3. Secondary Consideration of Non-Obviousness

Respondents' Position: Respondents assert that Align's reliance on secondary considerations of non-obviousness is not persuasive. Respondents say that there is no doubt that Align has been a commercial success. Respondents continue that Dr. Valley, Align's expert, did not consider the factors noted by the Federal Circuit in *Ormco I.* Respondents say that Dr. Valley does not appear to attribute any of Align's commercial success to: (1) resolving aesthetic concerns associated with braces, (2) eliminating abrasive discomfort associated with wires and braces, (3) reduced pain of treatment, or (4) better ease of brushing and flossing because the appliances were removable. Respondents say that Align contended in *Ormco I* that these accomplishments were critically important to its commercial success, they are apparently of no moment now.

Respondents assert that Dr. Valley's conclusions on Align's computerized design and manufacturing demand close scrutiny. Respondents say that Dr. Valley testifies that Align's commercial success is directly connected the use of computers to: (1) fabricate aligners which "facilitate major tooth movements over multiple treatment stages," (2) create a powerful communication tool between the clinician and patient, and (3) create three-dimensional visualizations that allow clinicians to quickly determine the feasibility of a treatment plan. (Citing CX-1247C at Q. 497) Respondents argue that Dr. Valley's first contention was effectively rejected by the Federal Circuit in *Ormco I.* Respondents say that the Federal Circuit's opinion describes in detail how an orthodontist named Dr. Lloyd Truax, in prior art, fabricated multiple orthodontic appliances to treat patients in multiple stages. (Citing *Ormco I* at 1307-09) Respondents reason that Align's fabrication of multiple appliances that facilitate tooth movements over multiple stages cannot be used to avoid obviousness here because that concept

was disclosed in the prior art. (Citing *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) ("[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art."))

Respondents argue that Dr. Valley's remaining two contentions likewise fail. Respondents assert that The Federal Circuit noted in *Ormco I* that "commercial success" of the patent holder is not relevant if that success is due to an unclaimed feature. (Citing *Ormco I* at 1312) Respondents say that the patent claims at issue here claim digital modeling of treatment for the fabrication of appliances. Respondents continue that nowhere do the patents at issue in this investigation claim a communication tool between the clinician and patient or three-dimensional visualizations that allow clinicians to determine the feasibility of their treatment plans. Respondents contend that the features Dr. Valley describes are not claimed and cannot support any conclusion of "commercial success" that cuts against obviousness.

Respondents assert that Align has itself presented substantial evidence that weighs against Dr. Valley's testimony. Respondents say that Align's 10-K filing for the period ending December 31, 2003 is typical. (Citing CX-1266) Respondents aver that Align has a complete section describing the "Benefits of Invisalign." (Citing CX-1266-007) Respondents continue that the section describes the aesthetic and comfort factors addressed in *Ormco I*. Respondents say that nowhere in the section does Align claim computer modeling or the use of intermediate data sets as a benefit. Respondents continue that the same is true for Align's section on "Competition." (Citing CX-1266-0014) Respondents say that Align describes the "principal competitive factors for orthodontic appliances" as: (1) aesthetic appeal of the treatment method; (2) comfort associated with the treatment method; (3) oral hygiene; (4) effectiveness of treatment; (5) ease of use; and (6) dental professional's chair time. (Citing CX-1266-014)

Respondents aver that Align made no mention of computer modeling or digital data sets. According to Respondents, these were the factors Align considered critical three years before the Federal Circuit rejected them as "secondary considerations" in *Ormco I*. Respondents argue that only now does Align assert that the digital files are Align's alleged reasons for its "commercial success."

Respondents assert that Dr. Valley also opines that "Align's invisalign products met a long felt need for an aesthetic, removable alternative to fixed appliances." (Citing CX-1247C at Q. 501) Respondents say that one typical article she cites was entitled "Invisible Orthodontics" and, as Dr. Valley notes, indicates that an invisible appliance is the "holy grail" of orthodontics. (Citing CX-1272 and CX1247C at Q. 510) Respondents say that the article's theme is described in the first paragraph: "One of the attributes of a perfect appliance is its aesthetics; an invisible appliance is the holy grail of orthodontics. The reasons are obvious. Who would not want to be able to have his teeth straightened if it could be done without metal braces?" (Citing CX-1272)

Respondents argue that these arguments, particularly addressing the aesthetics of an invisible appliance, are precisely the arguments Align made in *Ormco I*. Respondents say that the Federal Circuit specifically considered Align's argument that its product offered the same aesthetic, comfort and hygienic properties that Dr. Valley lauds here. (Citing *Ormco I*, 463 F.3d at 1311-13) Respondents continue that the arguments were not enough to overcome obviousness and were expressly rejected when the Federal Circuit held "Nor has Align submitted probative evidence that claimed and novel features met a long felt but unresolved need." (Citing *Ormco I*, 463 F.3d at 1313) Respondents say that Align offers no reason why the result should be different in this case.

Respondents contend that the Federal Circuit held in *Ormco I* that evidence of any "secondary consideration" is significant only if there is a nexus with the claimed invention. (Citing *Ormco I*, 463 F.3d at 1311-12) Respondents say that Align's arguments about initial skepticism and subsequent industry praise are flawed because neither the skepticism, nor the praise, it cites are directed to the "digital data sets" that are the subject of this investigation and the patent claims at issue here. Respondents add that both the skepticism and praise are directed to the use of the removable orthodontic appliances to treat complicated cases. Respondents say that this skepticism could therefore apply equally to the multiple appliances referenced in Kesling from the 1940s or Dr. Nahoum's article from the 1960s.

Respondents say that Align attempts to prove the initial skepticism through Dr. Valley's witness statement and several articles she cites. (Citing CX-1247C at Q. 521-531) Respondents disagree, saying that nowhere does Align or Dr. Valley suggest that any skepticism was directed toward Align's ability to create computer models or "digital data sets" concerning the projected treatment; rather, most of the cited articles appear to accept the digital modeling as proficient and only challenge the use of removable appliances for complex orthodontic cases. Respondents say that this skepticism goes to the apparatus itself—the removable appliances called aligners—and not to any particular method of making that appliance. Respondents continue that the patent claims here do not claim any such apparatus. Respondents say that because the skepticism Align and Dr. Valley cite is directed to the use of appliance instead of the methods for making it, that skepticism cannot support the claims.

Respondents add that the same is true for Align's arguments concerning industry praise. Respondents say that Dr. Valley testified about the number of dentists who are trained to use the Invisialign product, but there is no link to the subject of the patent claims at issue here. (Citing

CX-1247C at Q.537-543) Respondents conclude, as a result, that Dr. Valley's opinions on "industry praise" fail to establish a viable "secondary consideration."

Respondents assert that Align failed to establish the "secondary consideration" of copying. Respondents say that the evidence demonstrates that Align itself copied the relevant prior art. Respondents continue that the evidence disproves that either OrthoClear or CCUS copied Align; rather, the evidence Align tendered at the hearing indicates that Align actually copied Ormco's intellectual property. Respondents say that the 10-K filings Align offered describe Ormco's successful pursuit of patent infringement against Align. Respondents aver that Ormco initially sued Align during 2000. (Citing CX-1266-018) Respondents say that on February 25, 2009, the presiding federal district court granted judgment in Ormco's favor, finding that Align infringed Ormco's patented technology. (Citing CX-1204-042) Respondents continue that on August 16, 2009, Align settled by paying Ormco a settlement valued at $76.7 million. (Citing CX-1201-048)

Respondents argue that the evidence also disproves that Align's intellectual property was copied by OrthoClear or CCUS. Respondents say that Dr. Nadeem Arif, a former employee of both Align and OrthoClear and current employee of CCPK, testified that OrthoClear's process involved sectioning a physical model of a patient's teeth, placing them on pins, and inserting the pins into a base plate to re-locate the teeth during projected treatment. (Citing Tr. at 214:4 to Tr. 216:9) Respondents say that none of Align's claims address such a process. Respondents continue that Dr. Pumphrey testified that all of the appliances for the Invisalign product were fabricated and delivered to the doctor before the patient's treatment began. (Citing Tr. at 406:8-16) Respondents say that OrthoClear used a system in which it fabricated only two appliances at a time, which was more efficient for doctors. (Citing Tr. at 407:10-408:12)

Respondents argue that Dr. Valley does not form an opinion that either OrthoClear or CCUS actually copied Align; rather she instead makes a series of statements such as she "has been informed there is evidence" that suggests similarities between the companies' products or that she "has been informed" that OrthoClear used similar software. (Citing CX-1247C at Q. 546-547) Respondents assert that Dr. Valley's hedged and equivocal statements are not evidence of copying.

Respondents assert that the prior art demonstrates that long before Align, orthodontists had applied digital methods to earlier mechanical methods of modeling the movement of teeth to create digital data that represented successive tooth positions. Respondents say that the prior art also teaches the use and fabrication of series of appliances and shows controlling a fabrication machine to make positive models of tooth arrangement. Respondents say that Align contended likewise in prior litigation. Respondents alternatively contend that the asserted claims are simply the application of modern digital methods to long existing mechanical methods, and because the application of modern digital methods was previously disclosed in the prior art, the asserted claims are invalid as obvious.

Align's position: Align asserts that even if a proper obviousness analysis had been advanced, the asserted claims of Align's patents are nonobvious based on secondary considerations. Align says that such evidence is tied to Align's commercial embodiment of the asserted claims, the Invisalign products. (Citing *See* CX-1254C ¶ 219 at 79-80; CX-1247C at Q. 487-488) Align continues that sales and market share provides strong evidence of commercial success. (Citing *See Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360-61 (Fed. Cir. 1999)) Align asserts that revenues from sales of Invisalign products have increased since its commercial introduction and the volume of cases shipped has tripled between 2004 and 2011.

(Citing CX-1254C ¶¶ 221-222 at 80-81; CX-1247C at Q. 489-492, 498-99; CX-1265 at 37; CX-1266 at 46; CX-1267 at 47; CX-1204 at 53-54; CX-1201 at 43-44) Align says that in 2009, Invisalign had 87.2% of the clear aligner market by volume and 95.26% by revenue. (Citing CX-1254C ¶¶ 223-224 at 81-82; CX-1247C at Q. 493-494; CX-1268 at 17-18; CX-1259) Align says that Dr. Valley confirmed that Align's commercial success is directly connected to the claims. (Citing Tr. at 803:22-804:16, 805:8-19; CX-1254C ¶¶ 225-230 at 77-79; CX-1247C at Q. 495-497)

Align asserts that a long-felt need resolved by an invention is evidence of non-obviousness. (Citing *Star Sci.*, 655 F.3d at 1376) Align says that Invisalign met a long-felt need for aesthetic, removable appliances that: (i) serve as an alternative to fixed appliances; and (ii) can treat moderate to severe malocclusions over multiple treatment stages. (Citing CX-1254C ¶¶ 231-239 at 84-87; CX-1247C at Q. 500-511, 519-20; CX-1269C at 15, 29-30; CX-1288 at 2-8; CX-1271 at 1, 5; CX-1272) Align continues that removable aesthetic orthodontic appliances with these capabilities did not exist before Invisalign. (Citing CX-1254C ¶¶ 240-244 at 87-89; CX-1247C at Q. 512-515; CX-1273 at 1; CX-1274 at 5; CX-1275 at 8) Align says that satisfaction of this long-felt need is tied to the claims. (Citing CX-1254C ¶¶ 245-246 at 89; CX-1247C at Q. 516-518)

Align asserts that Evidence of the skepticism and disbelief of an invention supports nonobviousness. (Citing *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1350 (Fed. Cir. 2007)) Align says that Considerable skepticism existed in the orthodontic community regarding Invisalign. (Citing CX-1254C ¶¶ 247-253 at 90-92; CX-1247C at Q. 521-529, 530-31; CX-1277C at 22-23) Align explains that there was doubt as to whether Invisalign would work in

"more complex cases" or was merely a "marketing gimmick." (Citing CX-1254C ¶¶ 247-253 at 90-92; CX-1247C at Q. 521-529; CX-1269C at 30; CX-1274 at 4; CX-1278 at 2; CX-1260)

Align asserts that industry praise of an invention supports nonobviousness. (Citing *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling U.S., Inc.*, 699 F.3d 1340 (Fed. Cir. 2012)) Align says that in 2002, Align won the Canon Communications LLC Medical Design Excellence Award. (Citing CX-1254C ¶ 256 at 92; CX-1247C at Q. 534-535; CX-1279) Align continues that in 2004, Align received the Frost and Sullivan Technology Leadership of the Year Award for Invisalign's role in creating an "entirely new concept for a well-established product technology[.]" (Citing CX-1254C ¶ 257 at 92-93; CX-1247C at Q. 534, 536; CX-1280 at 1-3) Align avers that virtually all U.S. orthodontists have undergone Invisalign training and Invisalign is taught in most dental schools. (Citing CX-1254C ¶ 258 at 93; CX-1247C at Q. 537-538; CX-1281 at 5; CX-1282 at 3) Align continues that Invisalign has been recognized repeatedly as a "game-changer" in the field of orthodontics due to its ability "to treat extraordinarily difficult malocclusions to a high standard of care without the need for fixed appliances or dentoalveolar surgery." (Citing CX-1254C ¶¶ 258-260 at 93-94; CX-1247C at Q. 539-543; CX-1283 at 6; CX-1284 at 1-2)

Align contends that copying also provides compelling evidence of non-obviousness. *See Akamai Techs. v. Cable & Wireless Internet Servs.*, 344 F.3d 1186, 1196 (Fed. Cir. 2003). Align argues that OrthoClear misappropriated Align's IP and used modified versions of Align's software. (Citing CX-1254C ¶¶ 262-264 at 94-95; CX-1247C at Q. 544-546, 549-50; CX-1267 at 33-34) Align says that Respondents copied Invisalign and Align's software. (Citing Tr. at 314:4-318:11, 319:22-320:9; CX-1254C ¶¶ 265-271 at 95-96; CX-1247C at Q. 544, 547; CX-1151C.1 at 127:22-133:1; CX-0116C; CX-1241C) Align continues that Respondents' copying is directly

tied to the claims. (Citing Tr. at 415:15-416:7; CX-1254C ¶¶ 270-271 at 96; CX-1247C at Q. 548)

Align asserts that Respondents' wrongly assert that Align's method of creating visual images of tooth arrangements is not recited in the asserted claims. Align says that its claims specifically recite a method for creating visual images based on digital data sets representing substantially accurate shapes of a patient's actual teeth. (Citing JX-0003 at 27 (2:27-53)) Respondents say that as Dr. Valley opined that these images may be used as a diagnostic tool between the clinician and the patient and support the commercial success of Align's inventions. (Respondents say that CX-1254C at ¶¶ 228-230, at 83-84; CX-1247C at Q. 496-497) Align disagrees with Respondents' reliance on a single 10-K to claim that Align never acknowledged either "computer modeling" or the use of "digital data sets" as being commercially beneficial. Align says that this 10-K actually discusses the benefits of being able to (i) "visualize treatment," (ii) determine a "likely outcome," and (iii) produce highly customized aligners in volume. (Citing CX-1266 at 7, 11)

Align disagrees with Respondents' argument that Invisalign satisfied a long-felt need solely because of its aesthetic appeal. Align says that Invisalign met a long-felt need for a removable appliance with the ability to treat moderate to severe malocclusions over multiple treatment stages without the disadvantages of fixed appliances, of which only one was poor aesthetics. (Citing CIB at 46; CX-1247C at Q. 501-502, 516-518.) Align says that Respondents rely solely on CX-1272 for the proposition that aesthetics is the "holy grail" of orthodontics. (Citing RIB at 73) Align says that the article further discusses the disadvantages of existing manual methods for creating existing removable appliances that were limited to "cases requiring small changes" as well as "[a]dvances in computer programs" that would allow for a series of

models to be created from start to final position to facilitate tooth movements. (Citing CX-1272 at 1-2)

Align disagrees with Respondents' argument that the evidence concerning the initial skepticism and later industry praise is insufficiently related to the asserted claims. Align says that skepticism existed in the orthodontic community regarding Align's computerized system. (Citing CX-1278 at 2) Align continues that the industry later recognized and praised Invisalign's ability to facilitate major tooth movements, including Align's system for fabricating aligners. (Citing CX-1280 at 1-2; CX-1275 at 9)

Align asserts that Respondents fail to rebut the evidence showing that OrthoClear and the Respondents copied Align's inventions. Align says that Respondents ignore their own copying and address only Align's allegations regarding OrthoClear, and limit their arguments only to a small portion of OrthoClear's entire process to improperly assert that none of OrthoClear's processes and/or products were copied from Align. Align continues that Respondents also argue that Dr. Valley did not form an opinion as to whether OrthoClear or CCUS copied Align. Align disagrees, explaining that Dr. Valley specifically testified that: (i) there was "evidence that both [Respondents and OrthoClear] have sold products that embody the inventions disclosed in Align's patents[,]"; (ii) she considered this evidence; and (iii) it supported her conclusions regarding the nonobviousness of the asserted Align patent claims. (Citing CX-1247C at Q. 148-152)

Staff's Position: Staff says that the issue of secondary considerations need not even be reached, because Respondents have failed to provide, as a preliminary matter, any evidence of any motivation to combine any of the prior art references in any particular manner.

