outside versus the lack of growth inside the U.S.?

A. I mean, one of the main differences is Align's practices.

Q. How's the scanner situation different outside the United States versus inside the United States?

A. So Align actually accepts scans from 3Shape TRIOS 3 outside of the United States, versus inside the United States, they only accept scans from the iTero.

Q. I want to ask one more time just so we're all clear.

They accept scans from nonAlign scanners

outside the United States?

A. Yes.

Q. And that is not true inside the United States?

A. Correct.

Q. What effect does that have?

A. Yeah. I mean, you can see when you have even more -- a slightly more open system outside of the United States, that when the customers have choice, they choose ClearCorrect.

Q. Ms. Sterling, you're the corporate representative, right?

A. Yes.

Q. So I want to ask you as the corporate representative some questions about the important issues at the core of this case, fair?

A. Fair.

Q. Has ClearCorrect -- just to be brutally honest, has ClearCorrect been profitable in the United States?

A. No. We have not.

Q. Ms. Sterling, if the iTero lock-in system you just described was removed in the United States and if there was an even playing field, would ClearCorrect be able to increase production to account for that increased demand?

02:37 A. Absolutely.
02:37 Q. How so?
02:37 A. We have room in our Round Rock facility to take on additional capacity of aligners.
02:37 Q. Two times more capacity?
02:37 A. Absolutely.
02:37 Q. Three times more capacity?
02:37 A. Yes.
02:37 Q. What about four times more capacity?
02:37 A. Yes.
02:37 Q. Ms. Sterling, you've spoken a lot about your work at ClearCorrect. I want to ask you, what has that work meant to you?
02:37 A. I'm extremely proud of the work that I personally have done and what we do at ClearCorrect.
02:37 I get to work with extremely talented people, and the products that we make make differences in patient's lives. And for me to be able to be in the position I am and get to see that impact, it's super rewarding.
02:37 Q. If there was a level playing field instead of a tilted playing field, if there was a level playing field, do you believe ClearCorrect is capable of competing with Align?
02:38 A. Absolutely.

02:38 Q. How, if at all, have Align's actions impacted ClearCorrect's ability to compete fairly?
02:38 A. I mean, we don't even get the products to the customers, right? The customers, the -- are locked into Align. So we don't even get -- allowed our patients to get exposure to ClearCorrect.
02:38 Q. Can I ask you some questions about the allegations Align has made in this case?
02:38 A. Yeah.
02:38 Q. What's your understanding of their accusations about ClearCorrect?
02:38 A. They're alleging that we are infringing on several patents.
02:38 Q. And when you first learned about those accusations, how'd you react?
02:38 A. I was shocked and then frustrated.
02:38 Q. Why were you shocked and why were you frustrated?
02:38 A. Because we invest countless resources in research and development and independently create our own materials. We do not infringe.
02:39 Q. Sitting here today -- and you've been sitting at that table for this whole trial, right?
02:39 A. Yes.
02:39 Q. And all the evidence you've heard so far,

right?

A. Yes.

Q. Do you still hold that view?

A. Absolutely.

Q. Does ClearCorrect as a company, as a company, agree with Align's accusations in this lawsuit?

A. No.

Q. What is the company's position on those accusations?

A. We do not infringe.

Q. Ms. Sterling, one last question.

Why'd you come back to Texas from Switzerland to testify to this jury in this lawsuit today?

A. Yeah. I mean, ultimately I'm here because at ClearCorrect and Straumann, we have chosen to take a fundamentally different approach to the way that we approach business. We believe in partnership and collaboration and co-creation and ultimately having an open system that allows doctors to choose the right technology to meet their patients' needs.

We have invested countless resources and R&D and independently have created the tools and technologies that meet the patients' needs that I just explained.

What Align is alleging in this case is not

only false but is just another attempt to try to lock out competition. And at the end of day, what that means is that doctors don't have the options for their patients.

And at ClearCorrect and Straumann, we take that very seriously. And for me, personally, I felt it was important to be here so that we were able to hear all of the facts.

Q. Thank you very much, Ms. Sterling.

MR. UNDERWOOD: Your Honor, I pass the witness.

