Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 38 of the '874 patent is anticipated by Lemchen.

Lemchen addresses "orthodontic bracket ***placement*** on a malocclused tooth to correct the malocclusion." (CX-945, Abstract (*see also* 1:63-2:8) (emphasis added) While Lemchen discusses "specific force vectors," it does so in the context of a system of bracket-adhesive ***placement*** and does not include disclosure of applying digital data to "generate … intermediate positions." (*See e.g.* CX-945, 4:35-38) A typical allusion in Lemchen states, "The preferred embodiment takes into account the relative resistance to movement of various teeth or groups of teeth. Bracket positions are customized to account for these forces." (CX-945, 5:35-38) As Lemchen makes clear, the concept of force magnitudes and directions of orthodontic forces, were used from the beginning of orthodontic treatment. (CX-945, 1:11-20) Asserted claim 38 of the '874 patent goes well beyond Lemchen when it teaches generating intermediate positions and including in the data "indicating restraints on movement of the patient's teeth and applying the data to generate the intermediate positions." There is no evidence to connect the disclosures of Lemchen to the teachings of asserted claim 38.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 38.

d. Asserted claim 39.

Asserted claim 39 depends from claim 1 and reads:

> The method of claim 1, wherein generating the set of intermediate positions includes determining the minimum amount of transformation required to move each tooth from the initial

> position toward the final position and creating the intermediate positions to require the minimum amount of movement.

(JX-006, 34:60-65)

Respondents' Position: Respondents incorporate their disclosure categories 6 and 7 which are discussed in section IV.H.1.a and c, *supra*.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.1.a and c, *supra*.

Align alleges that the limitation "determining the minimum amount of transformation required to move each tooth from the initial position toward the final position and creating the intermediate positions to require the minimum amount of movement" is not disclosed by any of the prior art. (Citing RIB at 144-148)

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated by Lemchen, I could still find that claim 39 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 39 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 39 of the '874 patent is anticipated by Lemchen.

The difference between dependent claim 38 and dependent claim 39 is the amount of movement of the patient's teeth that is contemplated. Dependent claim 38 focuses on data "indicating restraints on movement of the patient's teeth," and dependent claim 39, looks to

"determining the minimum amount of transformation required to move each tooth from the initial position toward the final position." (JX-006, 34:56-65)

My analysis of this issue in section IV.H.1, supra, is equally applicable to this discussion and is incorporated here by this reference.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 39.

e. Asserted claim 41.

Asserted claim 41 depends from claim 1 and reads:

> The method of claim 1, wherein generating the set of intermediate positions includes generating intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes.

(JX-006, 35:4-7)

Respondents' Position: Respondents incorporate their disclosure categories 6 and 7, which are discussed in sections IV.H.1.a and c, *supra*.

Align's position: Align provides no argument beyond that which it forwarded in a general response to Respondents' invalidity argument in sections IV.H.1.a and c, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated by Lemchen, I could still find that claim 41 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 41 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 41 of the '874 patent is anticipated by Lemchen.

As evidenced by the summary of Respondents' argument in section IV.H.1.c, supra, Respondents make no effort to demonstrate that Lemchen discloses generating intermediate positions for one tooth in which the tooth "undergoes translational movements of equal sizes." There is simply no mention of this limitation of dependent claim 41 in Respondents' argument.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 41.

f. Asserted claim 62.

Asserted claim 62 depends from claim 1 and reads:

> The method of claim 1, further comprising delivering data identifying the intermediate treatment positions to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final position.
>
> (JX-006, 36:12-16)

Respondents' Position: Respondents incorporate their disclosure categories 9 and 10, discussed in section IV.H.1.f, *supra.*

Align's position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in sections IV.H.1.a and c, *supra.*

Align avers that the limitation "delivering data identifying the intermediate treatment positions to an appliance fabrication system…" is not disclosed by the prior art. (Citing RIB at 144-148)

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated by Lemchen, I could still find that claim 62 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 62 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 62 of the '874 patent is anticipated by Lemchen.

Respondents' argument relies in part upon the non-existent finding that Lemchen incorporates the entirety of Kesling by reference. Nevertheless, regardless of whether or not the entirety of Kesling is incorporated into Lemchen, I would find that Respondents have not demonstrated by clear and convincing evidence that Lemchen anticipates each and every limitation in the element of claim 62.

Respondents' candid assessment of Kesling is that it discloses manually sectioning out the teeth from the physical model and manually moving each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material. Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-4:58)

As discussed, *supra*, Lemchen addresses "orthodontic bracket ***placement*** on a malocclused tooth to correct the malocclusion." (CX-945, Abstract (*see also* 1:63-2:8) (emphasis added) It does not address the creation of individual dental repositioning aligners. Asserted claim 62 of the '874 patent teaches delivering data identifying … intermediate treatment positions to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final position. The data produced in the invention of Lemchen is used to assist in the creation and placement of brackets and arch wires. (CX-945, 3:61-4:39)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 62.

2. Obviousness

Lemchen, Kesling, and the knowledge of one of ordinary skill in the art

a. Asserted Claim 1

Respondents' Position: Respondents incorporate the disclosures of the prior art identified in the anticipation section addressing this preamble to Claim 1 of the '874 patent together with knowledge of one of ordinary skill in the art as described in the section addressing claim 1 of the '325 patent. Respondents assert that neither Lemchen, nor the incorporated Kesling patent, limit the time when the disclosed appliances are generated and the appliances can be generated prior to the patient wearing any appliance.

First, Respondents address the issue of motivation to combine generally, and say that Align's expert, Dr. Rekow, stated that:

> The evolution of computers in the 1970s and 1980s enticed many inventors to explore dental and orthodontic applications using and manipulating digital data. Ideas that were explored, as seen below were demonstrated, included opportunities where manual manipulations were automated. The time consuming manipulation of plaster casts to model orthodontic treatment options was replaced by systems that modeled multiple combinations of tooth movement, permitting the clinician to choose the most ideal. Labor-intensive design and fabrication of dental restorations was replaced by computer-aided design and manufacturing systems to speed delivery . . . .

(Citing RX-103C at 2)[24] Respondents contend that the related nature of the subject matters and the problems addressed made the combination obvious. Respondents add that Dr. Rekow stated that the Lemchen reference and the Kesling reference were combined based on her analysis of the references in the Lemchen patent. Respondents assert that Dr. Rekow's report states that Lemchen's methods for digital 3-D modeling was a representation of Kesling's physical 3-D modeling. (Citing RX-103C at 16) Respondents conclude that these references with the knowledge of one of ordinary skill show that the asserted claims are obvious. Respondents then take the position that the topics in this section are common to the obviousness analysis for each claim and are incorporated therein to avoid repetition. In their view, each asserted claim is obvious in light of the identified prior art references with the knowledge of one of ordinary skill.

Respondents argue that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66–3:6) Respondents contend that a PHOSITA would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. Respondents

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[24] This use of the cited reference violates the limited scope contained in my ruling on Align's Motion in Limine No. 6, and is rejected.

allege that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents state that Lemchen also expressly incorporated the disclosure of Kesling to explain the inventor's 3-D modeling methodology, quoting:

> In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,

(Citing CX-945, 3:36–40) Respondents reason that Lemchen stated that FIG. 3 was one example of a repositioned tooth arrangement, and a PHOSITA would understand that this same method would apply equally to the intermediate or successive tooth arrangements that are described in Kesling, because the methodology is the same for all successive tooth arrangements from the initial position to the final position. Respondents add that intermediate or successive tooth arrangements are inherent in tooth modeling, because one cannot model tooth movement accurately without including the intermediate steps. (Citing RX-113C, Q. 48)

Respondents argue that the figures in Kesling demonstrate that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-944, Fig. 7) Respondents assert that Kesling expressly discloses: (1) intermediate or successive models representing tooth positions; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-113C, Q. 33)

Respondents say that Lemchen discloses methods that include controlling a fabrication machine, quoting:

> The present method may be utilized in conjunction with computer-aided design and computer-aided manufacturer (CAD/CAM), as described in the

> Rekow article referred to above, to provide a machined or cast base conforming to the tooth morphology . . . .

(Citing CX-945, 5:4–8) Respondents add that Lemchen also describes the use of a "laboratory model of the tooth . . . ." and the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-945, 5:21–24) Respondents contend that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated. (Citing RX-113C, Q. 43)

Respondents say that Lemchen expressly stated that the three-dimensional modeling methods, using software, "may be derived by conventional means for the particular method of treatment elected by the orthodontist." (Citing CX-945, 3:25–26) Respondents continue that Lemchen similarly stated in the detailed description that there "are a number of methods of treatment commonly used by the orthodontist." (Citing CX-945, 3:43–46) Respondents reason that as a result Lemchen expressly recognizes that its methods may be used with different types of orthodontic treatment. Respondents conclude that a PHOSITA would understand that other treatment methods, such as the aligner treatment method disclosed in Kesling could be used with the digital methods disclosed in Lemchen. (Citing RX-113C, Q. 49)

Respondents says that a PHOSITA would understand that the methods of Kesling were not limited to brackets (which are custom fabricated in the disclosed methods to conform to the surface of the teeth) and arch wires. Respondents argue that the incorporation of the disclosures of Kesling and "the other statements concerning other treatment methods" makes it clear that the Lemchen methodology applies beyond brackets and archwires. Respondents say Kesling's disclosures are limited to methods for making polymeric shell appliances based on a series of three-dimensional tooth models, and a PHOSITA would understand the incorporation of Kesling

to mean that the methods of Lemchen would apply to polymeric shell appliances, the orthodontic appliance expressly described in Kesling. Respondents add that a PHOSITA would also understand that the modeling of teeth movement is the same, regardless of the type of orthodontic appliance used. (Citing RX-113C, Qs. 49, 51)

Respondents continue that Lemchen also disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-945, 5:15–20) Respondents argue that these disclosures render the claim obvious.