Analysis and Conclusions: I have found that Respondents have failed to prove by clear and convincing evidence that any of the asserted claims of the '325 patent are rendered obvious by the prior art. It is, therefore, unnecessary for me to consider Align's contentions regarding secondary considerations. Nevertheless, assuming *arguendo* that the Commission finds that one or more claims of the '325 patent are rendered obvious by the prior art asserted by Respondents, I would find that Align has not adduced evidence of secondary considerations that would overcome a clear and convincing showing of obviousness. Because Align's arguments on secondary considerations of non-obviousness addressed all patents generally (and did not directly address any specific patents) (CIB at 45-47, CRB at 47-49), this analysis applies also for the asserted claims of the '880, '487, '511, '666, '863, and '874 patents.

Secondary considerations may include evidence of copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention. *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). Reviewing the evidence of secondary considerations is an important step in the obviousness analysis. As explained by the Federal Circuit:

> It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness. Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) (citations omitted).

Even when evidence of secondary considerations is present, it cannot overcome a strong *prima facie* showing of obviousness. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

In *Ormco I,* the Federal Circuit rejected Align's attempt to show commercial success as a secondary consideration to overcome obviousness, concluding "that the evidence does not show that the commercial success ***was the result of claimed and novel features.***" 463 F.3d at 1312-13 (emphasis added). In that case, the Court explained that evidence of commercial success, or other secondary considerations,[15] is only significant if there is a nexus between the claimed invention and the commercial success. *Id. at 1312* (citing *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563 (Fed.Cir.1997)). The Court also pointed out that the presumption that commercial success is due to the patented invention applies "if the marketed product embodies the claimed features, and is coextensive with them." *Id.* at 1312 (Citing *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed.Cir.2000).) The court noted that where the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant. *Id.* at 1312 (Citing *Brown & Williamson*, 229 F.3d at 1130; *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed.Cir.2000); *J.T. Eaton*, 106 F.3d at 1571). So too, if the feature that creates the commercial success was known in the prior art, the success is not pertinent. *Id.* at 1312 (Citing *J.T. Eaton*, 106 F.3d at 1571; *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed.Cir.1983).)

I have found in Section VI.C, *infra*, that Align has proven that it practices claim 21 of the '325 patent, claim 1 of the '880 patent, claim 3 of the '487 patent, claim 1 of the '511 patent,

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[15] The Federal Circuit included in its reasoning that the assertion of meeting "a long-felt but unresolved need" and the "failure of others" must also arise from "claimed and novel features." (*Ormco I* at 1313)

claim 7 of the '863 patent, and claim 1 of the '874 patent. Although Align provides evidence that it has been commercially successful in selling its clear aligners, the evidence cited by Align links the commercial success of Align to the demand for an aesthetic alternative to traditional brackets and the ability to treat "moderate and severe occlusions." (CX-1247C at Q. 497) Specifically, Dr. Valley testifies that:

> Prior to invisalign's introduction, there was a strong consumer demand in the adult orthodontics market for an aesthetic alternative to traditional brackets and wires that could perform major tooth movements over multiple treatment stages. The invisalign products met this demand.

(CX-1247C at Q. 497) Dr. Valley continues that:

> The commercial success of the invisalign products is therefore directly connected to Align's novel method of fabricating aligners by generating intermediate or successive digital data sets based on an initial digital data set and final digital data set. ***Using these digital data sets, Align is able to automatically fabricate unique and highly specific aligners that can facilitate major tooth movements over multiple treatment stages***. This is contrasted with other removable appliances that were capable of only minor tooth movements using a manual method of creating individual appliances. Align's novel method of correcting moderate and severe malocclusions undoubtedly contributed to Invisalign's commercial success.

(*Id.* (emphasis added)) Other than Dr. Valley's conclusory statement that the use of "digital data sets" allows Align to "automatically fabricate unique and highly specific aligners," Dr. Valley does not tie the ability to treat "moderate and severe malocclusions" to the inventions claimed in the claims upon which Align relies to support its domestic industry argument for any of the patents in suit. Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the

prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Similarly, Align fails to tie the long-felt need to the claimed inventions. Dr. Valley testified that:

> Align's invisalign products met a long felt need for an aesthetic, removable alternative to fixed appliances.

(CX-1247C at Q. 501) Dr. Valley continued that:

> Removable orthodontic appliances that existed at the time were limited by the small amount of tooth movements possible through their use. This prevented them from being a viable alternative for patients with moderate and severe malocclusions. In such systems, individual appliances had to be crafted by hand, either by the clinician or a lab technician. If a large movement over several treatment stages was required, it was necessary for an operator to manually divide this movement into small, precise stages, a process that was prone to human error and inaccuracies.

(CX01247C at Q. 512) Dr. Valley also testified that:

> Align's solution to the limitations of other removable appliances is directly connected to elements and features recited in the asserted patent claims. The asserted claims recite a new treatment modality of using computer assisted technology to scan models of a patient's teeth in order to produce digital data sets projecting stages of tooth movements from an initial to final arrangement and all successive arrangements in between. The digital data sets are then used to efficiently fabricate a series of polymeric shell appliances. The use of a computerized system solved the problem of having a human operator attempt to manually divide a larger tooth movement into small, precise movements.

(CX-1247C at Q. 518) Although Dr. Valley says that the claims recite a "new treatment modality," she fails to tie this "new treatment modality" to the specific limitations of the claims upon which Align relies to support its domestic industry argument for any of the patents in suit

or to explain which features of the claims actually "solved the problem of having a human operator attempt to manually divide a larger tooth movement into small, precise movements." (*Id.*)

Align also failed to show that skepticism and disbelief was directed to the claimed inventions rather than removable aligners in general. Dr. Valley testified that:

> From personal experience, the leading reasons orthodontists did not use Invisalign included skepticism that it was capable of more than simple cases, skepticism because it looked too simple and skepticism that anything other than fixed appliances were capable of controlling tooth movements.

(CX-1247C at Q. 523) Dr. Valley continued that:

> Align found that while orthodontists believed the invisalign system could work in easier to treat patients, there was skepticism as to whether it would work in more complex cases. The focus group studies likewise found that general practitioners were hesitant to adopt this new type of treatment approach quickly.

(CX-1247C at Q. 526) Other than this skepticism regarding Invisalign products generally, Dr. Valley did not provide any evidence that tied this skepticism to the invention addressed by the claims relied upon for purposes of domestic industry for any of the patents in suit. (*See id.*) Dr. Valley also failed to show that awards given to Align were directed to the claimed invention rather than Align's removable aligners in general or the ability of Align to treat complex cases with clear aligners. (CX-1247C at 534). As I found above, Align has not tied the ability to treat complex cases with clear aligners to the inventions claimed in the claims relied upon for purposes of domestic industry for any of the patents in suit.

Regarding evidence of copying, although Align has averred that there is evidence of process similarities and evidence of former OrthoClear employees working for Respondents, Align has not introduced evidence showing actual copying. (*See* CIB at 47) Notably, one of the

exhibits cited by Align, CX-116C, actually suggests that what the former employees of Align and OrthoClear learned from Align and OrthoClear "may conflict" with what Respondents do. (CX-116C) Such a conflict weighs against a finding of actual copying.[16] As a result, I find that Align has failed to introduce sufficient evidence to show actual copying by Respondents. Based upon all of the foregoing, and assuming *arguendo* that the Commission finds that one or more claims of patents in suit are rendered obvious by the prior art asserted by Respondents, I would find that Align has not adduced evidence of secondary considerations that would overcome a clear and convincing showing of obviousness for any of the patents in suit.

C. The '880 Patent

1. Anticipation

a. Claim 1

Asserted claim 1 teaches:

> A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:
>
> a) obtaining a digital data set representing an initial tooth arrangement;
>
> 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 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.

(JX-0002 at 22:12-29)

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[16] This does not, however, weigh against a finding of infringement.

Respondents' Position: Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents incorporate by reference the section addressing the anticipation of the preamble of Claim 1 of the '325. Respondents also incorporate by reference Disclosure Categories 1, 5, 7, 9, and 10 here. Respondents argue that the first element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Category 1. Respondents assert that the second element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Categories 5, 7, and 9. Respondents contend that the third element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Categories 7 and 9. Respondents assert that the fourth element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Category 10.

Respondents say that claim 1 teaches: 1) obtaining a digital initial tooth arrangement; 2) obtaining a repositioned tooth arrangement; 3) obtaining a series of successive digital tooth arrangements; and 4) fabricating polymeric shell appliances that correspond to the successive tooth arrangements. Respondents argue that the novelty of claim 1 is flatly contradicted by the Lemchen/Kesling reference, and Dr. Rekow's opinions confirm this, when she opined that Lemchen taught "[f]ull three-dimensional modeling in orthodontic treatment planning . . . ." (Citing RX-0103C at 16) Respondents continue that Dr. Rekow opines that Lemchen taught a digital method of the physical method taught by Kesling. (Citing RX-0103C at 16) Respondents add that Kesling taught fabrication of a series of polymeric shell appliances made using the corresponding physical models. (Citing CX-0944 at 2:43 – 4:70) Respondents conclude, as a result, that that the Lemchen/Kesling reference anticipates this claim because there is no material

difference between the claim and the prior art.

Align's Position: Align argues that Respondents' '880 invalidity positions are unsupported and insufficient to meet their high burden for invalidity. Align says that Respondents have no particular evidence to support their invalidity case, as no claim charts explaining where each claimed element is shown in the cited references is in evidence - because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-20:4; 651:14-653:25) Align continues that the prior art references simply fail to disclose all elements of either of the asserted claims of the '880 patent, individually or under any combination. (Citing CX-1247C at Q. 606, 610; CX-1258) Align says that the failings of the prior art are explained in CIB Section IV.F.4. Align asserts that elements of the asserted claims of the '880 are missing from each prior art reference are illustrated in CDX-0156—CDX-0157. Align says, for example, none of the prior art discloses, *inter alia*, "fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets."

Align says that Respondents contend that all of the asserted claims of the '880 patent are anticipated by Lemchen and "as incorporated," Kesling. Align argues that this argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Moreover, Respondents' argument is wrong. Align says that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described in CIB Section IV.F.4.c. Align continues that even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of either claim 1 or 3. (Citing CIB Section IV.F.4.c)

Align asserts that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, "successive digital data sets" ('880 claim 1) or "fabricating a

predetermined series of dental incremental position adjustment appliances" ('880 claim 1). (Citing RIB at 86-87)

Align argues that Respondents failed to make a *prima facie* showing of anticipation. (Citing CRB Section IV.H; Tr. at 19:11-20:4, 651:14-653:25) Align says that Respondents rely on the flawed theory that Lemchen incorporates the entire disclosure of Kesling. (Citing CRB Section IV.H.1; CIB at 49-51) Align says that even assuming incorporation, Lemchen/Kesling fails to disclose all elements of any asserted claim. (Citing CIB at 48-51; CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0156—CDX-0157) Align continues that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing CRB Section IV.H.4) Align says that Respondents also misapply their "disclosure categories" with respect to claims 1 and 3 of the '880 patent. (Citing *id.*)

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '880 patent, the Staff's discussion of anticipation in SIB Section IV.E.1 applies equally for the '880 patent.

Staff asserts that Respondents have failed to demonstrate clearly and convincingly that any Asserted Claim of the '880 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claims of the '880 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff says that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff says that in their Post-Hearing Brief, Respondents attempt to make up this shortcoming by

comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '880 patent. Staff says that because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2)

Staff argues that even if Respondents' comparison of their prior art references with the Asserted Claims of the '880 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded.

Staff concludes, as a result, that there is a lack of evidence explaining clearly and convincingly how the prior art discloses, teaches, or suggests each and every element of the Asserted Claims of the '880 patent.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings here. Even assuming that Lemchen incorporated the entirety of Kesling, the combination does not disclose each and every limitation of the asserted claims.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "obtaining a series of successive digital data sets representing a series of successive tooth arrangements," as required by claim 1.

In Section IV.B.1.a, *supra*, I also find that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. I incorporate and reaffirm that finding and rationale here. As a result, I also find that Lemchen does not disclose "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" as required by claim 1.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "***fabricating two or***

more dental appliances to be used successively to adjust the position of teeth between an initial tooth arrangement and a repositioned tooth arrangement, ***the digital data sets on which they are based having been created before any of said two or more dental appliances in the series are fabricated***," as required by the construction for "fabricating a predetermined series of dental incremental position adjustment appliances" found in Section III.B.2, *supra*.

In Section IV.B.1.a, supra, I find that Kesling also does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I incorporate and reaffirm that finding and rationale here.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates claim 1 of the '880 patent.

b. Claim 3

Claim 3 depends from claim 1 and teaches:

> A method as in claim 1, wherein the step of obtaining a digital data set representing a repositioned tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set.

(JX-002 at 22:33-41)

Respondents' Position: Respondents assert that dependent claim 3 is anticipated by Lemchen and, as incorporated, Kesling. Respondents incorporate by reference Disclosure Category 4.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1. Align additionally asserts that Respondents fail to point to any portion of the

prior art that they contend discloses "defining boundaries about at least some of the individual teeth" ('880 claim 3). (Citing RIB at 86-87)

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '880 patent is anticipated by Lemchen with the incorporation of Kesling. Although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). Thus, I find that Lemchen with the incorporation of Kesling, does not reveal the subject matter of claim 3.

2. Obviousness

a. Claim 1

Respondents' position: Respondents assert that claim 1 is obvious. Respondents incorporate by reference the section of RIB addressing the preamble of Claim 1 of the '325. Respondents also incorporate by reference Disclosure Categories 1, 5, 7, 9, and 10 together with the knowledge of one of ordinary skill. Respondents argue that these disclosures demonstrate that the claim was obvious.

Align's Position: Align says that Respondents argue that all of the asserted claims of the '880 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align argues that Respondents' argument fails for a myriad of reasons. Align says that this particular combination was disclosed for the first time in the *JSCI*, as explained in Align's *Motion in Limine No. 4*, and is therefore improperly raised now. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align argues that Respondents' argument is also wrong because these references, in any combination, fail to disclose all the elements of claims 1 or 3, as discussed in CIB Sec. IV.F.4. Align continues that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Section IV.F.2.b) Align contends that secondary considerations support a finding of non-obviousness. (Citing CIB Section IV.F.2.c)

Align says Respondents identified several other combinations in the RJSCI. Align contends that none were properly raised in Respondents' Prehearing Brief, and have been waived, for the reasons discussed above in CIB Section IV.F.2. Align argues alternatively that as explained in Sec. IV.F.2.a, IV.F.4, and illustrated in CDX-0156—CDX-0157, no combination of the prior art discloses all elements of the asserted claims of the '880 patent.

Align argues that any obviousness contentions or combinations have been waived. (Citing CRB Section IV.H.2) Align alternatively argues that none of the asserted claims are obvious. Align says that Respondents failed to make a *prima facie* showing of obviousness. (Citing CRB Section IV.H; Tr. at 19:11-20:4, 651:14-653:25) Align continues that any combination of prior art other than Lemchen and Kesling was waived. (Citing CRB Sec.

IV.H.2.a) Align says that the combination of Lemchen and Kesling cannot render any of the asserted claims obvious; it does not disclose all elements of any of the asserted claims. (Citing CIB at 48-51; CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0156—CDX-0157) *Align* continues that Respondents' obviousness theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing Sec. IV.H.4) Align says that Respondents also misapply their "disclosure categories" with respect to claims 1 and 3 of the '880 patent. (Citing *id.*) Align continues that none of the prior art discloses all elements of any of the asserted claims, in ***any*** combination. (Citing CIB at 47-52; CX-1247C at Q. 606, 610; CX-1258; CDX-0156—CDX-0157) Align says that there is no evidence of a motivation to combine the prior art. (Citing CRB Section IV.H.2.b) Align concludes that, secondary considerations show nonobviousness. (Citing CRB Section IV.H.2.c; CIB at 45-47)

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '880 patent, the Staff's discussion of obviousness in SIB Section IV.E.2, applies equally for the '880 patent.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 1 of the '880 patent is obvious. Respondents have asserted two separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 4.1.2.2, their references in that pre-hearing brief amount to a general

discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '880 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 99-106) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 4.1.2.2, Respondents failed to identify any specific combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 49). Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

In order to prevail on their claim that the asserted claims of the '880 patent are invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling discloses all of the limitations of the asserted claims. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and

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

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '880 patent. In section IV.C.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '880 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '880 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art does not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 104, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it

was obvious to combine Lemchen and Kesling. I incorporate that finding and reaffirm it here. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of the asserted claims of the '880 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the

those references to create the method claimed in the invention of the '880 patent.

b. Claim 3

Respondents' Position: Respondents contend that claim 3 is obvious. Respondents incorporate Disclosure Category 4 together with the knowledge of one of ordinary skill addressed in the '325 section. Respondents argue that these disclosures demonstrate that the claim was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '880 patent is rendered obvious by that combination.

