

## PUBLIC VERSION

CCUS and/or CCPK do not practice the following limitations of claim 5 for the reasons set forth below.

Regarding the preamble and the first limitation, Respondents argue that based on the plain meaning of the claim language, “individual teeth” means 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. Respondents say that Dr. Valley testified an actual tooth includes the root. (Citing Tr. at 707:25-708:6) Respondents aver that what CCPK sections, and manipulates, is only part of a tooth, and it therefore moves only parts of teeth. Respondents continue that {

} Respondents say Mr. Beers only identifies CCPK as practicing this limitation. (Citing CX-1150C at Q. 302) Respondents argue that there is no evidence that CCUS practices this claim limitation.

Regarding the second element of claim 5, Respondents argue that, for the reasons discussed immediately above, the Respondents do not “move” the “tooth boundaries” “relative to other teeth” in an “image” “to produce the final data set.” Accordingly, Respondents say this limitation is not met by the Respondents. Also, Respondents aver that Mr. Beers only identifies CCPK as practicing this limitation. (Citing CX-1150C at Q. 302) Respondents argue that there is no evidence that CCUS practices this claim limitation.

In its reply brief, Respondents note that dependent claim 5 contains an element relating to “defining boundaries” around individual teeth. Respondents argue that Align’s post hearing brief makes misstatements and assertions that CCPK operators “define boundaries” around individual teeth. (Citing RRB at § 3.F.3) Respondents aver that CCPK operators do not “define

## PUBLIC VERSION

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 concerning the CCPK operators’ actual conduct, it has failed to meet its burden of proof on the independent claims’ associated elements.

**Staff’s Position:** Applying the ALJ’s rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 5 of the ‘863 patent by selling digital data sets. (Citing CX-1150C at Q. 302-303 and CX-1198C at 245-248 (collectively discussing claim 5 of the ‘863 patent))

**Analysis and Conclusions:** If I had found that Align had failed to prove that Respondents infringe claim 1 and/or claim 4, it would follow that Align failed to prove infringement of claim 5, which depends from 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 claims 1 and 4. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 5 of the ‘863 patent. Mr. Beers testified that {

PUBLIC VERSION

}

Respondents miss the mark when they assert that 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.” (RPHB at 17, 158, and 189) 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 “individual teeth” in either the SRJCC or its post-hearing brief. Moreover, the portion of Dr. Mah’s testimony addressing this construction was excluded. (RX-0129C at Qs. 53, 60) 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.” {

} All that is required is “defining boundaries about” individual teeth. (JX-005 at

## PUBLIC VERSION

14:20) Based on the foregoing testimony and evidence introduced during the hearing, I find that Respondents meet this limitation.

Thus, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 5 when it produces the data sets in Pakistan according to the process set forth in this claim.

### 4. Claim 6

Claim 6, which depends from claim 1, states:

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

providing a computer system having at least one processor and memory;

providing to the computer system the digital model of the patient's dentition;

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

producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets.

(JX-005 at 14:24-35)

**Align's Position:** Align asserts that the preamble of claim 6 is not limiting, and Respondents have waived any such position in their Prehearing Brief. As explained above, Align argues that CCPK practices each of the elements of claim 1.

Regarding the first and second elements of claim 6, Align argues that {



}

Align submits that Respondents do not contest infringement of this element. (Citing RPBH at 190; RX-0129C at Q. 65)

Regarding the third element of claim 6, Align argues that {

}

Align says that Respondents assert their “all digital sets,” “final tooth arrangement,” and “clinician determination” non-infringement arguments. Align argues that the “all digital sets” and “final tooth arrangement” arguments are incorrect for the reasons discussed above in claim

1. Align further contends that Respondents assert that, {

} Align asserts that Respondents presented no evidence to support this argument. Align also asserts that {

}

In its reply brief, Align argues that Mr. Beers testified that the element of providing to the computer system a digital model representing a final tooth arrangement is satisfied by CCPK providing the predetermined final tooth arrangement to the Generate Steps function. (Citing CX-1150C at Q. 306) Align submits that Respondents fail to address this evidence. Align continues that Respondents' improperly construed the term "based on" to assert that each appliance must be based on the immediately preceding appliance, not the initial, and must fail for at least that reason.

Thus, Align argues that Respondents infringe claim 6 and violate Section 337 for the same reasons as claim 1.

**Respondents' Position:** Regarding claim 6, Respondents say they do not infringe this dependent claim because they do not infringe independent claim 1. Respondents add that there is no infringement of claim 6 because certain steps in claims 1 and 6 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 they do not practice the following limitations of claim 6 for the reasons set forth below.

Regarding the preamble and the first element of claim 6, Respondents say that Mr. Beers states that CCPK performs this step. (Citing CX-1150C at Q. 304 and 305; RX-129C at Q. 128) Respondents argue that, assuming, as Mr. Beers suggests, that this step is performed by scanning "a 3D physical model of a patient's teeth taken from dental impressions" and subsequently sending that information to another party, there is no evidence that CCPK performs this limitation. (Citing RX-129C at Q. 128)

## PUBLIC VERSION

Regarding the second element of claim 6, Respondents argue that neither CCUS nor CCPK “provide” a digital data set representing a final tooth arrangement to a computer system. Respondents aver 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 contend 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 argue 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 Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 306; RX-129C at Q. 129) Respondents argue that there is no evidence that CCUS practices this claim limitation. (Citing RX-129C at Q. 129)

Regarding the third element of claim 6, 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 models 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. Respondents say that their process is phase-based. (Citing Tr. 416:8-17) Respondents aver 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 416:8-17) Respondents maintain that {

}

Respondents submit that the design of the appliances is not “based on” both of the “previously

## PUBLIC VERSION

provided initial and final digital data sets.” Instead, Respondents contend that {

} Additionally, Respondents say Mr. Beers only identifies conduct by CCPK as meeting this limitation. There is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CX-1150C at Q. 307; CPHB at 545)

**Staff’s Position:** Applying the ALJ’s rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 6 of the ‘863 patent by selling digital data sets. (Citing CX-1150C at Q. 304-308 and CX-1198C at 248-256 (collectively discussing claim 6 of the ‘863 patent))

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 claim 6 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. For the same reasons stated with respect to the ‘325 patent, Staff asserts that this argument should be rejected.

In its reply brief, Staff also says that Respondents argue that they do not infringe claim 6 of the ‘863 patent because (i) the claimed “manipulating the visual image to reposition individual

## PUBLIC VERSION

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 (above), 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 6, 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 6 of the ‘863 patent. Regarding the first and second elements of claim 6, I find that credible evidence shows that CCPK practices these elements. Mr. Beers testified that {

}

{

}

Thus, Align has shown by a preponderance of evidence that CCPK practices “providing a computer system having at least one processor and memory” and “providing to the computer system the digital model of the patient’s dentition.”

I find that credible evidence shows that CCPK practices the third element of claim 6. Mr. Beers testified that {

**PUBLIC VERSION**

}

I find that credible demonstrates that CCPK practices the fourth element of asserted claim

6. Mr. Beers testified that {

}

Furthermore, Mr. Arif 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 {

}

Moreover, the CCUS FDA submission states that using “FreeForm Modeling,” a certified dental lab technician creates a treatment setup following a dentist’s prescription. (CX-078 at 55) The submission 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

## PUBLIC VERSION

untreated state and the teeth in a fully treated state. (*Id.*) The 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.*)

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 for the same reasons as described above with respect to the fourth element of claim 4.

Thus, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 6 when it produces the data sets in Pakistan according to the process set forth in this claim.

### 5. Claim 7

Claim 7, which depends from claim 6, recites:

A method as in claim 6, wherein the step of providing a digital model 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-005 at 14:36-44)

**Align's Position:** Align asserts that CCPK practices this claim {

}



## PUBLIC VERSION

Align says Respondents assert their “individual teeth” non-infringement argument, which is incorrect for the reasons discussed in claim 5. Align adds 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 192) Align argues that this is insufficient to raise an infringement defense. Thus, Align contends that Respondents infringe claim 7 and violate Section 337 for the same reasons as claims 1 and 6.

**Respondents’ Position:** The Respondents say they do not infringe dependent claim 7 because they do not infringe independent claim 1. In addition, Respondents say there is no infringement of claim 7, because certain steps in claims 1, 6 and 7 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 they do not practice the following limitations for the reasons set forth below.

Regarding the preamble and first limitation of claim 6, Respondents refer to their discussion concerning claim 4, and contend that Respondents’ process does not define boundaries about “individual teeth.” Also, Respondents say Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 310) Respondents assert that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 552)

Respondents refer to their argument concerning claim 4 and contend they do not practice the second element of claim 7, because they do not “move” the “tooth boundaries” “relative to other teeth” in an “image.” Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 310) Respondents say that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 552)

In its reply brief, Respondents note that dependent claim 7 contains elements relating to “manipulating a visual image” on a computer screen or “defining boundaries” around individual

## PUBLIC VERSION

teeth. Respondents argue that Align's post hearing brief makes misstatements and assertions that CCPK operators "manipulate visual images" or "define boundaries" around individual teeth.

(Citing RRB at § 3.F.3) Among other things, Respondents aver that {

} 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.

**Staff's Position:** Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 7 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 309-311 and CX-1198C at 256-259 (collectively discussing claim 7 of the '863 patent))

**Analysis and Conclusions:** If I had found that Align had failed to prove that Respondents infringe claim 1 and/or claim 6, it would follow that Align failed to prove infringement of claim 7, which depends from claim 6 (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 claims 1 and 6. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 7 of the '863 patent. I find that credible evidence shows that CCPK practices each and every element

of claim 7. Mr. Beers testified that {

}

Mr. Pumphrey testified that {

}

I find unpersuasive Respondents “individual teeth” non-infringement argument for the same reasons as describe above with respect to claim 5.

