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whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

I find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 1 of the '666 patent. Claim 1 is complete without the preamble, and the preamble merely restates what is apparent from the final two elements of the claim itself—the claimed method is a method for generating a plurality of digital data sets that represent tooth positions progressing from the initial tooth position to the final tooth position. As a result, I find that the preamble of claim 1 is not limiting.

Assuming, *arguendo*, that the preamble of claim 1 is a limitation, I find that Respondents' process practices the preamble of claim 1. Employees of CCUS and CCPK admitted that {

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} The foregoing admissions of employees of Respondents, along with Respondents' own documents, show that the CCPK, in executing the "stepping" process, produces a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial (the scan of the stone model) to a final (the "treatment setup") arrangement.

Respondents argument that the preamble is not practiced because the claim language expressly requires the production of digital data sets representing a series of tooth arrangements progressing "from an initial arrangement to a final arrangement" while other asserted patent claims use the language "towards" a final arrangement" is not persuasive. As noted above, Mr. Arif admitted {

} (Tr. at 172:15-173:8, 190:20-191:25) Thus, it is clear that CCPK produces a complete set of digital data sets from the initial position to the final position before any appliances are worn by a patient.

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The admissions of employees of Respondents, along with Respondents' own documents, discussed above also show that CCPK meets the first and second elements of claim 1. Mr. Rathore admitted that CCPK has purchased computer workstations for creating digital data sets. (Tr. at 443:15-444:15) This shows that CCPK "provid[es] a computer system." Additionally, as noted above, CCUS documents further state that {

}

(CX-078 at 55; Tr. at 248:9-249:3) By importing the initial digital data sets into FreeForm Modeling software running on CCPK's computers, CCPK practices the second element of claim 1. Respondents do not contest that these elements are practiced.

I find that CCPK also practices the third element of claim 1. Respondents argue unpersuasively that they do not practice this element because the term "individual teeth" means a representation of a three-dimensional model that resembles an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. First, I find that Respondents have waived the right to offer a construction for the term "individual teeth." Respondents did not propose a construction for "individual teeth" in the Second Revised Joint Claim Construction Chart. (*See* SRJCCC) Also, Respondents cite no evidence that shows a clear intent to limit the meaning of this limitation as Respondents' propose. As a result, I reject this argument by Respondents.

Treating the substance of the assertion, the evidence introduced at the hearing shows that Respondents' process includes a step of "defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set."

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} the claim does not preclude including gum tissue within the “defin[ed] boundaries.” All that is required is “defining boundaries about” individual teeth. (JX-004 at 15:35-37) Based on the foregoing testimony and evidence introduced during the hearing, I find that CCPK meet this limitation.

I also find that CCPK practices the fourth element of claim 1. Respondents argue unpersuasively that they do not “mov[e] at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set,” as required by claim 1. {

} Based on this testimony, I find that Respondents’ process meets this limitation of claim 1.

I find that CCPK practices the fourth element of claim 1 when it conducts the “stepping” process. As noted above, {

} The foregoing admissions make clear that CCPK practices the fourth element of claim 1 when it completes the stepping process and creates data sets for all of the steps between the initial position and the final position. Respondents’ arguments based on the requirement that digital data sets representing a series of tooth arrangements progressing “from the initial tooth



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arrangement to the final tooth arrangement” be produced before any appliances are worn is not persuasive for the same reasons discussed above regarding the preamble of claim 1.

The fact that a “mid-course correction” may occur during treatment under Respondents’ process does not preclude a finding of infringement. Respondents admitted that a “mid-course correction,” under which changes are made to the treatment of a patient after treatment has begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if “mid-course corrections” resulted in a course of treatment being stopped, it would only apply to a subset of all cases handled by Respondents. Also, Respondents admitted that {

} (Tr. at 195:7-

196:4, 205:24-206:15, 224:14-21, 318:21-319:3) For any given patient for whom “mid-course corrections” are provided, there will necessarily be a final “mid-course correction” after which no additional “mid-course corrections” will take place in his treatment. After this final “mid-course correction,” Respondents will generate intermediate digital data sets between the new initial and new final tooth positions that will be used for all of the remaining treatment series.

The fact that a Clinician may “exercise[] professional judgment” in generating the intermediate digital data sets does not prevent the intermediate digital data sets from being “based on” the initial and final digital data sets. The admission and documents discussed above show that {

} An exercise of “professional judgment” does not change the fact that the intermediate digital data sets are based on the initial and final digital data sets. Based upon all of the foregoing, I find that CCPK directly infringes claim 1 when it creates intermediate digital data sets in Pakistan using Respondents’ process.

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### 2. Claim 3

Claim 3 teaches:

A method as in claim 1, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

(JX-004 at 15:52-55)

**Align's Position:** Align argues that CCPK practices claim 3 when generating the successive, intermediate tooth arrangements {

} Align continues that

Respondents argue that they do not infringe because: (i) a phase-based system does not produce the requisite “successive digital data sets;” and (ii) {

} (Citing RPHB at 160, 169-70). Align says that regarding (i), this appears to be Respondents’ “all data sets” argument, and is incorrect for the reasons discussed above. Align continues that regarding (ii), neither Respondents nor Dr. Mah provide any particular evidence to support their argument. Align says that {

}

Align concludes that Respondents infringe and violate Section 337 for the same reasons as claim 1.

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**Respondents' Position:** Respondents argue that they do not infringe claim 3 because they do not infringe the independent claim. Respondents add that {

} (Citing Tr. 336:8 to 338:17) Respondents conclude, as a result, that Respondents do not meet this limitation. (Citing RX-0129C at Q. 108)

Respondents contend that claim 3 requires the interpolation between the initial and final digital data sets. Respondents say that the only evidence Align cites concerning this element is the CCPK operators' use of the "Generate Steps" function of the FreeForm software.

Respondents say that Align's post hearing brief makes significant misstatements concerning the operation and use of the "Generate Steps" software feature. Respondents continue that the interpolation does not actually occur as Align suggests; rather the evidence shows {

} Respondents conclude that Align bases its infringement arguments on its misstatements about the way CCPK operators use the "Generate Steps" function and has therefore failed to meet its burden of proof.

**Staff's position:** Staff addresses claims 1 and 3 together, as reflected in Staff's Position regarding claim 1.

**Analysis and Conclusions:** : If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 3, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

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Nevertheless, I have found that Respondents infringe asserted claim 1. I also find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 3 of the '666 patent. Respondents argue unpersuasively that because Respondents' technicians use independent judgment in the staging process, they do not "determin[e] positional differences between the initial data set and the final data set and interpolat[e] said differences," as required by claim 3 of the '666 patent. Respondents essentially contend that the word "interpolating" forecloses any human intervention. Respondents cite no support for this position, and did not propose a construction for "interpolating" in the SRJCCC. As a result, Respondents waived any claim construction arguments on this claim term.