Respondents incorporate Disclosure Categories 1, 7, and 10, which are discussed in section IV.H.1.a, combined with the knowledge of one of ordinary skill in the art. Respondents also incorporate their discussion of treatment plans[25].

Align's Position: Align argues that the combination of Lemchen with Kesling, and "the knowledge of one of ordinary skill in the art" was disclosed for the first time in the *JSCI*, and is therefore improperly raised now and has been waived. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence and the combination of Lemchen and Kesling fail to disclose all the elements of any of the asserted claims of the '874 patent, "as discussed above[26]". Align states that a PHOSITA at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances

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[25] Inasmuch as, Respondents' argument about treatment plans adds nothing relevant or material to the issue of obviousness, I reject it as without merit and will not further discuss it.

[26] In its reply brief, Align cites to CIB at 48-51; CX-1247C, Qs. 568-569; CX-1254C ¶ 274 at 97; and CDX-158—163) to support this argument.

(Kesling). (Citing CIB Sec. IV.F.2.b) Align adds that secondary considerations support a finding of non-obviousness. (Citing CIB Sec. IV.F.2.c)

In its reply brief, Align argues that Respondents failed to make a *prima facie* showing of obviousness. (Citing CRB Sec. IV.H; and Tr. at 19:11-20:4, 651:14-653:25). Align adds that the USPTO considered Lemchen and Kesling during the prosecution of the '874 patent, further demonstrating that the asserted claims are not obvious. (Citing JX-006 at 1-2) Align says that Respondents' obviousness theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing CRB Sec. IV.H.4)

Staff's Position: Staff refers to its discussion of obviousness in SIB Section IV.E.2, and says it applies equally here.

Analysis and Conclusions: While Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 6.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render any specific asserted claim of the '874 patent obvious.[27] There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 147-154) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

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[27] Align correctly argues that the Respondents also fail to identify the claim(s) addressed by the prior art.

In order to prevail on their claim that asserted claim 1 of the'874 patent is invalid as obvious, Respondents must first demonstrate that Lemchen, either alone or in combination with Kesling, and the knowledge of a PHOSITA discloses all of the limitations of asserted claim 1. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. (See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007))

There is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen or Kesling to follow the method in the '874 patent. In section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. In the interest of brevity, I will not repeat that discussion here; but I reaffirm that finding and its rationale.

In section IV.H.1.a, I found that Lemchen does not reveal the requirement of "generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions" taught in the second element of asserted claim 1and that Lemchen does not, in any way, address, disclose, or hint at, multiple removable appliances or generating successive appliances. In the interest of brevity, I will not repeat that discussion; but I reaffirm those findings and the rationale supporting them.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of asserted claim 1. As described, *supra*, Figure 1 only

describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position."

Assuming arguendo that Lemchen incorporated the entirety of Kesling by reference, I found in section IV.H.1.a that those two references taken together would still not disclose each and every element of asserted claim 1 of the '874 reference. Notably, I found that Kesling only contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. (CX-1247C, Qs. 144-145; CX-944, 5:22-32) I concluded that Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on digital data. Rather, Kesling discloses manually making an appliance using tools, supplies, and materials, including, inter alia, (i) articulating the plaster cast; (ii) taking an impression of the teeth of the plaster cast, and (iii) making a mold filled with the appliance material. (CX-944, 3:65-4:58)

Consistent with the foregoing, I found that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. Based upon the foregoing findings, it follows that Lemchen combined with Kesling would not provide any impetus for a PHOSITA to combine the teachings of Lemchen and Kesling to produce the invention of asserted claim 1 of the '874 patent. I will not repeat my analysis in full in the interest of brevity; but that analysis and the conclusions reached are reaffirmed here.

While Respondents' expert, Dr. Mah, opines to the contrary, I find that his testimony was conclusory and unconvincing. (See RX-113C, Qs. 113-121)

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '874 patent are present in Lemchen combined with Kesling, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in asserted claim 1of the '874 patent.

b. Asserted Claim 2

Respondents' Position: The Respondents incorporate the disclosures identified as their Disclosure Category 1 together with knowledge of one of ordinary skill in the art as described in RIB section 3.5.2.2 addressing claim 1 of the '325 patent.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.H.2.a, *supra.*

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 2 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 2 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 2 of the '874 patent is rendered obvious by that combination.

In section IV.H.1.b, *supra*, I found that Lemchen does not reveal generating the initial data regarding malocclused teeth from a physical model of the patient's teeth as shown in Kesling. In the interest of brevity, I will not repeat the discussion in section IV.H.1.b in its entirety; but I reaffirm that finding and the rationale for it.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 2 of the '874 patent are present in Lemchen combined with *Kesling*, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 2 of the '874 patent.

c. Asserted Claim 38

Respondents' Position: Respondents incorporate Disclosure Category 6 combined with the knowledge of a PHOSITA.

Respondents argue that Lemchen discloses that his method "produces appropriate force magnitudes at various stages of treatment to move the tooth to its ideal position." (Citing CX-945, 2:37–38) Respondents contend that a PHOSITA would understand that the "various stages of treatment" would refer the successive stages of treatment typical in orthodontic treatment, and would understand that "appropriate force magnitudes" would mean that any threshold limits on movement would not be exceeded. Respondents reason this is because the only way that movement could exceed a threshold limit is by the application of inappropriate or excessive force on the tooth. Respondents add a PHOSITA would also understand that "appropriate force magnitudes" would mean at least the minimum force necessary to move the teeth toward the

successive stage of treatment, otherwise the treatment would be ineffective[28]. (Citing RX-113C at Qs. 57, 58)

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.H.2.a, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 38 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 38 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 38 of the '874 patent is rendered obvious by that combination.

In section IV.H.1.c, *supra*, I fully discussed Respondents argument using their disclosure category 6. In the interest of brevity, I will not repeat that discussion here; but I reaffirm the findings and rationale in section IV.H.1.c.

A portion of Respondents' argument in section IV.H.1.c said that a PHOSITA would also understand that "appropriate force magnitudes" would mean at least the minimum force necessary to move the teeth toward the successive stage of treatment, otherwise the treatment

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[28] Respondents identify this argument as their disclosure category 6.

would be ineffective[29]. Respondents offered the testimony of their expert, Dr. Mah, to prove this point; but that brief testimony amounts to mere conclusory opinions without any supporting rationale demonstrated. It is unhelpful. (See RX-113C at Qs. 57, 58)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 38.

d. Asserted Claim 39

Respondents' Position: Respondents incorporate Disclosure Categories 6 and 7 and the knowledge of a PHOSITA, all of which are discussed in section IV.H.2.a and c, and the references to the record contained therein.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.H.2.a, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 39 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 39 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

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[29] Respondents identify this argument as their disclosure category 6.

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 39 of the '874 patent is rendered obvious by that combination.

In the interest of brevity, by this reference I incorporate the discussion, findings and rationale in section IV.H.2.a and c.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 39.

e. Asserted Claim 41

Respondents' Position: Respondents incorporate Disclosure Categories 6 and 7, discussed in sections IV.H.2a and c, combined with the knowledge of a PHOSITA.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.2.a, *supra.*

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 41 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 41 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 41 of the '874 patent is rendered obvious by that combination.

In the interest of brevity, by this reference I incorporate the discussion, findings and rationale in sections IV.H.2.a and c, *supra*.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 41.

f. Asserted Claim 62

Respondents' Position: Respondents incorporate Disclosure Categories 9 and 10, discussed in section IV.H.1.f, *supra*, combined with the knowledge of a PHOSITA.

Arguing disclosure category 10, Respondents say Kesling disclosed "tooth positioning appliances" that were "adapted to . . . bring the teeth of a user of such an appliance into a pre-determined ideal or desirable position without the necessity for the use of metallic bands, wires or any of the other appliances of the prior art." (Citing CX-944, 1:1-6) Respondents say Figure 7 shows that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-944, Fig. 7)

Respondents contend that Kesling further teaches that each aligner in the series is made by molding a polymeric material over positive models of intermediate or successive tooth arrangements. Respondents assert, first a cast of the teeth in their initial position is created using

traditional methods. (Citing CX-944, 2:43–49) Respondents admit that each individual tooth is manually sectioned out by an operator using a scroll saw, and the operator manually moves each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material. Respondents say a positive model of the teeth in their new position is made, and the aligners are fabricated by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-944, 3:30-4:70 and Figure 3) Respondents conclude that the incorporated disclosures of Kesling demonstrate methods for producing a series of polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements, and Kesling therefore discloses: (1) intermediate or successive models representing tooth positions; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement.

Respondents contend that Lemchen discloses methods that include controlling a fabrication machine, quoting:

> The present method may be utilized in conjunction with computer-aided design and computer-aided manufacturer (CAD/CAM), as described in the Rekow article referred to above, to provide a machined or cast base conforming to the tooth morphology . . . .

(Citing CX-945, 5:4–8) Respondents assert that the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-945, 5:21–24) Respondents argue that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated.

Regarding their disclosure category 9, Respondents argue that Lemchen disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital

information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-945, 5:15–20)

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.2.a, *supra.*

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 62 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 62 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 62 of the '874 patent is rendered obvious by that combination.

In the interest of brevity, by this reference I incorporate the discussion, findings and rationale in sections IV.H.1.f and IV.H.2.a[30], *supra.*

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the

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[30] Reference to this section is to that portion that discusses combining the Lemchen reference with Kesling and the knowledge of a PHOSITA.

knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 62.

V. INFRINGEMENT

A. Applicable Law

A complainant must prove either literal infringement or infringement under the doctrine of equivalents. Infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). A preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n. 15 (Fed. Cir. 2005).