Thus, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 7 when it produces the data sets in Pakistan according to the process set forth in this claim.

#### **6. Claim 8**

Claim 8, which depends from claim 6, teaches:

A method as in claim 6, wherein the step of producing the plurality of models comprises determining positional differences between the initial digital model and the final digital model and interpolating said differences.

(JX-005 at 14:45-48)

## PUBLIC VERSION

**Align's Position:** Align asserts that CCPK practices the element of claim 8 when { } for the reasons described with respect to the second element of claim 1. (Citing CIB at Sec. I.E.7; CX-1150C at Q. 313) Align avers that Respondents admit that this "generating" is done by { } (Citing Tr. at 676:23-677:5) Align says 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 means that the 'positional differences ...' are not interpolated" (Citing RPHB at 192)

Regarding (i), Align asserts that this appears to be Respondents' "all data sets" argument, and is incorrect as described in claim 1. Regarding (ii), Align contends that Respondents fail to provide any particular evidence to support their argument. Align avers that their argument is contrary to the evidence. Align argues that {

} according to Respondents' process. Align argues that Respondents infringe claim 8 and violate Section 337 for this claim, for the same reasons as claims 1 and 6.

**Respondents' Position:** Regarding claim 8, Respondents say that they do not infringe this dependent claim because they do not infringe independent claim 1. Respondents add there is no infringement of claim 8, because certain steps in claims 1, 6 and 8 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents recite claim 8 and aver that the operators' use of their individual judgment to adjust the teeth locations to avoid collisions, as described at the hearing, means that the "positional differences between the initial

## PUBLIC VERSION

data set and the final data set” are not interpolated. (Citing JX-005, 14:45-48; and Tr. 336:8 to 338:17) Respondents assert that the {

} (Citing RX-129C at Q. 133) Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 313) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 556)

In their reply brief, Respondents contend that dependent claim 8 contains an element requiring the interpolation between initial and final digital models. Respondents argue that the only evidence Align cites concerning this element is the {

} Respondents assert that Align’s post hearing brief makes significant misstatements concerning the operation and use of the “Generate Steps” software feature. (Citing RRB § 3.F.1) Respondents say that the interpolation does not actually occur as Align suggests. Rather, Respondents aver that the evidence shows {

} Respondents argue 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. Respondents contend that, {

} Align has not established the interpolation element.

**Staff’s Position:** Applying the ALJ’s rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 8 of the ‘863 patent by selling digital data sets.

## PUBLIC VERSION

(Citing CX-1150C at Q. 313-314 and CX-1198C at 259 (collectively discussing claim 8 of the ‘863 patent))

**Analysis and Conclusions:** If I had found that Align had failed to prove that Respondents infringe claim 1 and/or claim 6, it would follow that Align failed to prove infringement of claim 8, which depends from claim 6 (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 claims 1 and 6. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 8 of the ‘863 patent. I find that credible evidence shows that CCPK practices this claim. Mr. Beers testified that {

} Respondents’ argument that they do not perform “interpolation” also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6)

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

} Regarding (i), this appears to be Respondents' "all data sets" non-infringement argument, and is incorrect for the same reasons as described with respect to the second element of claim 1. Regarding (ii), Respondents fail to provide any particular evidence to support their argument, and the evidence shows the contrary. I find persuasive Align's argument that {

} Even if there were modifications after FreeForm is used, it does not change the fact that interpolation is performed by Freeform according to Respondents' admitted process. (*Id.*)

Thus, I find that Align has shown by a preponderance of the evidence that CCPK infringes claim 8 when it produces the data sets in Pakistan according to the process set forth in this claim.

## 7. Violation of Section 1337(a)

**Align's Position:** Align argues 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 and 4-8 of the '863 patent. Alternatively, Align argues that CCPK violates 337(a)(1)(B)(i) by directly infringing claims 1 and 4-8 of the '863 patent under 35 U.S.C. § 271(g) by importing, offering to sell, or selling digital data sets made by Respondents' process. Finally, Align argues that "CCUS uses those same digital data sets, and therefore also violates 337(a)(1)(B)(i) for similar reasons."

Align says that Respondents admit that, { }, digital data from CCPK has been sent to CCUS in the U.S. for the purpose of making the physical models used to fabricate

PUBLIC VERSION

aligners for sale to U.S. providers. (Citing Tr. at 320:2-9, 320:12-15, 364:20-365:12, 442:19-23)

Align asserts that CCPK receives payment from CCUS for that digital data. (Citing Tr. at 320:2-9, 364:20-365:12, 373:24-374:4; CX-1160C.2 at 278:2-9, 294:2-7, 296:3-7; CX-1160C.3 at 422:25-423:8) Thus, Align argues that CCPK sold or offered to sell the digital data in the U.S., and that these digital data sets were brought into the U.S. {

} (Citing Tr. at 316:4-22, 320:12-15, 442:19-23;

CX-1160C.1 at 97:22-98:2; CX-1160C.3 at 472:3-17) Align avers that these digital data sets are then used by CCUS to fabricate the infringing aligners that it sells in the U.S. Based on the foregoing, Align asserts that Respondents have jointly or individually imported into the U.S., sold for importation into the U.S., and/or sold in the U.S. after importation the accused digital data sets.

**Respondents' Position:** Respondents assert the general defense that Respondents cannot infringe the asserted claims of the '863 patent where part of the method is performed in the US and part of the method is performed in Pakistan. Respondents assert that the Federal Circuit has 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 argue that the Federal Circuit held:

We 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 principle, "if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability" has



## PUBLIC VERSION

long been recognized by the Federal Circuit. (Citing *id.* (citing *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 836 (2002))

Respondents argue that there can be no infringement under 271(a) if any part of a step is performed outside of the U.S. Respondents acknowledge that I held that it is not necessary to show underlying infringement under Section 271 in order to establish a violation of Section 337(a)(1)(B)(i), but disagree with my statutory interpretation. Respondents say that Align has chosen to rely on the substantive provisions of 271 (a), (b) and (g) as the basis for its infringement allegations. Accordingly, Respondents submit that the case law interpreting those provisions applies.

Respondents assert 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. For example, Respondents say that 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. to make the CCUS products. (Citing *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 813 F.Supp.2d 602, 613-14 (D. Del. 2011)) 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 submit 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). Accordingly, Respondents argue 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.

**Staff’s Position:** Staff says that Align asserts infringement of claims 1 and 4-8 of the ‘863 patent under 19 U.S.C. § 1337(a)(1)(B)(i) as follows:

## PUBLIC VERSION

CCPK directly infringes claims 1 and 4-8 of the '863 patent under 35 U.S.C. § 271(g) by offering to sell or selling digital data sets, digital models, or treatment plans in the United States.

Staff says that Align also alleges, in the alternative, infringement under 19 U.S.C. § 1337(a)(1)(B)(ii) for claims 1 and 4-8 of the '863 patent.

Based on the Staff's understanding of the legal standards of patent infringement, Staff is of the view that: (a) Align's § 271(g) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i) is legally improper, and (b) only Align's alternative infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii) is legally proper. When applying the Staff's understanding of the legal standards of patent infringement to Align's allegations of infringement under 19 U.S.C. § 1337(a)(1)(B)(i), Staff is of the view that CCPK would not infringe the asserted claims of the '863 patent under 35 U.S.C. § 271(g).

Staff says, however, that given my rulings regarding patent infringement under Section 337 in Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding)), Align's § 271(g) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i) may be determined to be legally proper. Staff asserts, that when applying the ALJ's rulings regarding patent infringement under 19 U.S.C. § 1337(a)(1)(B)(i), the evidence demonstrates that CCPK directly infringes each of the asserted claims of the '863 patent under 35 U.S.C. § 271(g) by selling digital data sets.

Additionally, Staff asserts that the same evidence supports a finding of direct infringement of each of the asserted claims of the '863 patent under 19 U.S.C. § 1337(a)(1)(B)(ii). In particular, Staff argues that the evidence shows that CCPK practices each element of the asserted claims of the '863 patent, and that the evidence demonstrates that CCUS

## PUBLIC VERSION

and CCPK violate 19 U.S.C. § 1337(a)(1)(B)(ii) by importing digital data sets that are produced by the claimed methods of the '863 patent.

**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, 4, 5, 6, 7, and 8 in Pakistan to produce the digital data sets (as found in Section V.G.1-6, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

### H. The ‘874 Patent

#### 1. Claim 1

Claim 1 recites:

A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:

receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof;

generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and

generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,

PUBLIC VERSION

wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.

(JX-006, 32:37-56)

**Align's Position:** Align submits that the preamble is not limiting, because it merely states the purpose of the claimed method. (Citing *Pitney Bowes*, 182 F.3d at 1305) Align says that Respondents have not asserted the contrary in their *Prehearing Brief*, and have therefore waived such a position.

Align adds that if the preamble was found to somehow be limiting, Respondents practice the preamble when {

} Citing CIB

Sections I.E.1, 7 and 10; and CX-1150C, Q. 316) Align notes that Respondents generally assert their “computer implemented” and “treatment plan” arguments as non-infringement bases, which are incorrect for the reasons discussed in CIB section IV.D.