{

} Respondents' argument that they do not perform "interpolation" also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6) Based upon all of the foregoing, I find that Respondents' process includes a step of interpolating the differences between the two tooth positions. Because claim 3 is a "comprising" or open-ended claim, the mere fact that another step is completed after interpolation does not defeat a finding of infringement. Rather, the Federal Circuit has explained that "[t]he transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003). As a

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result, I find that Align has shown by a preponderance of the evidence that CCPK practices dependent claim 3 of the '666 patent. Based upon all of the foregoing, I find that CCPK directly infringes claim 3 when it creates intermediate digital data sets in Pakistan using Respondents' process.

### 3. Claim 7

Claim 7 teaches:

A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:

providing a computer system;

providing to the computer system digital data set representing an initial tooth arrangement;

providing to the computer system a digital data set representing a final tooth arrangement;

interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:64-16:13)

**Align's Position:** Align asserts that the preamble of claim 7 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes*, 182 F.3d at 1305) Align says that Respondents have waived any contrary position in their Prehearing Brief and an infringement analysis of the preamble is unnecessary.

Alternatively, Align argues that if the preamble were limiting, CCPK practices the preamble by producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement. (Citing Evidence Categories 1,

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2, 5, 7; CX-1150C at Q. 273) Align says that Respondents assert their “all data sets” and “final tooth arrangement” arguments as non-infringement bases, which are incorrect as discussed above regarding claim 1.

Align argues that Respondents practice the first element of claim 7 because it is identical to the first element of claim 1, and is practiced by CCPK as discussed in Sec. IX.B.1.b. See Sec. I.E.2; CX-1150C at Q. 284. The second element (“providing to the computer ...”) is similar to the second element of claim 1, and is practiced by CCPK as discussed regarding claim 1.

(Citing Evidence Categories 1 and 2; CX-1150C at Q. 285) Align says that Respondents do not dispute that they practice these elements. (Citing RPHB at 161, 170; RX-0129C at Q. 110)

Align asserts that CCPK practices the third element (“providing to the computer system a digital data set representing a final tooth arrangement”), using FreeForm, by providing the predetermined final tooth arrangement to the Generate Steps function. (Citing Evidence Categories 5 and 7; CX-1150C at Q. 286) Align says that {

} (Citing

Evidence Categories 5, 9 and 10; CX-1150C at Q. 286) Align says that Respondents argue that they do not infringe because “‘provide’ does not mean ‘generate’,” but provide no further explanation. (Citing RPHB at 161, 171)

Align contends that CCPK practices the fourth element (“interpolating positional differences...”) by {

} (Citing Evidence Category 7; CX-1150C at Q. 287) Align says that

Respondents admit that {

} (Citing Tr. at 676:23-

677:5)

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Align says that Respondents argue that they do not infringe because: (i) a phase-based system does not produce the requisite “successive digital data sets;” and (ii) the operators’ “use of their individual judgment to adjust the teeth locations to avoid collisions means that the ‘positional differences ...’ are not interpolated.” Align says that regarding (i), this appears to be Respondents’ “all data sets” argument, and is incorrect for the reasons identified above regarding claim 1. Align says that regarding (ii), neither Respondents nor Dr. Mah provide any particular evidence to support their argument. Rather, Align says that the “individual judgment” cited by Respondents is applied by operators before they use FreeForm when preparing the DPS. Align continues that even if this after-occurring modification does occur, it does not change the fact that interpolation is performed by Freeform according to Respondents’ process, and that interpolation falls within the scope of this claim.

Align concludes that because CCPK imports, offers to sell, or sells digital data sets in the U.S. that are made according to each of claimed steps by the joint CCUS/CCPK process, CCPK directly infringes under 35 U.S.C. § 271(g). Align continues that Respondents’ importation is also a violation of 19 U.S.C. § 1337(a)(1)(B)(ii). Alternatively, Align says that CCUS uses those digital data sets in the U.S., and therefore also directly infringes under 35 U.S.C. § 271(g).

Align says that Respondents advance yet another new claim construction that “provide” does not mean “create” or “generate” and that CCPK’s creation of a final tooth arrangement is not “providing” the arrangement. Align disagrees, saying that Respondents misrepresent Align’s argument. Align says that it asserts CCPK practices the third element by providing the final tooth arrangement to the “Generate Steps” function in FreeForm. (Citing CX-1150C at Q. 286) Align avers that this is different from producing the final tooth arrangement using FreeForm.

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Align says that Respondents do not address the action identified by Align, and therefore have no defense to it.

**Respondents' Position:** Respondents argue that because claim elements of claim 7 are performed by both CCUS in the United States and CCPK in Pakistan, claim 7 of the '666 patent, a method claim, is not infringed.

Respondents contend that based on the context of the patent and the related prosecution history, one skilled in the art would understand the preamble would require that all of the "plurality" of "discrete tooth arrangements" "progress" from the "initial" tooth arrangement to the "final" tooth arrangement as projected and be produced prior to active treatment.

Respondents say that CCUS's process is phase-based. (Citing Tr. at 416:8-17) Respondents continue that this means that the clinician does not determine the successive tooth arrangements that are required until after the initial appliances have been fabricated and after treatment has begun. (Citing Tr. at 328:1-329:10; 416:8-17) Respondents say that the clinician makes this determination based upon an evaluation of the patient's progress and the Clinician's prescription. (Citing Tr. at 328:1-329:10; 416:8-17) Respondents conclude, as a result, that CCUS's phase-based process does not meet this limitation. (Citing RX-0129C at Q. 109)

Respondents argue that neither CCUS nor CCPK "provide" a digital data set representing a final tooth arrangement to a computer system, as required by the second element of claim 7. Respondents say that the evidence demonstrates that CCPK operators create a digital model of the patient's teeth as they would be arranged in accordance with the doctor's prescription. (Citing Tr. 329:11 to 341:21) Respondents assert that this is not "providing" the data set to a computer, it is using the computer to "create" or "generate" such a data set. Respondents



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continue that one skilled in the art would understand “provide” does not mean “generate” and this limitation is not met by the Respondents.