CROSS-EXAMINATION

BY MR. DURST:

Q. Good afternoon, Ms. Sterling.

A. Good afternoon.

Q. My name is Tim Durst. We met in the courtroom earlier.

A. Yes.

Q. Now, Ms. Sterling, you are the global head of marketing for Straumann?

A. I'm the global head of marketing for ClearCorrect at Straumann.

Q. You're employed by Straumann. Your contract is with Straumann?

A. Yes. My contract is with Straumann.

02:41 Q. Ms. Sterling, I'd like to show you PDX No. 1.81, which you saw when you were sitting here in the courtroom during opening statement.

02:42 I'm going to pull that up. It'll be here on the screen.

02:42 A. Okay.

02:42 Q. This shows the growth rate of aligner companies over this period of time in the United States.

02:42 Do you understand that?

02:42 A. I understand that.

02:42 Q. And a number of these companies that are listed here are the companies that you identified as your competitors, right?

02:42 A. Yes.

02:42 Q. So Spark's a competitor?

02:42 A. Correct.

02:42 Q. Angel is a competitor?

02:42 A. Yes.

02:42 Q. SureSmile is a competitor?

02:42 A. Yes.

02:42 Q. Each of these companies over this period of time for which we have data, their revenues are growing, aren't they?

02:43 This shows those revenues growing, doesn't it,

Ms. Sterling?

A. This shows their growth rates, yes.

Q. No. There's no rates expressed here, ma'am.

This shows their revenues are growing by dollars.

A. Okay.

Q. Right?

A. That's what this shows.

Q. And then if we do one click, we see ClearCorrect, right?

A. Correct. Yes.

Q. ClearCorrect's story is different. It's not growing, is it?

A. It's not growing.

Q. Now, were you -- do you remember Mr. Lahlouh told the jury that he sells his product Zendura FLX not only to ClearCorrect but a number of these other competitors, right?

A. Right.

Q. So Spark and Angel, they buy and use the same materials in their aligners that your company does?

A. Correct.

Q. So in some of these products, they use the same materials as you, right?

A. They use the same materials.

02:44 Q. And all of these companies, they compete in the United States, same as you, right?
02:44 A. Yes.
02:44 Q. And all of these companies, they -- they compete against Align too, don't they?
02:44 A. Yes.
02:44 Q. And they are succeeding and growing, aren't they, ma'am?
02:44 This chart shows us those other companies are growing; isn't that true, ma'am?
02:44 A. I don't know the data behind this.
02:44 Q. Ma'am, does this chart show that these companies are growing year over year in revenue?
02:44 A. Yes.
02:44 Q. While ClearCorrect is not?
02:44 A. Yes.
02:44 Q. So something different is going on with ClearCorrect, isn't it?
02:44 A. Something's happening with ClearCorrect.
02:44 Q. Yes. Now, might it be that it's a product issue? Could be, right? Could be a product quality issue, right?
02:45 A. Maybe.
02:45 Q. Could be?
02:45 Well, do you know -- you know -- you've heard

about the problems at Round Rock and scrap rates and the retooling rates? You've heard about those?

A. I heard it, yes.

Q. That could be impacting ClearCorrect, couldn't it?

A. One of the reasons, yes.

Q. That could be one of the reasons it's not growing while the competitors are growing. That could be it, right?

A. Could be one of the reasons why we're not growing.

Q. And it could be that they spend more money in marketing. That's possible, right? They could be doing a better job at marketing than you. That's possible, isn't it?

A. It's possible.

Q. It could be -- Ms. Sterling, with all due respect, it could be that they're better managed than ClearCorrect too. That's possible too, isn't it?

A. It's possible.

Q. Now, I want to -- I want to go back now to a slide that Mr. Underwood used in your direct examination, and it is JTX-60.

Now, Ms. Sterling, did you mean to tell the jury that iTero was a closed system?

02:46 A. Yes.
02:46 Q. This shows us --
02:46 MR. DURST: Let's highlight that iTero
02:46 line, Mr. Smith.
BY MR. DURST:
02:46 Q. Let's just be sure we know what we're looking
02:46 at here. These are the cases -- meaning the number of
02:46 patient prescriptions. These are the cases that were
02:46 submitted to ClearCorrect over the course of these
02:46 years, right?
02:46 A. Right.
02:46 Q. And over the course of these years, 50,000
02:47 ClearCorrect aligners were ordered based upon scans
02:47 from Align's iTero customers?
02:47 A. Out of 1.5 million, yes.
02:47 Q. Align's iTero scanner?
02:47 A. Yes.
02:47 Q. And your scanners are listed on here too,
02:47 aren't they?
02:47 A. Yes.
02:47 Q. And so if you look at your scanners, one of
02:47 them is the next line, Virtuo Vivo.
02:47 Do you see that?
02:47 A. Yes.
02:47 Q. So more ClearCorrect aligners were made using

the Align system than were made using Straumann's Virtuo Vivo, right?