Focusing on the first element of asserted claim 1, Align asserts that CCPK practices this element when it {

} (Citing CIB section I.E.1, 9; and CX-1150C, Q. 317) Align alleges that Respondents do not contest that they infringe this element. (Citing RPHB at 226, 233-34; and RX-129C, Q. 145)

Regarding the second element of asserted claim 1, Align contends that CCPK practices this claim element when {

} (Citing CIB section I.E.7; and CX-1150C, Q. 318) Align says that Respondents generally assert their “all data sets” and “final tooth arrangement” arguments

## PUBLIC VERSION

(Citing RPHB at 226-27, 234) as the bases for their non-infringement arguments, which are incorrect for the reasons discussed in CIB section IV.D.

Align says that CCUS practices the third element of asserted claim 1 when it {  
} (Citing CIB section I.E.10; and CX-1150C, Q. 319) Align adds that Respondents assert their “all aligners” argument (Citing RPHB at 227, 234) as a non-infringement basis, which is incorrect for the reasons discussed in CIB section IV.D.

Turning to the fourth element of asserted claim 1, Align argues that CCUS practices this element, because {  
} (Citing CIB sections I.E.7, 10; and CX-1150C, Q. 320) Align says that Respondents assert their “all aligners” argument (Citing RPHB at 227-28, 235) as a basis for their non-infringement position, which is incorrect for the reasons discussed in CIB section IV.D.

In its reply brief, Align says that Respondents have asserted only their global non-infringement arguments as to claims 1 and 2.

**Respondents’ Position:** Respondents incorporate by reference the discussion of their general defenses in Sections 3.3.1.1 to 3.3.1.14, *supra*.

Respondents say that Align contends the first and third elements of the claim are practiced by CCUS in the United States and the first and second elements are practiced by CCPK in Pakistan. (Citing Tr. at 585:22-586:13) Respondents reason, therefore, claim 1 of the ‘874 patent, a method claim, is not infringed. (Citing RIB section 3.3.1.3)

Respondents turn to the preamble of asserted claim 1, and argue that a PHOSITA “would understand a computer-implemented method to require an automated process carried out by

## PUBLIC VERSION

computer programs.” Respondents contend that this limitation does not mean a manual method carried out with the assistance of a computer, but rather requires that each step be computationally implemented on a computer. Respondents refer to the discussion of the ‘511 patent, claim 1, at RIB section 6.2.2, and aver that they do not use a computer implemented method because { } (Citing Tr. 329:17 to 341:21; and RX-129C, Q. 144)

Respondents add that they do not create orthodontic treatment plans. Referring to their argument in the discussion of the ‘487 patent, Respondents say a “treatment plan” is only created by a Clinician during the treatment of patients. Respondents reason that, because neither of them treats patients nor creates a “treatment plan” “as that term is understood by those skilled in the art,” they do not meet this limitation.

Skipping to the second element of asserted claim 1, Respondents argue that, a PHOSITA would understand that this limitation requires that all of the “set” of “intermediate positions” “toward which the teeth will move” from the “initial position” to the “final position” as projected be produced prior to active treatment. Respondents contend that a “final position” can only be a projection at the treatment stage prior to active treatment. Respondents add that {

} Respondents say 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, Q. 146) Respondents conclude that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C, Q. 318) Respondents argue there is no evidence that CCUS practices this claim limitation.

## PUBLIC VERSION

Turning to the third element of asserted claim 1, Respondents argue that a PHOSITA would understand that this limitation requires that all of the “plurality” of “successive appliances” be produced prior to active treatment. Respondents contend that CCUS’s phase-based system does not meet this limitation, because the appliances are made as patient treatment progresses. (Citing Tr. 416:8-17; and RX-129C, Q. 147) Respondents add that Mr. Beers only identifies conduct by CCUS as meeting this limitation, and there is no evidence that CCPK practices this claim limitation. (Citing CX-1150C, Q. 319)

Focusing on the fourth element of asserted claim 1, Respondents argue that this limitation requires that “the plurality of successive appliances” be generated prior to the “wearing of any appliance” of “said plurality.” Respondents continue that the “stage of treatment that comes after the wearing of an appliance is called ‘active treatment.’” Respondents say that stages of treatment are not defined by CCUS’s phase-based delivery of aligners, and “the plurality” refers to the entire series of aligners. Respondents aver that this is confirmed by the statements made by Align during the prosecution of this patent, and CCUS’s phase-based system does not meet this limitation, {

} (Citing Tr. 416:8-17) Respondents argue that nothing in the patent specification or prosecution history suggests that “stages of treatment” was meant to indicate phase-based delivery of aligners rather than its ordinary meaning to a PHOSITA. (Citing RX-129C, Q. 148) Respondents say that Mr. Beers only identifies conduct by CCUS as meeting this limitation, and there is no evidence that CCPK practices this claim limitation. (Citing CX-1150C, Q. 320)

In their reply brief, Respondents reiterate that they do not prepare “treatment plans,” and argue that Align’s post hearing brief asks “the Court to apply a different definition of the phrase

## PUBLIC VERSION

that is inconsistent with its plain and ordinary meaning, the evidence introduced in the case, and state law concerning the corporate practice of medicine.”

Referring to RRB section 3.F.2, Respondents say that Align’s post hearing brief “makes significant misstatements concerning the manner in which [CCPK] operators make the computer files, the functions of the FreeForm software, and the manner in which [CCUS] receives the computer files from [CCPK] and when those files can be used to actually make orthodontic appliances.” Respondents reiterate that CCUS uses a phase-based system that is much different from the method claimed in the independent claim of the ‘874 patent.

Respondents add that RRB section 3.G.1-2 describes the inconsistency between Dr. Valley’s opinions concerning invalidity and Align’s theories of infringement. Respondents argue that if Respondents are found to infringe based on Align’s characterization of the evidence concerning the creation of “digital data sets,” the infringed claims must also be found invalid in light of the prior art.

Respondents say the foregoing reasoning applies equally to the dependent claims 2, 38, 39, 41 and 62 of the ‘874 patent.

**Staff’s Position:** Staff says that Align asserts CCUS directly infringes claims 1, 2, 38, 39, 41, and 62 of the ‘874 patent “under 35 U.S.C. § 271(g)” by offering to sell, selling, or using aligners in the United States that are made by the joint CCUS/CCPK process, and CCPK contributes to that infringement “under 35 U.S.C. 271(c)” by creating the digital data.

Staff says that based on their understanding of the legal standards of patent infringement, Align’s section 271(g) infringement theory is legally improper for the reasons stated in SIB section III.B. Staff expresses the view that, when applying the Staff’s understanding of the legal standards of patent infringement to Align’s infringement theory, CCUS would not infringe under



## PUBLIC VERSION

35 U.S.C. § 271(g), and thus CCPK would not infringe under 35 U.S.C. § 271(c), any Asserted Claim of the '874 patent.

Staff concedes that, given “the ALJ’s rulings regarding patent infringement under Section 337 in Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding))”, Align’s section 271(g) infringement theory may be determined to be legally proper. Staff applies the rulings of Order No. 20, along with “a proper claim construction,” and on that basis expresses the views, *infra*.

Staff says that the evidence supports finding infringement of each of the Asserted Claims of the '874 patent “regarding patent infringement under Section 337.” Staff continues that the evidence demonstrates that CCUS directly infringes each of the Asserted Claims of the '874 patent by selling or using aligners in the United States that are made by the joint CCUS/CCPK process. Staff cites CX-1150C, Qs. 315-331; and CX-1198C at 276-291 in support of their view.

Staff continues that based upon CCUS’ infringement of the Asserted Claims of the '874 patent, the evidence shows that CCPK contributes to the infringement by creating the digital data sets. (Citing “CPRB, pp. 604 (CX exhibits cited for claim 1), 608 (CX exhibits cited for claim 2), 612 (CX exhibits cited for claim 38), 616 (CX exhibits cited for claim 39), 619 (CX exhibits cited for claim 41), and 622 (CX exhibits cited for claim 62); CX-1150C, Qs. 315-331; and CX-1198C at 276-291) Staff adds that its discussion of the elements of contributory infringement with respect to Group A of the '325 Patent, *supra*, also applies here with respect to the Asserted Claims of the '874 patent.

In its reply brief, Staff says that Respondents’ arguments of non-infringement of the Asserted Claim of the '874 patent are based on claim constructions that are contradicted by the intrinsic evidence, as discussed in the SIB section X.B. Staff contends that applying the ALJ’s

## PUBLIC VERSION

rulings regarding Section 271 and Section 337 and a proper claim construction, the evidence supports finding infringement of the Asserted Claim of the '874 patent.

**Analysis and Conclusions:** I find that Align has shown by a preponderance of the evidence that Respondents infringe asserted claim 1 of the '874 patent.

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 claim of the '874 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.

Next, I find that the preamble of asserted claim 1 is limiting. Whether to treat a claim preamble as a limitation is a determination made after a review of the entire patent. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). In *Catalina*, the Federal Circuit stated:

In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention."

*Id.* (citations omitted). The court went on to explain that "a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* at 809.

The invention at issue in *Catalina* was a system for distributing coupons to consumers through kiosks. The court had to determine whether the phrase "located at predesignated sites such as consumer stores" was a limitation when it appeared in the preamble. *Id.* at 807-808. The

## PUBLIC VERSION

court found that the phrase was not a claim limitation. The court examined the specification and found that the location of the kiosks was not an essential feature of the invention. *Id.* at 810.

The applicants did not rely on the preamble to distinguish the invention from the prior art during prosecution. *Id.* Importantly, the court found that the claim was complete without the preamble:

Moreover, deletion of the disputed phrase from the preamble of Claim 1 does not affect the structural definition or operation of the terminal itself. The claim body defines a structurally complete invention. The location of the terminals in stores merely gives an intended use for the claimed terminals.