In section IV.C.1.b, *supra*, I found that although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945

at 3:44-54). In the interest of brevity, I will not repeat the discussion in section IV.C.1.b in its entirety; but I reaffirm that finding and the rationale for it.

Nahoum and the knowledge of one of ordinary skill in the art do not fill these gaps. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 3 of the '880 patent are present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 3 of the '880 patent.

D. The '487 Patent

1. Anticipation

a. Claim 1

Claim 1 teaches:

> A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:
>
> receiving an initial digital data set representing an initial arrangement of the patient's teeth;
>
> producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;
>
> producing 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 the initial arrangement toward the final arrangement.

(JX-007 at 10:61-11:6)

Respondents' Position: Respondents say that while Align argues that the preamble is not an element of the claimed invention, the subject matter is disclosed in the prior art. Respondents incorporate the section addressing the preamble of Claim 1 of the '325 Patent. Respondents say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment:

> Full three-dimensional modeling in **orthodontic treatment planning** was described by Lemchen . . . . . This model is the mathematical representation of the physical model described by Kesling in 1949. . . . This digital/mathematical model was used for the **planning orthodontic treatment.**

(Citing RX-103C at 16 (emphasis added)) Respondents incorporate Disclosure Categories 1, 5, and 7.

Respondents incorporate Disclosure Category 1, and argue it discloses the first limitation of claim 1. Respondents incorporate Disclosure Categories 4 and 5, contending that they disclosing the second limitation of claim 1. Respondents assert that Disclosure Category 7 discloses the third limitation of claim 1.

Respondents argue that claim 1 is broadly directed to a method for "planning orthodontic treatment of a patient" and contains no limitations as to the appliance to be used. Respondents say that Lemchen anticipates this claim. Respondents continue that it is beyond dispute that Kesling's three-dimensional modeling method taught initial, final and intermediate tooth arrangements. (Citing CX-0944 at 2:50–3:1) Respondents says that these facts demonstrate that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align contends that Respondents' invalidity positions are wholly unsupported and totally insufficient to meet their high burden for an invalidity finding. Align says that Respondents have no particular evidence to support their invalidity case, as no claim

charts explaining where each claimed element is shown in the cited references is in evidence - because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-20:4; 651:14-653:25) Align continues that the prior art references simply fail to disclose all elements of any of the asserted claims of the '487 patent, individually or under any combination. (Citing CX-1247C at Q. 606, 610; CX-1258) Align adds that the failings of the prior art are explained in CIB Sec. IV.F.4. Align says that elements of the asserted claims of the '487 are missing from each prior art reference are illustrated in CDX-0164—CDX-0169. Align argues that none of the prior art discloses, *inter alia*, "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth."

Align says that Respondents contend that all of the asserted claims of the '487 patent are anticipated by Lemchen and "as incorporated," Kesling. Align disagrees, saying that this argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Alternatively Align asserts that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described in CIB Sec. IV.F.4.c. Align continues, saying that even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of the asserted claims. Align says that both Lemchen and Kesling were considered by the USPTO during the prosecution of the '487 patent, further confirming that the claims of the '487 patent are valid over Lemchen and Kesling.

Align says that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, "intermediate digital data sets" (claim 1) or "orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances" (claim 7). Align says that Respondents contend that all of the asserted claims are anticipated by Lemchen and "as

incorporated," Kesling. Align says that Respondents failed to make a *prima facie* showing of anticipation. (Citing CRB Section IV.H; Tr. at 19:11-20:4, 651:14-653:25) Align continues that Respondents rely on the flawed theory that Lemchen incorporates the entire disclosure of Kesling. (Citing CRB Section IV.H.1) Align says that even assuming incorporation, Lemchen/Kesling fails to disclose all elements of any asserted claim. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0164—CDX-0169) Align continues that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing CRB Section IV.H.4.) Respondents also misapply their "disclosure categories" with respect to at least claim 3 of the '487 patent. (Citing *id.*) Respondents say that the USPTO considered Lemchen and Kesling during the prosecution of the '487 patent, further demonstrating that the asserted claims are not anticipated. (Citing JX-0007 at 1-2)

Staff's Position: Staff contends that because Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '487 patent, the Staff's discussion of anticipation in SIB Section IV.E.1, *infra*, applies equally here.

Staff says that Respondents have failed to demonstrate clearly and convincingly that any asserted claim of the '487 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the asserted claims of the '487 patent. Staff continues that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff says that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff says that Respondents attempt to make up this shortcoming in their post-hearing brief by

comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '487 patent. Staff says that because Respondents admittedly did not make perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff argues that even if Respondents' comparison of their prior art references with the Asserted Claims of the '487 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings and rationale here. As noted in Section IV.B.1, *supra*, Lemchen and Kesling were considered by the United States Patent and Trademark Office during prosecution of the '487 patent (JX-007 at 1-2), and Respondents face a heighted burden to establish invalidity based on Lemchen and Kesling. Respondents, however, have failed even to meet the ordinary burden to prove by clear and convincing evidence that each and every limitation of the asserted claims is disclosed expressly or inherently.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," as required by claim 1.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "producing 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 the initial arrangement toward the final arrangement," as required by claim 1.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates claim 1 of the '487 patent.

b. Claim 3

Dependent claim 3 recites:

> The method of claim 1, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating

fabrication of shell appliances for a corresponding treatment stage.

(JX-007 at 11:10-13)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of claim 3 and incorporate Disclosure Categories 7 and 9.

Respondents assert that claim 3 is broadly directed to a method for "planning orthodontic treatment of a patient." Respondents say that claim 3's added limitation as to a shell appliance is not meaningful in the validity analysis because the models of dentition, virtual or physical, are necessarily configured as positive models of teeth arrangements which facilitates the fabrication of the shell appliances. Respondents say that this fact demonstrates that Lemchen reference anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling.

In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient

with a single set of brackets, not with plural polymeric shell appliances. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 3.

c. Claim 5

Claim 5 teaches:

> The method of claim 1, further comprising providing a plurality of the intermediate digital data sets to a fabrication operation for fabrication of a series of successive tooth repositioning appliances.

(JX-007 at 11:19-22)

Respondents' Position: The Respondents incorporate Disclosure Category 9. Respondents contend that Disclosure Category 9 discloses the subject matter of claim 5.

Respondents say that dependent claim 9 is broadly directed to a method for "planning orthodontic treatment of a patient." Respondents say that the claim's additional limitation of providing digital data of tooth arrangements to a fabrication operation is also anticipates by Lemchen reference. According to Respondents, Kesling taught fabrication of a series of aligners. (Citing CX-0944 at 2:50–3:1) Respondents say that Lemchen disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-0945 at 5:15–20) Respondents argue that this demonstrates that the Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 5 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 5 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 5 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling. In Section IV.B.1.a, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural appliances. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 5.

d. Claim 7

Claim 7 teaches:

> 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.

(JX-007 at 11:26-35)

Respondents' Position: Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter is disclosed in the prior art.

Respondents incorporate the section addressing the preamble of Claim 1 of the '325. Respondents say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment. (Citing RX-103C at 16.) Respondents incorporate Disclosure Categories 1, 5, and 7.

Respondents assert that Disclosure Category 2 discloses "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."

Respondents contend that Disclosure Categories 7 and 10 disclose "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."

This independent claim is broadly directed to an "orthodontic treatment plan." This claim relates broadly to incremental tooth repositioning appliance and is not limited to aligners. Respondents have identified evidence that demonstrates the invalidity of this claim in the Respondents' Post-Hearing Brief. That evidence is incorporated here.

Respondents argue that claim 7 requires: 1) a treatment plan residing on a computer readable storage media; 2) a plurality of intermediate digital tooth arrangements representing different orthodontic treatment stages. Respondents say that Lemchen clearly anticipates this claim. Respondents continue that contrary to Align's position here, Dr. Rekow's opinions confirm this:

> Full three-dimensional modeling in **orthodontic treatment planning** was described by Lemchen . . . . . This model is the mathematical representation of the physical model described by Kesling in 1949. . . . This digital/mathematical model was used for the **planning orthodontic treatment**.

(Citing RX-103C at 16 (emphasis added)) Respondents add that it is beyond dispute that Kesling's three-dimensional modeling method taught initial, final and intermediate tooth arrangements. (Citing CX-0944 at 2:50–3:1) Respondents contend that these facts demonstrate that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings a rationale here. Even assuming that Lemchen incorporated the entirety of Kesling, each and every limitation of the asserted claims is not disclosed.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," as required by claim 7.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," or "a treatment plan," which as construed in Section III.D.2, *supra*, requires "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement," as required by claim 7.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates claim 7 of the '487 patent.

e. Claim 8

Claim 8 teaches:

> The orthodontic treatment plan of claim 7, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage.

(JX-007 at 11:36-39)

Respondents' Position: Respondents argue that Disclosure Category 10 discloses the subject matter of claim 8.

Respondents assert that claim 8 is also broadly directed to an "orthodontic treatment plan." Respondents say that claim 8's added limitation of a shell appliance is not meaningful in

the validity analysis because the models of dentition, virtual or physical, are necessarily configured as positive models of teeth arrangements which facilitates the fabrication of the shell appliances. Respondents contend that this fact demonstrates that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be anticipated and invalid, I could still find that claim 8 is valid. Since, however, I have found claim 7 to be valid and ***not*** anticipated by Lemchen, claim 8 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 8. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 8 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling.

In Section IV.B.1.a, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. I incorporate and reaffirm that finding and rational here. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 8.

f. Claim 9

Claim 9 teaches:

> The orthodontic treatment plan of claim 8, wherein the shell appliances comprise a plurality of successive appliances having teeth receiving

> cavities, and wherein cavities of at least two successive appliances have different geometries shaped to receive and reposition the patient's teeth.

(JX-007 at 11:40-44)

Respondents' Position: Respondents incorporate Disclosure Category 10 and assert that it discloses the subject matter of claim 9.

Respondents argue that dependent claim 9 is also broadly directed to an "orthodontic treatment plan." Respondents say that claim 9's added limitation of successive appliances with teeth receiving cavities does not change the validity analysis because the appliances taught by Kesling have teeth receiving cavities. (Citing CX-0944 at Figure 7) Respondents conclude that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 7 and 8 to be anticipated and invalid, I could still find that claim 9 is valid. Since, however, I have found claims 7 and 8 to be valid and ***not*** anticipated by Lemchen, claim 9 is necessarily valid, because it depends from claim 7 via claim 8 and necessarily contains all of the elements of claims 7 and 8. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 7 and 8 are anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 9 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling.

Claim 8 teaches "the intermediate digital data sets for different orthodontic treatment

stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage." (JX-007 at 11:36-39) In order to reposition teeth, the successive shell appliances disclosed in claim 8 necessarily will have different shapes. As a result, I find that if Lemchen were found to anticipate claim 8, Lemchen also it would also anticipate claim 9.

2. Obviousness

a. Claim 1

Respondents' Position: Respondents incorporate the section of RIB addressing the preamble of Claim 1 of the '325. Respondents say that, contrary to its position here, Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment. (Citing RX-103C at 16) Respondents argue that this demonstrates that there is no difference between the Lemchen reference and this claimed invention. Respondents incorporate Disclosure Categories 1, 4, 5, and 7 together with the knowledge of one of ordinary skill. Respondents say that these disclosures show that the claimed invention was obvious.

Respondents assert that claim 1 is further rendered obvious in light of U.S. Patent No. 8,338,198 ("Wu") and the knowledge of one of ordinary skill. Respondents say that Wu describes a method of planning orthodontic treatment, simulating that treatment and the design of the orthodontic appliances to facilitate that treatment. (Citing RX-0095 at 4:14-20) Respondents continue that Wu describes the creation of a 3-D initial digital set by scanning an impression of the patient's dental arch. (Citing RX-0095 at 5:41-50) Respondents add that Wu describes segmentation of the 3-D digital model of the patient's dental arch, the relocation of the teeth in simulated, digitized orthodontic treatment, and use of the digitized simulation to demonstrate treatment outcomes and gain approval for the treatment. (Citing RX-0095 at 5:41-50; at 7:29-34;

at 8:55-58, at 7:2-3) Respondents argue that these disclosures show that the claimed invention was obvious.

Align's Position: Align says that Respondents argue that all of the asserted claims of the '487 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align argues that this particular combination was disclosed for the first time in the *JSCI*, as explained in Align's Motion in Limine No. 4, and is therefore improperly raised now. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align adds that Respondents' argument is wrong because these references, in any combination, fail to disclose all the elements of the asserted claims, as discussed in CIB Sections IV.F.2.a, IV.F.4. Align contends that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Sec. IV.F.2.b) Align continues that Lemchen and Kesling were considered by the USPTO during the prosecution of the '487 patent, further confirming that the asserted claims of the '487 patent are valid over these references. Align adds that secondary considerations support a finding of non-obviousness. CITING CIB Sec. IV.F.2.c)

Align says that Respondents identified several other combinations in the RJSCI. None were properly raised in Respondents' Prehearing Brief, and have been waived, for the reasons discussed in CIB Sec. IV.F.2. Align continues that, as explained in CIB Sections IV.F.2.a, IV.F.4, and illustrated in CDX-0164—CDX-0169, no combination of the prior art discloses all elements of the asserted claims of the '487 patent. Align says that Respondents contend that asserted claims 1, 3, 5, 7 and 8 of the '487 patent are "further rendered obvious in light of Wu

and the knowledge of one of ordinary skill in the art." Align says that any obviousness combination involving Wu has been waived because it was not disclosed in Respondents' Prehearing Brief. Align continues that Wu cannot render any of the claims obvious under any combination.

Align argues that Wu does not disclose, *inter alia*: (i) a plurality of digital data sets representing a plurality of tooth arrangements (Citing CX-1247C at Q. 410, 412, 414-415, 418-422; CX-1254C ¶ 185 at 69); (ii) intermediate digital data sets or tooth arrangements (Citing CX-1247C at Q. 410, 412, 414-415, 418-422); or (iii) numerous other elements of Align's claims (Citing CX-1247C at Q. 410, 412, 414-415, 418-422; CX-1258 at 37-42).

Staff's Position: Staff says that because Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '487 patent, the Staff's discussion of obviousness in SIB Section IV.E.2, *infra*, applies equally here.

Staff says that Respondents have failed to demonstrate clearly and convincingly that any asserted claim of the '487 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the asserted claims of the '487 patent. Staff continues that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff says that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff says that Respondents attempt to make up this shortcoming in their post-hearing brief by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '487 patent. Staff says that because Respondents admittedly did not make perform this

comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff argues that even if Respondents' comparison of their prior art references with the Asserted Claims of the '487 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ. Staff adds that Respondents' allegations of obviousness also include Wu (RX-0095), but Respondents fail to show how one of ordinary skill would have been motivated to combine Wu in any manner.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 1 of the '487 patent is obvious. Respondents have asserted three[17] separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, Nahoum, Lemchen, Kesling, Wu, and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 5.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '487 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the

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[17] It is not clear from Respondents' briefing whether Wu and the knowledge of one of ordinary skill in the art is a separate combination, or an additional reference to be combined with Lemchen, Kesling, and Nahoum. I have assumed, *arguendo*, that Wu is to be combined with Lemchen, Kesling, and Nahoum. Because Wu does not fill the gaps in Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, Wu also would not individually render claim 1 obvious.

hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 128-136) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 5.2.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 128) Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, Wu, and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, Wu and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling, Nahoum, or Wu to follow the methods in the '487 patent. In section IV.D.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '487 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '487 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a

former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 106, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it was obvious to combine Lemchen and Kesling. I incorporate that finding and rationale and reaffirm it here. Respondents do not, however, provide any basis for combining Nahoum and Wu with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum and Wu in combination with Lemchen and Kesling, I find that Nahoum and Wu do not provide the elements missing from the Lemchen and Kesling references. Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set and Lemchen is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or

digital data to assist in fabricating a dental appliance. I incorporate and reaffirm these findings and rationales here.

Wu does not disclose, or teach or suggest, or even remotely contemplate "producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," as required by claim 1. Rather, Wu is directed to a method for generating a three dimensional model of the teeth and dental arch of a patient. (RX-095 at 1:4-6) Although Wu discloses scanning a dental arch to create a digital model (*Id.* at 5:41-50) and enabling a user to "move any or all other teeth independently to simulate potential treatment options," (*Id.* at 7:29-35), Wu does not disclose producing plural intermediate digital data sets between these two models. (*See* RX-095) Respondents do not identify where this element is disclosed in Wu

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim of the '487 patent are present in Lemchen, either alone or in combination with Kesling, Nahoum, and Wu, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '487 patent.

b. Claim 3

Respondents' Position: Respondents assert that claim 3 is obvious in light of the prior art references and the knowledge of one of ordinary skill. Respondents incorporate the disclosures identified as Disclosure Categories 7 and 9 here together with the knowledge of one of ordinary skill as described in the section of RIB addressing the '325 Patent.