A. Right.

Q. And there are other Straumann scanners shown on here too, aren't there?

A. Yes.

Q. If you go to the Straumann SIRIOS scanner, that's one of your scanners?

A. Correct.

Q. Hardly registers, does it?

A. This is just test data. This isn't launched.

Q. It hardly registers, doesn't it?

A. Yes. It's just test data.

Q. So just to state the obvious, there were more ClearCorrect aligners made with Align's iTero scanner than with Straumann's SIRIOS scanner, right?

A. Right.

Q. And you said that -- did you mean to leave the impression that PVS impressions, that goop, that that is not a viable alternative for building aligners? Did you mean to leave the jury with that impression?

A. No. It's just not industry standard.

Q. Over the course of this time, over the course of this data, PVS impressions were far and away the largest source of orders for ClearCorrect aligners,

weren't they, ma'am?

A. Yes.

Q. Now, Ms. Sterling, your job is about trying to make for more sales of ClearCorrect, right?

A. Yes.

Q. That's what marketing does. You try to generate interest in the brand, loyalty to the brand, and drive more sales?

A. Yes.

Q. And you're in charge of that for ClearCorrect?

A. Yes.

Q. But you'd have to ask the folks in the home office for your budget, right?

A. Yes.

Q. And I think you said several times that your marketing budget is limited to the percentage of your sales.

Did I hear you correctly?

A. Correct.

Q. That's a Straumann decision to so limit the budget, isn't it, ma'am?

A. It's a ClearCorrect decision.

Q. And your budget, though, for ClearCorrect is approved by your boss, right?

A. Yes.

02:50 Q. You said in the same office over in Switzerland, you got your promotion, got more responsibility, you moved closer to the decision-makers and you sat in the same place as your boss, right?
02:50 A. Yes.
02:50 Q. And that's Mr. Kirsch?
02:50 A. Yes.
02:50 Q. And your boss's boss is there too, right?
02:50 A. Yes.
02:50 Q. The jury has heard from him, Mr. Daniellot?
02:50 A. Correct.
02:50 Q. And they make the decision about how much budget you get, don't they?
02:50 A. Based on ClearCorrect, yes.
02:50 Q. Ma'am, you told me -- do you remember we took your deposition in this case?
02:50 A. Yes.
02:50 Q. And Straumann makes that budgeting decision, don't they?
02:50 A. Yes.
02:50 Q. Straumann makes the budgeting decision for ClearCorrect?
02:50 A. ClearCorrect is a Straumann Group company.
02:50 Q. Okay, ma'am. Does Straumann --
02:50 THE COURT: I'm sorry. If you could just

answer his question directly, okay?

BY MR. DURST:

Q. Does Straumann set the marketing budget for ClearCorrect?

A. Yes.

Q. And there have been times, ma'am, when you've asked for more money, right?

A. Yes.

Q. And Mr. Kirsch has said no?

A. Yes.

Q. Now, you said your budget is $2 million for marketing?

A. In the United States.

Q. And the United States is your largest market?

A. Yes.

Q. So in your largest market, you have $2 million of budget, correct?

A. Correct.

Q. And four people?

A. Yes.

Q. For all 50 of these great United States?

A. Yes.

Q. Four people?

A. Yes.

Q. All right. And do you know, ma'am, how

much -- do you know how much of a percentage of Straumann's revenue is your budget?

A. I do not.

Q. Well, let's work through that.

MR. DURST: May I have the ELMO, please?

BY MR. DURST:

Q. Okay. So I have to scan out a little bit here. All right. I'd ask you to help me create this aid for the jury, okay?

A. Okay.

Q. All right. So the Straumann ClearCorrect marketing budget for aligners.

In the United States, how much is that?

A. 2 million.

Q. All right. Now, let's look at the Straumann revenues.

MR. UNDERWOOD: Your Honor, may we approach?

THE COURT: Sure.

(Bench conference.)