*Id.*

In *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1256 (Fed. Cir. 1989), the claim preamble was “[a]n optical waveguide comprising.” The court found that the preamble served as a limitation because the specification was clear that the invention was limited to fibers working as waveguides. As the court explained: “[t]he invention is restricted to those fibers that work as waveguides as defined in the specification, which is not true with respect to fibers constructed with the limitations of paragraphs (a) and (b) only.” *Id.* at 1257.

I find that the situation before me is closer to *Corning Glass* than *Catalina*. Here, the term “computer implemented method” is necessary to give meaning to the claims. The entire ‘874 patent is clearly devoted to a computer implemented method for completing the steps in the asserted claims. (*See generally* JX-006) The term makes clear that all of the elements listed in the claim body must be performed using a computer. This term adds a limitation that is not otherwise present in the claim. This is supported by the specification, which repeatedly describes using a computer to perform the steps of the methods described in the claims. (*See e.g.* JX-006; 3:7-9, 3:35-47, 4:3-9, 6:61-7:14, 10:12-15, 12:4-15) The preamble is the only place in asserted claim 1 at which the use of a computer to perform the steps in the claim is required.

## PUBLIC VERSION

Respondents contend that their processes are not “computer implemented” as required by the limitation in the preamble, and through this argument they attempt to offer a construction the term “computer implemented method.” I reaffirm my rejection of that attempt and my rationale for that rejection detailed, *supra*, at section III.E.3.

Based upon the construction adopted at section III.E.3, I find that Respondents clearly practice the limitation of the preamble that teaches a “computer implemented method.” This is best demonstrated by the testimony of Jarrett Pumphrey, CEO of CCUS, in which he admitted that Respondents’ process is implemented using computers and digital data, and described in detail the portions of the process that are automated and the portions that are interactive. (Tr. 314:4-320:15; 322:17-326:9; 329:11-339:10; 249:1-3; and CX-78 at p. 055, *et seq.*)

Respondents’ contention that they do not create orthodontic treatment plans is another disingenuous attempt to argue construction after having failed to provide a construction for this term in the SRJCCC, and it is rejected as waived. Nevertheless, assuming *arguendo* that one were to find that the Respondents’ construction of the term “treatment plan” was not waived, I find that their proposed construction is clearly incorrect. I refer to the discussion of construction of the term “treatment plan” set forth in section III.G.3, *supra*, and I reaffirm the construction applied to the term “treatment plan” and the rationale for it.

Applying the correct construction of the term to the term “treatment plan,” I find that CCPK practices the preamble of asserted claim 1 by {

}

Respondents did not dispute that they practice the first element of asserted claim 1, and I find that the evidence offered by Align demonstrates that this element practiced when {

PUBLIC VERSION

} (CX-1157C.1, 41:24-47-5, 47:22-50-17; CX-1157C.2)

Turning to the second element of asserted claim 1, as discussed in section V.E, *supra*, Align's expert, Dr. Beers, opined that this element is met. He testified that {

}

{

} which is discussed in detail in section V.E, *supra*. In the interest of brevity, I will not repeat Mr. Latif's testimony and my discussion of it here; but by this reference I incorporate the testimony and my analysis of it into the instant discussion.

{

## PUBLIC VERSION

} His testimony is set forth in section V.E., *supra*. In the interest of brevity, I will not repeat Dr. Arif's relevant testimony and my discussion of it here; but by this reference I incorporate the testimony and my analysis of it into the instant discussion.

Asserted claim 1 of the '874 patent teaches a computer implemented method of creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final desired positions. The second element of asserted claim 1 is met when data for individual tooth paths has been entered into FreeForm by the operator, and the operator causes FreeForm to generate the aggregate tooth paths into a set of intermediate positions toward which the teeth will move while moving from the initial positions toward a final position. The fact that asserted claim 1 does not specifically teach the interactive approach used by CCPK in entering the tooth path data for each individual tooth prior to generating the set of intermediate positions does not detract from this finding. Asserted claim 1 states "the method comprising," and that term is well understood in patent law to mean "including but not limited to." (*See e.g. Exergen Corp v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009))

Regarding the third element of asserted claim 1, Respondents assert that their system does not generate a plurality of appliances "from the initial positions toward the final positions," because their system is phased and the appliances are made as patient treatment progresses. It is obvious from Respondents' asserted defense that they are confusing the terms "to" and "toward" as they relate to the movement of a patient's teeth in the scheme of the '874 patent.

The term "to" generally means that the object reaches a destination, and the term "toward" generally means that the object is moving in the direction of a destination. (*Crane Co. et al. v. Sandenvendo America, Inc.*, 2009 U.S. Dist. LEXIS 47509 at \*20-21 (E.D. Tex. June 5,

## PUBLIC VERSION

2009)) Both terms are used in asserted claim 1. In the preamble the claim refers to repositioning a patient's teeth from initial positions *to* final positions. In the second and third elements of asserted claim 1, the inventor describes the movement (or repositioning) of the patient's teeth "from the initial positions **toward** the final positions." (JX-006, 32:39, 32:46-47, and 32:52-53)

The use of these two different terms within the claim makes clear that the method is to be used to create a treatment plan to achieve the final result of moving the patient's teeth from an initial position to reach a final position. In accomplishing this goal, the elements of the claim teach, *inter alia*, generating a plurality of intermediate positions to assist the teeth to move in the direction of the desired final position. In addition, the claim requires generating a plurality of appliances designed to move teeth from the initial positions in the direction of the final position.

The claim does not teach that the plurality of intermediate positions or the plurality of the successive appliances about which it speaks must, in fact, move the teeth from the initial position to actually reach the final position. The claim anticipates the specific set of facts present here in which the plurality of positions and appliances are directed at a partial movement toward the final goal.

Respondents do not deny that they generate a plurality of successive appliances as described in the third element; they only deny that they produce all of the appliances needed to move the patient's teeth from the initial positions to reach the final positions. Achieving this result is not a requirement of the third element of asserted claim 1. I find that CCUS practices the third element of asserted claim 1 when it generates a plurality of appliances as described in the third element to reposition teeth from the initial positions in the direction of the final positions. (CX-1150C, Q. 319)

## PUBLIC VERSION

Consistent with my finding regarding the third element, I find that the fourth element of asserted claim 1 is practiced as long as the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of “said plurality” so as to reposition the teeth. This limitation does not require that all of the successive appliances necessary to cause the teeth to reach their final positions be generated before the patient wears the first appliance. Respondents concede that Mr. Beers identifies conduct by CCUS as meeting this limitation. (Citing CX-1150C, Q. 320)

Align’s argument and my conclusion regarding the third and fourth elements of claim 1 are wholly consistent with Align’s position when processing the application that resulted in the ‘874 patent. Align argued that neither of the two references cited by the examiner contemplated making a plurality of appliances at the outset of treatment. They taught making one set of appliances at a time. Align did argue that claim 1 taught:

“...generating, at the outset of treatment, a plurality of sets of appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth *from the initial positions to the final positions*.”

(JX-016, at 273)(underlined bold in original)(italics added)

Subsequently, the applicant submitted an amended claim wherein the third element read:

“generating a plurality of sets of appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions to the final positions,”

(JX-016, at 293)

A further amendment was submitted, however, that contained the language of the third and fourth elements of claim 1 as it appears in the ‘874 patent, omitting *inter alia* the word “to” and substituting for it the word “toward.” This change was part of an amendment that occurred



## PUBLIC VERSION

at the suggestion of the examiner during a telephone interview between the examiner and the applicant's representative. (*See* JX-016, at 309 and 300 respectively) Ultimately the patent issued with the word "toward" in the third element of claim 1. (JX-016, at 382)

It is apparent from the discussions chronicled in the application wrapper, that the focus was primarily on the difference between creating one set of appliances at the outset of treatment versus creating a plurality of appliances. (*See e.g.* JX-016, at 273, 274, 300) Thus, while it is true that the applicant did use the word "to" at one point during the discussion, that was not the basis for the final action issuing the '874 patent, which ultimately issued using – at the apparent suggestion of the examiner – the word "toward."

Based upon the foregoing, I find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

### **2. Claim 2**

Asserted claim 2 depends from claim 1 and recites:

The method of claim 1, wherein receiving the initial digital data set comprises receiving data obtained by scanning a physical model of the patient's teeth.

(JX-006, 32:57-59)

**Align's position:** Align contends that CCUS practices this element by {

} (Citing CIB sections I.E.1 and 9; and CX-

1150C, Q. 322) Align alleges that Respondents did not contest that they infringe this element.

## PUBLIC VERSION

(Citing RPHB at 228, 235; and RX-129C, Q. 149) Align concludes that “Respondents infringe for the same reason as claim 1.”

**Respondents’ Position:** The Respondents contend that they do not infringe this dependent claim, because they do not infringe the independent claim. Respondents add that there is no infringement of claim 2, because “certain steps in claims 1 and 2 are alleged to take place in Pakistan, and certain steps in the U.S.” (Citing RIB section 3.3.1.3)

**Analysis and Conclusions:** Respondents do not deny that CCUS digitally scans a physical model of the patient’s teeth. They merely argue that they do not infringe this dependent claim based upon their argument that they do not infringe asserted claim 1 from which claim 2 depends.

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 2, 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. In addition, Align has produced credible evidence that CCPK practices this element by {

} (See testimony of Atif Kiyani at CX-1157C.1, 18:22-19:8, 23:15-16, 26:2-16, 41:24-47-5, 47:22-50-17; and CX-1157C.2, all of which is discussed in detail in section V.H.1, *supra*)

I find, therefore, that CCPK practices the element of asserted claim 2 of the ‘874 patent.