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). Literal infringement requires the patentee to prove that the accused device contains each and every limitation of the asserted claim(s). *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004).

Contributory infringement requires the patentee to prove that: (1) there is an act of direct infringement in violation of section 337; (2) the accused device has no substantial non-infringing uses; (3) the component is a material part of the invention; and (4) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724; Comm'n Op. (Dec. 21, 2011) at n.9 (citing *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010)). In addition to the foregoing factors, the Federal Circuit has explained that the patentee must also demonstrate that the alleged infringer "knew that the

combination for which its components were especially made was both patented and infringing." *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004) (quoting *Preemption Devices, Inc. v. Minn. Mining & Mfg., Co.*, 803 F.2d 1170, 1174 (Fed. Cir. 1986)).

B. The '325 Patent

1. General Arguments

Align's Position: Align says that Respondents assert they "cannot jointly infringe" and that their conduct cannot be "combined" for purposes of showing infringement. Align disagrees, saying that the Federal Circuit in *Akamai* identified the specific factual situation in this Investigation (*i.e.*, where CCUS has induced CCPK to perform part of its process (*see* Section IV.C.)) as an example of when its new inducement standard would apply (*Akamai*, 692 F.3d. at 1309) and that the joint performance of the claimed process provided the requisite "direct" infringement. Align continues that CCUS exercises complete control over CCPK.

Align says that Respondents have long known about Align's patents and processes and have attempted to structure their relationship to disguise CCPK's role (Citing CX-0166C; CX-0305C) and in an effort to avoid infringement liability. Align continues that this structure is not arms-length (and was called a "sham" (Citing Order No. 63 at 42 (December 31, 2012) in Inv. 337-TA-562), and neither CCPK (Citing CX-1162C.1 at 194:5-14, 207:1-11; CX-1162C.2 at 302:17-303:12; 387:21-388:8) nor CCUS (Citing CX-1160C.3 at 461:4-462:8.; CX-0916C at 18-46) have maintained corporate formalities.

Align asserts that since its creation, {

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Align disagrees with Respondents' argument that Align cannot rely upon CCPK's "foreign conduct to argue infringement." Align says that infringement can include situations where process steps are performed both inside and outside the U.S. by multiple parties. (Citing 35 U.S.C. § 271(g), 35 U.S.C. § 271(b); and 19 U.S.C. § 1337(a)(1)(B)(ii))

Align also disagrees with Respondents' assertion that 35 U.S.C. § 271(g) claims cannot be advanced in the ITC. Align says that the ITC has instructed that the term "infringe" includes "all forms of infringement," which would include § 271(g) claims. (Citing *Certain GPS Chips*, 2010 ITC LEXIS 582, at *81) Align continues that while it is true that the ITC has found that the defenses of § 271(g) do not apply in the context of a violation under 337(a)(1)(B)(ii), this does not mean that Align cannot rely on § 271(g) to show infringement. (Citing *Certain Sucralose*, INV. No. 337-TA-604, Comm'n Op., 2009 ITC LEXIS 727, at *44 (Apr.28, 2009)) Align argues that it is asserting § 271(g) in connection with a violation under § 337(a)(1)(B)(i), not §337(a)(1)(B)(ii). (Citing *Certain Recombinant Erythropoietin,* Inv. No. 337-TA-281, 1989 ITC LEXIS 56, at *9) Align continues that while the Commission found that the defenses for § 271(g) are limited by their implementation language to actions under Title 35, the language defining infringement in § 271(g) is not so limited.

Align additionally disagrees with Respondents' argument that "transmission of information" is not covered by § 271(g). Align says that this argument is inapplicable to a majority of Align's asserted claims, because Align is asserting direct infringement under § 271(g) by CCUS's offering to sell, selling, or using aligners in the U.S. – not digital data. Align continues that for Align's remaining claims where the accused product is a digital data set, this argument is legally unsupported.

Align says that Respondents cite *Bayer*, which held that the scope of the phrase "a product which is made by a process patented in the United States," as used in 35 U.S.C. § 271(g), does not cover "research data or information obtained from using the patented methods," as somehow being on point. Align continues that the research information in *Bayer* was effectively an answer to a question or inquiry (*e.g.,* whether a substance is X or Y) – not a product, and thus not comparable to products such as the digital data sets here.

Align contends that other courts have found that digital data similar to the digital data sets imported by Respondents is a "product" under § 271(g). (Citing *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp. 2d 985, 995 (N.D. Cal. 2007)) Align says that In *CNET*, the court found that an imported electronic catalogue is a "product" under § 271(g), and distinguished *Bayer* by explaining that:

> [u]nlike Bayer, where the patented process was not used in the actual manufacture of the drug, the patented process in this case is directly used to manufacture the catalog. In other words, while practicing each step of the research method in Bayer did not lead to the creation of a drug, practicing each step of the method in this case leads directly to the creation of a catalog.

(Citing i*d.* at 993) Align continues that the *CNET* court further noted that the creation of a product catalogue stored on computer readable media was no different from a product catalogue manufactured and assembled on paper bound with stitching, glue, or staples. (Citing *id.* at 994) Align contends that here, as in *CNET*, practicing each step of the asserted claims leads to the creation of the digital data sets. Align adds that like the electronic catalogue in *CNET*, the digital data is the digital version of a physical model. (Citing Tr. at 400:4-7; CX-0868C)

Align notes that the district court in Align's previous dispute with Ormco has already found that digital 3D models, similar to the digital data sets at issue here, are covered by § 271(g). (Citing *Ormco Corp. v. Align Tec. Inc.*, 8:03-cv-00016-CAS-AN, slip op. at 9 (C.D. Cal.

Aug. 3, 2009) ("Ormco III").) Align says that Respondents have ignored this holding notwithstanding that they often cite to the Ormco dispute.

Align says it is not clear that the defenses of § 271(g) would be available as a defense under § 337(a)(1)(B)(i). (Citing *Kinik Co. v. ITC*, 362 F.3d 1359, 1363 (Fed. Cir. 2004)) Align adds that even if the defenses of § 271(g) are available, they would be inapplicable to Align's infringement assertions. Align says that it is asserting direct infringement, under § 271(g), for example, by CCUS's sale, offer for sale, or use of aligners, and CCPK's sale, offer for sale, or importation of digital data sets. Align continues that in either case, the accused product has not been changed and has not become a trivial part of another product.

Align says that the intent of Congress when adopting the Process Patent Act Amendments Act of 1988, which enacted § 271(g), was to ***preserve*** the full extent of that jurisdiction. Align continues that 35 U.S.C. §§ 271(a), (b), and (c) are available in Commission actions, and Congress has not added specific language to 19 U.S.C. §1337 indicating that they may be so used. Align notes that 19 U.S.C. §1337(a)(1)(B)(i) simply uses the word "infringe" and there is nothing in the statutory language, the legislative history or any decision of the Commission or any court that would support a reading of that word to exclude any act of infringement as defined in § 271 of the Patent Act, including the acts defined under § 271(g).

Align says that a party may certainly infringe under § 271(g) where the process steps are performed both inside and outside the U.S. (Citing *Avery Dennison Corp. v. UCB Films PLC*, 1997 U.S. Dist. LEXIS 16535, at *6-8 (N.D. Ill. Oct. 17, 1997); *Zoltek Corp. v. United States*, 85 Fed. Cl. 409, 420 (Fed. Cl. 2009) (rev'd on other grounds by 672 F.3d 1309 (Fed. Cir 2012)) Align says that Respondents reliance on *Asahi Glass* is misplaced because the district court in that case merely declined to address § 271(g) where there was already a remedy under § 271(a).

(Citing *Asahi Glass Co. Ltd. v. Guardian Indus. Corp.*, 813 F. Supp. 2d 602, 613-14 (D. Del. 2011))

Align asserts that infringement under § 271(g) is not limited to "importation." Align says that one can also infringe under § 271(g) by offering to sell, selling, or using a product made by a process patented in the U.S. Align continues that infringement by these acts relates to the product as sold or used – not as it is imported. (Citing *Avery*, 1997 U.S. Dist. LEXIS 16535, at *7) Align continues that the court in *Avery* held that, where the first two steps of a three step process were performed outside the U.S. by the manufacturer and the third step was performed in the U.S. by the retailer, the entire three-step process could directly infringe under § 271(g), and that the manufacturer was a contributory infringer. (Citing *Id.* at *3-7)

Align asserts that *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1323 (Fed. Cir. 2005) is not on point because it is directed to e-mail messages. Align says that the more applicable analysis is that in *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp. 2d 985, 995 (N.D. Cal. 2007). Align avers that Respondents attempt to distinguish their products from the electronic catalog in *CNET* by claiming that the digital data set is mere "information, not a copy of a physical object." Align disagrees, saying that Respondents have admitted that the digital data set is "a virtual three-dimensional model of the patient's teeth," (Citing Tr. at 315:10-18, 170:18-24, 171:8-11; 171:25-172:6) and are used to fabricate appliances. (Citing Tr. at 168:24-169:2, 320:6-321:2)

Respondents' Position: Respondents assert that Mr. Beers combines the conduct of the Respondents to reach his conclusion that there is direct infringement. Respondents say that this is improper as a matter of law in the context of a claim for direct infringement. (Citing *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (permitting

combined conduct only for a claim of induced infringement)) Respondents continue that CCUS and CCPK cannot jointly infringe. Respondents say that Align has previously contended that CCPK improperly caused CCUS to infringe and now contends that CCUS caused CCPK to infringe. Respondents disagree, saying that the evidence presented at the hearing shows that CCUS and CCPK are two separate entities.