MR. UNDERWOOD: I apologize for the delay, Your Honor. I wanted to raise two issues, both as part of the Court's motions in limine -- or orders in limine.

The first relates to I think where

02:53 Mr. Durst is going, into total company revenues, which we believe is off limits under the Court's standing MILs. And then as an additional matter --

THE COURT: Are you headed there?

MR. DURST: I am headed there, Your Honor.

MR. UNDERWOOD: And as an additional matter, the Court granted our motion in limine on Straumann's dental implant business and revenues related to that. Both of those orders in limine preclude this line of questioning, given where he said he's going.

THE COURT: So, Mr. Durst, how do you get to a total amount of revenue without including the other products that are not in the case?

MR. DURST: Your Honor, she has testified that her budget is set by Straumann and said it's a percentage of revenue. They've been talking about all of our revenue since Day 1 in the opening -- in the opening statement, Your Honor. They've been talking about our revenue then.

Your Honor, Straumann is a defendant here. This is not like I'm trying to bring in somebody who is not a defendant.

Those people sat over there in

Switzerland. They make the decision about budget. They make it based on a percentage of revenue. And their revenue is relevant, Your Honor. And they've opened the door to this.

MR. UNDERWOOD: May I respond that, Your Honor?

THE COURT: Yes.

MR. UNDERWOOD: It's based on ClearCorrect, Your Honor, and the products in this case.

Straumann may set it. She has testified to that. But they don't set it based upon dental implant revenues. Those are completely separate. The products aren't in this case, has nothing to do with the way they set their budgets.

MR. DURST: That seems, to me, Your Honor, something that could be addressed on redirect.

THE COURT: So here's the deal. I don't -- we can't unring this bell if we -- which way I rule -- I mean, if I allow you to do it.

I'm going to not permit it at the moment, and you can finish with her. And we can take this up in a more robust way and I can fully understand, for example, who the plaintiff is in the antitrust case and how the damages are -- I mean, I don't know -- you all

know the minutia of which companies are which and which products are which and all that.

It seems to me, off the top of my head, that if the defendant is asking for antitrust damages, then, Mr. Durst, you would be right in getting a total number, but I don't know that.

So for now, I'm going to not allow you to ask that total number. But after we take it up, I'll allow you to recall her to the stand and ask that question if I decide that you can do it.

MR. DURST: Your Honor, I appreciate that accommodation, but there is no time like the present. And they have --

THE COURT: Mr. Durst. You had me at you appreciate the accommodation. So that's my ruling.

MR. DURST: Okay.

MR. UNDERWOOD: Thank you, Your Honor.

(Bench conference concludes.)

MR. DURST: Thank you, Judge.

BY MR. DURST:

Q. Ms. Sterling, do you know the percentage of revenue that $2 million represents?

MR. UNDERWOOD: Your Honor, I'm going to re-urge the same objection we just discussed.

THE COURT: Sustained.

MR. DURST: Your Honor -- so let me ask the question a different way.

BY MR. DURST:

Q. Ms. Sterling, you said it's set as a percentage of revenue?

A. Yes.

Q. The marketing budget. What is that percentage?

A. In general, we follow around 7 to 10 percent of revenue.

Q. 7 to 10 percent of revenue?

A. Yeah.

Q. And so your marketing spend is going down this year?

A. Can you clarify the question?

THE COURT: And by "your," I think if you would say the name of who you mean by "your," just so I know.

BY MR. DURST:

Q. We're talking about the $2 million in ClearCorrect advertising?

A. In marketing, yes.

Q. And you said it's a percentage of revenue?

A. Yes.

Q. We've seen that your revenue's going down?

02:57 A. Yes.
02:57 Q. Your marketing spend, it's going down, isn't it, ma'am?
02:57 A. It's reevaluated at the beginning of each year.
02:57 Q. And when is that?
02:57 A. In January.
02:57 Q. In January.
02:57 So next January, your marketing spend will go down?
02:57 A. Likely.
02:57 Q. And it went down last year too, didn't it?
02:57 A. It's been around 2 million.
02:57 Q. But as the revenue goes down, which you have said is happening, your spend is going down?
02:57 A. In general.
02:57 Q. And ClearCorrect is not -- they spend
02:58 virtually no money on direct-to-consumer marketing, correct?
02:58 A. Correct.
02:58 Q. So it's never going to be the case in all
02:58 likelihood that a patient will walk into an orthodontist office and ask for ClearCorrect, right?
02:58 A. I can't say that.
02:58 Q. Well, you put no marketing effort behind