## PUBLIC VERSION

### 3. Claim 38

Asserted claim 38 depends from claim 1 and recites:

The method of claim 1, wherein generating the set of intermediate positions includes receiving data indicating restraints on movement of the patient's teeth and applying the data to generate the intermediate positions.

(JX-006, 34:56-59)

**Align's position:** Align argues that CCPK practices this element when {

} (Citing, CIB section I.E.6; and CX-1150C, Q. 324) Align says that Respondents assert their “computer-implemented” argument as a non-infringement basis, which is incorrect for the reasons discussed in CIB section IV.D. (Citing RPHB at 228, 235-36) Align says that Respondents also argue that the “data indicating restraints on movement” does not include bridges or other objects that are not moved. (*Id.* at 228, 236) Align says Respondents’ argument is unclear; “but this appears to be an improperly raised claim construction issue that is unsupported by any particular evidence.” Align concludes “Respondents infringe for the same reason as claim 1.”

In its reply brief Align says that Respondents’ arguments regarding claim 38 attempt to read in the “computer-implemented” requirement to the claim, which is a claim construction argument not properly raised, and therefore waived. (Citing CRB section IV.F.4) Align adds that “Respondents seem to apply a restrictive construction of the term “restraints” – to apply only to teeth, and not simulated tooth objects (bridges) – which Respondents also failed to raise in the *SRJCCC*, and is therefore waived.” (Citing Tr. at 8:4-9:4)

## PUBLIC VERSION

**Respondents' Position:** Respondents reiterate that they do not infringe this dependent claim, because they do not infringe the independent claim, and there is no infringement of claim 38 because certain steps in claims 1 and 38 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3)

Respondents continue, Mr. Beers relies solely upon the case submission form that includes a prescription from a Clinician. (Citing CX-1150C, Q. 324) Respondents say that Mr. Beers states that because a {

} that this limitation is met by the Respondents. Respondents assert that claim 1 requires a "computer-implemented method" for receiving "data indicating restraints on movement of the patient's teeth" and for "applying the data to generate the intermediate positions." Respondents argue that an operator reading a prescription would not meet this limitation. Respondents add that this limitation requires that the "data indicating restraints on movement" apply to the teeth that are being moved, not bridges or other objects that are not moved. Respondents reason that this limitation is not met by the Respondents, (Citing RX-129C, Q. 150) and there is no evidence that CCUS practices this limitation.

**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 38, 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. In addition, Align has produced credible evidence that CCPK practices this element. I found in section V.E. and I here reaffirm that, {

}

{

}

Based upon the foregoing, I find that CCPK practices the element of asserted claim 38.

**4. Claim 39**

Asserted claim 39 depends from claim 1 and recites:

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)

**Align's position:** Align contends that CCPK practices this element when {

} Align says that rather than addressing this,

Respondents take issue with Mr. Beers' description of their process, and argue that they do not infringe because the linear translation is not necessarily the most "effective" treatment. (Citing

## PUBLIC VERSION

RPHB at 229, 236; and RX-129C, Q. 151) Align asserts that “effective” does not appear in claim 39, and Respondents’ argument is therefore irrelevant. Align says that Respondents also argue that {

}

(Citing RPHB at 229, 236; and RX-129C, Q. 151) Align contends that Respondents presented no evidence to support this argument and adds that this after-occurring modification does not change the fact that {

} Align concludes that

“Respondents infringe for the same reason as claim 1.”

In its reply brief Align says that it presented sufficient evidence through the testimony of Mr. Beers and CCPK’s operator, Mr. Latif, to show that {

} (Citing CX-1150C, Qs. 135, 326,

328; and CX-1158C.1-3 at 62:25–75:13) Align says that Respondents seek to apply their “individual judgement” argument to this element; but it is unsupported in view of the cited evidence. Align adds that such an adjustment is irrelevant, as the infringing action has already occurred. Align concludes that Respondents have no infringement defense for this claim.

**Respondents’ Position:** Respondents argue that they do not infringe this dependent claim, because they do not infringe the independent claim. Respondents reiterate that there is no infringement of claim 39, because certain steps in claims 1 and 39 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3)

Respondents add that the evidence demonstrates the CCPK operators manually dictate the projected tooth movement. (Citing Tr. 329: 11-341:21) Respondents aver that the CCPK

{  
} (Citing Tr. 329:17-341:21) Respondents say the process described at the hearing was detailed; but never included any discussion of “minimum amounts of transformation required” or “creating the intermediate positions to require the minimum amount of movement.” Respondents conclude that this limitation is not met by the Respondents. (Citing RX-129C, Q. 151) Respondents add that there is no evidence that CCUS practices this limitation.

**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 39, 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. In addition, Align has produced credible evidence that CCPK practices this element. Mr. Latif testified about how

{  
} (CX-1158C.1, 48:9-21, 49:9-18, 51:4-10, 58:10-21, 62:25-63:5, 76:1-5)

Based upon the foregoing, I find that CCPK practices the element of asserted claim 39.

## 5. Claim 41

Asserted claim 41 depends from claim 1 and recites:

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)

PUBLIC VERSION

**Align's position:** Align argues that CCPK practices this element when {  
} (Citing Tr. at 676:23-677:5) Align contends  
that by definition, "a linear interpolation along a straight line translational movements of equal  
sizes." Align says that Respondents again argue that {

} Align  
concludes that "Respondents infringe for the same reason as claim 1."

In its reply brief Align says that regarding claim and 41, Align presented sufficient  
evidence through the testimony of Mr. Beers and CCPK's operator, Mr. Latif, to show that  
{

} but it is unsupported in view of the cited evidence. Align adds that  
such an adjustment is irrelevant, as the infringing action has already occurred. Align concludes  
that "Respondents have no infringement defense for these claims."

**Respondents' Position:** Respondents argue that they do not infringe this dependent  
claim, because they do not infringe the independent claim. Respondents add there is no  
infringement of claim 41, because certain steps in claims 1 and 41 are alleged to take place in



## PUBLIC VERSION

Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3) Respondents assert that there is no competent evidence that the Respondents generate “intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes.” To the contrary, Respondents say the evidence demonstrates the {

} (Citing Tr. 329:17-

341:21) Respondents say the process described at the hearing included no discussion of “generating intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes.” Respondents add that Align’s reference to the “generate next steps” function of the Freeform software is also unavailing because the evidence demonstrated that {

} (Citing Tr. 336:8-338:5)

Respondents conclude there is no real evidence of tooth movement of equal sizes, and therefore, this limitation is not met by the Respondents. (Citing RX-129C, Q. 152) Finally, Respondents argue there is no evidence that CCUS performs this this limitation.

**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 41, 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. In addition, Align has produced credible evidence that CCPK practices this element. Align contends that by

**PUBLIC VERSION**

definition, “a linear interpolation along a straight line translational movements of equal sizes.” ,  
Jarrett Pumphrey admitted that in the accused process, {

} (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 evidence shows that CCPK practices this element of claim 41 when its {  
}

I find that CCPK practices the element of asserted claim 41.

**6. Claim 62**

Asserted claim 62 depends from claim 1 and recites:

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)

**Align’s position:** Align contends that CCPK practices this element when {  
} (Citing CIB  
sections I.E.9 and 10; and CX-1150C, Q. 330) Align alleges that Respondents did not contest  
that they infringe this element. (Citing RPHB at 230, 237; RX-129C, Q. 153) Align concludes  
that “Respondents infringe for the same reason as claim 1.”

## PUBLIC VERSION

**Respondents' Position:** Respondents argue that they do not infringe dependent claim 62, because they do not infringe the independent claim. Respondents continue that there is no infringement of claim 62, because certain steps in claims 1 and 62 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3) Respondents contend they do not meet this claim limitation, because even under Align's case theory there are not "final positions." Respondents aver that the evidence shows that the goal position for patients has always been the arrangement stated in the doctor's prescription. (Citing Tr. 353:5-23) Respondents assert that there have never been "final positions" in CCUS's process. Respondents conclude that Align has not offered any evidence that CCPK fabricates an appliance or practices this claim limitation.

**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 62, 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. In addition, Align has produced credible evidence that CCPK practices this element. I found in section V.H.1 that Respondents do not deny that they generate a plurality of successive appliances as described in the third element; they only deny that they produce all of the appliances needed to move the patient's teeth from the initial positions to reach the final positions. At the hearing on this matter, Respondents' witness, Jarrett Pumphrey, testified that {

} (Tr. 315:24-318:3)

Based upon the foregoing, I find that CCUS directly infringes asserted claim 62.

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

Based upon all of the foregoing I have found that there is an act of direct infringement of asserted claim 1 of the '874 patent when CCUS and CCPK act in concert to fabricate appliances using the data sets created by CCPK in the method described in the preamble and the first and second elements of asserted claim 1 and subsequently imported into the United States. I have found that CCPK practices the preamble, and the first and second elements of asserted claim 1 of the '874 patent. In addition I have found that CCUS practices all limitations added by dependent claims 2 and 62, and that CCPK practices all limitations added by dependent claims 38, 39 and 41. Because CCUS and CCPK act in concert to infringe claim 1, I find that CCUS and CCPK also act in concert to infringe dependent claims 2, 38, 29, 41 and 62 (infringement of which includes practice of all elements of claim 1). CCPK contributes to this infringement by providing digital data sets for importation, as explained below.

In section V.B.17, I described in detail how the elements required to demonstrate contributory infringement are met by Respondents, and I concluded that those elements have been met for the '874 patent. I will not repeat that discussion here; but I reaffirm my findings and the rationale for them.