Respondents say that CCPK is not a subsidiary of CCUS. (Citing Tr. at 355:22-24) Respondents continue that CCUS has never owned any part of CCPK (Citing Tr. at 356:3-5) and there is no common ownership between the companies. (Citing Tr. at 356:9-11) Respondents say that they keep separate finances, have no common officers, directors or business departments, and do not have consolidated financial statements or tax returns. (Citing Tr. at 356:6-8, 356:12-24) Respondent say that CCUS did not cause the incorporation of CCPK and their daily operations are kept separate. (Citing Tr. at 358:1-3, 357:4-6)

{ } (Citing Tr. at 319:7-11) Respondents argue that this is no different than any contractor giving job specifications to a subcontractor. {

} (Citing Tr. at 359:2– 360:4)

Respondents argue that Align offered no evidence of the business formalities that have been ignored by Respondents. Respondents add that Mr. Rathore testified that CCPK is a Pakistani

corporation, and he has followed the instructions of his attorneys and CPAs to do whatever is required by the laws of Pakistan. (Citing Tr. at 446:5-15)

Respondents add that even if there were an overlap of ownership, the law is settled that absent a strong showing of one party exerting control over the other party or inducement, the conduct cannot be combined. (Citing *Akamai Tech., Inc.*, 692 F.3d at 1307-08) Respondents conclude that Align's claims of infringement should be denied for each theory based on joint infringement between CCUS and CCPK.

Respondents assert that the Federal Circuit has also held that "[u]nder section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device." (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005)) Respondents continue that the Federal Circuit held that "[w]e therefore hold that a process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country." (Citing *id.* at 1318) Respondents contend that the Federal Circuit has recognized the principle that "if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability . . . ." (Citing *id.* (citing *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 836 (2002))) Respondents conclude that there can be no infringement under 271(a) if any part of a step is performed outside of the U.S.

Respondents argue that even if 271(g) did apply in Section 337 investigations, it would not apply in a case of "divided infringement" where part of the process is performed in the U.S. Respondents say that in *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 813 F.Supp.2d 602, 613-14 (D. Del. 2011), a federal court declined to apply § 271(g) to domestically-manufactured goods since § 271(a) covers those uses by providing the patentee with a cause of action against the domestic suppliers who use the process in the U.S.. Respondents contend that the plain

language of § 271(g) also requires importation of "a product which is made by a process patented in the United States." Respondents assert that if a part of the process is done in the U.S. after importation, there would be no product made by a patented process at the time of importation under § 271(g). Respondents conclude that Align's arguments of infringement should be denied as to any patent claims that are practiced, at least in part, both in the United States and in Pakistan.

Respondents agree with the Staff that 35 U.S.C. § 271(g) is not available as a basis for infringement under Section 337 and adopt the arguments in the Staff's Brief. Respondents say that the Federal Circuit held in *Kinik Co. v. International Trade Commission*, 362 F.3d 1359 (Fed. Cir. 2004) that the defenses under 271(g) do not apply in Section 337 proceedings. Respondents contend that it logically follows that 271(g) cannot be used affirmatively as a basis for relief under Section 337.

Respondents assert that Align's claims under 35 U.S.C. § 271(g) also fail a matter of law because 271(g) does not apply to the transmission of information, such as computer files, digital data sets and treatment plans as alleged by Align. Respondents say that the Federal Circuit has held "[w]e conclude that infringement under 35 U.S.C. § 271(g) is limited to physical goods that were manufactured and does not include information generated by a patented process." (Citing *Bayer AG v. Housey Pharm., Inc.* 340 F.3d 1367, 1368 (Fed. Cir. 2003)) Respondents continue that The Federal Circuit has reaffirmed this ruling, holding that the "transmission of information" is not covered by § 271(g). (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1323 (Fed. Cir. 2005))

Respondents say that Align has suggested that the district court in *CNET Networks, Inc. v. Etilize, Inc.* 528 F.Supp.2d 985, 995 (N.D. Cal. 2007) overturned this long settled Federal

Circuit precedent. Respondents disagree, saying that the product in that case was an electronic copy of catalogs and the *CNET* Court found that there was no distinction between the electronic copy of the catalog and the physical catalog. Respondents contend that this holding stands in stark contrast to Align's allegations here. Respondents say that Align alleges that digital data, treatment plans, and computer files are generated as a result of its asserted claims. Respondents contend that data is information, not a copy of a physical object, and § 271(g) does not apply.

Respondents argue Align's claims under § 271(g) are precluded because there is a material change between the "product" alleged to be "imported" that supposedly contributes to infringement and the product ultimately sold, physical aligners. Respondents contend that while the Federal Circuit in *Kinik* held that the defenses of § 271(g) do not apply in Section 337 investigations, Respondents submit that if the substantive provisions of § 271(g) did apply, then the defenses would have to apply as well and would preclude a finding of infringement.

Respondents assert that Section 1337(a)(1)(B)(i) protects against only unfair acts involving "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that "infringe a valid and enforceable United States patent …" (Citing 19 U.S.C. § 1337(a)(1)(B)(i)) Respondents say that the Commission has explained that only infringement that occurs in the importation, sale after importation, or sale for importation can form the basis for a violation of Section 337. (Citing *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. at 10 (Dec. 21, 2011)) Respondents argue that the articles must infringe at the time of importation and a violation cannot be based on purely domestic activity like testing of an infringing product. (Citing *id.* at 14)

Respondents assert that Section 1337(a)(1)(B)(i) does not apply to Align's method claims, which are the vast majority of the asserted claims (other than the three claims of the '487 patent directed to "treatment plans"). Respondents say that to the extent that Align argues that CCUS is inducing conduct by CCPK, Section 337(a)(1)(B)(i) does not apply because Align is essentially arguing an unfair act in the exportation of information or computer files from the U.S. to Pakistan. Respondents say that this is not an unfair act in the importation of articles into the United States, and would be outside of the Commission's jurisdiction.

Respondents argue that for method claims, a complainant must prove infringement at the time of importation in order to demonstrate a violation of Section 337. (Citing *Electronic Devices* at 17) Respondents say that the Commission noted in *Electronic Devices* that "[m]erely importing a device that may be used to perform a patented method does not constitute direct infringement of a claim to that method." (Citing *Id.* at 12) Respondents conclude that there can be no violation of Section 337(a)(1)(B)(ii) if part of the patented process is performed in the United States. Respondents add that there can be no violation of Section 337(a)(1)(B)(ii) at the time of importation for the asserted method claims that are directed to fabricating orthodontic appliances. Respondents say that it is undisputed that those appliances are not fabricated until after the digital information prepared in Pakistan is received in the United States and no dental appliances have been made, and thus no allegedly infringing product exists, that has been "made, produced, processed, or mined under, or by means of" a process patent at the time of "importation."

Respondents assert that Align relies in substantial part upon CCPK's foreign conduct to argue infringement, which is contrary to well settled law. Respondents say that there is a strong presumption against the extraterritorial application of United States patent law. (Citing *Cardiac*

Pacemakers, Inc. v. St. Jude Medical, Inc., 576 F.3d 1348, 1365 (Fed. Cir. 2009)) Respondents continue that the Federal Circuit has been especially clear on this point as it pertains to the direct infringement of method claims. (Citing *NTB, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1313 (Fed. Cir. 2005)) Respondents add that the Federal Circuit has also held that "[u]nder section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device." (Citing *id.*) Respondent say that "if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability . . . ." (Citing *id.*)

Respondents say that to the extent Align attempts to argue infringement under the doctrine of equivalents, it has not met its burden, and any such claim should be precluded based on Align's failure to provide adequate disclosures and support for any contention under the doctrine of equivalents. Respondents incorporate by reference the arguments made in their Motion in Limine concerning doctrine of equivalents. Respondent say that I held that Align may not offer any particularized evidence, including testimony, regarding infringement under the doctrine of equivalents. (Citing Tr. 41:8-14; 42:7-14.) Respondents further contend that where Align fails to establish infringement of any claim element, the evidence is insufficient to show infringement of that claim element under the doctrine of equivalents.

Respondents assert that Align's expert witness on infringement, Andrew Beers, was accepted as an expert only in "3D computer software and graphics and their use in orthodontics as software, including clear aligners" and was not accepted as an expert in orthodontics or as any type of dental professional. (Citing Tr. at 512:1-11) Respondents say that his expert report was obviously written by Align's lawyers, and Mr. Beers signed it without even reading it carefully. (Citing Tr. at 516:7-9, 518:11-16, 519:4-10, 520:7-15, 520:16-24, 521:2-9, 521:10-19)

Respondents continue that Mr. Beers testified that he "can't really talking [sic] about infringement;" rather, he offered "an analysis of all the elements in the claim and a comparison to what the Respondents do." (Citing Tr. at 531:1-7) Respondents say that his witness statement is replete with his conclusions about infringement (Citing CX-1150C at Q. 170, 173, 175, 177, 184, 185, 187, 188, 195, 197, 199, 212, 214, 216, 227, 238, 240, 246, 248, 250, 254, 255, 257, 258, 260, 261, 268, 269, 271, 279, 281, 288, 290, 296, 301, 303, 308, 311, 314, 321, 323, 325, 327, 329, 331, 338) Respondents conclude that Mr. Beers should not be viewed as providing independent, credible proof on any issue on which Align bears the burden and since he was Align's only expert witness on infringement, Align has not met its burden of proof on any claim, and Respondents should not to be found to have infringed any claim at issue in this case.