Respondents say that the operators’ use of their individual judgment to adjust the teeth locations to avoid collisions means that the “positional differences between the initial data set and the final data set” are not interpolated, as required by the fourth element of claim 7. Respondents conclude, as a result, that they do not meet the fourth limitation. (Citing RX-0129C at Q. 112)

Respondents contend that the plain meaning of the fourth element of claim 7 requires all of the tooth arrangements progressing from the “initial tooth arrangement” to the “final tooth arrangement” to be produced as a series. Respondents say that CCUS’s phase-based process does not meet this limitation. (Citing Tr. at 416:8-17; RX-0129C at Q. 113)

Respondents argue that claim 7, contains elements requiring digital data sets progressing from the initial to final positions and interpolation to create the data sets. Respondents say that Align failed to establish these elements for the same reasons described above regarding claims 1 and 3: (1) the method of creating digital data sets required by the claim does not correspond to the evidence of the Respondents’ phase-based system and (2) Align’s arguments about interpolation does not match the actual evidence about the way CCPK operators use the “Generate Steps” function of the software.

**Staff’s position:** Staff addresses claims 1, 3, and 7 together, as reflected in Staff’s Position regarding claim 1.

**Analysis and Conclusions:** I find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 7 of the ‘666 patent. The preamble of claim 7 is identical to the preamble of claim 1. Like Claim 1, claim 7 is complete without the preamble,

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and the preamble merely restates what is apparent from the final two elements of the claim itself—the claimed method is a method for generating a plurality of digital data sets that represent tooth positions progressing from the initial tooth position to the final tooth position. As a result, I find that the preamble of claim 7 is not limiting.

Assuming, *arguendo*, that the preamble of claim 7 is a limitation, based on the evidence discussed in Section V.F.1, *supra*, regarding the identical preamble of claim 1, which I incorporate and reaffirm here, I find that the preamble of claim 7 is practiced by CCPK.

The first and second elements of claim 7 are identical to the first and second elements of claim 1. Based on the evidence discussed regarding claim 1 in Section V.F.1, *supra*, which I incorporate and reaffirm here, I find that the first and second elements of claim 7 are practiced by CCPK.

The third element of claim 7 is practiced by CCPK when {  
} Respondents' arguments on this element are not persuasive. As noted above, {

} practice the third element of claim 7.

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I find that CCPK practices the fourth element of claim 7 when it conducts the “stepping” process. As noted above, {

} (CX-107C at 5:33) Respondents’ argument that they do not perform “interpolation” also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6) The foregoing admissions make clear that CCPK practices the fourth element of claim 1 when it completes the stepping process and creates data sets for all of the steps between the initial position and the final position. Respondents’ arguments based on the requirement that digital data sets representing a series of tooth arrangements progressing “from the initial tooth arrangement to the final tooth arrangement” be produced before any appliances are worn is not persuasive for the same reasons discussed above regarding the preamble of claim 1.

The fact that a “mid-course correction” may occur during treatment under Respondents’ process does not preclude a finding of infringement. Respondents admitted that a “mid-course correction,” under which changes are made to the treatment of a patient after treatment has begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if “mid-course corrections” resulted in a course of treatment being stopped, it would only apply

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to a subset of all cases handled by Respondents. Also, Respondents admitted that when a “mid-course correction” does take place, the entire accused process {

} (Tr. at 195:7-

196:4, 205:24-206:15, 224:14-21, 318:21-319:3) For any given patient for whom “mid-course corrections” are provided, there will necessarily be a final “mid-course correction” after which no additional “mid-course corrections” will take place in his treatment. After this final “mid-course correction,” Respondents will {

}

The fact that a Clinician may “exercise[] professional judgment” in generating the intermediate digital data sets does not prevent the intermediate digital data sets from being “based on” the initial and final digital data sets. The admission and documents discussed above show that the FreeForm software uses the initial digital data set and the final digital data set, or “treatment setup,” in generating the intermediate digital data sets. An exercise of “professional judgment” does not change the fact that the intermediate digital data sets are based on the initial and final digital data sets. Based upon all of the foregoing, I find that CCPK directly infringes claim 7 when it creates intermediate digital data sets in Pakistan using Respondents’ process.

### 4. Claim 9

Claim 9 teaches:

A method as in claim 7, wherein the step of providing a digital data set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth on a visual image provided by the computer system;

and moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-004 at 16:18-27)

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**Align's Position:** Align argues that CCPK practices the first element of claim 9 by using FreeForm to section up the 3D digital scan into individual tooth objects. (Citing Evidence Categories 3 and 4; CX-1150C at Q. 289) Align says that Respondents assert only their "individual teeth" argument as a non-infringement basis (Citing RPHB at 163, 172), which is incorrect for the reasons discussed regarding claim 1.

Align contends that CCPK practices the second element of claim 9 by {  
} (Citing Evidence Categories 3 and 4; CX-1150C at Q. 289) Align says that Respondents have not disputed that they practice this element in their Prehearing Brief. (Citing RPHB at 163, 172) Align concludes that Respondents infringe and violate Section 337 for the same reasons as claim 7.

**Respondents' Position:** Respondents argue that they do not infringe dependent claim 9 because they, as stated above, do not infringe the independent claim. Respondents say that CCUS's process does not define boundaries about "individual teeth" or move tooth boundaries "relative to the other teeth," and, accordingly, this limitation is not met by the Respondents.

Respondents contend that claim 9 contains elements requiring "defining boundaries" around teeth and moving those "tooth boundaries." Respondents say that Align's post hearing brief makes significant misstatements and assertions that CCPK operators "manipulate visual images" or "define boundaries" around individual teeth. Respondents continue that other things, CCPK operators do not "define boundaries" around individual teeth and, instead, identify subsets of data that include soft tissue (gums), a tooth crown, and portions of adjacent tooth crowns. Respondents assert that because Align bases its infringement arguments on misstatements

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concerning the CCPK operators' actual conduct, it has failed to meet its burden of proof on the dependent claim's associated elements.

**Staff's position:** Staff addresses claims 1, 3, 7, and 9 together, as reflected in Staff's Position regarding claim 1.

**Analysis and Conclusions:** If I had found that Align had failed to prove that Respondents infringe claim 7, it would follow that Align failed to prove infringement of claim 9, which depends from claim 7. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 7. I also find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 9 of the '666 patent.

Respondents argue unpersuasively that they do not practice the first element of claim 9 because the term "individual teeth" means a representation of a three-dimensional model that resembles an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. First, I find that Respondents have waived the right to offer a construction for the term "individual teeth." Respondents did not propose a construction for "individual teeth" in the Second Revised Joint Claim Construction Chart. (*See* SRJCCC) Respondents cite no evidence that shows a clear intent to limit the meaning of this limitation as Respondents' propose. As a result, I reject this argument by Respondents.