Respondents say that this claim is further rendered obvious in light of Wu and the knowledge of one of ordinary skill. Respondents say that Wu describes the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment and

describes traditional CAD/CAM dental applications including the CEREC system of digital prototyping used for fabricating positive models of teeth. (Citing RX-0095 at 1:47-52; at 3:7-17) Respondents contend that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '487 patent is rendered obvious by that combination. In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In Section IV.D.2.a, *supra*, I find that Wu does not disclose producing plural intermediate digital data sets between the initial and final data sets. I incorporate and reaffirm these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 3 of the '487 patent are present in Lemchen combined with Kesling, Nahoum, Wu and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 3 of the '487 patent.

c. Claim 5

Respondents' Position: Respondents contend that dependent claim 5 is obvious in light of the prior art references and the knowledge of one of ordinary skill. Mr. Beers identifies common evidence that he contends covers this claim as Evidence Category 9. CX-1150C at Q. 249. Respondents incorporate Disclosure Categories 9 and 10 together with the knowledge of one of ordinary skill as described in the section addressing the '325.

Respondents argue that this claim is further rendered obvious in light of Wu and the knowledge of one of ordinary skill in the art. Respondents contend that Wu describes the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment and describes traditional CAD/CAM dental applications including the CEREC system of digital prototyping used for fabricating positive models of teeth. (Citing RX-0095 at 1:47-52; at 3:7-17) These disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I

determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 5 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, claim 5 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 5 of the '487 patent is rendered obvious by that combination. In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In Section IV.D.2.a, *supra*, I find that Wu does not disclose producing plural intermediate digital data sets between the initial and final data sets. I incorporate and reaffirm these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 5 of the '487 patent are present in Lemchen combined with Kesling, Nahoum, Wu and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 5 of the '487 patent.

d. Claim 7

Respondents' Position: Respondents incorporate the section of RIB addressing the preamble of Claim 1 of the '325 Patent. Respondent say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment. (Citing RX-103C at 16) Respondents argue that this demonstrates that there is no difference between Lemchen and this claimed invention.

Respondents incorporate Disclosure Categories 1, 2, 5, 7, and 10 here together with the knowledge of one of ordinary skill in the art.

Respondents argue that claim 7 is further rendered obvious in light of Wu and the knowledge of one of ordinary skill in the art. Respondents say that Wu describes the creation of an orthodontic treatment plan and the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment. (Citing RX-0095 at 1:47-52) Respondents continue that Wu describes the creation of an orthodontic treatment plan, simulated orthodontic treatment, and storage on a computer readable storage media. (Citing RX-0095 at 5:41-50, 6:60-61, 7:29-34, 8:55-58, and 7:2-3) Respondents contend that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 7 of the '487 patent is obvious. Respondents have asserted three separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of

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

Similar to claim 1, discussed *supra*, I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 5.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '487 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 128-136) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 5.2.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 128) Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, and Wu and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to create "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," or "a treatment plan," which as construed in Section III.D.2, *supra*, requires "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement." In section IV.D.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of claim 7 of the '487 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious claim 7 of the '487 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 106, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it was obvious to combine Lemchen and Kesling. I incorporate that finding and reaffirm it here.

Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 7 of the '487 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the treatment plan claimed in claim 7 of the '487 patent.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Wu and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Wu to produce the treatment plan of the '487 patent.

Wu does not disclose, or teach or suggest, or even remotely contemplate "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," or "a treatment plan," as required by claim 7. Rather, Wu is directed to a method for generating a three dimensional model of the teeth and dental arch of a patient. (RX-095 at 1:4-6) Although Wu discloses scanning a dental arch to create a digital model (*Id.* at 5:41-50) and enabling a user to "move any or all other teeth independently to simulate potential treatment options," (*Id.* at 7:29-35), Wu does not disclose producing plural intermediate digital data sets between these two models. (*See* RX-095) Respondents do not identify where this element is disclosed in Wu.

Respondents also do not argue that this element would be obvious to one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 86, 118)

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of claim 7 of the '487 patent is present in Wu, either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

e. Claim 8

Respondents' Position: Respondents argue that dependent claim 8 is obvious in light of the prior art references with the knowledge of one of ordinary skill in the art. Respondents

incorporate Disclosure Category 10 together with the knowledge of one of ordinary skill as described in this brief addressing the '325 patent.

Respondents say that claim 8 is further rendered obvious in light of Wu and the knowledge of one of ordinary skill. Respondents continue that Wu describes the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment and describes traditional CAD/CAM dental applications including the CEREC system of digital prototyping used for fabricating positive models of teeth. (Citing RX-0095 at 1:47-52; at 3:7-17) Respondents conclude that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 8 is valid. Since, however, I have found claim 7 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, claim 8 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 7. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 8 of the '487 patent is rendered obvious by that combination. In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural

polymeric shell appliances. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In Section IV.D.2.a, *supra*, I find that Wu does not disclose producing plural intermediate digital data sets between the initial and final data sets. I incorporate and reaffirm these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that "the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage" (as required by claim 8 of the '487 patent) is disclosed by Lemchen combined with Kesling, Nahoum, Wu and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 8 of the '487 patent.

f. Claim 9

Respondents' Position: Respondents argue that dependent claim 9 is obvious in light of the prior art references with the knowledge of one of ordinary skill. Respondents incorporate Disclosure Category 10 together with the knowledge of one of ordinary skill as described in this brief addressing the '325. Respondents conclude that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I

determined claims 7 and 8 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 9 is valid. Since, however, I have found claims 7 and 8 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 9 is necessarily valid, because it depends from claim 7 via claim 8 and necessarily contains all of the elements of claims 7 and 8. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 7 and 8 are rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 9 of the '487 patent is rendered obvious by that combination.

In section IV.D.1.f, *supra*, I found that if Lemchen anticipated claims 7 and 8, it would also anticipate claim 9. As a result, assuming *arguendo* that claims 7 and 8 are obvious over Lemchen combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that claim 9 is obvious based on the rationale discussed in section IV.D.1.f.

E. The '511 Patent

1. Anticipation

Respondents' Position:

The preamble of asserted claim 1 of the '511 patent reads:

> A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:

(JX-001, 11:4-5)

Addressing the preamble, Respondents incorporate the portion of their brief discussed in section IV.B, *supra*, addressing the anticipation of the preamble of Claim 1 of the '325 patent. Respondents say that while Align argues that the preamble is not an element of the claimed

invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents note that in 1943, Dr. Kesling filed an application that resulted in U.S. Patent No. 2,467,432. (the '432 patent or "Kesling")(Citing CX-944) Respondents assert that Kesling expressly discloses: (1) a plurality of tooth arrangements; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-113C, Q. 49)

Respondents say that in 1989, Dr. Lemchen applied for what ultimately became U.S. Patent No. "Re. 35,169" (the '169 patent or "Lemchen") (Citing CX-945) Respondents assert that Dr. Lemchen disclosed a digital method for three dimensional modeling of teeth movement that was the same as the manual method disclosed in Kesling. (Citing RX-113C, Qs. 39-40) Respondents claim that this digital modeling includes intermediate or successive tooth arrangements. (Citing RX-113C, Q. 41) Respondents say that Lemchen disclosed methods for the fabrication of multiple custom appliances based on the three dimensional modeling. (Citing RX-113C, Q. 42) Respondents conclude that Lemchen disclosed using positive models generated from digital data. (Citing RX-113C, Qs. 42-43)

Respondents say that contrary to its position in this investigation, Align previously recognized that "Capitalizing on work of the dental CAD/CAM systems, Lemchen describes approaches [that] acquire data, automatically determine . . . ideal position for an individual patient, design . . . configuration to conform to the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design." (Citing RX-102C at 6) Respondents state that, Align contended in that litigation that "the idea of fabricating custom appliances," for orthodontic treatment "was not new in 1990." (Citing RX-102C at 7)

The first element of asserted claim 1 teaches:

> for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;

(JX-001, 11:6-8)

Regarding this element, Respondents incorporate their Disclosure Category 7, in which they represent that Lemchen discloses that "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66-3:6) Respondents contend that one skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. Respondents assert that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents allege that Dr. Rekow, on behalf of Align, also recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement, quoting:

> **Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen** *[59 Lemchen, ALN005891-895; 60 Lemchen, ALN005821-829]*. The first step in this process was acquisition of digital data defining the shape and location of the malocclused tooth or teeth respect to the patient's jaw. A variety of techniques, including those described by Rekow *[89 Rekow, ALN128301-305]* were capable of capturing the required data. The required data, in most applications, were a complete 3D model of the upper and lower dental arches and associated jaw structure *[59 Lemchen, ALN005893, col 3, lines 13-19]*. This model is the mathematical representation of the physical model described by Kesling in 1949. *[*Kesling, *'432 patent, ALN125695-699]* This digital/mathematical model was used for the planning orthodontic treatment.

(Citing "RX-103C at 16" (bracketed information is in the original, bold added by Respondents) Respondents argue that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three dimensional modeling of teeth movement

digitally through a series of incremental or intermediate steps from an initial position to the desired position.

The second element of asserted claim 1, requires:

> calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and

(JX-001, 11:9-12)

Turning to the second element of asserted claim 1, Respondents incorporate their Disclosure Categories 6 and 7, in which they state that the Kesling reference discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions, quoting:

> the present tooth positioning appliances may be used for changing the position of teeth from the [initial position] to that of [the pre-determined ideal or desirable position] by using a multiplicity or a **plurality** of different steps and making intermediate tooth positioning devices, which are to move the teeth only a fraction of the way toward their final position.

(Citing CX-944, 2:50-3:1 (emphasis added by Respondents) Respondents aver that the Kesling reference describes the necessity of making a plurality of appliances as "obvious" and quote:

> While I have illustrated an appliance and described the technique for producing only the last or final change to the desired ideal position, it will also be evident that this appliance and technique may be employed in a **plurality** of steps for moving the teeth step by step from any extreme position to the desired and final position; but in such cases it will obviously be necessary to make a number of different appliances, each representing one step of attainment toward the final positioning of the teeth.

(Citing CX-944, 5:22-32) (emphasis added by Respondents)

Respondents assert that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66-3:6) Respondents contend that one skilled in the art would understand this to

mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. Respondents allege that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents reiterate the quote from Dr. Rekow, quoted *supra*, and their contention that Align used the quote to support the position that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement. (Citing "RX-103C at 16") Respondents reiterate that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three dimensional modeling of teeth movement digitally through a series of incremental or intermediate steps from an initial position to the desired position.

Respondents argue that Lemchen discloses that his method "produces appropriate force magnitudes at various stages of treatment to move the tooth to its ideal position." (Citing CX-945, 2:37-38) Respondents posit that one skilled in the art would understand that the "various stages of treatment" would refer the successive stages of treatment typical in orthodontic treatment. (Citing RX-113C, Q. 57) Respondents add that one skilled in the art would also understand that "appropriate force magnitudes" would mean that any threshold limits on movement would not be exceeded, because the only way that movement could exceed a threshold limit is by the application of inappropriate or excessive force on the tooth. Respondents conclude that one skilled in the art would also understand that "appropriate force magnitudes" would mean at least the minimum force necessary to move the teeth toward the

successive stage of treatment; otherwise the treatment would be ineffective. (Citing RX-113C, Q. 58)

The third element of asserted claim 1, states:

> generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

(JX-001, 11:13-19)

Finally, concerning the third element, Respondents incorporate their Disclosure Category 10 and allege that the Kesling reference disclosed "tooth positioning appliances" that were "adapted to . . . bring the teeth of a user of such an appliance into a pre-determined ideal or desirable position without the necessity for the use of metallic bands, wires or any of the other appliances of the prior art." (Citing CX-944, 1:1-6) Respondents add that Figure 7 shows that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-944, Fig. 7)

Respondents continue that Kesling teaches that each aligner in the series is made by molding a polymeric material over positive models of intermediate or successive tooth arrangements. First a cast of the teeth in their initial position is created using traditional methods. (Citing CX-944, 2:43-49) Then, each individual tooth is manually sectioned out by an operator using a scroll saw. (Citing CX-944, 3:30-43) Next, the operator manually moves each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material. (Citing CX-944, 3:30-60) Then, a positive model of the teeth in their new position is made. (Citing CX-944, 3:61-64 and Figure 3) Respondents continue, the aligners are then fabricated by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-944, 3:65-4:70)

Respondents assert that Lemchen discloses methods that include controlling a fabrication machine:

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

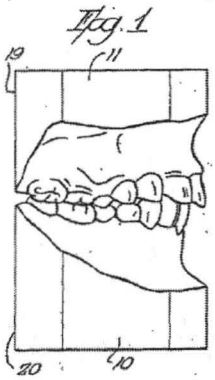
(Citing CX-945, 5:4-8) Respondents aver that the inventors also describe the use of a "laboratory model of the tooth . . . ." And as described above, the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch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

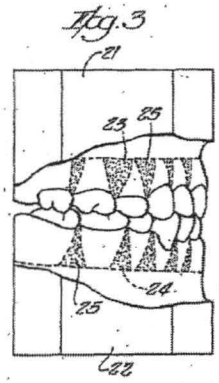
Respondents allege that contrary to its position in this investigation, Align previously argued that the references cited by Lemchen, including the Rekow reference, disclosed using CAD/CAM systems to control fabrication machines to produce positive models of teeth. (Citing "RX-103C at 17-26")

Align's Position: Align says that Respondents contend that ***all*** of the asserted claims are anticipated by Lemchen, including "as incorporated" Kesling. (Citing RPHB at 44, 98, 127, 146, 175, 205 and 240) Align argues that Respondents' anticipation defense fails as a matter of law because it relies on the flawed assumption that Lemchen incorporates the full disclosures of Kesling, which Align contends is wrong as a matter of law. Align states that, to incorporate by reference, the host document "must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." (Citing *Advanced Display Sys., Inc. v. Kent State Univ.*,212 F.3d 1272, 1282 (Fed. Cir. 2000)) Align argues that "mere reference to another [patent] is not an incorporation of anything therein."

(Citing *In re De Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973); *Certain Digital Imaging Devices*, Inv. No. 337-TA-717, I.D., 2010 WL 5646142, at *53 (USITC May 12, 2011) (Rogers, J.))

Align asserts that Lemchen only briefly refers to two figures from Kesling. (Citing CX-945, 3:14-15 ("[a] physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432"); *id.* at 3:35-40) and includes Figures 1 and 3 in its brief for reference.





Align quotes the text of Lemchen, "[i]n order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. *See*, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432"). Align contends that these are references to FIGS. 1 and 3 as examples of models, nothing else. Align avers that Lemchen does not say that the entire disclosure of Kesling, or any of its particular methods, is incorporated. Align alleges that Dr. Valley agrees that Lemchen cites the figures as examples of what models look like and does not otherwise address Kesling or the relationship between the figures. Align adds that Kesling FIGS. 1 and 3 do not disclose the claim elements that are absent from Lemchen. (Citing CX-1247C, Qs. 249, 251-258; and CX-1254C ¶¶ 112-117 at 42-46)

Align says that contrary to the express description found in the words of Lemchen that cite to Kesling's FIGS. 1 and 3 as examples of models, Dr. Mah contends, "[i]t is only in the context of the entire disclosure [of Kesling] that the significance of the model displayed as

Figure 1 [or Figure 3] as a representation of the patient's teeth prior to treatment [or as a modified tooth arrangement] is understood." (Citing RX-113C, Qs. 47-48) Align says these contentions lack merit, and observes that one of ordinary skill in the art would have understood the concept of a representation of teeth based on FIGS. 1 and 3 without needing to review Kesling's entire disclosure. Concluding, plaster tooth arrangements were commonly known and used. (Citing CX-1247C, Qs. 264-265; CX-1254C ¶ 117 at 45-46; and Tr. at 786:24-787:17, 788:11-789:8, 796:13-798:6)

In its reply brief, Align adds that the majority of Kesling is completely unrelated to FIG. 1 or FIG. 3, and notes, for example, Kesling discusses the design of an impression tray:

> The proportions of this tray are made with a view to making it the pattern for the tooth positioning appliance, which will later be worn in the mouth; and therefore it is desirable to dispense with any unnecessary bulk in the design of the tray. The tray 30 is preferably made of a suitable relatively stiff material which is initially plastic and which is moldable so that the tray may be molded to correspond substantially to the arch of the teeth of the patient without having more than a few sizes of trays.

(Citing CX-944, 4:24-35) Align continues that Kesling also contemplates the patient using its rubber appliance while sleeping:

> The tooth positioning appliance of Fig. 7 may be worn at night by the patient, and while he is sleeping; and it is found that in a short time the patient will become accustomed to wearing the appliance, which also prevents mouth breathing, due to the fact that the mouth is closed on the appliance during sleep. Breathing through the nose is then a matter of necessity, and the present appliance may also be used to prevent undesirable breathing noises during sleeping.