02:58 trying to make that happen; isn't that true?
02:58 A. We don't invest in direct to consumer.
02:58 Q. Okay. Ma'am, do you put any effort behind
02:58 trying to put yourself in a situation where a patient
02:58 walks into a orthodontist office and says, if I get
02:58 aligners, I want them to be ClearCorrect?
02:58 A. Yes. We do.
02:58 Q. Okay. You do not do that by advertising to
02:58 the consumers, do you?
02:58 A. We do not.
02:58 Q. Okay. Now, Ms. Sterling, I'd like to go to a
02:59 couple more of the exhibits that Mr. Underwood called
02:59 up. And let's turn to DTX-2236.
02:59 You see this document? This is what
02:59 Mr. Underwood asked you about.
02:59 A. Yes.
02:59 Q. Do you know why he asked you so many questions
02:59 about six-year-old documents instead of more current
02:59 documents?
02:59 A. I do not know.
02:59 Q. 2020 were the exhibits that he used with you
02:59 primarily, weren't they?
02:59 A. Yes.
02:59 Q. Now, let's go to Page No. 4 of this document.
02:59 And in this page, your team is identifying the

North American market overview, right?

A. Yes.

Q. And so in the categories, established brands, newcomers, and direct to customers, right?

A. That's what it says.

Q. And you guys call yourself an established brand.

Do you see that?

A. Yes. I see that.

Q. And some of the newcomers, like Angel, their revenues are increasing, aren't they?

A. Can you clarify?

Q. Well, you have Angel as a newcomer. That means new to the market, right?

A. Yeah.

Q. And we saw that their revenue is increasing substantially year over year, right?

A. Yes.

Q. And you also had this other category called Direct to Consumers.

Do you see that?

A. Yes.

Q. And in direct to consumers, that's where these companies might sell directly to a consumer. That's pretty simple, right?

A. Correct.
Q. And so if we were to look at the proper definition of the market, it would include this direct to consumer?
A. Yes.
MR. DURST: Now, let's also go to Slide No. 8, please.
BY MR. DURST:
Q. And on Slide No. 8, tell the jury what your team is evaluating here.
A. The North America value proposition perception.
Q. And it looks like Invisalign is up in the upper right, right?
A. Yes. That's what that says.
Q. And that's telling us that of all these competitors, and then particularly relative to ClearCorrect, Invisalign has the highest quality perception, right?
A. That's what the document says.
Q. Well, that's your document, isn't it, ma'am?
A. I wasn't here in 2020.
Q. So do you -- have you lost confidence in this document?
A. No. I just wasn't part of preparing it.

Q. Okay. Invisalign has the highest quality perception over ClearCorrect and all the rest?

A. That's what this says.

Q. And it also says that Invisalign has the most comprehensive treatment of all the rest, doesn't it?

A. Yes. That's what this says.

Q. We're going to rescue you from your 2020 documents and look at a couple more recent ones, all right?

A. Okay.

Q. Let's go to your 2024 plan, and let's -- let's call up how about the PTX-126. I'm not going to get there just quite yet.

Now, you recognize ClearCorrect's got a number of weaknesses in its offerings, right?

A. I wouldn't say it like that.

Q. Well, you recognize that lack of budget is a weakness, right?

A. No.

Q. Or employee experience and qualifications, those are weaknesses, aren't they?

A. No.

Q. Or manufacturing delays in quality issues, those are weaknesses too, right?

A. No.

03:03 Q. All right. So let's look at Exhibit 126.

03:03 What is Exhibit 126? We can't put it on the screen yet. I don't think it's admitted.

03:03 Can you look at it on your screen and tell the jury what that is?

03:03 A. It's the Ortho 2024 Marketing Plan.

03:03 MR. DURST: Your Honor, I move to admit Exhibit PTX-126.

03:03 MR. UNDERWOOD: No objection.

03:03 THE COURT: Admitted.

03:03 BY MR. DURST:

03:03 Q. This document, ma'am --

03:03 MR. DURST: Let's display it, please.

BY MR. DURST:

03:03 Q. Was a document that was prepared by two of your team members, right?

03:04 A. Correct.

03:04 Q. Sarah and Celeste, they work for you?