Treating the substance of the assertion, the evidence introduced at the hearing shows that Respondents' process includes a step of "defining boundaries about at least some of the individual teeth on a visual image provided by the computer system." Mr. Jarrett Pumphrey

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admitted that {

} Although the cut up sections depicted in CX-0889C include portions of gum tissue, the claim does not preclude including gum tissue within the “defin[ed] boundaries.” All that is required is “defining boundaries about” individual teeth. (JX-004 at 15:35-37) Based on the foregoing testimony and evidence introduced during the hearing, I find that CCPK meet this limitation.

I also find that CCPK practices the second element of claim 9. Respondents argue unpersuasively that they do not “mov[e] at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set,” as required by claim 9. Mr. Jarrett Pumphrey admitted that {

} (Tr. at 332:20-333:9; CX-0889C) Based on this testimony, I find that Respondents’ process meets this limitation of claim 9. Based upon all of the foregoing, I find that CCPK directly infringes claim 9 when it creates intermediate digital data sets in Pakistan using Respondents’ process.

**5. Violation of Section 1337(a)**

**Align’s Position:** Align asserts that Respondents violate 337(a)(1)(B)(ii) by importing, selling for importation, or selling after importation the digital data sets made according to claims 1, 3, 7 and 9 of the ‘666 Patent. Alternatively, Align contends that CCPK violates 337(a)(1)(B)(i) by directly infringing claims 1, 3, 7 and 9 of the ‘666 Patent under 35 U.S.C. §

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271(g) by importing, offering to sell, or selling digital data sets made by Respondents' process. Align adds that because CCUS uses those same digital data sets, CCUS therefore also violates 337(a)(1)(B)(i) for similar reasons.

**Staff's position:** Staff argues that when applying my rulings regarding patent infringement under Section 337, the evidence demonstrates that CCPK directly infringes each of the Asserted Claims of the '666 patent under 35 U.S.C. § 271(g) by selling digital data sets. Staff continues that when applying the Staff's understanding of the legal standards of patent infringement, the evidence shows that CCUS and CCPK directly infringes each of the Asserted Claims under 19 U.S.C. § 1337(A)(1)(B)(ii) by importing the digital data sets that are produced by the claimed methods. Staff concludes that the evidence shows that CCUS and CCPK violate 19 U.S.C. § 1337(A)(1)(B) by importing digital data sets.

**Analysis and Conclusions:** 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[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: . . . (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." By importing digital data sets (as found in Section II.C, *supra*) that are made by CCPK, which practices the entire process of claims 1, 3, 7, and 9 in Pakistan to produce the digital data sets (as found in Section V.F.1-4, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

### G. The '863 Patent

#### 1. Claim 1

Claim 1 recites:

A method for producing digital models of dental positioning appliances,  
said method comprising:



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providing a digital model of a patient's dentition;

producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;

providing a digital model of at least one attachment device; and

positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

(JX-005 at R1:55-67)

**Align's Position:** Align asserts that the preamble of asserted 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 found to be limiting, one of ordinary skill in the art would interpret the preamble to refer to the digital models discussed in the patent, which are of a patient's dentition used to fabricate the aligner, and not the actual aligner. Align notes that the second element of claim 1 specifically refers to "models of the dentition." Align contends that one of skill would not, as Respondents allege, read the claim as being limited to digital models of "appliances." Align argues that CCPK practices the preamble by producing a plurality of digital models representing a plurality of tooth arrangements using FreeForm, which are used by CCUS to fabricate appliances. (Citing CIB at Sec. I.E.1 and 7-10; CX-1150C at Q. 292)

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Regarding the first element of claim 1, Align contends that CCPK practices this element

{

} (Citing CIB at Sec. I.E.1 and 9; CX-1150C at Q. 293)

Align says that Respondents do not contest Align's identification of CCPK's infringing actions.

(Citing RPHB at 187)

Align refers to Evidence Category No. 1 – "Initial Digital Data Set." In that evidence category, Align says that {

}

{



} (Citing CX-937C; Tr. at 247:14-248:5; CX-

1164C.1 at 101:6-18)

Align also refers to Evidence Category No. 9 – “Transfer of Digital Data Sets.” In that evidence category, Align avers that {

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} (Citing CX-090C at 28-49; CX-

1158C.1-3 at 54:1-83:18; CX-107C; CDX-020C-21C) Align avers that the tooth arrangement in

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each “step” (*i.e.*, the resulting intermediate tooth arrangement) represents an aligner step in the patient’s treatment. More specifically, Align says that each step contains an intermediate digital data set which will be used by CCUS to make an aligner.

Align describes the process of {

}

{

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Align contends that {

}

{





} (Citing CX-

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1150C at Q. 134, 198, 280, 287, 313; CX-090C at 44-47; CX-107C; CX-087C at 1-2; CX-1158C.1-3 at 71:11-72:18)

{

} (Citing CX-1158C.1-3 at 71:11-72:18)

With respect to the second element of claim 1, Align disagrees with Respondents' "final tooth arrangement" non-infringement argument. (Citing RPHB at 187) Align says that Respondents assert they do not infringe the claims of the '863 patent because the phrase "final tooth arrangement" in the claims "can only be a projection at the treatment stage prior to active treatment." (Citing RPHBB at 16) Align asserts 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.

First, Align argues that Respondents' construction was not identified in the SRJCCC. Second, Align asserts that neither Respondents nor Dr. Mah cite to any supporting evidence. Third, 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-003 at 10:36-43; JX-004 at 6:7-17; CX-1150C at Q. 347) Align submits 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 – it manipulates the image into a final position according to the clinician's prescription and receives approval. Align argues that, even in the event of a "mid-course

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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)

With respect to the second element of claim 1, Align disagrees with Respondents “all data sets” non-infringement argument. Align says that Respondents assert they do not infringe the claims of the ‘863 patent because phrases such as “modified digital models” and “models” require that *all* data sets for a patient’s treatment be “produced prior to active treatment.” (Citing RPHB at 16, 110-11, 119-20, 159, 189-90) First, Align asserts that this construction was not identified in the SRJCCC. Second, Align says Respondents cite to no supporting evidence. Third, Align argues that Respondents still infringe under this construction, because CCPK completes the stepping or staging for all stages prior to CCUS making the first set of appliances for active treatment (“phase 1”). (Citing CX-1150C at Q. 130-136, 347, 352) Align contends that, while CCUS says it forms aligner sets only four at a time (a “phase”), CCPK prepares all of the tooth arrangements for all aligners in all phases before treatment begins.