Staff's Position: Staff says that Section 337(a)(1)(B)(i) prohibits "the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) *infringe* a valid and enforceable United States patent." (Citing 19 U.S.C. §1337(a)(1)(B)(i) (emphasis added)) Staff continues that the Commission has held that the word "infringe" in Section 337(a)(1)(B)(i) "derives its legal meaning from 35 U.S.C. § 271, the section of the Patent Act that defines patent infringement." (Citing *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software*, Inv. 337-TA-724, Comm'n Opinion at 13-14 (December 21, 2011) ("*Electronic Devices*")) Staff explains that Section 271 defines infringement "to include direct infringement (35 U.S.C. § 271(a)) and the two varieties of indirect infringement, active inducement of infringement and contributory infringement (35 U.S.C. § 271(b), (c))." (Citing *id.*) Staff adds that the term "articles that -- infringe" in Section 337(a)(1)(B)(i) references "the status of the articles at the time of importation." *Id.* Staff says that indirect infringement can be found,

at the time of importation, if the imported articles induce infringement or contributorily infringe based on a subsequent (*i.e.*, post-importation) direct infringement of a method claim. (Citing *Electronic Devices*, Inv. No. 337-TA-724, Comm'n Opinion at 18-19)

The Staff disagrees with the finding in Order No. 20, and Staff says that the Commission has made clear that, for purposes of Section 337(a)(1)(B)(i), the meaning of "infringe" derives from Section 271. (Citing *Electronic Devices*, Inv. 337-TA-724, Comm'n Opinion at 13-14) Staff continues that the Commission has also rejected attempts that seek to interpret the word "infringe" more broadly than the statutory meaning. (Citing *id.* at 17-19) Staff reasons that activity which does not constitute "infringement" (either direct or indirect) under Section 271 does not constitute infringement under Section 337(a)(1)(B)(i).

Staff argues that direct infringement of a method claim, for purposes of Section 337(a)(1)(B)(i), must occur pursuant to 35 U.S.C. § 271(a) and cannot be premised on 35 U.S.C. § 271(g). (Citing *Certain DC-DC Controllers and Products Containing the Same*, Inv. 337-TA-698, Comm'n Opinion at 13 (January 4, 2013) ("*DC-DC Controllers*")) Staff concludes that where the steps of a method are not all performed within the United States, no direct infringement exists.

Staff says that Section 271(a) is commonly understood as the "direct infringement" statute, and requires that each step of a claimed method be performed within the United States. (Citing 35 U.S.C. § 271(a); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2065 (2011); *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1309 (Fed. Cir. 2012) ("*Akamai*"); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("*NTP*"); *Electronic Devices*, Inv. 337-TA-724, Comm'n Opinion at 13. Staff continues that the Commission has acknowledged that section 271(a) applies to analysis of method claims in

Commission proceedings. (Citing *DC-DC Controllers, supra*; *Electronic Devices*, *supra*, at 17-18) Staff says that Section 271(g)'s status before the Commission was discussed in *Kinik Co. v. International Trade Commission*, 362 F.3d 1359 (Fed. Cir. 2004). Staff explains that in *Kinik*, the Federal Circuit affirmed the Commission's determination that the defenses to 35 U.S.C. §271(g), concerning the meaning of product "made by a patented process," do not apply in section 337(a)(1)(B)(ii) actions. (Citing 362 F.3d at 1363) Staff says that the Commission and the Federal Circuit noted that section 271(g)'s language expressly limited the application of these defenses "for purposes of this title" -- *i.e.*, to actions brought in district court pursuant to Title 35, not before the Commission pursuant to Title 19. (Citing *Certain Abrasive Products Made Using A Process For Powder Pre-Forms*, Inv. 337-TA-449, 2002 WL 31093607 at *2, Comm'n Opinion (July 26, 2002)("*Abrasive Products*"); *Kinik*, 362 F.3d at 1362) Staff continues that the Federal Circuit further acknowledged the legislative distinction between the different tribunals with regard to certain infringement issues. (Citing *Kinik*, 362 F.2d at 1363.)

Staff argues that *Kinik*'s holding regarding Section 271(g)'s defenses indicates that Section 271(g) infringement claims are also not cognizable as direct infringement before the Commission. Staff says that In light of *Kinik*, asserting 35 U.S.C. § 271(g) before the Commission would extend the word "infringe," as used in Section 337(a)(1)(B)(i), beyond the meaning of patent infringement under 35 U.S.C. § 271 by imposing one portion of section 271(g) without its concomitant limitations, and would therefore be improper.

Staff contends that Congress enacted 35 U.S.C. § 271(g)'s process patent provisions at the same time, and within the same act, as it incorporated the Commission's separate process patent authority into 19 U.S.C. 1337(a)(1)(B)(ii). (Citing *Abrasive Products*, Inv. 337-TA-449, 2002 WL 31093607 at *2, Comm'n Opinion) Staff argues that had Congress intended to

incorporate the process patent standards of 35 U.S.C. § 271(g) into the Commission's authority regarding process patents, it could have done so explicitly. (Citing *id.*) Staff concludes that the *Kinik* court indicated that the Commission assesses overseas violations of process patents pursuant to the pre-existing Tariff Act process patent provisions of 19 U.S.C. § 1337(a)(1)(B)(ii), and that the Section 271(g) exceptions do not apply to these (B)(ii) claims. (Citing *Amgen, Inc. v. International Trade Commission*, 565 F.3d 846, 851 (Fed. Cir. 2009))

Staff avers that it is not aware of any post-*Kinik* Commission opinions that have adopted an infringement theory based on 271(g). Rather, Staff says that in *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, the ALJ's Final Initial and Recommended Determination discussed the legal standards for infringement, referring in passing to 271(a) and 271(g). (Citing *Id.*, 2006 WL 1196473 at *48) Staff continues that in the opinion reviewing that decision, the Commission re-characterized the infringement determination as one that should be assessed pursuant to Section 337(a)(1)(B)(ii). (Citing *Rubber Antidegradants*, Inv. 337-TA-533, Comm'n Opinion at 2, 9 n.2 (July 24, 2006) ("We understand the term 'infringe' in this investigation as referring to a violation of section 337(a)(1)(B)(ii).")) Staff reasons that the Commission's correction provides an additional indication that, under current precedent, allegations concerning overseas violations of process patents should be brought pursuant to 19 U.S.C. § 1337(a)(1)(B)(ii), not through 35 U.S.C. § 271(g). Staff concludes, as a result, that a finding of "direct infringement" pursuant to Section 337(a)(1)(B)(i) -- specifically, direct infringement to support a finding of induced or contributory infringement -- must meet 35 U.S.C. § 271(a) standards for infringement.

Staff says that Section 337(a)(1)(B)(ii) prohibits "the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner,

importer, or consignee, of articles that are "made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable patent." (Citing 19 U.S.C. §1337(a)(1)(B)(ii)) Staff continues that the Commission has held that "infringement" can also be found pursuant to Section 337(a)(1)(B)(ii). (Citing *Rubber Antidegradants*, Comm'n Opinion at 2, 9 n.2)

Analysis and Conclusion: There are three key disputes between the parties that are relevant to all asserted patents. The first dispute is whether or not all steps of a method claim must be practiced in the same country to find a violation of Section 337. In Order No. 20, I found that they do not. Section 337 and Section 271 create separate causes of action in separate tribunals and use different language in creating those causes of action. Section 337 addresses unfair practices in import trade, and it provides, in pertinent part:

> (a) Unlawful activities; covered industries; definitions
>
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> ***
>
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—
>
> (i)infringe a valid and enforceable United States patent … or
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 C.F.R. §§ 1337(a)(1)(B)(i) and (ii). In contrast, Section 271 addresses acts within the United States and provides, in relevant part, that "[e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent

therefor, infringes the patent." 35 U.S.C. § 271(a); *see NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1313 (Fed. Cir. 2005)(noting that "[t]he territorial reach of section 271 is limited" and holding that "a process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country.").

The Federal Circuit acknowledged the distinctions between the two statutory provisions, when it stated that "[t]he purpose of section 337 from its inception was to provide relief to United States industry from unfair acts, including infringement of United States patents by goods manufactured abroad." *Lannom Mfg. Co., Inc. v. U.S.I.T.C.*, 799 F.2d 1572, 1580 (Fed. Cir. 1986).

The Commission, too, has recognized the distinctions between Sections 337 and 271. The Commission has explained that the word "infringe" in section 337 derives its legal meaning from 35 U.S.C. § 271. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011)("Certain Electronic Devices") The Commission made clear, however, that a violation of section 337 does not depend upon a violation of section 271, when it said:

> [W]e do not agree . . . that direct infringement must precede importation in order for the Commission's remedial orders to reach products, such as software, that contributorily infringe [Complainants][] patents.
>
> By its terms, section 337 is not limited to articles that directly infringe a valid and enforceable United States patent. As the ALJ noted, ***section 337 does not distinguish between direct, contributory, or induced infringement***, and the Commission has adopted the ALJ's finding that section 337 incorporates the indirect forms of infringement provided for in the patent statute.

Certain Hardware Logic Emulation Systems, Inv. No. 337-TA-383, Comm'n Op. (March 1998) (citations omitted)(emphasis added).

Staff cites *Certain DC-DC Controllers and Products Containing the Same*, Inv. 337-TA-698, Comm'n Opinion at 13 (January 4, 2013) ("*DC-DC Controllers*") to support its position that direct infringement of a method claim, for purposes of Section 337(a)(1)(B)(i), must occur pursuant to 35 U.S.C. § 271(a) and cannot be premised on 35 U.S.C. § 271(g). In the enforcement action related to a Consent Order issued previously in *DC-DC Controllers*, the Commission recited, "Direct infringement of a method claim can only be shown by performance of the patented method in the United States." (Citing *NTP v. RIM* and *Certain Electronic Devices,* *17)

NTP v. RIM is not controlling on this point. The Commission has made clear (and Staff concedes) that, while an act of direct infringement is a requirement to find contributory infringement, there is no requirement that the direct infringement occur prior to importation, and articles that contributorily infringe prior to importation may be the subject of Commission remedial orders. *Certain Hardware Logic Emulation Systems*, Inv. No. 337-TA-383, Comm'n Op. at 18-19 (March 1998). I reaffirm my finding that the parties' arguments regarding the territorial limitations found in *NTP v. RIM* to apply to 35 U.S.C. § 271 are irrelevant to whether or not Respondents violate 19 U.S.C. § 1337(a)(1)(B)(i) or (ii).