03:04 A. Yes.

03:04 Q. That's half your team, I guess?

03:04 A. No. These were worked in global.

03:04 Q. Those were done in -- oh. So some of the work is done in Switzerland?

03:04 A. This was in Round Rock.

03:04 Q. But they're in Switzerland?

A. No. They're in Round Rock.
Q. Okay. So they're global team members. They're not focused on the United States?
A. In part they are.
Q. Well, they used -- you and your team, you used this document to set the strategy for the coming year, right, for last year for 2025?
A. We used this for 2024.
Q. Okay. And you looked at the document, had responsibility for it, et cetera, right?
A. I looked at the document, yes.
Q. And part of the analysis is to look at something called SWOT, S-W-O-T?
A. Yes.
Q. What is that?
A. Strength, weaknesses, opportunities, and threats.
Q. What's the "W" stand for?
A. Weaknesses.
Q. Weaknesses.
Okay. Let's go to Page 33. This is your SWOT analysis?
It's on the screen too, ma'am, if you prefer.
A. Yes. This is a SWOT analysis.
Q. And this calls out weaknesses?

A. Perceived weaknesses, yes.
Q. And the first is: Low marketing budgets compared to your competition.
Right?
A. That's what this says.
Q. And read the second one for the jury.
A. Varying levels of experience and qualifications across internal teams.
Q. And then it goes on and says: Manufacturing delays and quality issues are also weaknesses.
Right?
A. That's in the weaknesses column, yes.
Q. Pardon?
A. Yes. It's in the column.
Q. So your team perceives these weaknesses even if you don't?
A. The team wrote this, yes.
Q. Now, you agree that a product -- that product quality can impact customer perception, right?
A. Yes.
Q. And so if you have good quality, it can positively increase customer perception?
A. Yes. It's one of the --
Q. And good quality would increase the likelihood of making more sales?

A. It may be one of the reasons.
Q. Now, there's another side to that coin, right? So bad quality can also impact customer perception?
A. It can impact.
Q. And bad quality can also hurt your sales?
A. It could impact it, yes.
Q. Well, you could lose customers over bad quality, can't you?
A. Yes.
Q. And, you know, and a bad scan. You talked about scanners. A bad scan can lead to a bad aligner fit, right?
A. Yes.
Q. And good scans lead to better outcomes?
A. I wouldn't say that.
Q. Well, good scanners and good scans lead to better -- better prescriptions?
A. Lead to better models.
Q. Which lead to better aligners?
A. Yes.
Q. And so it's important for companies to want to control the quality of the scan or focus on the quality of the scan that comes in for purposes of making an aligner. You would agree with that?
A. One of the things, yes.

Q. Because it leads to higher quality and better products and better customer perception, doesn't it, ma'am?

A. One of the things, yes.

Q. Now, let's -- for clear aligners, you have to scan differently -- pardon me.

For ClearCorrect, you have to scan differently, don't you?

A. Yes.

Q. You have to scan more of the gums than you do for other aligners?

A. Yes.

Q. And that's a decision that ClearCorrect has made?

A. We've made the decision to have a high trim line.

Q. That's a decision that the company made?

A. Yes.

Q. And that impacts the -- or that changes the scan that you have to do?

A. Yes.

Q. It's harder for doctors to scan for those, isn't it?

A. No.

Q. They have to go deeper in the mouth to scan,

right?

A. Not necessarily.

Q. Let's show the jury what we're talking about with the different trim lines.

MS. DURIE: Let's go to PDX-29 -- or pardon me. Let's go to PTX-75, Page 11.

BY MR. DURST:

Q. And we have prepared -- you see here we have ClearQuartz. That's ClearCorrect up in the left, right?

A. Yes.

Q. And Essix, that's one of your competitors?

A. Yes.

Q. See that there?

MR. DURST: Let's pull those out. I'm going to show you what we've done. And pulling those out, it will be PDX-29, but let's go ahead and pull those out and highlight them with PDX-29, Mr. Smith.

There we go. Here's a better look.