Regarding the third and fourth elements of claim 1, Align argues that CCPK practices these elements when {

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}

Align argues that, when used, the aligner must be designed with a corresponding receptacle for the attachment device. Align says that, to do this, {

} (Citing CX-413C at 1-2; CX-1160C.1 at 93:12-15) Align says that Respondents do not contest Align's identification of CCPK's infringing actions. (Citing RPHB at 188; RX-129C at Q. 65)

In its reply brief, Align says that in their PreHearing Brief, Respondents asserted they do not infringe claims of the '863 patent because phrases such as "modified digital models" and "models" require that *all* data sets for a patient's treatment be "produced prior to active treatment." (Citing RPHB at 26, 93, 120) Align avers that Respondents present a new argument in their PostHearing Brief that:

ClearCorrect'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. (Citing Tr. at 416:8-17) ClearCorrect's phase-based system does not meet this limitation.

(Citing RIB at 22; 25, 37, 93, 120, 125, 139) Align asserts that, while Respondents provide no further explanation for why their "phase-based system does not meet this limitation," it appears

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that they are: (i) seeking to graft onto the claim a requirement that a “clinician”<sup>53</sup> must determine the successive tooth arrangements; and (ii) 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 argues that all of Respondents’ arguments are meritless. First, Align says that neither the construction advanced in the PreHearing Brief nor that advanced in the PostHearing Brief was identified in the SRJCCC. Align maintains that both arguments are therefore improper. (Citing Tr. at 8:4-9:4) Align notes that the construction advanced in their PreHearing Brief has already been excluded on this basis. (Citing RX-0129C at Q. 50) Second, Align submits that positions advanced in the PostHearing Brief regarding these elements were not identified in the PreHearing Brief, and are therefore waived. (Citing G.R. 8.2) Third, Align asserts that Respondents cite to no supporting intrinsic evidence for any of their varying constructions.

Align continues that, even if either of Respondents’ arguments (i.e., the PreHearing Brief or PostHearing Brief arguments) is accepted, Respondents’ process would still infringe. Align argues that {

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<sup>53</sup> Align objects to Respondents reliance on factual statements unsupported by evidentiary citations, and that were specifically excluded from Dr. Mah’s statement pursuant to Align’s *Motion in Limine* No. 3, for example which state that a “Clinician does not determine all of the successive tooth arrangements that are required until after treatment has begun, based upon the patient’s progress,” and that “[t]he Clinician makes this determination based upon based upon an evaluation of the patient’s progress and the Clinician’s prescription.” (Citing *Compare RIB* at 22, 25, 26, 28, 31, 35, 37, 93, 113, 120, 125, and 139 with e.g. RX-129C at Q. 50 (excluded portion))

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} (Citing CIB at 12-16) Align argues that it does not matter if subsequent phases are later changed – CCPK has already performed the step of determining the intermediate tooth arrangements.

Align also 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 contends 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 argue that neither CCUS nor CCPK infringes claim 1 of the ‘863 patent. First, Respondents say that Align contends the first element and part of the second element are practiced by CCUS in the United States. (Citing Tr. at 559:9-560:19; CX-1150C at Q. 294) Respondents say Align contends that part of the second element and the third and fourth elements are practiced by CCPK in Pakistan. (Citing Tr. at 541:23-542:1; 545:6-10; 546:12-19; CX-1150C at Q. 295) Therefore, Respondents argue that claim 1 of the ‘863 patent, a method claim, is not infringed. (Citing RIB at Sec. 3.3.1.3)

Second, Respondents assert that the following steps are not performed by CCUS and/or CCPK for the additional reasons set forth below. Respondents assert that they do not infringe the preamble of claim 1, “A method for producing digital models of dental positioning appliances, said method comprising,” because they do not produce digital models of “dental positioning appliances.” (Citing Tr. 348:8-22; RX-0129C at Q. 118) Regarding the first element of claim 1, “providing a digital model of a patient’s dentition,” Respondents aver that CCUS scans the physical model of the patient’s teeth. (Citing Tr. 329:17 to 330:8) Respondents assert that there is no evidence that CCPK performs this limitation. (Citing RX-0129C at Q. 119)

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Regarding the second element of claim 1,

producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;

Respondents argue that, based on the context of the patent and the related prosecution history, one skilled in the art would understand that this limitation would require that all of the “plurality” of “modified digital models” progress successively from the initial tooth arrangement to the final tooth arrangement and be produced prior to active treatment. Respondents assert that a final tooth arrangement can only be a projection at the treatment stage prior to active treatment. (Citing Tr. at 778:5-23; RX-0129C at Q. 120) Respondents argue that this means that the Clinician does not determine the successive tooth arrangements that are required until after treatment has begun. (Citing Tr. 416:8-17) Respondents assert that the Clinician makes this determination based upon an evaluation of the patient’s progress and the Clinician’s prescription. Respondents argue that the phase-based system of the Respondents does not meet this limitation. (Citing RX-129C at Q. 120) Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing *id.*) Respondents argue that there is no evidence that CCUS practices this claim limitation.

Regarding the third element of claim 1, Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing RX-129C at Q. 121) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 523; RX-129C at Q. 121)

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In its reply brief, Respondents argue that they do not make digital models of appliances as the preamble of independent claim 1 recites. (Citing RIB at § 8.3.1) Respondents quote the transcript in support of its assertion:

Q. Does ClearCorrect made digital models of the appliance?

A. No.

Q. Does ClearCorrect Pakistan make digital models of the appliance?

A. No.

Q. And the appliance is the aligner, right?

A. That's right.

Q. Has ClearCorrect USA ever made a digital to your knowledge of an appliance?

A. No.

Q. Or Pakistan, has it?

A. No.

(Citing Tr. at 348:9-24) Respondents contend that there is no dispute in this case that CCUS uses digital models of a patient's dental arch to fabricate physical models of that arch. (Citing Tr. at 341: 2-21) Respondents assert that the actual orthodontic appliances, the aligners, are made by thermoforming a sheet of plastic over that physical model. (Citing Tr. at 341: 2-21) Respondents say that no digital model of the actual appliance ever exists. Respondents contend that Align disregards the claim's language requiring a digital model of the appliance. (Citing CIB at 121) Respondents argue that Align failed to prove the creation of a digital model of any appliance, which means that it has failed to prove infringement of independent claim 1.