Respondents' infringement results in a violation of Section 337. 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

## PUBLIC VERSION

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 creating appliances using the method described in asserted claim 1, importing and using digital data sets that are made by the process of claim 1 (as found in Section II.C, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

## VI. DOMESTIC INDUSTRY

### A. Applicable Law

In patent-based proceedings under section 337, a complainant must establish that an industry “relating to the articles protected by the patent...exists or is in the process of being established” in the United States. 19 U.S.C. § 1337(a)(2) (2008). Under Commission precedent, the domestic industry requirement of Section 337 consists of an “economic prong” and a “technical prong.” *Certain Data Storage Systems and Components Thereof*, Inv. No. 337-TA-471, Initial Determination Granting EMC’s Motion No. 471-8 Relating to the Domestic Industry Requirement’s Economic Prong (unreviewed) at 3 (Public Version, October 25, 2002).

The “economic prong” of the domestic industry requirement is satisfied when it is determined that the economic activities set forth in subsections (A), (B), and/or (C) of subsection 337(a)(3) have taken place or are taking place. *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, USITC Pub. No. 3003, 1996 ITC LEXIS 556, Comm’n Op. at 21 (Nov. 1996). With respect to the “economic prong,” 19 U.S.C. § 1337(a)(2) and (3) provide, in full:

(2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.

(3) For purposes of paragraph (2), an industry in the United States

## PUBLIC VERSION

shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned-

- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or
- (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the domestic industry requirement. *Certain Integrated Circuit Chipsets and Products Containing Same*, Inv. No. 337-TA-428, Order No 10, Initial Determination (Unreviewed) (May 4, 2000), citing *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Commission Op. at 15, USITC Pub. 3003 (Nov. 1996).

To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 (April 11, 2005). “The test for satisfying the ‘technical prong’ of the industry requirement is essentially same as that for infringement, i.e., a comparison of domestic products to the asserted claims.” *Alloc v. Int’l Trade Comm’n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery*, Inv. No. 337-TA-419, Order No. 43 (July 30, 1999).

### **B. Economic Prong**

**Align’s position:** Align says that Respondents do not contest domestic industry, and Align believes it is not at issue. Align says that its primary business is the development, design,

## PUBLIC VERSION

manufacture, sale and marketing of its Invisalign system in the U.S. (Citing CX-1235C at Q. 19; CX-1236C at Q. 8; CX-1237C at Q. 18)

Align asserts that it has made significant investment in plant, equipment, labor, and capital. Align says that it is headquartered in San Jose, California (“California Facility”). (Citing CX-1236C at Q. 4) Align continues that the California Facility has approximately {

} (Citing CX-1237C at Q. 26) Align says that most of {

} work at the California Facility. (Citing *Id.* at Q. 27)

Align continues that it {

} (Citing *id.*) Align’s says that its

California Facility {

} (Citing *Id.*)

Align says that it currently employs approximately { } employees in the U.S., including {

} (Citing *Id.* at Q. 30) Align says that the U.S.-based R&D employees design and improve Align’s process, including the proprietary “Treat” suite of software applications. (Citing *Id.* at Q. 31) Align continues that its “Treat” software, which has been developed, upgraded, and maintained on a continuing basis since Align’s inception, assists its technicians in preparing treatment plans for the planned movement of patients’ teeth. (Citing CX-1236C at Q. 15-21; CX-1237C at Q. 33) Align says that as of 2010, Align had {

} R&D employees developing, upgrading, and testing “Treat.” (Citing CX-1236C at Q. 24; CX-1237C at Q. 31) Align continues that in 2010 alone, Align’s {

} (Citing CX-1237C at Q. 32)

PUBLIC VERSION

Align says that it has also {  
} (Citing *Id.* at Q. 52) Align says that in 2010 and 2011,  
Align {  
} (Citing *id.*) Align says that all of the technology that is used {  
} (Citing CX-1236C at Q.  
11-14; CX-1237C at Q. 52)

Align asserts that because Align's primary business is the development, design,  
manufacture, sale, and marketing of its Invisalign system and its various elements, and because  
all of the asserted patents pertain to the Invisalign system, most of Align's business activities  
constitute exploitation of the asserted patents in the U.S., as well as overseas. Align says that it  
has {  
} in developing the manufacturing capacity and software  
necessary to create highly customized, highly precise, medical-quality aligners in volume.  
(Citing CX-1236C at Q. 10) Align says that since 2005, Align has {

} (Citing CX-1237C at Q. 37-38) Align says that as a result of these investments,  
over 1.2 million patients in the U.S. have entered treatment with Invisalign. (Citing *Id.* at Q. 50)

Align says that it directly supports the academic and research community through  
funding and grants for Invisalign-related scientific research. For example, Align {

} to  
better understand orthodontic treatment with clear aligners. (Citing *id.* at Q. 37)

Align says that it also {  
}  
to train and certify over 67,000 dental professionals in the U.S. on the use of its Invisalign



PUBLIC VERSION

system. (Citing *Id.* at Q. 41-42) Align continues that a U.S. team of Align personnel is devoted to developing and implementing the training and certification of dental professionals. (Citing *Id.* at Q. 40)

Align avers that it made significant investments to create and establish a U.S. market for Invisalign. Align says that its U.S. marketing consists of direct-to-consumer marketing, including print, television, and social media advertising; materials for use in doctors' offices; presentations at events; direct-to-doctor advertising; and e-mail campaigns. (Citing *Id.* at Q. 44-45) Align says that in 2010 alone, { } to market Invisalign in the U.S. (Citing *id.* at Q. 46)

Align contends that it also has an extensive patent portfolio and an in-house team that works with outside counsel to manage that portfolio. (Citing *id.* at Q. 55) Align says that it has spent considerable amounts of money to defend its intellectual property rights, including for example, { } pursuing patent and trade secret infringement suits in multiple venues against OrthoClear. (Citing *id.*) Align continues that Align previously offered a license to OrthoClear for Invisalign technology, although that deal was never consummated. (Citing *id.* at Q. 57) Align says that it estimates it likely { } engaging in those licensing negotiations. (Citing *id.*)

Align argues that it has introduced more than enough evidence to prove that the economic prong of Domestic Industry is satisfied and Staff agrees. (Citing SIB at 115-17) Align says that although Respondents cannot contest Align's showing (Tr. at 47:6-8, 78:13-19, 79:9-17.), they argue that:

[w]hile Align has presented evidence of expenditures relating to its Treat software and its business generally, it has not made a prima facie showing of how those expenditures relate to each of the specific patents asserted in this investigation

## PUBLIC VERSION

(Citing RIB at 148)

Align argues that Respondents' argument is contrary to the applicable precedent, which does not require expenditures to be segregated on a per patent basis. (Citing *Certain Wireless Commc'n Devices*, Inv. No. 337-TA-745, I.D. at 365 (Apr. 24, 2012) ("the Commission recognizes those who hold intellectual property rights do not usually account for expenses and profit on a per patent basis"); *Certain Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm'n Op. at 26 (Dec. 2009) ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation."))

**Respondents' Position:** Respondents' Position: Respondents say that while Align has presented evidence of expenditures relating to its Treat software and its business generally, it has not made a prima facie showing of how those expenditures relate to each of the specific patents asserted in this investigation. Respondents conclude, as a result, that Align has failed to make a prima facie case that it meets the economic prong of the domestic industry requirement.

Respondents say that Align's Post-Hearing Brief has presented evidence of expenditures relating to its Treat software and its business generally, but still has not made a prima facie showing of how those expenditures relate to each of the specific patents asserted in this investigation.

**Staff's Position:** Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry. (Citing Tr. at 47:20-48:4)

Staff contends that the evidence supports finding that Align has made significant investment in both (i) plant and equipment and (ii) labor and capital with respect to Align's Invisalign System. Staff says that Align's principal place of business is located in San Jose,

PUBLIC VERSION

California ("California Facility"), and consists of approximately { }

(Citing CX-1237C at Q. 25-26) Staff continues that the California Facility is home to Align's

{

} (Citing *id.*)

Staff says that the California Facility {

} (Citing *id.*) Staff continues that Align's {

} (Citing *id.*) Staff

says that prior to moving into the California Facility, Align rented a facility in Santa Clara,

California that was approximately {

} (Citing *id.*)

Staff says that in 2010, Align had over {

} (Citing CX-1237C at Q. 30 and 32) Staff continues that the

U.S.-based research and development employees work to design and improve Align's process,

including Align's proprietary software. (Citing CX-1237C at Q. 31 and 33) Staff says that in

2010, Align {

} (Citing CX-1237C at Q. 32 and 37) Staff continues that Align also { } to

train dental professionals in the United States on how to use Invisalign and {

} to market Invisalign in the United States. (Citing CX-1237C at Q. 42 and 46) Staff

says that between 2005 and 2011, Align { } to

develop and upgrade its software. (Citing CX-1237C at Q. 38) Staff continues that over 1.2

PUBLIC VERSION

million patients in the United States have entered treatment with Invisalign. (Citing CX-1237C at 50)

Staff concludes that the evidence supports finding that Align has made significant investment in both (i) plant and equipment and (ii) labor and capital with respect to Align's Invisalign System.