Electronic Devices, too, is not controlling. In that case it was argued that mere importation of an infringing device practiced a "method" covered by a patent. The Commission held that "the act of importation is not an act that practices the steps of the asserted method claim." The Commission went on to say that "[m]erely importing a device that may be used to perform a patented method does not constitute direct infringement of a claim to that method." *Electronic Devices*, at 17 (Citing, *inter alia*, *NTP v. RIM*) Nothing in *Electronic Devices* touches

on the specific facts of the case before me. Here, the scope of the investigation includes both 19 U.S.C. §§ 1337(a)(1)(B)(i) and (ii).

While I recognize that the word "infringe" in section 337 derives its legal meaning from 35 U.S.C. § 271, I do not concur with Staff that proof of a violation of direct infringement pursuant to 19 U.S.C. §§ 1337(a)(1)(B)(i) requires that all elements of 35 U.S.C. § 271(a) be met – including the requirement that the violation occur in the United States. In addition, I note that the case at bar is one that involves patents-in-suit that protect processes. Importation of articles that are made or produced pursuant to claimed processes are properly treated under 19 U.S.C. § 1337(a)(1)(B)(ii). Using Staff's logic regarding 35 U.S.C. § 271(a) consistently, one would reason that the latter claims would then refer back to 35 U.S.C. § 271(g).

I believe that Staff makes an incorrect logical leap when they argue that *Kinik*'s holding regarding Section 271(g)'s defenses indicates that Section 271(g) infringement claims are also not cognizable as direct infringement before the Commission. In fact, in *Kinik Company v. ITC,* 362 F.3d 1359 (Fed. Cir., 2004), the court noted at page 1361,

> The Commission held that the recently enacted defenses to infringement, when the issue is offshore practice of a patented process, do not apply to infringement actions before the International Trade Commission.

and at, page 1362,

> The Commission relied for its interpretation on the Process Patent Amendments Act of 1988, which states, in adding § 271(g) to Title 35, that "[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available ... under section 337 of the Tariff Act of 1930, or under any other provision of law." Pub. L. 100–418, § 9006(c). The Commission held that the new defenses under § 271(g) were not intended to be available in ITC actions, for to hold otherwise would deprive the patent owner of a remedy available under the Tariff Act. **The Commission pointed to the explicit statement that the existing scope of**

> **§ 337 actions would not be diminished**, and that § 271(g), in the clause introducing the new defenses to infringement by overseas practice, states that they are "for purposes of this title." Such clause would have been unnecessary unless it served to avert conflict between the Patent Act and the Tariff Act, for the contemporaneous record shows that such conflict was recognized. *See Duncan v. Walker,* 533 U.S. 167, 174, 121 S.Ct. 2120, 150 L.Ed.2d 251 (2001) (it is "a cardinal principle of statutory construction" that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant"). (emphasis added)

The court found,

> The purpose of § 271(g) was to authorize the district courts to adjudicate and impose liability for infringement based on the overseas practice of processes patented in the United States, upon importation of the products of those processes. **Previously, remedy was available only by exclusion action under the Tariff Act.**

(*Kinik,* at 1362)(emphasis added)

In upholding the Commission's ruling the court discussed this issue in detail, saying

> The Commission ruled that the enactment of § 271(g) preserved § 337(a) undiminished by the new defenses provided for § 271(g) actions in district court. To the extent that there is any uncertainty or ambiguity in the interpretation of § 337(a) and its successor § 1337(a)(1)(B)(ii), deference must be given to the view of the agency that is charged with its administration. *Chevron U.S.A., Inc. v. Natural Resources Defense Council,* 467 U.S. 837, 843, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). In *Amgen, Inc. v. United States Int'l Trade Comm'n,* 902 F.2d 1532, 1540 n. 13 (Fed.Cir.1990) **this court observed that no material changes were made in the text of § 1337(a)(1)(B)(ii) as reenacted in 1988, despite the concurrent enactment of § 271(g), reinforcing the intention to preserve the scope of former § 337a.** The *Amgen* court pointed out that § 271(g) expressly limited the new defenses to infringement "for purpose of this title." Although Kinik argues that it is anomalous to create a legislative distinction in the defenses available in different tribunals, before this enactment there was an even greater distinction, for overseas manufacture could not be reached at all in the district courts.

(*Kinik* at 1363)(emphasis added)

It is readily apparent from the foregoing discussion in *Kinik* that, contrary to Staff's argument, while the defenses of § 271(g) were found not to apply to exclusion cases before the Commission, that finding did not eliminate § 271(g) as a source to be used by the Commission in a manner similar to § 271(a).

Based upon all of the foregoing, I find that Respondents do not escape a violation of Section 337 as a matter of law merely because they practice some elements of the asserted method claims within the United States and other elements of the asserted method claims outside of the United States[31]. This is true for all patents-in-suit in this investigation.

The second dispute between the parties is based on Respondents' argument that the digital data sets cannot be found infringing because they are not "articles" within the scope of 19 U.S.C. § 1337. For the reasons discussed in Sections II.A and II.C, these arguments are unpersuasive.

The third general dispute between the parties is whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers. The essence of Respondents' argument is that because Mr. Beers (i) was accepted as an expert only in "3D computer software and graphics and their use in orthodontics as software, including clear aligners," (Tr. at 511:25-512:11) (ii) said that he "can't really talk[] about infringement," (Tr. at 531:1-7), and (iii) made

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[31] In *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1309 (Fed. Cir. 2012) ("*Akamai*") the Federal Circuit held that in indirect infringement cases, the underlying "direct infringement" doesn't require that a single entity practice all the steps of a claim; rather, all of the claimed steps must be performed. While not directly relevant to the question of whether or not claims must be practiced entirely within the same country, it does establish that CCUS and CCPK cannot escape responsibility by asserting that they only performed some of the elements while the other party performed other elements.

mistakes in his witness statement regarding where "festooning" occurs (Tr. at 518:11-16), Mr. Beers cannot be relied upon to show infringement. This argument is without merit.

Mr. Beers was accepted as an expert in 3D computer software and graphics and their use in orthodontics as software, including clear aligners. (Tr. at 511:25-512:11) His expertise falls within the scope of one of ordinary skill in the art found in Sections III.B.2, III.C.2, III.D.2, III.E.2, III.F.2, III.F.2, and III.G.2, *supra*. Mr. Beers' testimony that he "can't really talk[] about infringement" was taken out of context and does not warrant preventing Mr. Beers from providing testimony on infringement. Immediately after the statement cited by Respondents, Mr. Beers explained that "I can do exactly what I presented, which was an analysis of all the elements in the claim and a comparison to what the Respondents do." (Tr. at 531:4-7)

Regarding the mistakes made by Mr. Beers in his witness statement about where "festooning" occurs, the errors clearly were typographical in nature based on the context of the witness statement. In response to Question 193, Mr. Beers stated that "[a]lthough ClearCorrect USA festoons and provides four digital models to ClearCorrect USA at a time, eventually, ClearCorrect Pakistan will have produced and provided the entire treatment plan, from initial to final tooth arrangement, to ClearCorrect USA." (CX-1150C at Q. 193) Mr. Beers clearly did not intend to say that CCUS provided digital models to itself, and such a statement was clearly in error. Mr. Beers explained the errors during cross-examination. (Tr. at 518:11-16) Based upon all of the foregoing, Respondents' argument based on Mr. Beers qualifications is without merit.

2. Claim 1

Asserted claim 1 teaches:

> A method for facilitating a tooth repositioning dental treatment, including producing a plurality of digital sets representing a plurality of tooth arrangements, said method comprising:

providing an initial digital data set representing an initial tooth arrangement;

presenting a visual image based on the initial data set;

manipulating the visual image to reposition individual teeth in the visual image;

producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;

producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets.

(JX-0003 at R1:29-48)

Align's position: Align contends that the asserted claims of the '325 Patent are process claims with straightforward language. Align avers that Respondents' processes infringe these claims, as explained in full in the direct testimony of Align's expert, Andrew Beers (Citing CX-1150C at Q. 149-240), along with his detailed "claim chart" comparison of the claim language with Respondents' process (Citing CX-1198C at 99-188).

Align asserts that CCUS's aligners are made according to each of the claimed steps in claim 1 by the joint CCUS/CCPK process, and are sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align continues that CCUS's aligners directly infringe under 35 U.S.C. § 271(g).

Turning to the claims, Align says that the preamble of claim 1 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)) Align continues that Respondents have not asserted the

contrary in their Prehearing Brief, and have therefore waived such a position. Align concludes, as a result, that an infringement analysis of the preamble is unnecessary.

Alternatively, Align asserts that if the preamble is limiting, Respondents practice the preamble by their joint method of designing, making and selling clear aligners, where {

} (Citing CX-1150C at Q. 201) Align continues that Respondents provide these aligners to patients to "facilitate" dental treatment. Align says that {

} Align adds that these physical models are positive representations of the patient's tooth arrangements at each step, based on the digital models. (Citing CX-0875C (single printed physical mold))

Align says that {

} Align says that the aligners are meant to be worn for period of three weeks, 22 hours a day, in proper sequence. (Citing Tr. at 342:7-15; CX-0074A at 26, 28; CX-078 at 25.) Align continues that the tooth arrangement of each subsequent aligner, or the geometry of the aligner, changes slightly in order

to progressively reposition the teeth. (Citing CX-078 at 25) Align adds that CCUS ships paperwork with the aligners that describes the "treatment plan" prepared for the dentist that includes the four steps of the phase. (Citing CX-078 at 64-68; CX-0069 (an example of this paperwork from a sample case)) Align refers to this evidence regarding Respondents' process as evidence category 10.