**Staff's Position:** Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 1 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 291-296 and CX-1198C at 226-238 (collectively discussing claim 1 of the '863 patent))



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In its reply brief, Staff asserts that Respondents' arguments of non-infringement of the asserted claim of the '863 patent advance claim construction arguments that were not properly identified in the Second Joint Revised Claim Construction Chart and are not properly supported by any intrinsic (or extrinsic) evidence. In particular, Staff says that Respondents argue that they do not infringe, *inter alia*, claim 1 of the '863 patent because the claimed "plurality of modified digital models" requires that all of the modified digital models progress from the initial tooth arrangement to final tooth arrangement and be produced prior to active treatment. (Citing RIB at 120) Staff says that Respondents made a similar argument with respect to the '325 patent, and for the same reasons stated with respect to the '325 patent, Staff asserts that Respondents' argument should be rejected.

**Analysis and Conclusions:** First, addressing Respondents' incorporation by reference of their general defenses, I incorporate and reaffirm the analysis and conclusions reached in section V.B.1, *supra*, treating the three issues relevant to the asserted claims of the '863 patent, to wit: (1) whether or not all steps of a method claim must be performed in the same country; (2) whether or not digital data sets are "articles" within the scope of 19 U.S.C. § 1337; and (3) whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

I find that Align has proven by a preponderance of the evidence that Respondents' process for producing digital models of dental positioning appliances infringes asserted independent claim 1. Align has introduced evidence that CCPK practices each and every element by making digital models according to claim 1.

Regarding the preamble, I find that Respondents waived the argument that the preamble is limiting because Respondents did not make this argument in either its prehearing brief or the

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SRJCCC. *See* G.R. 8.2 (“Any contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn.”) Moreover, even if Respondents did not waive their right to argue that the preamble is limiting, I find that the preamble is not limiting because it merely states the purpose of the claimed method, and thus an infringement analysis is not necessary. *Pitney Bowes, Inc. v. Hewlett-Packard Company*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citing *Rowe v. Dror*, 112 F.3d 473 (Fed. Cir. 1997)). In *Pitney*, the Federal Circuit found that, if the body of the claim “fully and intrinsically” sets forth the complete invention, including all of its limitations, and the preamble offers “no distinct definition of any of the claimed invention’s limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.” *Id.* The preamble should only be construed if, when read in the context of the entire claim, recites limitations of the claim, or if it is “necessary to give life, meaning, and vitality” to the claim. *Id.*

Here, I find that the preamble’s statement that the patent claims a method for “producing digital models of dental positioning appliances” is merely a statement that describes the invention’s intended field of use. Each element of the claim can be understood without reference to context of the preamble. (*See contra id.* (discussing that the term “the generated shapes” that appeared for the first time in the last limitation of the claim at issue could only be understood in the context of the preamble statement which provided the antecedent basis))

Alternatively, even if the preamble is limiting, the evidence demonstrates that CCPK practices the preamble. In the context of the claim language, I find that one of ordinary skill in the art would understand the preamble to refer to digital models of the patient’s dentition which

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are used to fabricate aligners. (JX-005 at R1:59-61<sup>54</sup>) The first element of claim 1 recites “providing a digital **model of a patient’s dentition**,” and the second element of claim 1 recites “producing a plurality of modified **digital models of the dentition**.” (*Id.* (emphasis added.) Also, Mr. Andrew Beers, Align’s technical expert, testified that one of ordinary skill in the art would interpret the preamble to refer to the digital models discussed in the patent, which are of the patient’s dentition used to fabricate the aligner, and not of the actual aligner. (CX-1150C at Q. 292) Thus, I find Respondents’ argument unpersuasive that one of ordinary skill in the art would understand the preamble, and the rest of the claim as being limited to digital models of “appliances.”

Interpreting the preamble to refer to digital models of the patient’s dentition, I find that Align has introduced credible evidence, including testimony and documents, that CCPK practices the preamble. Mr. Beers, Align’s technical expert, testified that CCPK produces a plurality of digital models representing a plurality of tooth arrangements, using software called “FreeForm.” Mr. Beers testified that CCUS uses those digital models to fabricate custom made successive tooth positioning appliances. (CX-1150C at Q. 292)

Mr. Arif, the clinical director of orthodontics at CCPK, testified that the aligners made by CCUS are made using the digital models provided by CCPK. (Tr. 205:17-20; 168:1-169-2) In explaining that process, he testified that {

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<sup>54</sup> See Ex Parte Reexamination Certificate (“the Reexamination Certificate”) appended to the ‘863 patent. The designation “R” will be used to refer to the Reexamination Certificate.

}

{

}

Finally, the evidence shows that CCUS submitted a premarket submission to the U.S. Food and Drug Administration (“the FDA submission”) to show CCUS’s system, which was prepared in the ordinary course of business. (CX-078; Tr. 248:9-249:3) The FDA submission states that using “FreeForm Modeling,” a 3D modeling program from SensAble Technologies, a certified dental lab technician creates a treatment setup following a dentist’s prescription. (CX-

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078 at 55) The submission states that the technician sections up the digital model as he would a physical model. (*Id.*) The submission also states that a treatment setup shows how the teeth will look after the dentist's prescribed treatment occurs, and that the treatment setup shows the 3D models of the teeth in an untreated state and the teeth in a fully treated state. (*Id.*) The submission continues that CCUS sends this treatment setup to the prescribing doctor for review and approval. (*Id.*) The FDA submission shows that, after the doctor approves the treatment setup, CCPK creates intermediate models using FreeForm, which take the case from the untreated state to the fully treated state. (*Id.*) The submission explains that each 3D model has very minor change from the model before it. The submission also states that Clear Correct then fabricates physical models using the digital models. (*Id.* at 56)

I find that credible testimony shows that CCPK practices the first element of asserted claim 1. Mr. Beers testified that {

} Thus, Align has shown by a preponderance of evidence that CCPK practices "providing a digital model of a patient's dentition."

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I find that the credible testimony and documentary evidence demonstrate that CCPK practices the second element of asserted claim 1. Mr. Beers testified that {

}

{

}

In addition, Align has presented a video clip that show a {

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{

}

{

} (*Id.*)

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Mr. Beers explained that {

}

{

}

Thus, Align has shown by a preponderance of evidence that CPPK practices “producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment, and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model.”