Staff says that based on my ruling that Respondents have waived their right to contest the issue of domestic industry (Citing Tr. at 47:20-48:4), Respondents' arguments on domestic industry should be rejected. Staff says that Respondents did not dispute (and did not rebut) Align's evidence. Staff concludes as a result that Complainant has made a *prima facie* case showing that there is a domestic industry with respect to each Asserted Patent. (Citing *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, Final Initial Determination on Violation of Section 337 at 286-292 (July 29, 2010); *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, Final Initial Determination on Violation of Section 337 at 190 (Dec. 1, 2008))

**Analysis and Conclusions:** I found that Respondents waived the right to contest the issue of domestic industry. (Tr. at 46:20-48:4; *see also* Tr. at 72:10-82:7) Because of this waiver, I instructed Align that it only needed to make a *prima facie* showing of domestic industry. (*Id.*) I find that Align has made the required *prima facie* showing that it meets the economic prong of the domestic industry requirement. In Section VI.C, *infra*, I find that Align practices claims of 6 of the 7 patents in suit by using software to design and manufacture dental aligners. Align { } on its facility in California (CX-1237C at Q.25-26) which is home to Align's {

} (CX-1237C at Q. 27) Align's

## PUBLIC VERSION

research and development employees work to design and improve Align's processes, including the "treat" suite of software applications it uses to practice the patents in suit discussed above. (See CX-1237C at Q. 31) Based on this evidence, I find that Align has made a *prima facie* showing that it has made a significant investment in plant and equipment related to the articles protected by the patents in suit.

Align employs { } who "work to design and improve Align's process, including the proprietary 'treat' suite of software applications." (CX-1237C at Q. 31) Align pays its { } (CX-1237C at Q. 32). Based on this evidence, I find that Align has made a *prima facie* showing that it has made significant employment of labor or capital in the United States related to the articles protected by the patents in suit.

Because Align has made a *prima facie* showing that it has made a significant investment in plant and equipment and has made significant employment of labor or capital in the United States, I find that Align has established that the Economic Prong of Domestic Industry is met. See 19 U.S.C. §§ 1337(a)(2) and (3).

### C. Technical Prong

#### 1. The '325 Patent (claim 21)

**Align's position:** Align asserts that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing Tr. at 618:21-619:2) Align says that because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 21 of the '325 patent. (Citing Tr. at 47:6-13)

PUBLIC VERSION

| CLAIM  | ALIGN METHOD  |
|--|---|
| 21. A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising:  | Align fabricates a series of individualized, custom-created polymeric aligners, used to reposition teeth. CX-1235C at Q. 20, 23.  |
| providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;  | {   |
| controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and   | Using the digital data set of the digital model with a modified tooth arrangement, Align fabricates a positive model of the patient's teeth in the modified arrangement. CX-1235C at Q. 20, 23.   |
| producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. | Align fabricates at least one dental aligner as a negative of the positive model by molding polymeric material over the positive model. CX-1235C at Q. 23. Each aligner covers a plurality of teeth in an upper or lower jaw of the patient, and the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. <i>Id.</i> at Q. 20, 23. |

Align argues that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Inv. No. 337-TA-691, Order No. 18 at 25-26 (Aug. 2010)) Align says that Align's expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided un rebutted testimony that Align practices each of the asserted claims (including claim 21 of the '325 patent), and that Invisalign is the commercial embodiment of Align's asserted patents. Align continues that Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the patents in suit in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18, 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align contends that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, I.D. at 190 (Oct.

PUBLIC VERSION

2011) (Rogers, J.); *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, I.D. at 290-91 (July 2010) (Rogers, J.))

Align argues that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 79:9-17)

**Respondents' Position:** Respondents assert that Align failed to make a *prima facie* case that it satisfies the technical prong requirement with regard to at least one claim of each of the patents in suit. Respondents say that Align's evidence relating to the technical prong as it relates to each patent, a portion of the witness statement of Eric Kuo, was stricken as improper expert testimony. (Citing Tr. 45:12-48:4) Respondents continue that Align is left with conclusory statements that do not satisfy its burden of proof. Respondents conclude, as a result, that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to each asserted patent.

**Staff's Position:** Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '325 patent. (Citing Hearing Tr. at 47:20-48:4)

Staff argues that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '325 patent is met with Align's practice of at least claim 21 of the '325 patent. Staff says that the evidence demonstrates the following: (1) Align practices the preamble of claim 21 of the '325 patent, if limiting, when Align fabricates a series of individualized, custom-created aligners used to reposition teeth. (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L); (2) Align practices the first element of claim 21 of the '325 patent when Align {

## PUBLIC VERSION

} (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L); (3) Align practices the second element of claim 21 of the '325 patent when Align fabricates a positive model of the patient's teeth in the modified arrangement, using the digital data set of the digital model with a modified tooth arrangement. (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L); and (4) Align practices the third element of claim 21 of the '325 patent when Align fabricates at least one dental aligner as a negative of the positive model by molding polymeric material over the positive model. Each aligner covers a plurality of teeth in an upper or lower jaw of the patient, and the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L)

Staff says that Respondents argue that Complainant has failed to show that it satisfies the (i) "technical prong" requirement with respect to each Asserted Patent and (ii) the "economic prong" requirement. Staff contends that based on my ruling that Respondents have waived their right to contest the issue of domestic industry (Citing Hearing Tr. at 47:20-48:4), Respondents' arguments should be rejected.

Staff contends that, as shown above, the evidence supports finding that Complainant has made a *prima facie* case demonstrating that there is a domestic industry with respect to each Asserted Patent. Staff says that Respondents do not contest the testimony explaining Align's processes provided by Eric Kuo (CX-1235C at Q. 20-23) or the "Domestic Industry Claim Charts" for the patents in suit attached to the Corrected Complaint (Exhibits L-R). Staff continues that Respondents do not contest the testimony that Align's Invisalign product practices asserted claims of the patents in suit provided by Complainant's expert Maureen Valley. (Citing



## PUBLIC VERSION

RX-1247C at Q. 70-74 and 486-488) Staff says that while Respondents do contest the commercial success of Align's Invisalign product, Respondents do not contest that Align's Invisalign product is a commercial embodiment of asserted claims of the patents in suit. (Citing RIB at 70-72) Staff reasons that because Respondents did not dispute (and did not rebut) such evidence, the Staff is of the view that Complainant has made a *prima facie* case showing that there is a domestic industry with respect to each Asserted Patent. (Citing *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, Final Initial Determination on Violation of Section 337 at 286-292 (July 29, 2010); *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, Final Initial Determination on Violation of Section 337 at 190 (Dec. 1, 2008))

**Analysis and Conclusions:** I find that Align has made a *prima facie* showing that it practices claim 21. I explained at the prehearing conference that Align needed only to put on a *prima facie* case on how they met the domestic industry requirement, and that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr. at 47:2-48:4) Respondents' argument that the exclusion of Dr. Kuo's concluding opinion on whether or not Align's process practices the claims of the patents is unpersuasive. At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of asserted claim 21 in its post-hearing brief. (CX-1235C at Qs. 20-23; CIB at 74-75) Therefore, I find that Align has made a *prima facie* showing that it practices claim 21 of the '325 patent, as demonstrated in the following claim chart:

| CLAIM   | ALIGN METHOD   |
|---|--|
| 21. A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising: | Align fabricates a series of individualized, custom-created polymeric aligners, used to reposition teeth. CX-1235C at Q. 20, 23. |

## PUBLIC VERSION

|  |   |
|--|---|
| providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;  | {   |
| controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and   | Using the digital data set of the digital model with a modified tooth arrangement, Align fabricates a positive model of the patient's teeth in the modified arrangement. CX-1235C at Q. 20, 23.   |
| producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. | Align fabricates at least one dental aligner as a negative of the positive model by molding polymeric material over the positive model. CX-1235C at Q. 23. Each aligner covers a plurality of teeth in an upper or lower jaw of the patient, and the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. <i>Id.</i> at Q. 20, 23. |

### 2. The '880 Patent (claim 1)

**Align's Position:** Align argues that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing RJSCI ¶ 39; Tr. at 618:21-619:2) Align says that Respondents affirmatively state that Align practices claim 1 of the '880 Patent as part of their claim construction analysis. (Citing RPHB at 87) Align continues that, because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 1 of the '880 patent. (Citing Tr. at 47:6-13)

| CLAIM ELEMENT   | ALIGN METHOD   |
|---|--|
| 1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising: | Align fabricates a series of individualized, custom-created aligners, used to incrementally reposition teeth, wherein the geometries of each of the appliances in the series are determined prior to fabrication. CX-1235C at Q. 20, 23. |
| a) obtaining a digital data set representing an initial tooth arrangement;  | Align obtains an initial digital data set representing an initial tooth arrangement by {   |
| b) obtaining a repositioned tooth   | {  |

PUBLIC VERSION

| CLAIM ELEMENT   | ALIGN METHOD   |
|---|--|
| arrangement based on the initial tooth arrangement;   | }  |
| c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and   | {  |
| d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement. | Align fabricates a series of custom-created aligners based on the plurality of digital data sets, wherein each aligner comprises polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said aligners correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement. CX-1235C at Q. 20, 23. |

Align contends that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Order No. 18 at 25-26) Align says that its expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided un rebutted testimony that Align practices each of the asserted claims (including claim 1 of the ‘880), and that Invisalign is the commercial embodiment of Align’s asserted patents. Align continues that Dr. Valley’s testimony is based upon: (i) her familiarity with Align’s products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align’s domestic industry charts (both of which set forth, in detail, Align’s processes) for the asserted patents in this Investigation; and (iii) an application of both parties’ proposed claim constructions. (Citing Tr. at 803:15-18; 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align argues that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, I.D. at 190; *Certain Bulk Welding Wire Containers*, I.D. at 290-91)

## PUBLIC VERSION

Align says that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 78:13-19, 79:9-17)

**Respondents' Position:** Citing to their arguments regarding the '325 patent, Respondents assert that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to the '880 patent.