Align asserts that CCUS practices the first element of claim 1, which requires "providing an initial digital data set …," {

}

Align says that {

} (Citing Tr. at 170:25-171:7, 315:19-23, 329:22-330:8; CX-1160C.3 at 472:3-13; CX-1164C.1 at 101:13-102:17; CX-1151C.1 at 211:22-214:13.) Align continues that {

} (Citing Tr. at 170:25-172:9, 206:21-207:3, 315:19-316:3, 329:22-330:8; CX-0090C at 3-4 ("Download the allocated case data . . ."); CX-1151C.1 at 212:1-11; CX-1160C.3 at 472:3-13) Next, Align says that {

} (Citing Tr. at 173:18-21, 178:23-179:3, 330:11-20, 474:11-21, 526:6-11; CX-0090C at 3-4; CX-1151C.1 at 198:12-199:9, 214:16-215:6; CX-1157C.1-3 at 48:13-49:15.)

Align contends that {

} Align avers that these models all represent a patient's initial tooth arrangement. (Citing Tr. at 219:24-220:5, 225:17-22; CX-0090C at 3-26; CX-1157C.1-3 at 47:25-62:22, 78:11-18) In the process, Align says that {

} (Citing Tr. at 171:25-172:6; CX-078 at 55; CX-0090C at 20-21 ("<Case#>-Before_Upper.Stl," "<Case#>-Before_Lower.Stl."); CX-1157C.1-3 at 78:11-18) Align continues that {

} (Citing Tr. at 172:10-14; CX-0090C at 20-26.)

Align says that next, {

} (Citing Tr. at 219:24-220:5, 257:3-8; CX-0092C) Align explains that the { } (Citing Tr. at 219:24-220:5, 225:17-22; CX-0110C at 2.) Align continues that {

} (Citing Tr. at 168:14-20, 316:12-22; CX-0110C at 2; CX-1160C.1 at 97:22-25; 98:15-99:12; CX-0110C at 2; CX-1151C.1 at 235:8-17)

Align says that next, {

} (Citing Tr. at 190:14-23, 191:4-7, CX-1157C.1-3 at 60:2-62:22). Align continues that {

}

Align avers that Respondents' protocols aim to produce "[d]igital files required to produce accurate thermoformable models which will result in aligners for patient cases from beginning to end of their clear aligner therapy treatment" (Citing CX-0110C at 2; Tr. at 180:18-181:3), and CCUS has verified the accuracy of the software used to create the 3D digital models of the patients' teeth, and therefore produce substantially accurate shapes of the teeth in their initial, intermediate and final positions. (Citing CX-0937C; Tr. at 247:14-248:5; see also CX-1164C.1 at 101:6-18) Align refers to this evidence regarding Respondents' process as evidence category 1.

Align asserts that CCUS alternatively practices this element when it {

} (Citing CX-1150C at Q. 204) Align asserts that CCPK also performs this element when it { } (Citing CX-1150C at Q. 204) Align continues that CCPK alternatively practices this element when it {

} (Citing CX-1150C at Q. 204.) Align avers that Respondents take no issue with Align's identification of CCUS's

infringing actions, but argue that there is no evidence that CCPK performs this limitation. Align says that Respondents did not contest infringement of this element in their interrogatory responses, and thus cannot argue non-infringement here.

Align asserts that CCPK practices the second element of claim 1, which requires "presenting a visual image …," when it {

} (Citing CX-1150C at Q. 205) Align says that {

} (Citing CX-0090C at 6-8; CX-078 at 55; CX-0104C; CX-0105C; Tr. at 179:4-13; CX-1157C.1- 3 at 49:2–50:17; CX- 1151C.1 at 198:12–199:9, 298:7–311:7; CDX-0012C; CDX-0013C) Align continues that {

} (Citing Tr. at 173:18-21; CX-0889C; CX-0104C; CX-0105C; CX-0106C; CX-0107C; CX-0090C at 31-55; CX-1157C.3 at 50:23-80:13) Align refers to this evidence regarding Respondents' process as evidence category 3. Align adds that Respondents do not contest they infringe this element. (Citing RX-0129C at Q. 47)

Align asserts that CCPK practices the third element of claim 1, which requires "manipulating the visual image…," after it {

}

(Citing CX-1150C at Q. 206) Align says that {

} (Citing Tr. at 329:22-333:9;

CX-0090C at 8-19; CX-0104C; CX-0105C; CX-0106C; CX-1157C.1-3 at 49:14-67:4; CDX-0014C; CDX-0015C)

Align says that {

} (Citing Tr. at 329:22-331:12; CX-0090C at 8-16; CX-1157C.1-3 at 49:2-54:9, 56:23-59:19.) Align continues that {

} (Citing Tr. at 311:3-10, 323:12-19; CX-1157C.1-3 at 50:15-52:2 {

} 52:15-54:9, 56:23-59:19, and 70:13-20; CX-0104C; CX-1158C.1-3 at 99:3-100:18; CX-0090C at 8-16; CX-0864C.) Align avers that boundaries are defined around each tooth, and may necessarily include gum material below the crown. (Citing CX-0865C; CX-0104 at 2:30-4:50; CX-1157C.1-3 at 52:15-54:9, 56:23-59:19) Align says that "tooth" is used in the asserted patents, and in Respondents' documents, as inclusive of the tooth and such additional materials. (Citing JX-0002 at 12:51-56; CX-0090C at 8, 14)

Align says that {

} (Citing Tr. at 190:20-191:7; CX-1157C.1-3 at 55:6-56:22, 60:20-62:3; CX-0104C at 11:30-12:35; CX-0090C at 9; CX-1158C.1-3 at 53:20-22) Align continues that {

} (Citing Tr. at 171:16-172:9, 191:1-14, 325:7-14; CX-0889C; CX-1157C.1-3 at 61:14-69:3; CX-0104C; CX-0105C) Align avers that to move the teeth, {

} (Citing CX-1157C.1-3 at 60:20-63:4, 63:15-69:3, 72:22-77:14; CX-1158C.1-3 at 100:19-101:21; CX-0105C; CX-0106C) Align refers to this evidence regarding Respondents' process as evidence category 4.

Align asserts that CCPK practices the fourth element of claim 1, which requires "producing a final digital data set …," by {

} (Citing CX-1150C at Q. 207) Align says that {

} (Citing Tr. at 171:16-172:9, 191:8-14, 325:7-14, 333:3-9; CX-0889C; CX-1157C.1-3 at 60:20-63:4, 63:15-69:3, 72:22-77:14; CX-1158C.1-3 at 53:23-25, 100:19-101:21; CX-0106C) Align says that {

} (Citing Tr. at 171:16-172:9, 191:8-14, 209:21-24, 210:5-20; CX-1157C.1-3 at 68:22-69:3; 73:2-77:14, 78:9-79:4; CX-0090C at 20-26 ("<Case#>-After_Upper.Stl" and "<Case#>-After_Lower.Stl")) Align continues that {

} (Citing Tr. at 172:10-14, 335:19-336:7; CX-0090C at 17-25; CX-1157C.1-3 at 48:14-68:21, 78:11-79:4) Align says that once the treatment setup is approved, {

} Align refers to this evidence regarding Respondents' process as evidence category 5.

Align contends that CCPK practices the fifth element of claim 1, which requires "producing a plurality of intermediate digital data sets …," when it {

} (Citing CX-1150C at Q. 208) Align says that {

} (Citing CX-0090C at 28-49; CX-1158C.1-3 at 54:1-83:18; CX-0107C; see CDX-0020C-21C) Align avers that the tooth arrangement in each "step" (i.e., the resulting intermediate tooth arrangement) represents an aligner step in the patient's treatment.

Align says that before stepping/staging can begin, the {

}

(Citing CX-0090C at 27-49; CX-1158C.1-3 at 51:4-83:21, 98:2-99:2) Align continues that the {

} (Citing Tr. at 325:21-326:9, 333:12-19, 334:2-9; CX-1158C.1-3 at 54:1-62:21; CX-0981; CX-0090C at 28-36; CX-0900C.) Align continues that {

}

(Citing CX-0086C at 1; CX-0090C at 28-29; CX-1158C.1-3 at 56:14-62:21) Align says that the

{

} (Citing CX-0090C at 28-29; see CX-0086C; CX-1158C.1-3 at 56:14-62:21.)

Align explains that the results of this calculation provide the minimum number of steps required to take the tooth from its initial to final position. (Citing CX-0090C at 28-29.)

Next, Align says that the {

} (Citing CX-0090C at 32; CX-0086C at 2; CX-0110C) Align continues that {

} (Citing CX-0086C at 1; CX-1158C.1-3 at 58:22-59:9, 62:16-63:2) Align says that {

} (Citing CX-0086C at 1)

Align contends that the {

} (Citing CX-1158C.1-3 at 67:2-86:14; CX-0107C) Align says that {

} (Citing CX-1158C.1-3 at 72:5-75:13; CX-0107C at 5:30-7:15) Align continues that the {

} (Citing CX-090C at 44; CX-0107C at 5:33) According to Align, at this point, {

} (Citing CX-0107C at 5:30-

7:15; see CX-0087C at 1; CX-1158C.1-3 at 62:25–72:18 (e.g. 70:5-71:4); CX-1151C.1 at 316:18–319:2)

Align says that {

}

(Citing CX-0107C at 5:30-7:15) Align continues that that {

} (Citing CX-0107C; CX-0087C at 1; CX-1158C.1-3 at 62:25–72:18; CX-0981; CX-1151C.1 at 198:12–199:9, 237:10–238:10, 259:4–260:4, 305:23–316:7.)

Align says that {

} (Citing CX-0087C at 1-2; CX-0107C; CX-1158C.1-3 at 68:21-70:4) According to Align, {

} (Citing CX-0087C at 1-2; CX-0107C; CX-1158C.1-3 at 69:16-70:4.)