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I find unpersuasive Respondents “all data sets” non-infringement argument. Respondents assert they do not infringe this element because it requires that all data sets for a patient’s treatment be “produced prior to active treatment.” (RIB at 120) First, I find that Respondents have waived the right to offer a construction for any term contained in this claim element. Respondents only offered “plain and ordinary meaning” as a construction for the term “distinct successive incremental dental appliance” in both the SRJCC and its post-hearing brief. (SRJCCC at 8; RIB at 119) As I found in Section III.F.3, assertion of “plain and ordinary meaning,” without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int’l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

In Section III.F.3, I rejected Respondents argument that they do not infringe this claim element because it requires that all of the ‘plurality’ of ‘modified digital models’ progress successively from the initial tooth arrangement to the final tooth arrangement and be produced *prior* to active treatment.” (RIB at 120) As discussed in claim construction for the ‘863 patent, the third limitation of the second element only requires that one digital model (representing a single “treatment stage”) is used to fabricate one dental appliance. The claim element recites in pertinent part that “each modified model ... is to be used in fabrication of *a* distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model.” (JX-005 at R1:63-67 (emphasis added)) Nothing in this limitation requires that a specific total number of models be produced before the fabrication of dental positioning appliances.

Credible evidence demonstrates that Respondents infringe even under their own construction. Mr. Beers testified that {

} (CX-1150C at Q.

130-136, 347, 352) I find, too, that Dr. Mah's testimony regarding this claim element is conclusory and without corroboration. Dr. Mah merely states that CCUS's process is phase-based, and that in his opinion, the phase-based system of Respondents does not meet this limitation. (RX-129C at Q. 120)

Similarly, I find unpersuasive Respondents' "final tooth arrangement" non-infringement argument. Respondents argue that they do not infringe the claims of the '863 patent because, in their process a clinician has the ability to change the course of treatment during a mid-course correction, after treatment has already begun. I find, as I did with respect to the '325 patent, that Respondents admitted that mid-course corrections are not made in every case. (Tr. at 224:11-13) Respondents also admitted that when a mid-course correction takes place, the accused process is executed again, using new initial and new final tooth positions, between which intermediates data models are generated. (Tr. at 195:7-196:4; 205:24-206:15; 224:14-21; 318:21-319:3) Thus, immediately after a mid-course correction, Respondents generate intermediate digital models that represent successive treatment stages of an orthodontic treatment and infringe the second element of claim 1.

Regarding the third and fourth elements of claim 1, I find that credible evidence shows that CCPK practices these elements. Mr. Beers testified that {

}

{

} (CX-413C at 1-2)

Based on all the foregoing, I find that Align has proven by a preponderance of the evidence that CCPK infringes independent claim 1 when it produces the data sets in Pakistan according to the process set forth in this claim.

## **2. Claim 4**

Claim 4, which depends from claim 1, states:

A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:

presenting a visual image based on the digital model of the patient's dentition;

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

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

producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-005 at 14:4-16)

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**Align's Position:** Regarding the preamble of claim 4, Align argues that the preamble is not limiting, and Respondents have waived any such position in their Prehearing Brief. Align asserts that CCPK practices each of the elements of claim 1.

Align contends that CCPK practices the first element of asserted claim 4 when using FreeForm to present a visual image on screen of the 3D scanned digital image of the patient's dentition. (Citing CIB Sec. I.E. 1 and 3; CX-1150C at Q. 297) As described above with respect to the first element of claim 1 for Evidence Category 1 – "Initial Digital Data Set," {

}

{

}

{

}

{

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{

}

{

} Align says that the term “tooth” is used in the asserted patents {  
} as inclusive of the tooth and such additional materials. (Citing JX-  
002 at 12:51-56 (“The crown of the tooth, as well as the gingivae tissue immediately below the  
crown are separated from the rest of the geometry, and treated as an individual unit, referred to

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as a tooth.”); {

}

{

}

(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-105C; CX-106C)

Align asserts that Respondents assert their “manipulating a visual image” argument as a non-infringement basis, which is incorrect. (Citing RPHB at 188) Align says that Respondents assert they do not infringe the claims of the ‘863 patents because “manipulating a visual image” cannot include manipulation by entering coordinates. (Citing RPHB at 15, 188) First, Align argues that this is a claim construction argument not identified in the SRJCCC. Second, Align asserts that the intrinsic record shows the opposite of Respondents’ position. {

} (JX-

003 at 13:64-14:11; CX-1150C at Q. 124-125). Third, Align contends that, as admitted by Dr.

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Mah, { }

(Citing RX-129C at Q. 48) Align avers that Respondents did not contest that CCPK practices this element. (Citing RPHB at 188; RX-129C at Q. 65)

Regarding the third element of claim 4, Align argues that CCPK practices this element, { }

(Citing CIB at Sec. I.E.5; CX-1150C at Q. 299) Alternatively, Align contends that CCPK practices this claim {

} (Citing CIB at Sec. I.E.5; CX-1150C at Q. 299)

Align refers to Evidence Category No. 5: “Final Digital Data Set.” In that evidence category, Align submits that {

}

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Align argues that, {

(Citing CX-090C at 44-47; CX-087C at 1-2; CX-1158C.1-3 at 51:4-83:21; CX-107C)

Align disagrees with Respondents' "final tooth arrangement" non-infringement argument, which Align argues fails for the reasons as described above with respect to the second element of in claim 1. (Citing RPHB at 188; RX-129C at Q. 65)

Regarding the fourth element of claim 4, Align argues that CCPK practices this element using {

} Align disagrees with Respondents' "all data sets," "final tooth arrangement," and "clinician determination" arguments as non-infringement bases, for the reasons described above with respect to the second element of claim 1. (Citing RPHB at 189)

Thus, Align asserts that Respondents infringe claim 4 and violate Section 337 for the same reasons as claim 1.

**Respondents' Position:** Regarding claim 4, Respondents argue that they do not infringe this dependent claim because they do not infringe independent claim 1. In addition, Respondents assert that there is no infringement of claim 4 because certain steps in claims 1 and 4 are alleged



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to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents continue that CCUS and/or CCPK do not practice the following limitations of claim 4 for the reasons set forth below.

Regarding the preamble and the first limitation of claim 4, Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. Respondents argue that there is no evidence that CCUS practices this limitation, and that Align agrees. (Citing CPHB at 532; RX-129C at Q. 122)

Regarding the second element of claim 4, Respondents argue that this limitation requires that a “visual image” be manipulated in order to reposition individual teeth. Respondents say that the visual image reflects the coordinates that have been entered. Respondents maintain that, { } Respondents state that this is not “manipulating the visual image.” (Citing RX-129C at Q. 123) Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 532)

Regarding the third element of claim 4, Respondents argue that a “final tooth arrangement” can only be a projection at the treatment stage prior to active treatment. (Citing RX-129C at Q. 124) Respondents assert that their phase-based system does not meet this limitation. Under the Respondents phase-based system, Respondents say aver that the Clinician exercises professional judgment as to the design of the successive orthodontic appliances to be used after active treatment has begun. (Citing Tr. 416:8-17) Respondents say that the digital data sets are not finalized until perhaps years after the patient’s active treatment begins. (Citing