Id. at 5:4-13. Align asserts that Kesling further compares the tooth positioning device to "unsightly" 1940s braces:

> The present device may be kept more sanitary than devices which are relatively permanently attached to the teeth, as the present device may be cleaned before and after every using. It has been found that where the present invention is employed, the unsightly metal wires and bands of the conventional tooth positioning devices of the prior art may be removed from the teeth of the patient

> much sooner, and the present device usually produces a finished job in from four to six months.

Id. at 5:67-6:2. Align argues that these sections of Kesling, among others, have nothing to do with the plaster models of FIGS. 1 and 3, which Align says illustrates the fallacy of Respondents' mantra that reading such portions of Kesling is somehow necessary to understand "the significance of" FIGS. 1 and 3. (Citing RIB at 40)

Align adds that Respondents claim that Lemchen "applies beyond brackets and archwires." *Id.* at 41. Align says that Respondents are wrong, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets. (Citing CX-1247C, Qs. 190-191; and CX-1254C ¶¶ 90-91 at 32-33) Align states that here, Respondents rely on language from Lemchen regarding "methods of treatment." (Citing RIB at 40-41) Align argues that, "methods of treatment" in Lemchen refer to different methods of treating a patient with brackets and archwires – not aligners. (Citing CX-1247C, Qs. 215-219; CX-1254C ¶ 98 at 35-36; and Tr. at 798:7-799:25. Align says that Respondents also allege that "modeling of teeth movement is the same, regardless of the type of appliance used." (Citing RIB at 41) Align says once again, Respondents are wrong. (Citing CX-1247C, Qs. 221-222; and CX-1254C ¶ 99 at 37) Align counters that the anchorage needs and, therefore, the biomechanics of tooth movement, vary depending on the type of appliance used. (Citing CX-1247C, Qs. 221-222; and CX-1254C ¶ 99 at 37)

Align goes on to argue that, even if Kesling is somehow deemed to be fully incorporated in Lemchen, then Lemchen/Kesling still fails to anticipate any of Align's asserted claims because it does not disclose all elements of any of those asserted claims.

Focusing on asserted claim 1 of the '511 patent, Align contends that Respondents' invalidity positions are unsupported and insufficient to meet their high burden for invalidity.

Align argues that Respondents have no particular evidence to support their invalidity case, as no claim charts explaining where each claimed element is shown in the cited references are in evidence, because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-25; 651:14-653:25)

Align adds that elements of asserted claim 1of the '511 patent are missing from each prior art reference as illustrated in CDX-0145. Align avers, for example, none of the prior art discloses, *inter alia*, "calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments."

Align argues that Dr. Valley provided a full analysis of each reference in both her expert report (CX-1254C) and witness statement (CX-1247C). Align contends that based on her analysis, Dr. Valley opined that specific elements of each claim are not disclosed by the prior art. (Citing CX-1258) Align refers to CDX-130 and CDX-0169 to illustrate the missing claim elements for each prior art reference based upon Dr. Valley's testimony.

Moreover, as depicted in CDX-0288 and shown on the face of the patents (and reexam certificates), Lemchen was considered by the USPTO and determined not to preclude issuance of the claims. (Citing JX-001 at 2)

Focusing on substance, Align avers that Lemchen discloses a method for determining orthodontic bracket placement and is directed to a single fixed appliance used for the duration of a patient's treatment, rather than a removable appliance. Align says that Lemchen's disclosure is limited to the idea of treating a patient with the single set of brackets. (Citing CX-945, 1:55-2:8; CX-1247C, Qs. 190-191; CX-1254C ¶¶ 90-91 at 32-33; and CX-1264 at 5) Align contends that the concept of intermediate digital data sets or tooth arrangements is, therefore, absent from, and irrelevant to, Lemchen. (Citing CX-1247C, Qs. 183-185; and CX-1254C ¶ 82 at 29-30)

Align adds that, in fact, Lemchen teaches away from the use of intermediate arrangements. (Citing CX-1247C, Qs. 225-227; and CX-1254C ¶ 97 at 34-35)

Align argues that Lemchen does not disclose, *inter alia*: (1) intermediate or successive digital data sets or tooth arrangements (Citing CX-1247C, Qs. 183-185; and CX-1254C ¶ 82 at 29-30); (2) polymeric shell appliances (Citing CX-1247C, Qs. 183, 186-189; CX-1254C ¶¶ 85-86 at 31-32; and CX-1264 at 5); (3) positive models of modified tooth arrangements based on digital data sets (Citing CX-1247C, Qs. 183, 186-189, 207, 209-214; CX-1254C ¶ 87 at 32; and CX-1264); (4) multiple removable appliances or fabricating intermediate or successive appliances based on digital data sets (Citing CX-1247C, Qs. 183, 190-191; and CX-1254C ¶¶ 90-91 at 32-33); (5) threshold limits (Citing CX-1247C, Qs. 233-235; and CX-1254C ¶ 105 at 39-40); (6) interpolation or movements of equal sizes (Citing CX-1247C, Qs. 236-238; and CX-1254C ¶ 106 at 40); (7) substantially accurate shapes of a patient's teeth in a modified arrangement (Citing CX-1247C, Qs. 239-240; and CX-1254C ¶ 108 at 41); (8) attachment devices (Citing CX-1247C, Qs. 241-243; and CX-1254C ¶ 109 at 41-42); or (9) "numerous other elements of the asserted claims." (Citing CX-1247C, Qs. 275-277; and CX-1258 at 9-15)

Align turns to Kesling, in the event that one were to find Kesling incorporated by reference into Lemchen, and argues that Kesling generally discloses tooth positioning appliances made manually using tools and equipment available in the 1940s (*e.g.*, plaster and wax). Align asserts that its inventive concept of determining intermediate states based on the initial and final states is absent from Kesling. Align says, rather, Kesling only disclosed a reactive process, done one step at a time, where subsequent appliances are created by repeating the process for making the first. Align avers that Kesling makes one appliance at a time, and it does not disclose a proactive method of determining intermediate tooth positions at the outset based on both the

initial and final positions. (Citing CX-1247C, Qs. 142-145; CX-1254C ¶¶ 63 at 21-22, 65 at 23; and Tr. at 790:9-791:20)

Align contends that Kesling does not disclose, *inter alia*: (1) digital data sets or models of a dentition (2) intermediate or successive tooth arrangements based on initial and final positions (3) fabricating a dental appliance, or controlling a fabrication machine, based on a digital data set (Citing CX-1247C, Qs. 141-147; CX-1254C ¶¶ 62-63 at 21-22, 65 at 23, 67 at 24-25; and Tr. At 791:21-793:5); or (4) "numerous other elements" (Citing CX-1247C, Qs. 137-162; and CX-1258 at 2-8)

Align concludes that based upon the evidence cited, supra, even if Lemchen is found to have incorporated Kesling by reference the two references taken together as one would still fail to disclose all elements of asserted claim 1 of the '511 patent. (Citing CX-1247C, Qs. 568-569; and CX-1254C ¶ 274 at 97)

In its reply brief, Align says that neither Respondents nor Dr. Mah explained how the elements of Align's claims read on the prior art in view of their "ever-changing claim constructions" or Align's or Staff's proposed constructions. Align asserts that Respondents simply state in a conclusory footnote, "[t]he Respondents' arguments regarding invalidity for each of the asserted patents, both anticipation and obviousness, apply whether the Court adopts Align's, Respondents' or the Staff's claim constructions." (Citing RIB at 39 n.3) Align argues that Respondents' failure to address claim construction is fatal to their invalidity defenses. (Citing *Certain Digital Photo Frames & Image Display Devices*, Inv. No. 337-TA-807, Order No. 44 at 11 n. 1 (Aug. 2, 2012) (Rogers, J.); *Nano-Second Tech. Co. v. Dynaflex Int'l*, 2011 U.S. Dist. LEXIS 111836, at *5 (C.D. Cal. Sept. 28, 2011))

Align contends that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, "a computer-implemented method for segmenting an orthodontic treatment path into segments," "receiving a tooth path," or "calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments." (Citing RIB at 108-109)

Align adds that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. Align refers to Section IV.H.4 of its Reply brief.

In Section IV.H.4 of its reply brief, Align argues that Respondents have manufactured 10 "disclosure categories" that set forth their contentions regarding Lemchen and Kesling. Align contends that despite the fact that Respondents failed to present an element-by-element invalidity analysis of the asserted claims at the hearing, Respondents now purport to apply these disclosure categories to each asserted claim, for both anticipation and obviousness. (Citing RIB at 42-70, 85-87, 97-103, 108-109, 115-118, 127-135, 144-148) Align argues that Respondents' disclosure categories do not support either defense.

Align argues that this "new purported element-by-element" analysis should be wholly rejected under GR 8.2 because it was not disclosed in Respondents' *PreHearing Brief*. (Citing RPHB at 44-67, 98-106, 127-36, 146-54, 174-83, 205-17, 240-48) Align contends, too, that the "disclosure categories" consist of mischaracterizations of Lemchen and Kesling that are largely unsupported by anything other than attorney argument. Align continues that the disclosure categories do not address numerous elements of the asserted claims. Finally, Align says that Respondents' methodology is flawed, because Respondents fail to apply their disclosure categories consistently with the methodology used by Align's expert.

While Align addresses all of Respondents' disclosure categories in its reply brief, only 6,

7 and 10 are relevant to the asserted claim of the '511 patent.

Addressing Respondents' disclosure category 6, Align says that Respondents identify purported "disclosures relating to restraints on movement …" (Citing RIB at 145-146) Align asserts that Respondents contend that Lemchen discloses threshold limits on tooth movement, relying on Dr. Mah's "flawed interpretation" of Lemchen's reference to "appropriate force magnitudes." *Id.* (*Citing* CX-0945, 2:37-38; and RX-133C, Qs. 57-58) Align counters that a PHOSITA would understand this portion of Lemchen as merely describing the function of an archwire and the forces to effect treatment, not an indication that Lemchen contemplated or determined any threshold limits of linear or translational rotation. (Citing CX-1247C, Qs. 233-235; and CX-1254C ¶ 105 at 39-40)

Next, Align says that Respondents identify purported "disclosures relating to generating the intermediate tooth arrangements or digital models as Disclosure Category 7." (Citing RIB at 49-51)

Align says that Respondents claim that Kesling "discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions." (*Id.* at 49) Align says that its inventive concept of determining intermediate states based on both the initial and final states is absent from Kesling. (Citing CX-1247C, Qs. 144-145; and CX-1254C ¶ 65 at 23) Align contends that Kesling only disclosed a reactive process, done one step at a time, where subsequent appliances are created by repeating the process for making the first appliance. (*Id.*; Tr. at 790:9-791:20) Align emphasizes that Kesling makes one appliance at a time and does not disclose a proactive method of determining intermediate tooth positions at the outset based on both the initial and final tooth positions. (Citing CX-1247C, Qs. 144-145; CX-1254C ¶ 65 at 23).

Align states that Respondents claim that Dr. Rekow "recognized that [Kesling] broadly disclosed a three dimensional method for modeling tooth movement that included successive tooth arrangements that proceeded from the initial to the final[.]" (Citing RIB at 49 (*citing* RX-103C)) Align avers that the Rekow Report merely describes Kesling's wax setups (Citing RX-103C at 12-13), and does not contradict Dr. Valley's explanation of Kesling's reactive process, described above.

Align notes that Respondents cite Lemchen at 2:66-3:6, claiming that "[o]ne skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes." (Citing RIB at 49-50) Align demurs, saying that a PHOSITA would understand Lemchen as simply indicating that repositioning teeth into the finish position may involve using software. Align contends that Lemchen does not disclose the concepts of treatment segments, interpolation, or equal-sized translational movements between tooth positions. (Citing CX-1247C, Qs. 236-238; and CX-1254C at ¶ 106 at 40)

Align says that Respondents claim the Rekow Report "demonstrates that one skilled in the art would understand that [Lemchen] incorporates [Kesling] and discloses three dimensional modeling of teeth movement digitally through a series of incremental or intermediate steps from an initial position to the desired position." (Citing RIB at 50 (citing RX-103C)) Align counters that Lemchen does not incorporate Kesling. (Referring to CIB Sec. IV.H.1) Align continues, the concept of intermediate digital data sets or tooth arrangements is absent from, and irrelevant to, Lemchen. (Citing CX-1247C, Qs. 183-185; and CX-1254C ¶ 82 at 29-30) Align argues that Lemchen is limited to the idea of treating a patient with a single set of brackets and teaches ***away***

from using intermediate arrangements (Citing CX-1247C, Qs. 190-191, 225-227; and CX-1254C ¶¶ 90-91 at 32-33, 97 at 34-35) Finally, Align contends that the Rekow Report plainly does not indicate that Lemchen discloses intermediate steps or incorporates Kesling. (Citing RIB at 50 (quoting RX-103C at 16))

Align notes that Respondents also cite *Ormco II*, claiming that "Align previously successfully argued to the Federal Circuit that Lemchen disclosed an incremental approach to calculating desired tooth positions[.]" (Citing RIB at 50-51) Align contends that that *Ormco II* does not contain Align's characterizations of Lemchen. (Citing CIB Sec. IV.H.3) Align adds that the statement by Ormco inventors solely discusses "finish positions of the teeth," not any incremental approach or intermediate steps. (*Id.*)

Align states that throughout their *PostHearing Brief*, Respondents rely on Disclosure Category 7 for Align's claim elements relating to, *e.g.*, intermediate digital data sets and successive digital data sets. (Citing for example, RIB at 58, 86) Align counters that nowhere in Disclosure Category 7 do Respondents actually contend that the prior art discloses intermediate or successive digital data sets. (Citing *id.* at 49-51) Align alleges that the prior art does not disclose these elements. (Citing CX-1247C, Qs. 141-145, 183-185; CX-1254C ¶¶ 62-63, 65, 82 at 21-23, 29-30; and Tr. at 791:21-793:5.

Align turns to Disclosure Category 10, and says that in that category Respondents identify purported "disclosures relating to the fabrication of the appliances … " (Citing RIB at 51-52) Align alleges that Respondents mischaracterize the disclosures of Kesling and Lemchen. Align says that Respondents contend that Kesling discloses making an appliance "by molding a polymeric material over positive models." (*Id.* at 51) Align aver that Kesling discloses making

an appliance by filling a cast with rubber, not molding it over a positive model. (Citing Tr. at 789:9-790:8)

Align notes that Respondents contend that Kesling discloses "using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement." (Citing RIB at 52) Align contends that Kesling discloses using dental materials, tools, and an articulating device, not a fabrication machine. (Citing CX-944, 3:65-4:70, Fig. 4; CX-1247C, Q. 153; and CX-1254C ¶ 72 at 26)

Align says Respondents contend that Lemchen discloses "the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated." (Citing RIB at 52) Align cites Dr. Valley's testimony to say that Respondents cite to disparate portions of Lemchen that do not combine the concepts of fabrication, positive models, and digital data sets. (Citing CX-1247C, Qs. 209-210; and CX-1254C ¶ 109 at 41-42)

Staff's Position: Staff refers to SIB section IV.E.1, which they say applies equally here, because Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claim of the '511 patent.

In their reply brief, Staff expresses the view that Respondents have failed to demonstrate clearly and convincingly that the Asserted Claim of the '511 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claim of the '511 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff notes that the claim chart has been excluded. (Citing Tr. at 18:13-19:25) Staff asserts that in their Post-Hearing Brief,

Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '325 patent. Staff argues that, because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2)

Staff adds, even if Respondents' comparison of their prior art references with the Asserted Claim of the '511 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says, in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness; but that testimony is merely conclusory, because it references a claim chart that has been excluded by the ALJ.

Staff concludes that there is a lack of evidence explaining clearly and convincingly how the prior art discloses, teaches, or suggests each and every element of the Asserted Claim of the '511 patent.

Analysis and Conclusions: In section IV.B.1, I found that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. In the interest of brevity, I will not repeat that discussion here; but I reaffirm that finding and the rationale for it.

I also find that Respondents have failed to carry their burden to prove by clear and convincing evidence that Lemchen, including those portions of Kesling that are incorporated by reference into Lemchen, anticipates each and every element of asserted claim 1 of the '511 patent.

The plain language of asserted claim 1 teaches:

> A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:
>
> for each tooth in a set of teeth, receiving a tooth path for the motion of the

tooth from an initial position to a final position;

calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and

generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

(JX-001, 11:4-19)

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. Lemchen does not, then, reveal the requirement of "a segmentation of the aggregate tooth paths into a plurality of treatment segments" taught in the second element of asserted claim 1 of the '511 patent.

Lemchen does not, in any way, address polymeric shell appliances, which are taught in the third element of asserted claim 1 of the '511 patent. Lemchen does not in any way disclose, or hint at, multiple removable appliances or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Rather, Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances. (CX-945, 1:55-57; 1:63-2:8; CX-1247C at Q. 186) According to the credible testimony of Dr. Valley, this is different from fabricating brackets or other appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. (CX-945, 1:56-62; 3:55-63; CX-1247C at Q. 190)

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of asserted claim 1. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.1.a, supra, I find that Kesling also does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I incorporate and reaffirm these findings and rationales here.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates asserted claim 1 of the '511 patent.