BY MR. DURST:

Q. Now, you said -- I think you said "high." And what do you call your trim line?

A. Flat.

Q. High and flat.

The upper visual there shows what we're

03:09 talking about, right?
A. Correct.
Q. Yellow line highlights the high and flat trim line of your aligners?
A. Correct.
Q. And Essix has a lower trim line, right?
A. Yes.
Q. And it's what we call scalloped to follow the shape of the tooth?
A. Yes.
Q. So it's not as tall?
A. Correct.
Q. And most of the rest of the market uses the scalloped trim line, don't they?
A. Yes.
Q. And that's what's Essix uses? It's what Align uses, right?
A. Yes.
Q. And it's harder or different to scan for your aligners than it is to scan for these other aligners, isn't it?
A. It's different.
Q. It's so different that sometimes you have to spend some of your precious marketing dollars in educating doctors how to scan differently for

ClearCorrect.

That's true, isn't it, ma'am?

A. Yes. Part of our education is to -- how to scan.

Q. Ma'am, do you have to spend part of your limited marking dollars -- marketing dollars teaching doctors how to scan differently for ClearCorrect?

A. A very small part, yes.

Q. You spend part of your money on that, don't you?

A. Yes.

Q. And you do that because ClearCorrect made a difference -- made the decision to have that different product line, right, the trim line?

A. Differentiate, yes.

Q. Okay. Now, let's go -- let's switch gears just a little bit. I want to -- I want to show you PTX-126, please. This is the same document that we were looking at a moment ago.

MR. DURST: Let's go to Page 7 of this, please.

BY MR. DURST:

Q. In this document, your team is saying: Together we have an incredible opportunity.

Do you see that?

03:10 A. Yes.
03:11 Q. Do you know what is an ortho start, Ms. Sterling?
03:11 A. It's the number -- it's ortho treatment.
03:11 Q. An ortho treats teeth straightening of any kind. That's an ortho start, isn't it?
03:11 A. Yes.
03:11 Q. So that includes braces?
03:11 A. Yes.
03:11 Q. And aligners?
03:11 A. Yes.
03:11 Q. And your team here is saying there are 600 million potential patients out there, right?
03:11 A. Yes.
03:11 Q. And there have only been 22 million teeth-straightening starts, right?
03:11 A. Yes.
03:11 Q. And then the reason I thought your people were from Switzerland, because it's -- the currency size of the market is expressed 7 billion. That's in Swiss Francs, right?
03:11 A. Yes.
03:11 Q. And so that's the -- there's opportunity there, right?
03:11 A. There's opportunity.

03:11 Q. And of all these ortho starts, these
03:12 22 million, only one in four of those have been
03:12 aligners, right?
03:12 A. Right.
03:12 Q. The others have been largely braces, haven't
03:12 they, ma'am?
03:12 A. Yes.
03:12 Q. And so your team is trying to increase that
03:12 penetration of aligners, aren't they?
03:12 A. No.
03:12 Q. You're not. You're not trying to grow
03:12 aligners?
03:12 A. Not out of the ortho starts.
03:12 Q. You're trying to grow your aligner sales,
03:12 aren't you?
03:12 A. Yes.
03:12 Q. Okay. Now, you showed us the 2020 documents
03:12 that talk about what you call as the market, but
03:12 Straumann talks about the teeth-straightening market,
03:12 don't they?
03:12 A. I believe so.
03:12 Q. So if we look at a more recent document, like
03:12 a 2024 annual report, an annual report is something
03:12 that your parent company puts out; it goes out to
03:12 investors, right?

A. Yes.
Q. They have an obligation and they feel an obligation to tell the truth in that?
A. Yes.
Q. And to be straightforward and transparent?
A. Yes.
Q. And to be careful?
A. Be careful?
Q. Careful with their wording.
A. They want to be accurate.
Q. Yeah. And in that document, Straumann talks about the teeth-straightening market, don't they --
A. I'd have to see.
Q. -- in that annual -- okay. We can pull it up.
MR. DURST: It's PTX-1615, please.
BY MR. DURST:
Q. Do you recognize this as Straumann's 2024 annual report?
A. Yes. I do.
MR. DURST: Move to admit, Your Honor.
MR. UNDERWOOD: Your Honor, I don't have an objection, but may we briefly approach?
(Bench conference.)
MR. UNDERWOOD: I apologize, Your Honor. We don't have an objection to this being admitted, but

it does include the overall revenue numbers that we were mentioning earlier.

So subject to that caveat, that if he's not going to use those overall revenue numbers, we have no objection to its admission.

THE COURT: Let's -- I'll admit a redacted version --

MR. UNDERWOOD: Thank you, Your Honor.