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Tr. 342:24 to 343:14) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 532)

Regarding the fourth element of claim 4, Respondents argue that the plain meaning of the claim language requires production of a series of tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement, which would cover everything between the initial and final tooth arrangements. Respondents argue that this is distinct from the language of other claims that use “toward” rather than “to.” Respondents aver that CCUS’s phase-based method does not produce such a series. (Citing RX-129C at Q. 125) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 532)

In their reply brief, Respondents assert that because the actual evidence demonstrates that CCUS’s phase based system is significantly different from the method described in Align’s claims, and because Align bases its infringement arguments on misstatements about the Respondents’ process, Align has failed to meet its burden of proof. Respondents also note that dependent claim 4 contains an element relating to “manipulating a visual image” on a computer screen. Respondents argue that Align’s post hearing brief makes misstatements and assertions that CCPK operators “manipulate visual images.” (Citing RRB at § 3.F.3) Respondents aver that CCPK operators use a dialog box to enter tooth movements and do not alter the visual image by, for example, clicking a mouse and dragging an image of a tooth crown. Respondents assert that, because Align bases its infringement arguments on misstatements concerning the CCPK operators’ actual conduct, it has failed to meet its burden of proof on the independent claims’ associated elements.

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**Staff's Position:** Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 4 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 297-301 and CX-1198C at 238-245 (collectively discussing claim 4 of the '863 patent))

In its reply brief, Staff says that Respondents argue that they do not infringe claim 4 of the '863 patent because (i) the claimed "manipulating the visual image to reposition individual teeth in the visual image" requires that a "visual image" actually be manipulated in order to reposition individual teeth; (ii) the claimed "final tooth arrangement" requires a projection at the treatment stage prior to active treatment; and (iii) the claimed "individual teeth" requires a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. (Citing RIB at 121-125) Staff says that Respondents made these same arguments with respect to the '325 patent. For the same reasons stated with respect to the '325 patent, Staff asserts that these arguments should be rejected.

**Analysis and Conclusions:** If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 4, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 4 of the '863 patent. Regarding the preamble, I find that Respondents waived the argument that the preamble is limiting because Respondents did not make this argument in either its prehearing

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brief or the SRJCCC. Moreover, even if Respondents did not waive their right to argue that the preamble is limiting, I find that the preamble is not limiting because it merely states the purpose of the claimed method, and thus an infringement analysis is not necessary. *Pitney Bowes*, 182 F.3d at 1305. Also as discussed above, even if the preamble is limiting, credible evidence demonstrates that CCPK practices the preamble, which, in the context of the claim language, refers to digital models of the patient's dentition which are used to fabricate the aligner. (JX-005 at R1:59-61; CX-1150C at Q. 292)

I find that credible evidence shows that CCPK practices the first element of claim 4. Mr. Beers testified that {

} The video clip presented by

Align shows the same. (CX-1157C.3 at 50:23)

I find that credible evidence shows that CCPK practices the second element of claim 4. Mr. Beers testified that {

}

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{

}

I find unpersuasive Respondents “manipulating a visual image” non-infringement argument. (RPHB at 188) Respondents assert they do not infringe claims of at least the ‘325 and ‘863 Patents because “manipulating a visual image” cannot include manipulation by entering coordinates. (RPHB at 15, 188) First, I find that Respondents have waived the right to offer a construction for any term contained in this claim element. Respondents did not offer any construction for the term “manipulating a visual image” in either the SRJCC or its post-hearing brief. Second, the portion of Dr. Mah’s testimony addressing this construction was excluded. (RX-0129C at Qs. 48, 69) Third, Dr. Mah admits that {

}

Regarding the third element of claim 4, I find that credible evidence shows that CCPK practices this element. Mr. Beers testified that CCPK practices this element, using FreeForm, by manipulating the image to reposition the teeth into a final tooth arrangement. (CX-1150C at Q. 299) Mr. Beers explained that {

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}

{

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Respondents “final tooth arrangement” non-infringement argument, fails for the same reasons as described above with respect to the second element of claim 1.

I find that credible evidence shows that CCPK practices the fourth element of claim 4. Mr. Beers testified that CCPK uses the “Generate Steps” function in FreeForm to generate intermediary digital models, i.e. a plurality of modified digital models. Mr. Beers testified that

{

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} Video presented by Align shows the same. (CX-1158C.1-3  
at 72:13-18, 78:11-79:14)

I find unpersuasive Respondents' "all data sets" and "final tooth arrangement" non-infringement arguments for the same reasons as described above with respect to the second element of claim 1. I also find unpersuasive Respondents' "clinician determination" non-infringement argument that, {

}

Based upon the foregoing, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 4 when it produces the data sets in Pakistan according to the process set forth in this claim.

**3. Claim 5**

Claim 5, which depends from claim 4, states:

A method as in claim 4, wherein the manipulating step comprises:  
defining boundaries about at least some of the individual teeth; and  
moving at least some of the tooth boundaries relative to the other teeth in  
an image based on the digital data set.

(JX-005 at 14:18-23)

**Align's Position:** Align contends that CCPK practices this claim using FreeForm by sectioning up the 3D scan in order to individually move the teeth, as described above with

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respect to the second element of claim 4. (Citing CIB at Sec. I.E.4; CX-1150C at Q. 302) Align asserts that {

}

Align disagrees with Respondents' "individual teeth" non-infringement argument. Align says that Respondents assert they do not infringe claims of the '863 patent because the phrase "individual teeth" in the claims must be "a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material." (Citing RPHB at 17, 158, and 189)

First, Align argues that this construction was not identified in the SRJCCC. Second, Align asserts that Respondents cite to no supporting evidence. Third, Align contends that "teeth" is generally used in the asserted patents inclusively for the tooth and surrounding gum material (Citing JX-002 at 12:51-56 and CX-1150C at Q. 123, 348). Fourth, Align avers that Respondents themselves use "teeth" in such an inclusive manner. (Citing CX-1157C.1 at 54:1-9; CX-090C at 14)

Align also argues that Respondents also provide, without explanation, a conclusory statement that "Respondents do not 'move' the 'tooth boundaries' 'relative to other teeth' in an 'image.'" (Citing RPHB at 190) Align asserts that this is insufficient. Thus, Align contends that Respondents infringe claim 5 and violate Section 337 for the same reasons as claim 1.

**Respondents' Position:** Regarding claim 5, Respondents say they do not infringe this dependent claim because they do not infringe independent claim 1. Respondents argue that there is no infringement of claim 5 because certain steps in claims 1, 4 and 5 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents continue that