2. Obviousness

Respondents' Position: Respondents incorporate RIB section 3.5.2.1 addressing the preamble of Claim 1 of the '325 patent. Respondents also incorporate Disclosure Categories 6, 7, and 10 together with knowledge of one of ordinary skill as described in the section addressing claim 1 of the '325 patent.

Respondents' sole reference to "Nahoum" is that "Nahoum also taught methods for fabricating series of successive aligners in the 1960s. Respondents aver that Dr. Nahoum taught methods for fabricating a series of aligners by vacuum forming thermoplastics over positive models. (Citing RX-096) Respondents say that a PHOSITA would understand, in light of this reference, the following subject matter: 1) an initial tooth arrangement; 2) a projected final tooth arrangement; 3) intermediate or successive tooth positions, 4) the use or fabrication of a series of dental appliances, and 5) producing a positive model of a tooth arrangement." (Citing RX-113C, Qs. 88-89)

Align's Position: Align argues that this particular combination (i.e. Lemchen, Kesling and the knowledge of a PHOSITA) was disclosed for the first time in the *JSCI*, and is therefore improperly raised now.

Align asserts, too, that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align continues that Respondents' the references fail to disclose all the elements of claim 1. (Citing CIB Sec. IV.F.2.a) Align adds that a PHOSITA at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Sec. IV.F.2.b) Finally, Align contends that secondary considerations support a finding of non-obviousness. (Citing CIB Sec. IV.F.2.c)

In its reply brief, Align reiterates that any obviousness contentions other than Lemchen combined with Kesling have been waived. (Citing CIB Sec. IV.H.2) Align adds that there is no evidence of a motivation to combine the prior art. (Citing CIB Sec. IV.H.2.b)

In the cited CIB section IV.H.2, Align argues that Respondents waived any obviousness defense under GR 8.2 because their *PreHearing Brief* did not specify, *inter alia*, which asserted

claims they contend are obvious. (Citing RPHB at 48-67, 146-154 and 240-248) (discussion of various prior art references generally), 98-106, 128-136, 146-154, 175-183, 205-217, 240-248 (874). Align contends that the record is devoid of evidence supporting a *prima facie* showing of clear and convincing evidence that: (i) a particular combination of prior art discloses all elements of a claim; and (ii) one of ordinary skill in the art would have some reason to make the combination. (Citing CIB at 30-31)

Align says that Respondents' *PreHearing Brief* generally refers to a combination of Lemchen, Kesling, and "the knowledge of one of ordinary skill in the art." (Citing RPHB at 49, 98, 128, 147, 175, 205, 240) Align contends that this combination fails to disclose all elements of any of the asserted claims. (Citing CIB at 48-51; CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0130-CDX-0169)

Align argues that Respondents' *PostHearing Brief* again fails to set forth any coherent obviousness contentions. (Citing RIB at 61-70, 86-87, 100-103, 109, 117-118, 130-135, 146-148. Align asserts that Respondents moved backwards from the *RJSCI* and fail to even identify what combination of prior art they rely on for each asserted claim. *Id.* Align says rather, Respondents simply present a jumble of prior art references and occasionally a conclusory statement such as, "[t]his claim is thus obvious" or "[t]his independent claim is obvious in light of the identified prior art with the knowledge of one of ordinary skill in the art." *Id.* at 68-69.

Align states that I limited Respondents to motivations purportedly identified by the Rekow Reports (Citing RX-102C; RX-103C),[18] noting that Respondents faced an "uphill struggle" to identify any motivation to combine specific references. (Citing Tr. at 16:9-17:23)

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[18] Align says that beyond this restriction, Respondents' use of the Rekow Reports is even further limited to "showing that prior inconsistent positions were taken by Align in previous litigation." Tr. at 20:5-21:21.

Align says that Respondents only cursorily address motivation for their obviousness positions, citing 2 pages from RX-103C that fail to discuss any motivation. (Citing RIB at 62)[19] Align asserts that this position is also waived under GR 8.2, because it was not specified in Respondents' *PreHearing Brief*. (Citing RPHB at 49) Align adds that Respondents do not assert that there was a motivation to combine any specific prior art other than Lemchen and Kesling. (Citing RPHB at 62) Finally, Align argues that Respondents fail to rebut the evidence showing that one of ordinary skill in the art would not have combined Lemchen and Kesling. (Citing CX-1247C, Qs. 165-166, 280-281, 318-319, 349-350, 427-428, 452-453, 577; and CX-1254C ¶ 77 at 27-28, ¶ 121 at 47)

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claim of the '511 patent, the Staff's discussion of obviousness in SIB Section IV.E.2 applies equally here.

Staff is of the view that Respondents have failed to demonstrate clearly and convincingly that asserted claim 1 of the '511 patent is invalid, because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claim of the '511 patent. Staff says that, in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff notes that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff asserts that, in their Post-Hearing Brief, Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims

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[19] Align contends that Respondents are wrong in saying that Dr. Rekow stated that *Lemchen* and *Kesling* "were combined." (Citing RIB at 62) Align adds that the statement would not provide a motivation to combine Lemchen and Kesling.

of the '325 patent. Staff argues that, because Respondents admittedly did not make this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2)

Staff contends that, even if Respondents' comparison of their prior art references with the Asserted Claim of the '511 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says, in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness; but that testimony is merely conclusory, as it too references an excluded claim chart, purporting to show how and where the prior art discloses each element of each asserted claim.

Staff concludes that there is a lack of evidence explaining clearly and convincingly how the prior art discloses, teaches, or suggests each and every element of the Asserted Claim of the '511 patent.

Analysis and Conclusions: While Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 6.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render asserted claim 1 of the '511 patent obvious.[20] There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. Respondents' prehearing brief does not list any specific combination as rendering the asserted claims obvious. More specifically, the prehearing brief is devoid of a discussion of Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and

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[20] I note that, while Align is correct that the Respondents also fail to identify the claim(s) addressed by the prior art, there is only one asserted claim in the '511 patent. Despite the fact that Respondents refer to each of the asserted claims (plural) in this section of their prehearing brief, I will infer that their reference was to the only claim asserted.

the manner in which the prior art discloses each and every element of an asserted claim as required by Ground Rule 8.2. (RPHB at 147-154) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief. (Tr. 18:13-20:4) I find here that Respondents have waived the right to assert the combination of Lemchen, Kesling, Nahoum and the knowledge of a PHOSITA at the time of the invention.

Nevertheless, assuming *arguendo* that one were to find that the combination at issue here was not waived, then I would find that the Respondents have failed to meet their burden to prove by clear and convincing evidence that the combination of Lemchen, Kesling, Nahoum and the knowledge of a PHOSITA at the time of the invention renders asserted claim 1 obvious.

In order to prevail on their argument that asserted claim 1 of the'511 patent is invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling, and Nahoum discloses all of the limitations of asserted claim 1. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

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

There is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the method in the '511 patent which specifically requires, *inter alia*, that the dental appliances be fabricated using

digital data sets. In section IV.E.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of asserted claim 1 of the '511 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 1 of the '511 patent.

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references.

Lemchen does not in any way disclose, or hint at, multiple removable appliances or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond

a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here..

Dr. Mah's testimony on this subject is not helpful, because he expresses a series of conclusory opinions without citing to evidentiary support. (RX-113C, Qs. 101, 113-121)

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '511 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '511 patent.

F. The '666 Patent

1. Level of Ordinary Skill in the Art

Align's position: Align says that a person of ordinary skill in the field of the invention of the asserted claims is the same for all of the patents at issue.

Respondents' Position: Respondents say that, because the subject matter is the same, the applicable level of ordinary skill in the art is the same for all of the patents at issue.

Staff's Position: Staff says that, because the parties and the technical experts agree that the same level of ordinary skill in the art applies to all of the patents at issue, the Staff's discussion of the applicable level of ordinary skill in the art regarding the '325 patent also

applies to the '666 patent.

Analysis and Conclusions: In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all asserted patents at issue in this investigation. Based upon the similarities between the teachings of the '325 patent and the '666 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '666 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '666 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Like the '325 patent, the '666 patent discusses orthodontic principles (*see, e.g.,* JX-0004 at 1:22-2:9) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions. (JX-0004 at 6:7-17). The '666 patent does not, however, delve into the intricacies of the practice of orthodontics. (*See id.*) As in the '325 patent, the focus of the '666 patent is upon the methods used to generate digital data sets for treatment, including intermediate digital data sets representing tooth positions between the initial position and the final position. (*See, e.g.*, JX-0004 at 5:31-6:55, 9:20-13:4, 14:3-43) The '666 patent discusses, in detail, the manipulation of digital data to prepare the initial data set, generate the final tooth arrangement, and generate the intermediate digital data sets. (*Id.*) Based on the similarities between the disclosures of the '325 patent and the '666 patent, I find nothing in the record to indicate that one of ordinary skill in the art at the time of the invention of the asserted claims of the '666 patent is different than one of ordinary skill in the art for the '325 patent.

2. Anticipation

a. Claim 1

Claim 1 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system an initial digital data set representing an initial tooth arrangement;
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set;
>
> moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set; and
>
> producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:27-47)

Respondents' Position: Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents incorporate the section addressing the anticipation of the preamble of Claim 1 of the '325. Respondents incorporate Disclosure Categories 1, 2, 4, and 7. Respondents assert that Lemchen discloses "providing a computer system." Respondents say that Lemchen discloses the use of conventional CAD/CAM software on computers. (Citing CX-0945 at 2:66 – 3:6) Respondents identify these disclosures in this section relating to providing a computer as Disclosure Category 2.

Respondents argue that Lemchen discloses the second element of claim 1 and incorporate Disclosure Categories 1 and 2. Respondents continue that Lemchen discloses the third element of claim 1 and incorporate Disclosure Category 4. Respondents say that Lemchen discloses the fourth element of claim 1 and incorporate Disclosure Categories 4 and 5. Respondents contend that Lemchen discloses the fifth element of claim 1 and incorporate Disclosure Category 7.

Respondents argue that claim 1 is broadly directed to a method for producing digital teeth arrangements. Respondents continue that claim 1 claims: 1) providing a computer; 2) providing a digital initial tooth arrangement; 3) defining boundaries around individual teeth; 4) moving the tooth boundaries to produce a final data set; and 3) producing a plurality of intermediate digital tooth arrangements based on progressing from the initial to the final. Respondents argue that Lemchen anticipates this claim. Respondents continue that contrary to Align's position here, Dr. Rekow's opinions confirm this:

> Full three-dimensional modeling in **orthodontic treatment planning** was described by Lemchen . . . . . This model is the mathematical representation of the physical model described by Kesling in 1949. . . . This digital/mathematical model was used for the **planning orthodontic treatment**.

(Citing RX-103C at 16 (Emphasis added)) Respondents say that it is beyond dispute that Kesling's three-dimensional modeling method taught initial, final and intermediate tooth arrangements that were based on the initial and the final and progressed from the initial to the final. (Citing CX-0944 at 2:50–3:1) Respondents argue that these facts demonstrate that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align asserts that Respondents' invalidity positions are wholly unsupported and totally insufficient to meet their high burden for an invalidity finding. Align says that Respondents have no particular evidence to support their invalidity case, as no claim

charts explaining where each claimed element is shown in the cited references is in evidence - because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-20:4; 651:14-653:25) Align continues that the prior art references simply fail to disclose all elements of either of the asserted claims of the '666 patent, individually or under any combination. (Citing CX-1247C at Q. 606, 610; CX-1258) Align says that the failings of the prior art are explained in CIB Section IV.F.4. Align says that the elements of the asserted claims of the '666 missing from each prior art reference are illustrated in CDX-0146—CDX-0149. Align explains that for example, none of the prior art discloses, inter alia, "a plurality of successive digital data sets" or "tooth arrangements based on the initial and final digital data sets."

Align says that Respondents contend that all of the asserted claims of the '666 patent are anticipated by Lemchen and "as incorporated," Kesling. Align argues that this argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Alternatively, Align says that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described in CIB Section IV.F.4.c. Align continues that even assuming incorporation, Lemchen would still fail to disclose all elements of any of the asserted claims of the '666 patent.

Align argues that Respondents' invalidity defenses are unsupported. Align says that Respondents also fail to point to any portion of the prior art that they contend discloses "defining boundaries about at least some of the individual teeth" ('666 claim 1); "successive digital data sets" ('666 claims 1, 7); "determining positional differences … and interpolating said differences" ('666 claim 3); or "interpolating positional differences" ('666 claim 7). (Citing RIB at 115-118) Align adds that Respondents also address the wrong claim in attempting to address the validity of claim 9 of the '666 patent. *(Citing* RIB at 117; JX-0004 at 16:18-27)

Align says that Respondents contend that all of the asserted claims are anticipated by Lemchen and "as incorporated," Kesling. Align disagrees, saying that Respondents failed to make a prima facie showing of anticipation. (Citing Tr. at 19:11-20:4, 651:14-653:25) Align continues that Respondents rely on the flawed theory that Lemchen incorporates the entire disclosure of Kesling. Align adds that, even assuming incorporation, Lemchen/Kesling fails to disclose all elements of any asserted claim. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0146—CDX-0149) Align continues that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims and Respondents also misapply their "disclosure categories" with respect to at least claim 7 of the '666 patent.

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '666 patent, the Staff's discussion of anticipation in SIB Section IV.E.1 applies equally here.

Staff argues that Respondents have failed to demonstrate clearly and convincingly that any Asserted Claim of the '666 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claims of the '666 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." Staff says I excluded that claim chart, however. (Citing Tr. at 18:13-19:25) Staff continues that Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '666 patent. Staff says that

because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff asserts that even if Respondents' comparison of their prior art references with the Asserted Claims of the '666 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings here. Even assuming that Lemchen incorporated the entirety of Kesling, each and every limitation of the asserted claims is not disclosed.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets," as required by claim 1.

In Section IV.B.1.a, *supra*, I also find that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. I incorporate and reaffirm that finding and rationale here. As a result, I also find that Lemchen does not disclose "wherein said plurality of ***successive*** digital data sets represents a series of ***successive*** tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement" as required by claim 1.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. Although Respondents argue that Kesling teaches a plurality of steps and making "intermediate tooth positioning devices," In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 1.

Based upon all of the foregoing, I find that Lemchen does not anticipate claim 1.

b. Claim 3

Claim 3 teaches:

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

(JX-004 at 15:52-55)

Respondents Position: Respondents argue that Lemchen discloses the subject matter of claim 3, and incorporate Disclosure Category 7.

Respondents argue that dependent claim 3 is also broadly directed to a method for producing digital teeth arrangements. Respondents say that this claim's added limitation directed to interpolation as a means for determining positional differences dos not change the invalidity analysis. Respondents aver that Lemchen taught that the repositioning of the tooth positions was determined by conventional means using software. (Citing CX-0945 at 3:42-47) Respondents say that it is undisputed that interpolation is a common mathematical means. (Citing RX-0113C at Q. 59) Respondents continue that the Federal Circuit also noted the following characterization of Lemchen:

> The Lemchen patent relies, to produce the calculations, on the conventional calculation techniques employed in generalized CAD software. This in turn relies on a user interactive interface by which an operator contributes human decision making powers to manipulate images until the operator is satisfied that finish tooth position criteria have been met . . . .

(Citing *Ormco II at* 498 F.3d 1315) Respondents contend that this demonstrates that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1.

See In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '666 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen discloses "repositioning is done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist." (CX-945 at 3:44-46) Although Respondents say that interpolation is a common mathematical means, I find nothing in Lemchen actually disclosing interpolation, and Respondents identify no evidence that Lemchen actually disclosed interpolation. Thus, Lemchen with the incorporation of Kesling, does not reveal "determining positional differences between the initial data set and the final data set and interpolating said differences."

c. Claim 7

Claim 7 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system digital data set representing an initial tooth arrangement;
>
> providing to the computer system a digital data set representing a final tooth arrangement;
>
> interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

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

Respondents' Position: Respondents assert that while Align argues that the preamble of claim 7 is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents incorporate the section of this brief addressing the anticipation of the preamble of Claim 1 of the '325 Patent. Respondents incorporate Disclosure Categories 1, 2, 5, and 7.

Citing Disclosure Category 2, Respondents argue that Lemchen discloses the first element of claim 7. Respondents continue that Lemchen discloses the second element of claim 7 and incorporate Disclosure Categories 1 and 2. Respondents say that Lemchen discloses the third element of claim 7 and cite Disclosure Categories 5 and 7 for support. Respondents continue that Lemchen discloses the fourth element of claim 7 based on Disclosure Category 7.

Respondents assert that independent claim 7 is broadly directed to a method for producing digital teeth arrangements. Respondents say claim 7 contains no limitations as to the appliance to be used or the fabrication of an appliance. Respondents say that as described in the sections addressing Claims 1 and 5 of the '666 Patent, Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: Similar to claim 1, discussed *supra*, claim 7 requires "said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement." Similar to claim 3, discussed *supra*, claim 7 also requires "interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive

digital data sets." For the reasons discussed regarding claims 1 and 3, which I incorporate and reaffirm here, Lemchen does not disclose these elements and does not anticipate claim 7.

d. Claim 9

Claim 9 teaches:

> A method as in claim 7, wherein the step of providing a digital data set representing a final tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system;
>
> and moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-004 at 16:18-27)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of claim 9, citing Disclosure Categories 1, 4, 5.