**Staff's Position:** Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '880 patent. (Citing Tr. at 47:20-48:4)

Staff says that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '880 patent is met with Align's practice of at least claim 1 of the '880 patent. Staff says that the evidence shows the following:

- Align practices the preamble of claim 1 of the '880 patent, if limiting, when Align fabricates a series of individualized, custom-created aligners used to incrementally reposition teeth, wherein at least part of the aligners are predetermined. (Citing CX-1235C at Qs. 20-23; Corrected Complaint at Ex. P)
- Align practices the first element of claim 1 of the '880 patent when Align obtains an initial digital data set representing an initial tooth arrangement {  
}
- Align practices the second element of claim 1 of the '880 patent when Align {  
}
- Align practices the third element of claim 1 of the '880 patent when Align {  
}

## PUBLIC VERSION

- Align practices the fourth element of claim 1 of the '880 patent when Align fabricates a series of aligners based on the plurality of digital data sets, wherein each aligner comprises polymeric shells having cavities shaped to receive and resiliently reposition teeth, and the aligners correspond to the series of successive tooth arrangements progressing from the initial to a final tooth arrangement. (Citing CX-1235C at Qs. 20-23; Corrected Complaint at Ex. P)

Staff says that Respondents argue that Complainant has failed to show that it satisfies the (i) “technical prong” requirement with respect to each Asserted Patent and (ii) the “economic prong” requirement. Staff contends that based on my ruling that Respondents have waived their right to contest the issue of domestic industry (Citing Hearing Tr. at 47:20-48:4), Respondents’ arguments should be rejected.

Staff contends that, as shown above, the evidence supports finding that Complainant has made a *prima facie* case demonstrating that there is a domestic industry with respect to each Asserted Patent. Staff says that Respondents do not contest the testimony explaining Align’s processes provided by Eric Kuo (CX-1235C at Qs. 20-23) or the “Domestic Industry Claim Charts” for the patents in suit attached to the Corrected Complaint (Exhibits L-R). Staff continues that Respondents do not contest the testimony that Align’s Invisalign product practices asserted claims of the patents in suit provided by Complainant’s expert Maureen Valley. (Citing RX-1247C at Qs. 70-74 and 486-488) Staff says that while Respondents do contest the commercial success of Align’s Invisalign product, Respondents do not contest that Align’s Invisalign product is a commercial embodiment of asserted claims of the patents in suit. (Citing RIB at 70-72) Staff reasons that because Respondents did not dispute (and did not rebut) such evidence, the Staff is of the view that Complainant has made a *prima facie* case showing that there is a domestic industry with respect to each Asserted Patent. (Citing *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, Final Initial Determination on Violation of Section 337

## PUBLIC VERSION

at 286-292 (July 29, 2010); *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, Final Initial Determination on Violation of Section 337 at 190 (Dec. 1, 2008))

**Analysis and Conclusions:** I find that Align has made a *prima facie* showing that it practices claim 1 of the ‘880 patent. I explained at the prehearing conference that Align needed only to put on a *prima facie* case on how they met the domestic industry requirement, and that Respondents cannot offer a defense “because they have already stated that they waived it.” (Tr. at 47:2-48:4) Respondents’ argument that the exclusion of Dr. Kuo’s concluding opinion on whether or not Align’s process practices the claims of the patents is unpersuasive. At the hearing I said that Align “will have to put on a factual case about how their product works. Align can then argue how that relates to the patent.” (Tr. at 47:21-24) Dr. Kuo’s witness statement explains Align’s process and Align identifies how the process matches the elements of asserted claim 1 in its post-hearing brief. (CX-1235C at Qs. 20-23; CIB at 86-87) Therefore, I find that Align has made a *prima facie* showing that it practices claim 1 of the ‘880 patent, as demonstrated in the following claim chart:

| CLAIM ELEMENT   | ALIGN METHOD   |
|---|--|
| 1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising: | Align fabricates a series of individualized, custom-created aligners, used to incrementally reposition teeth, wherein the geometries of each of the appliances in the series are determined prior to fabrication. CX-1235C at Q. 20, 23. |
| a) obtaining a digital data set representing an initial tooth arrangement;  | Align obtains an initial digital data set representing an initial tooth arrangement by taking a {  |
| b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;                                       | {  |
| c) obtaining a series of successive digital data sets representing a series of  | {  |

**PUBLIC VERSION**

| CLAIM ELEMENT   | ALIGN METHOD   |
|---|--|
| successive tooth arrangements; and  | }  |
| d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement. | Align fabricates a series of custom-created aligners based on the plurality of digital data sets, wherein each aligner comprises polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said aligners correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement. CX-1235C at Q. 20, 23. |

**3. The '487 Patent (claim 7)**

**Align's Position:** Align asserts that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing RJSCI ¶ 62; Tr. at 618:21-619:2.) Align says that because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 7 of the '487 patent. (Citing Tr. at 47:6-13)

| CLAIM  | ALIGN METHOD  |
|--|---|
| 7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement. | Align receives from a dental provider a desired or prescribed arrangement for a patient's teeth. CX-1235C at Q. 21. Align technicians generate an orthodontic treatment plan for repositioning a patient's teeth to the desired arrangement using a series of individualized, custom-created aligners. CX-1235C at Q. 20, 22. { |



## PUBLIC VERSION

Align asserts that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Order No. 18 at 25-26) Align says that Align's expert witness on the technical prong of the domestic industry requirement, Dr. Valley, also provided unrebutted testimony that Align practices each of the asserted claims (including claim 7 of the '487), and that Invisalign is the commercial embodiment of Align's asserted patents. Align says that Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the asserted patents in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18; 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align argues that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, I.D. at 190; *Certain Bulk Welding Wire Containers*, I.D. at 290-91)

Align says that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 78:13-19, 79:9-17)

**Respondents' Position:** Respondents argue that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to the '487 patent. (Citing RIB Section 3.4) Respondents say that Align has failed to make a *prima facie* case that the technical prong of the domestic industry requirement is satisfied for the '487 patent. Align says that the claim upon which Align bases its domestic industry argument is claim number 7, an independent claim requiring an orthodontic treatment plan residing on a computer readable storage media. Align continues that as described in RRB section 4.1.1, the plain and ordinary meaning of a treatment plan is a treatment strategy composed by the treating doctor. Align



## PUBLIC VERSION

argues that such a meaning is consistent with applicable state laws, the evidence presented at the hearing, and Align's provisional application for which priority of the '487 patent is asserted. Respondents say that Align's domestic industry argument asserts that Align receives a desired or prescribed arrangement for a patient's teeth from "a dental provider." Respondents contend that the phrase "dental provider" makes no sense. Alternatively, Respondents say that assuming "dental provider" means the treating doctor, Align has still failed to establish the technical prong because it has offered no evidence or argument that the doctor's treatment plan resides on a computer readable storage media. (Citing CX-1235C at Q. 21) Respondents say that the only suggestion Align makes concerning data residing on a computer relates to the digital models created by Align technicians which, by definition, cannot be a treatment plan.

**Staff's position:** Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '487 patent. (Citing Tr. at 47:20-48:4) Staff continues that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '487 patent is met with Align's practice of at least claim 7 of the '487 patent. Staff explains that the evidence shows that Align practices all of the claim elements as follows: (i) Align receives from a dental provider a desired arrangement for a patient's teeth; (ii) Align generates an orthodontic treatment plan for repositioning a patient's teeth to a desired arrangement using a series of aligners; (iii) Align,

{

PUBLIC VERSION

} (Citing CX-1235C at Q. 20-23; Corrected

Complaint at Ex. R)

**Analysis and Conclusions:** I find that Align has made a *prima facie* showing that it practices claim 7 of the ‘487 patent. I explained at the prehearing conference that Align needed only to put on a *prima facie* case on how they met the domestic industry requirement, and that Respondents cannot offer a defense “because they have already stated that they waived it.” (Tr. at 47:2-48:4) Respondents’ argument that the exclusion of Dr. Kuo’s concluding opinion on whether or not Align’s process practices the claims of the patents is unpersuasive. At the hearing I said that Align “will have to put on a factual case about how their product works. Align can then argue how that relates to the patent.” (Tr. at 47:21-24) Dr. Kuo’s witness statement explains Align’s process and Align identifies how the process matches the elements of asserted claim 1 in its post-hearing brief. (CX-1235C at Qs. 20-23; CIB at 86-87) Therefore, I find that Align has made a *prima facie* showing that it practices claim 7 of the ‘487 patent, as demonstrated in the following claim chart:

## PUBLIC VERSION

| CLAIM  | ALIGN METHOD  |
|--|---|
| 7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement. | Align receives from a dental provider a desired or prescribed arrangement for a patient's teeth. CX-1235C at Q. 21. Align technicians generate an orthodontic treatment plan for repositioning a patient's teeth to the desired arrangement using a series of individualized, custom-created aligners. CX-1235C at Q. 20, 22. { |

In addition to being waived, Respondents' arguments that Align has not established that it creates a "treatment plan" is based on Respondents' incorrect construction for the term "treatment plan." As explained in Section III.D.2, *supra*, there is no requirement that a "treatment plan" be created by a clinician. As noted above, Align has made a prima facie showing that it generates a plurality of intermediate digital data sets and stores those intermediate digital data sets on a computer. As a result, Respondents' arguments are unpersuasive.

### 4. The '511 Patent (claim 1)

**Align's position:** Align notes that Respondents do not contest domestic industry, and Align believes it is not at issue. (Citing Tr. at 618:21-619:2) Nevertheless, Align argues that it has submitted substantial evidence (as outlined in the chart below) that it practices at least claim 1 of the '511 patent. (Citing Tr. at 47:6-13)