THE COURT: -- as of now. And if I change my mind, I'll allow Mr. Durst to get into that, we can unredact it.

MR. DURST: Your Honor, while we're up here, I need to raise another ruling of the Court.

So Ms. Sterling has here talked about, and Mr. Mueller talked about it in opening, 3Shape termination that we cut off. She spent a bunch of time talking about it, that we stopped interoperability with 3Shape in the United States.

And the Court has issued a ruling that says that we cannot get into the legal considerations of why we did that. It's already in the record. Defendants put it in the record that we did that because of patent litigation.

I intend to reference that patent litigation and go no further, Your Honor. So go no

03:14 further other than that patent litigation. Nothing
03:14 about legal considerations will be addressed.
03:15 THE COURT: How much time do you have
03:15 left?
03:15 MR. DURST: I have probably ten minutes
03:15 left.
03:15 THE COURT: Okay. So here's what we're
03:15 going to do: We're going to go ahead and break for the
03:15 day.
MR. DURST: For the day. Okay.
03:15 THE COURT: That way that takes care of
03:15 your issue about -- we'll break.
MR. DURST: Sure.
03:15 THE COURT: When we get back, we'll take
03:15 up everything we just took up. Way easier for me to do
03:15 it without the jury sitting there. And that way he'll
03:15 either be able to or not be able to ask her about the
03:15 stuff you want in this cross.
03:15 MR. DURST: Okay. Your Honor, could
03:15 we -- can we have her excused for that discussion?
03:15 THE COURT: What?
03:15 MR. DURST: Even though she's the
03:15 corporate representative, can we have her excused for
03:15 that discussion? It really relates to her testimony.
03:15 THE COURT: I'm sorry. I wasn't

following you. I think you can have her excused while we're debating what to do, because she is the witness on it. I think that's fair.

MR. DURST: Right.

THE COURT: But yeah. That's fine.

MR. UNDERWOOD: And, Your Honor, I apologize. Are we being dismissed for the day now?

THE COURT: Yes.

MR. UNDERWOOD: All right.

MR. DURST: Thank you, Your Honor.

THE COURT: Sure.

(Bench conference concludes.)

THE COURT: I feel like I already broke my promise to you that we were going to break at 3:00. So since the witness is a representative who's going to be here anyway when we resume on Monday, I see no reason to keep going today.

So ladies and gentlemen, we're done for the day. We're done for the week. I hope you have a wonderful evening. I hope you have a great weekend. I hope you come back here with a song in your heart on Monday morning, all bushy-tailed and bright-eyed to get going again. And we'll make sure that we turn the air-conditioner down over the weekend so it's more comfortable in here.

But please don't discuss the case with anyone, the evidence, and please don't do any research until -- or ever. But I will see you Monday morning.

THE BAILIFF: All rise.

(Jury exited the courtroom.)

THE COURT: You may be seated.

I apologize that I can't take this up now and get it resolved for you, but I really have to go do this hearing. But we'll take up Monday morning the issues, and I'll give you a roadmap, a little bit of a roadmap.

Mr. Durst, at the end you said she's testified a lot about X or Y, not that I don't believe you. But since you'll have the time, if you want to have actual parts of the transcript that you can point to and if you'll by Sunday, whatever you want to talk to me about, let the counsel know what you're planning to argue. That way, they'll be prepared to respond, and we'll do it more quickly Monday morning.

So other than the issues that we dealt with at the bench, I'll start with plaintiff.

Is there anything else we need to take up?

MR. DURST: Nothing further, Your Honor.

MR. MUELLER: Nothing from defendants.

Your Honor, just so we're clear, we will not discuss any testimony with Ms. Sterling.

THE COURT: Correct. Yes. That's right. Other than that, you're free speak to her, but you can't go over anything that Mr. Durst discussed with her.

MR. MUELLER: Absolutely. Absolutely. Thank you, Your Honor.

THE COURT: Okay. Anything else?

Okay.

(Hearing adjourned.)

UNITED STATES DISTRICT COURT)
WESTERN DISTRICT OF TEXAS)

I, Kristie M. Davis, Official Court Reporter for the United States District Court, Western District of Texas, do certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

I certify that the transcript fees and format comply with those prescribed by the Court and Judicial Conference of the United States.

Certified to by me this ^ day of ^ 2026.

/s/ Kristie M. Davis
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