Respondents say that the added limitation of claim 9 of using the minimum amount of transformation to require the minimum amount of movement does not affect the invalidity analysis. Respondents argue that Lemchen teaches that his method "produces appropriate force magnitudes to at various treatment stages of treatment to move the tooth to its ideal position." (Citing CX-0945 at 2:37-38) Respondents continue that the uncontroverted evidence establishes that the appropriate force magnitude means the minimum force necessary to move the teeth toward the successive stage of treatment. (Citing RX-0113C at Q. 58) Respondents contend that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: First, I note that Respondents' arguments do not address the

subject matter of claim 9. While Respondents' arguments are addressed to "minimum amount of transformation," claim 9 actually teaches:

> A method as in claim 7, wherein the step of providing a digital data set representing a final tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system;
>
> and moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-004 at 16:18-27) As a result, Respondents have failed to set forth any argument that claim 9 is anticipated.

Moreover, a patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be anticipated and invalid, I could still find that claim 9 is valid. Since, however, I have found claim 7 to be valid and ***not*** anticipated by Lemchen, claim 9 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 7. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 9 of the '666 patent is anticipated by Lemchen with the incorporation of Kesling. Claim 7 merely teaches "providing to the computer system a digital data set representing a final tooth arrangement." (JX-003 at 16:24-25) Even if this were disclosed by Lemchen, although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). Thus, I find that Lemchen with the incorporation of Kesling, does not reveal the subject matter of claim 9.

3. Obviousness

a. Claim 1

Respondents' Position: Respondents say that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is obvious in light of Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. Respondents incorporate the section of their brief addressing the anticipation of the preamble of Claim 1 of the '325 Patent here together with knowledge of one of ordinary skill in the art. Respondents assert that Disclosure Categories 1, 2, 4, 5, and 7 here together with knowledge of one of ordinary skill in the art show that the claimed invention was obvious.

Align's Position: Align says that Respondents argue that all of the asserted claims of the '666 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align says that this particular combination was disclosed for the first time in the JSCI, as explained in Align's Motion in Limine No. 4, and is therefore improperly raised now. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align argues that these references, in any combination, fail to disclose all the elements of any asserted claims, as discussed above. Align says that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Section IV.F.2.b) Align adds that secondary considerations support a finding of non-obviousness. (Citing CIB Section IV.F.2.c)

Align says that Respondents identified several other combinations in the RJSCI, but none were properly raised in Respondents' Prehearing Brief, and have been waived, for the reasons

discussed in CIB Section IV.F.2. Align contends that as explained in CIB Sections IV.F.2.a, IV.F.4, and illustrated in CDX-0146—CDX-0149, no combination of the prior art discloses all elements of the asserted claims of the '666 patent.

Align asserts that all obviousness contentions or combinations have been waived. Alternatively, Align says that none of the asserted claims are obvious because Respondents failed to make a *prima facie* showing of obviousness. (Citing Tr. at 19:11-20:4, 651:14-653:25) Align continues that any combination of prior art other than Lemchen and Kesling was waived. Align says that the combination of Lemchen and Kesling cannot render any of the asserted claims obvious; it does not disclose all elements of any of the asserted claims. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0146—CDX-0149) Align continues that Respondents' obviousness theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. Align argues that Respondents also misapply their "disclosure categories" with respect to at least claim 7 of the '666 patent. Align contends that none of the prior art discloses all elements of any of the asserted claims, in any combination. (Citing CX-1247C at Q. 606, 610; CX-1258; CDX-0146—CDX-0149) Align adds that there is no evidence of a motivation to combine the prior art and secondary considerations show non-obviousness. Align notes that Respondents have not even contended that at least claim 3 of the '666 patent is obvious.

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '666 patent, the Staff's discussion of obviousness in SIB Section IV.E.2 applies equally here.

Staff argues that Respondents have failed to demonstrate clearly and convincingly that any Asserted Claim of the '666 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claims of the '666 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." Staff says I excluded that claim chart, however. (Citing Tr. at 18:13-19:25) Staff continues that Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '666 patent. Staff says that because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff asserts that even if Respondents' comparison of their prior art references with the Asserted Claims of the '666 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 1 of the '666 patent is obvious. Respondents appear to have asserted two separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 7.5.2.2, their references in that pre-hearing brief amount to a general

discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '666 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 176-183) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 7.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 175). Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

In order to prevail on their claim that the asserted claims of the '666 patent are invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling discloses all of the limitations of the asserted claims. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and

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

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '666 patent. In section IV.F.2, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '666 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '666 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 102, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it

was obvious to combine Lemchen and Kesling. I incorporate that finding and reaffirm it here. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '666 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the

those references to create the method claimed in the invention of the '666 patent.

b. Claim 3

Respondents' Position: Respondents assert that claim 3 is obvious based on Disclosure Category 7 together with the knowledge of one of ordinary skill.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '666 patent is rendered obvious by that combination.

In section IV.F.1.b, *supra*, I found that although Lemchen discloses "repositioning is done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist" (CX-945 at 3:44-46); but I find nothing in in Lemchen actually disclosing interpolation. In the interest of brevity, I will not repeat the discussion in section IV.F.1.b in its entirety; but I reaffirm that finding and the rationale for it. Other than a conclusory statement from their expert that "interpolation is a

conventional mathematical means for determining positional differences," (RX-113C at Q.59) Respondents cite no evidence that interpolation would be obvious to one of ordinary skill in the art. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. As a result, I find that Nahoum necessarily does not disclose interpolating the differences between the initial data set and the final data set.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that interpolating the differences between the initial data set and the final data set is disclosed in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 3 of the '666 patent.

c. Claim 7

Respondents' Position: Respondents say that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is obvious in light of the prior art reference with the knowledge of one of ordinary skill in the art. Respondents incorporate the section of their brief addressing anticipation of the preamble of Claim 1 of the '325 Patent together with knowledge of one of ordinary skill. Respondents argue that Disclosure Categories 1, 2, 5, and 7 together with knowledge of one of ordinary skill as described in the section addressing claim 1 of the '325 patent show that the claimed invention was obvious.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: Claim 7 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system digital data set representing an initial tooth arrangement;
>
> providing to the computer system a digital data set representing a final tooth arrangement;
>
> interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:64-16:13) Similar to claims 1 and 3, discussed *supra*, claim 7 requires "interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets" and explains that "said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement." For the reasons discussed regarding claims 1 and 3, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 7 of the '666 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '666 patent.

d. Claim 9

Respondents' Position: Respondents assert that claim 9 is obvious based on Disclosure Categories 1, 4, and 5 together with knowledge of one of ordinary skill in the art as described in

the section addressing claim 1 of the '325. These disclosures show that the claimed invention was obvious.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 9 is valid. Since, however, I have found claim 7 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 9 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 7. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 9 of the '666 patent is rendered obvious by that combination.

In section IV.F.1.d, *supra*, I found that although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In the interest of brevity, I will not repeat the discussion in section IV.F.1.d and IV.B.2.a in their entirety; but I reaffirm those finding and the rationales for them.

Based upon the evidence before me, I find that Respondents have failed to show by clear

and convincing evidence that all of the limitations of asserted claim 9 of the '666 patent are present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 9 of the '325 patent.

G. The '863 Patent

1. Anticipation

a. Asserted Claim 1

Asserted claim 1 teaches:

> A method for producing digital models of dental positioning appliances, said method comprising:
>
> providing a digital model of a patient's dentition;
>
> producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;
>
> providing a digital model of at least one attachment device; and
>
> positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

(JX-005 at R1:57-67)

Respondents' position: Respondents assert that their arguments regarding anticipation for the '863 patent apply whether the Court adopts Align's, Respondents' or the Staff's claim constructions. Respondents also argue that the scope of the patent claims does not change between an infringement analysis and an invalidity analysis. Referring to Mr. Beers, Align's infringement expert, Respondents note that he identified categories of evidence that covers

common elements of the asserted claims. (Citing CX-1150C at Q. 91) Respondents assert that, because evidence of the subject matter for each category exists in the prior art, the asserted claims were anticipated. Respondents aver that categories 1, 3, 4, 5, 7, 9, and 10 are identified in the section addressing claim 1 of the '325 patent, category 2 is identified in the section addressing claim 1 of the '666 patent, and category 8 is identified in the section addressing claim 1 of the '863 patent.

Respondents incorporate Disclosure Categories 1, 7, and 8 for the preamble of claim 1, discussed *infra*. Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art references. Respondents incorporate by reference the section addressing the anticipation of the preamble of claim 1 of the '325 patent.

Regarding anticipation of the preamble of claim 1 of the '325 patent, Respondents argue that each of the asserted claims is anticipated by U.S. Patent No. RE 35,169 ("Lemchen") and, as incorporated U.S. Patent No. 2,467,432 ("Kesling") under 35 U.S.C. § 102(a). Respondents submit that the use of aligners in orthodontics is long standing. Respondents state that, in 1943, Dr. Kesling filed an application that resulted in U.S. Patent No. 2,467,432 ("Kesling"). (Citing CX-0944) Respondents assert that Kesling expressly discloses: (1) a plurality of tooth arrangements; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-0113C at Q. 49)

Respondents also say that, in 1989, Dr. Lemchen applied for what ultimately became U.S. Patent No. Re. 35,169 ("Lemchen"). (Citing CX-0945) Respondents assert that he disclosed a digital method for three dimensional modeling of teeth movement that was the same

as the manual method disclosed in the '432 Patent. (Citing RX-0113C at Q. 39-40) Respondents argue that this digital modeling includes intermediate or successive tooth arrangements. (Citing RX-0113C at Q. 41) Respondents contend that Lemchen disclosed methods for the fabrication of multiple custom appliances based on the three dimensional modeling. (Citing RX-0113C at Q. 42) Respondents also contend that Lemchen disclosed using positive models generated from digital data. (Citing RX-0113C at Q. 42-43)

Respondents continue that, contrary to its position in this investigation, Align previously recognized that "Capitalizing on work of the dental CAD/CAM systems, Lemchen describes approaches [that] acquire data, automatically determine . . . ideal position for an individual patient, design . . . configuration to conform to the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design." (Citing RX-0102C at 6) Accordingly, Respondents say that Align contended in that litigation that "the idea of fabricating custom appliances," for orthodontic treatment "was not new in 1990." (Citing RX-0102C at 7)

Regarding the first element, Respondents incorporate Disclosure Category 1, in which they represent that Lemchen discloses that an initial digital data set representing an initial tooth arrangement is generated, quoting:

> The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the malocclused tooth with respect to the patient's jaw. This information may be generated in a number of ways, such as electromechanically, by laser scanning, sonic ranging, digital video scanning or magnetically. Various devices which may be so utilized are described in Rekow, Computer Aided Design And Manufacture In Dentistry: A Review Of The State Of The Art, 58 The Journal of Prosthetic Dentistry 512 (1987).

(Citing CX-945, 2:54–63) Respondents assert that Dr. Lemchen specifically discloses that his method generates "accurate digital information" defining the teeth locations. (Citing CX-0945, 2:55-57)

Respondents state that Lemchen expressly incorporated the disclosures of Kesling to explain that the digital three-dimensional model of an initial tooth arrangement that they disclosed was the same as the manual three-dimensional model of an initial tooth arrangement revealed in Kesling, quoting Lemchen:

> in many applications of the preferred embodiment, a complete "model", as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432.

(Citing CX-945, 3:43–46)

Respondents say that contrary to its position here, Align previously recognized that Lemchen developed a digital representation of the physical model of an initial tooth arrangement described by Kesling, quoting:

> Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen *[59 Lemchen, ALN005891-895; 60 Lemchen, ALN005821-829]*. The first step in this process was acquisition of digital data defining the shape and location of the malocclused tooth or teeth [sic] respect to the patient's jaw. A variety of techniques, including those described by Rekow *[89 Rekow, ALN128301-305]* were capable of capturing the required data. The required data, in most applications, were a complete 3D model of the upper and lower dental arches and associated jaw structure *[59 Lemchen, ALN005893, col 3, lines 13-19]*. This model is the mathematical representation of the physical model described by Kesling in 1949. *[Kesling, '432 patent, ALN125695-699]* This digital/mathematical model was used for the planning orthodontic treatment.

(Citing RX-103C at 16)(bracketed information in the original)

Concerning the second element, Respondents incorporate Disclosure Category 7, in which they represent that Kesling discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions. (Citing CX-944, 2:50-3:1) Respondents say that Kesling describes the necessity of making a plurality of appliances as obvious. (Citing CX-0944, 2:50-3:1) Respondents say that in a previous litigation, Dr. Rekow, on behalf of Align, recognized that Kesling broadly disclosed a three dimensional method for modeling tooth movement that included successive tooth arrangements that proceeded from the initial to the final. (Citing RX-103C at 12-13)

Respondents say that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66-3:6) Respondents assert that one skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. (Citing RX-113C, Q. 59) Respondents say that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents aver that Dr. Rekow, on behalf of Align, also recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement. (Citing RX-103C at 16) Respondents contend that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three dimensional modeling of teeth movement digitally through a series of incremental or intermediate steps from an initial position to the desired position. Respondents say that Align

previously successfully argued to the Federal Circuit that Lemchen disclosed an incremental approach to calculating desired tooth positions. (Citing *Ormco II*)

Turning to the third and fourth elements, Respondents assert that Lemchen discloses the use of attachment devices in his digital three-dimensional modeling, including brackets. (Citing CX-945, 3:55-4:2) Respondents contend that Lemchen also discloses the method of "indirect" bonding, a method of creating polymeric shell appliances to place the attachment devices. (Citing CX-945, 3:64-4:12) Respondents identify these disclosures as Disclosure Category 8.

Align's position: Regarding the priority date for claim 1 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-005) As shown below, Align asserts that claim 1 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C, Q. 97; *Star Sci.*, 655 F.3d at 1371)

'863 Claim Element	Dec. 4, 1998 Priority Date
1. A method for producing digital models of dental positioning appliances, said method comprising:	CX-1252 at 3:25-28, 4:30-5:23, 5:5-16, 8:1-7, 8:10-28, 10:1-8, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6
providing a digital model of a patient's dentition;	CX-1252 at 3:25-28, 4:30-5:23, 8:1-7, 10:1-8, Figs. 1, 5.
producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6.
providing a digital model of at least one attachment device; and	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.
positioning the digital model of the attachment device on at least some of the plurality of modified digital models.	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.

Regarding the prior art and asserted claims, Align contends that Respondents' '863 patent invalidity positions are wholly unsupported and totally insufficient to meet their high burden for an invalidity finding. Align says that Respondents contend that all of the asserted claims of the '863 patent are anticipated by Lemchen and "as incorporated," Kesling. Align submits that this argument is unsupported, because no claim charts (or other explanation) showing this assertion in detail are in evidence. (Citing Tr. at 19:11-20:4; 651:14-653:25) First, Align asserts that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong. (Citing CIB Sec. IV.F.4.c) Second, Align argues that, even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of any of the asserted claims of the '863 patent. For example, Align contends that none of the prior art discloses, *inter alia*, "providing a digital model of at least one attachment device" or "positioning the digital model of the attachment device on at least some of the plurality of modified digital models." (Citing *id.*; CX-1247C at Q. 606, 610; CX-1258) Third, Align contends that both Lemchen and Kesling were considered by the USPTO during the re-examination of the '863 patent, further confirming that the claims of the '863 patent are valid over Lemchen and Kesling. (Citing RPHB at 44, 98, 127, 146, 175, 205, 240; CIB Sec. IV.F.4; CX-1251)

Specifically, Align says Dr. Valley provided a full analysis of each reference in both her expert report (CX-1254C) and witness statement (CX-1247C), and based on her analysis, Dr. Valley opined that specific elements of each claim are not disclosed by the prior art. (Citing CX-1258) Align says the missing claim elements for each prior art reference are illustrated in CDX-130 through CDX-169.

Align says, as depicted in CDX-288 and shown on the face of the patents (and re-exam certificates), almost every reference cited by Respondents was already considered by the

USPTO, and determined to not preclude issuance of the claims. (Citing JX-001 at 2; JX-002 at 2; JX-003 at 1-2, 21-26; JX-004 at 1-2; JX-005 at 1-2, 26-31; JX-006 at 1-4; JX-007 at 1-5; and CX-1250 at 257) Align submits that the USPTO has repeatedly approved the claims over Lemchen and Kesling.