Align contends that together {

} (Citing CX-0107C; CX-0090C at 44-47; CX-0087 at 1-2; CX-1158C.1-3 at 62:25–72:18; CX-1151C.1 at 198:12–199:9, 237:10–238:10, 259:4–260:4, 316:18–319:2) Align says that {

} (Citing CX-1158C.1-3 at 83:16-85:21; CX-1151C.1 at 262:12-263:13)

Align says that {

} (Citing Tr. at 193:3-16, 194:4-6, 477:3-14, 516:1-6; CX-1158C.1-3 at 70:21-71:1, 102:18-103:20; CX-0107C at 5:55-6:45) Align says that {

} (Citing Tr. at 316:12-22)

Align contends that {

} (Citing CX-1150C at Q. 134, 198, 280, 287, 313; CX-0090C at 44-47; CX-0107C; CX-0087C at 1-2; CX-1158C.1-3 at 71:11-72:18)

{

} Align refers to this evidence regarding Respondents' process as evidence category 7.

Align asserts that CCUS practices the sixth element of claim 1, which requires "fabricating a plurality of successive tooth repositioning appliances …," {

} Align refers to this evidence regarding Respondents' process as evidence category 9. Align continues that Respondents did not contest infringement of this element in their interrogatory responses and cannot argue non-infringement here.

Align disagrees with Respondents' "all data sets" non-infringement argument. Align says that Respondents assert they do not infringe claim 1[32] of the '325 patent because phrases such as "intermediate digital data sets" require that all data sets for a patient's treatment be "produced prior to active treatment." Align says that this construction was not identified in the SRJCCC. Align continues that Respondents cite to no supporting evidence for such a construction. Align contends that Respondents still infringe under this construction because

[32] Align says that Respondents also raise this argument for claims 11, 14, 31, 33, 35, and 38.

{

}

Align also contends that Respondents' "manipulating a visual image" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe claim 1[33] of the '325 patent because the phrase "manipulating a visual image" cannot include manipulation by entering coordinates. Align says that Respondents are wrong for three reasons. Align says that this is a claim construction argument not identified in the SRJCCC. Align continues that the intrinsic record shows the opposite of Respondents' position because the patent specifications describe an exemplary Graphical User Interface that provides a user with "instant and visual interaction with the digital model components," and is adapted for manipulating the image. (Citing JX-0003 at 13:64-14:11; CX-1150C at Q. 124-125). Align says that Dr. Mah admitted that by changing the coordinates of the teeth, the new visual image reflects those coordinates. (Citing RX-0129C at Q. 48) {

} (Citing CX-1157C.1 at 66:22-67:4; CX-1158C.1 at 100:25-101:21)

Align asserts that Respondents' "final tooth arrangement" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe claim 1[34] of the '325 patent

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[33] Align says that Respondents also raise this argument for claim 31.
[34] Align says that Respondents also raise this argument for claims , 11, 21, 31, 35, and 38.

because the phrase "final tooth arrangement" in the claims "can only be a projection at the treatment stage prior to active treatment." Align continues that Respondents appear to argue that the "final tooth arrangement" projected by Respondents' process is not really a "final tooth arrangement" because the clinician has the ability to change the course of treatment, and thus, a "final tooth arrangement" can only be the patient's actual tooth positions at the end of his treatment. Align contends that this construction was not identified in the SRJCCC and neither Respondents nor Dr. Mah cite to any supporting evidence. Align continues that the "final tooth arrangement" contemplated by the patents is simply the planned "final" position of the teeth, which is preferably according to a clinician's prescription. (Citing JX-0003 at 10:36-43; JX-0004 at 6:7-17; CX-1150C at Q. 347) Align says that Respondents' construction necessarily excludes preferred embodiments of the specification, and should be rejected. Align continues that planning a final position of teeth is exactly what Respondents' process does by manipulating the image into a final position according to the clinician's prescription and receiving approval. Align says that even in the event of a "mid-course corrections," or change to the course of treatment, Respondents must start the entire process over again to obtain a new "final" tooth arrangement. (Citing CX-1150C at Q. 137)

Align says that claim 1 of the '325 Patent specifies the production of a "final digital data set representing the final tooth arrangement" as part of its method. (Citing JX-0003 at 27 (1:38-40)) Align avers that the method creates the planned final tooth arrangement, which is confirmed by the specification of the '325 patent, which provides:

> after the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. In the preferred approach, individual teeth and other components will be "cut" to permit their individual repositioning or removal from the digital data. After thus "freeing" the components, the user will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them

> based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with the final arrangement, the ***final tooth arrangement*** is incorporated into a final digital data set (FDDS).

(Citing JX-0003 at 10:31-43 (emphasis added by Align)) Align reasons that it is therefore clearly the operator that is setting the "final tooth arrangement" as part of the process. Similarly, with respect to the "treatment plan" (*see* Sec. IV.F.5) produced by the method, the '325 patent teaches that:

> After the teeth and other components have been placed or removed so that the ***final tooth arrangement*** has been produced, it is necessary to generate a treatment plan, as illustrated in FIG. 6. The treatment plan will ultimately produce the series of INTDDS's and FDDS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial position to the final position over a series of successive steps.

JX-0003 at 12:30-38 (emphasis added). Align contends that this discusses a final tooth arrangement that is "produced" as part of the treatment plan – not one that is measured at the end of treatment.

Align asserts that Respondents' construction is contrary to the intrinsic record and excludes exemplary embodiments of the specification, and it should be rejected on that basis. (Citing *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)) Align says that Mr. Beers agrees that Respondents' construction is incorrect. (Citing CX-1150C at Q. 347) Align continues that Respondents' reference to Dr. Valley's comment that the "final tooth arrangement" "may not actually be the final location of the patient's teeth" is consistent with the intrinsic record. (Citing RIB at 31)

Align says that planning a final position of teeth is exactly what Respondents' process does by manipulating the image into a final position according to the clinician's prescription, which was confirmed by Dr. Arif. (Citing Tr. at 171:16-172:9; CX-0090C at 21) Align continues that {

} (Citing CX-1150C at Q. 137; CX-0090C at 26)

Align asserts that Respondents' "all aligners" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe claim 1[35] of the '325 patent because the phrase "plurality of successive tooth repositioning appliances" requires that "all" of the appliances or shells "be produced prior to active treatment." Align asserts that this is a claim construction argument not identified in the SRJCCC and neither Respondents nor Dr. Mah cite to any supporting evidence. Align says that Respondents fail to distinguish the claimed "appliances" from their "phase-based" approach because this phrase reads literally on either a single phase of four consecutive aligners (*e.g.*, "Phase 1") or a group of all the "phases" prepared by Respondents. (Citing CX-1150C) Align says that Respondents fail to explain why the claimed "appliances" do not read on their "phase-based" approach. Align continues that at least Respondents' "Phase 1" is fabricated prior to a patient's treatment and because there is no temporal requirement in the claims, it reads on Respondents' entire treatment system, regardless of the fact they are shipped in phases.

Align also contends that Respondents' "facilitating" non-infringement argument is incorrect. Align says that Respondents argue that they do not infringe claim 1[36] of the 325 patent because the phrase "method for facilitating a tooth repositioning dental treatment" in the claims "requires that a patient receive dental treatment," and they do not provide such "dental treatment." Align says that this construction was not identified in the SRJCCC and neither Respondents nor Dr. Mah (citing RX-0129C at Q. 45) cite to any supporting evidence. Align

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[35] Align says that Respondents also raise this argument for claims 11, 21, 34, 35, 38, and 39.
[36] Align says that Respondents also raise this argument for claims 11, and 31.

continues that all the preamble requires is "facilitating a tooth repositioning dental treatment" and providing aligners to a dentist facilitates treatment. (Citing CX-1150C at Q. 345) Align says that Respondents only "evidence" is extrinsic and is its own webinar book. (Citing CX-0084C). Align avers that this document was not identified in Respondents' PreHearing Brief, and is therefore improperly raised now. (Citing Ground Rule 8.2) Align contends that the document is irrelevant to claim construction because "facilitating" has an ordinary meaning that is not changed by the intrinsic record, and this meaning cannot be trumped by extrinsic evidence.

Align disagrees with Respondents' argument that CCUS's process is phase-based, meaning the Clinician does not determine all of the successive tooth arrangements that are required until after treatment has begun, based upon the patient's progress. Align avers that it appears Respondents are seeking to graft onto the claim a requirement that a "clinician" must determine the successive tooth arrangements and arguing that because a clinician might request changes be applied to phases occurring after phase 1, that the successive tooth arrangements originally determined by CCPK become somehow irrelevant. Align continues that Respondents' arguments regarding these elements were not identified in the PreHearing Brief and are therefore waived. (Citing Ground Rule 8.2) Align says that Respondents cite no supporting intrinsic evidence for any of their varying constructions and Respondents' effort to add a requirement that a clinician prepare the digital data sets is improper, for at least the reasons discussed with regard to their "treatment plan" argument.

Align says that {

} (Citing CX-1150C at Q. 130-136, 347, 352) Align explains that, in other words, while CCUS says it forms aligner sets only four at a time (a "phase"), {

}

Align asserts that even where a clinician alters the treatment plan after treatment has begun (which does not happen all the time), it must be done through a "mid-course correction," wherein the entire process begins again. (Citing CX-1150C at Q. 137) Align reasons that a "mid-course correction" includes preparing a new initial, a new final, and "stepping" the case all over again from the initial to the final. (Citing *id.*; Tr. at 205:21-206:15)

Respondents' Position: Respondents assert that the prevailing issue concerning the majority of the subject patent claims is the creation of computer files for the "intermediate" tooth arrangements. Respondents say that Align relies heavily upon {

}

Respondents contend that {