Align argues that Kesling generally discloses tooth positioning appliances made manually using tools and equipment available in the 1940s (*e.g.*, plaster and wax). (Citing CX-1247C, Qs. 142-143; CX-1254C ¶ 63 at 21-22) Align avers that its inventive concept of determining intermediate states based on the initial and final states is absent from Kesling. (Citing CX-1247C, Qs. 144-145; CX-1254C ¶ 65 at 23) Rather, Align submits that Kesling only disclosed a reactive process, done one step at a time, where subsequent appliances are created by repeating the process for making the first. (Citing CX-1247C, Qs. 144-145; CX-1254C ¶ 65 at 23; Tr. at 790:9-791:20) Align contends that Kesling makes one appliance at a time. Align asserts that Kesling does not disclose a proactive method of determining intermediate tooth positions at the outset based on both the initial and final positions. (Citing CX-1247C. Qs. 144-145; CX-1254C ¶ 65 at 23)

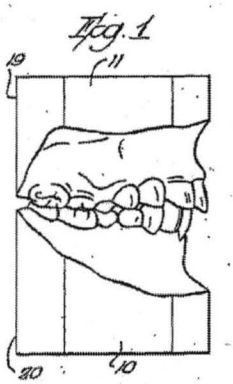
Align argues that Kesling does not disclose, *inter alia*: (i) digital data sets or models of a dentition (Citing CX-1247C, Qs. 141-143; CX-1254C ¶¶ 62-63 at 21-22); (ii) intermediate or successive tooth arrangements based on initial and final positions (Citing CX-1247C, Qs. 141, 144-145; CX-1254C ¶ 65 at 23; and Tr. at 791:21-793:5); (iii) fabricating a dental appliance, or controlling a fabrication machine, based on a digital data set (citing CX-1247C, Qs. 141, 146-147; CX-1254C ¶ 67 at 24-25); or (iv) numerous other elements (citing CX-1247C, Qs. 137-162; CX-1258 at 2-8).

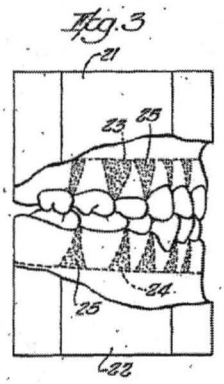
Align asserts that Lemchen discloses a method for determining orthodontic bracket placement. (Citing CX-945, 1:55-2:8) Align contends that Lemchen is directed to a single fixed appliance used for the duration of a patient's treatment, not a removable appliance. (Citing CX-1247C, Qs. 190-191; CX-1254C ¶¶ 90-91 at 32-33; CX-1264 at 5) Align submits that Lemchen's disclosure is limited to the idea of treating a patient with the single set of brackets. (Citing CX-1247C, Qs. 190-191; CX-1254C ¶¶ 90-91 at 32-33) Align avers that the concept of intermediate digital data sets or tooth arrangements is, therefore, absent from, and irrelevant to, Lemchen. (Citing CX-1247C, Qs. 183-185; CX-1254C ¶ 82 at 29-30) Align maintains that Lemchen teaches away from the use of intermediate arrangements. (Citing CX-1247C, Qs. 225-227; CX-1254C ¶ 97 at 34-35)

Align argues that Lemchen does not disclose, *inter alia*: (i) intermediate or successive digital data sets or tooth arrangements (citing CX-1247C, Qs. 183-185; CX-1254C ¶ 82 at 29-30); (ii) polymeric shell appliances (citing CX-1247C, Qs. 183, 186-189; CX-1254C ¶¶ 85-86 at 31-32; CX-1264 at 5); (iii) positive models of modified tooth arrangements based on digital data sets (citing CX-1247C, Qs. 183, 186-189, 207, 209-214; CX-1254C ¶ 87 at 32; CX-1264); (iv) multiple removable appliances or fabricating intermediate or successive appliances based on digital data sets (citing CX-1247C, Qs. 183, 190-191; CX-1254C ¶¶ 90-91 at 32-33); (v) threshold limits (citing CX-1247C, Qs. 233-235; CX-1254C ¶ 105 at 39-40); (vi) interpolation or movements of equal sizes (citing CX-1247C, Qs. 236-238; CX-1254C ¶ 106 at 40); (vii) substantially accurate shapes of a patient's teeth in a modified arrangement (citing CX-1247C, Qs. 239-240; CX-1254C ¶ 108 at 41); (viii) attachment devices (citing CX-1247C, Qs. 241-243; CX-1254C ¶ 109 at 41-42); or (ix) numerous other elements of the asserted claims (citing CX-1247C, Qs. 275-277; CX-1258 at 9-15).

Align contends that Respondents' claim that Lemchen incorporates the entire disclosure of Kesling is wrong as a matter of law. (Citing RPHB at 46-48) Align argues that, to incorporate by reference, the host document "must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." (Citing *Advanced Display Sys.*, 212 F.3d at 1282 (A "mere reference to another [patent] is not an incorporation of anything therein."; *In re De Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973)) Align argues that I have previously held that incorporation of a disclosed patent was limited to the express reference, and did not incorporate all disclosures contained within the patent. (Citing *Certain Digital Imaging Devices*, Inv. No. 337-TA-717, I.D., 2010 WL 5646142, at *53 (USITC May 12, 2011) (Rogers, J.))

Align argues that Lemchen only briefly refers to two figures from Kesling. (Citing CX-945, 3:14-15 ("[a] physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432"); *id.* at 3:35-40 ("[i]n the prior art, a similar step was accomplished manually in order to account





for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. *See*, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432") Align contends that the references to FIGS. 1 and 3 are only examples of models. Align submits that Lemchen does not say that the entire disclosure of

Kesling, or any of its particular methods, is incorporated. Align says that Dr. Valley agrees that Lemchen cites these Figures as examples of what models look like and does not otherwise address Kesling or the relationship between the Figures. (Citing CX-1247C at Q. 249, 251-258; CX-1254C ¶¶ 112-117 at 42-46) Align also argues that, Figures 1 and 3 of Kesling do not disclose the claim elements that are absent from Lemchen. (Citing CX-1247C at Q. 257-258; CX-1254C ¶¶ 112-117 at 42-46)

Align asserts that, contrary to the express description found in the words of Lemchen that cite to Kesling's Figures 1 and 3 as examples of models, Dr. Mah contends, "[i]t is only in the context of the entire disclosure [of Kesling] that the significance of the model displayed as Figure 1 [or Figure 3] as a representation of the patient's teeth prior to treatment [or as a modified tooth arrangement] is understood." (Citing RX-0113C at Q. 47-48) Align argues that these contentions lack merit. Align contends that one of ordinary skill in the art would have understood the concept of a representation of teeth based on Figures 1 and 3 without needing to review Kesling's entire disclosure. (Citing CX-1247C at Q. 264-265; CX-1254C ¶ 117 at 45-46; Tr. at 786:24-787:17, 788:11-789:8, 796:13-798:6) Align submits that plaster tooth arrangements were commonly known and used. (Citing CX-1247C at Q. 264-265; CX-1254C ¶ 117 at 45-46) Align also submits that, even if Lemchen fully incorporated Kesling, Lemchen/Kesling still would not disclose all elements of any of the asserted claims. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97)

Staff's position: Staff says that Respondents' arguments and Dr. Mah's testimony alleging anticipation of the asserted claims of the '325 patent are also made with respect to the asserted claims of the '863 patent. Staff's submits that their discussion of anticipation with respect to the '325 applies equally here. (Citing CIB Section IV.E.1)

In the Staff's view, the evidence does not demonstrate clearly and convincingly that any of the asserted claims of the '863 patent is anticipated by U.S. Patent No. 35,169 (Lemchen) (CX-0945) and, "as incorporated," U.S. Patent No. 2,467,432 (Kesling) (CX-0944). As a preliminary matter, the Staff is of the view that Lemchen does not incorporate the entirety of Kesling. Staff asserts that the evidence demonstrates that Lemchen includes two references to Kesling, specifically, (i) Lemchen refers to Figure 1 of Kesling to explain the representation of the digitized mathematical model of Lemchen; and (ii) Lemchen refers to Figure 3 of Kesling to disclose the method of moving teeth in a digitized mathematical model to a "finish" position. (Citing CX-1247C at Q. 252-256; CX-0945 at 2:66-3:16 and 3:32-40; CX-0944 at FIG. 1 and FIG. 3) Staff contends, however, that the evidence does not further demonstrate that Lemchen incorporates the concepts or teachings from Kesling beyond these figures. (Citing CX-1247C at Q. 259-274; CX-0945; CX-0944) Staff argues that the evidence does not demonstrate that Lemchen necessarily incorporates the entirety of Kesling. (Citing CX-1247C at Q. 259-274; CX-0945; CX-0944)

Staff argues that, even if it was determined that Lemchen necessarily incorporates the entirety of Kesling, the evidence does not show clearly and convincingly that any asserted claim of the '325 patent (or any of the other Asserted Patents) is anticipated by Lemchen and, "as incorporated," Kesling. (Citing CX-1247C at Q. 561-571; CX-1258 at 1-14) Staff asserts that Lemchen does not disclose, teach, or suggest, *inter alia*, (i) intermediate or successive digital data sets or (ii) intermediate or successive tooth arrangements. (Citing CX-1247C at Q. 178-186; CX-1258 at 8-14) Staff argues that Kesling does not disclose, teach, or suggest, *inter alia*, (i) intermediate or successive digital data sets; (ii) the use or fabrication of a series of dental

appliances or (iii) controlling a fabrication machine or producing a positive model of a tooth arrangement from a digital data set. (Citing CX-1247C at Q. 136-163; CX-1258 at 1-7)

Staff continues that Respondents' technical expert Dr. Mah provides only conclusory testimony about the subject matter of the prior art and the '863 patent rather than a detailed discussion of how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the Asserted Claims of the '325 patent (or any of the other Asserted Patents). (Citing RX-0113C at Q. 100-111) Staff says that Dr. Mah apparently prepared a claim chart setting forth more details about how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the asserted claims of the asserted patents, but I excluded that claim chart. (Citing Hearing Tr. at 18:13-19:25 (excluding RX-0124 and RX-0113C at Q. 110)) Staff submits that absent from the record is any evidence explaining clearly and convincingly how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the asserted claims.

Staff also asserts that the PTO considered both Lemchen and Kesling during the reexamination of the '863 patent, and the PTO still approved all of the asserted claims of the '863 patent. (Citing CX-1247C at Q. 135 and 177)

In sum, Staff argues that there is a lack of evidence demonstrating clearly and convincingly that any of the asserted claims of the '863 patent are anticipated by Lemchen and, "as incorporated," Kesling.

Analysis and Conclusions: In Section IV.B.1.a, *supra*, I found that Lemchen incorporates by reference only Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings here. Even assuming that Lemchen incorporated the entirety of Kesling, each and every limitation of the asserted claims is not disclosed.

First, I note that both Lemchen and Kesling were considered by the USPTO during the original prosecution and the re-examination of the '863 patent. (JX-005 at 1, 26-27 (Re-Exam References Cited)) As a result, Respondents must "overcome[e] the deference that is due to a qualified government agency presumed to have properly done its job" to show that the claims of the '325 patent are invalid. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

Respondents have failed even to meet their burden to prove by clear and convincing evidence that each and every limitation of the asserted claims is disclosed expressly or inherently in the cited references.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I reaffirm and incorporate these findings and rationales here.

Based on the evidence before me, I find that Lemchen does not disclose "producing a plurality of modified digital models of the dentition, wherein the modified models represent

successive treatment stages of an orthodontic treatment," as required by claim 1. I also find that Lemchen does not disclose "wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model," as required by claim 1.

Moreover, Lemchen discloses the use of a "machined or cast base" to assist in the positioning a bracket on a tooth. According to the unrebutted testimony of Dr. Valley, this is different from an "attachment device" within the meaning of the '863 patent. Dr. Valley provided the unrebutted testimony that the machined or cast base is simply a customization of the bracket. The machined or cast base is not an object that provides or secures repositioning force, anchoring ability, or retention force, and it is not used for the purpose of securing an orthodontic appliance. Also, the machined or cast base is not used with a removable positioning appliance. (CX-944, 5:3-14; CX-1247C at Q. 243)

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates asserted claim 1 of the '863 patent.

b. Asserted Claim 4

Asserted claim 4 recites:

> A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:
>
> presenting a visual image based on the digital model of the patient's dentition;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; and

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

(JX-005 at 14:-4-16)

Respondents' position:

Regarding the preamble and first element, Respondents incorporate Disclosure Category 1, discussed *supra* with respect to the first element of claim 1. Regarding the second element, Respondents incorporate Disclosure Category 4, in which they contend that Lemchen expressly discloses that the invention "may be utilized with some or all of the teeth in a given dental arch . . ." (Citing CX-0945 at 5:21 – 24) Respondents say that Align previously recognized that the CAD system described by Lemchen presented visual images based on the initial data set that are manipulated to reposition individual teeth. (Citing RX-103C at 16) Respondents continue that Align successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen discloses manipulating visual images to reposition individual teeth in the visual image. (Citing *Ormco II*).

Regarding the third element, Respondents incorporate Disclosure Category 5, in which they assert that Kesling discloses modeling a final tooth arrangement. Respondents say that Align previously contended that Kesling disclosed producing a final tooth arrangement through full 3-D modeling. (Citing RX-103C at 12-13) Respondents continue that Dr. Lemchen expressly incorporated the disclosure of Kesling to explain the final tooth arrangement in the disclosed three dimensional modeling methodology. (Citing CX-0945 at 3:36 – 40) Respondents aver that Align previously recognized that Lemchen disclosed producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image (Citing RX-103C at 16; and *Ormco II*).

Regarding the fourth element, Respondents incorporate Disclosure Category 7, discussed *supra* with respect to the second element of claim 1.

Align's position: Regarding the priority date for claim 4 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claims 4 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.,* 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra.*

'863 Claim Element	Dec. 4, 1998 Priority Date
4. A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:	*See* claim 1, above
presenting a visual image based on the digital model of the patient's dentition;	CX-1252 at 9:24-25, 10:6-8, 11:25-28.
manipulating the visual image to reposition individual teeth in the visual image;	CX-1252 at 4:1-3, 10:23-11:9, 11:25-12:3, Fig. 1.
producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; and	CX-1252 at 4:1-3, 8:10-12:17, Fig. 1.
producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6; 16:9-11, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 4 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated the Lemchen, claim 4 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 is anticipated by

Lemchen and one were to find that Lemchen incorporates all of Kesling by reference, I would find that Respondents have failed to show by clear and convincing evidence that claim 4 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I reaffirm and incorporate these findings and rationales here.

Based on the evidence before me, I find that Lemchen does not disclose "producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 4.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 4.

c. Asserted Claim 5

Claim 5 states:

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

(JX-005 at 14:18-23)

Respondents' position:

Respondents incorporate Disclosure Category 4, discussed *supra* with respect to the second element of claim 4.

Align's position: Regarding the priority date for claim 5 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 5 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.,* 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra.*

'863 Claim Element	Dec. 4, 1998 Priority Date
5. A method as in claim 4, wherein the manipulating step comprises:	*See* claim 4, above
defining boundaries about at least some of the individual teeth; and	CX-1252 at 9:16-28, 10:10-21, Fig. 1.
moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.	CX-1252 at 4:1-3, 10:23-11:9, 11:25-12:3, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 4 to be anticipated and invalid, I could still find that claim 5 is valid.

Since, however, I have found claims 1 and 4 to be valid and ***not*** anticipated by Lemchen, claim 5 is necessarily valid, because it depends from claim 1 via claim 4 and necessarily contains all of the elements of claims 1 and 4. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that claims 1 and 4 are anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 5 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information which defines the shape and location of each malocclused tooth in the patient's jaw," generating a mathematical model of the tooth and jaw, and then calculating the respective "finish positions" for each tooth. (CX-0945 at 1:55-62) Lemchen thus discloses defining boundaries about at least some of the individual teeth, which the first element of claim 5 requires. Lemchen, however, does not disclose moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set as the second element of claim 5 requires. Although Lemchen teaches generating a digital data set representing teeth in their "final" position, Lemchen does not disclose the specific details of how to generate a "final" digital data set.

Kesling was originally filed in 1943, and the patent issued in 1949, before the concept of digital data existed. According to Dr. Valley's unrebutted testimony, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64) As a result, I find that Kesling does not disclose "moving at least some of the tooth

boundaries relative to the other teeth in an image based on the digital data set," as required by claim 5.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claims 1 and 4, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 5.

d. Asserted claim 6

Claim 6 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)

Respondents' position: Regarding the preamble, first and second elements, Respondents incorporate Disclosure Category 2, in which they submit that Lemchen discloses the use of conventional CAD/CAM software on computers. (Citing CX-0945 at 2:66 – 3:6) Regarding the third element, Respondents incorporate Disclosure Categories 5 and 7, discussed *supra* with respect to the third and fourth elements of claim 4, respectively. Regarding the fourth element, Respondents incorporate Disclosure Category 7, discussed *supra* with respect to the second element of claim 1.

Align's position: Regarding the priority date for claim 6 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 6 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.,* 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra.*

'863 Claim Element	Dec. 4, 1998 Priority Date
6. A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:	*See* claim 1, above
providing a computer system having at least one processor and memory;	CX-1252 at 4:28-14:26, Fig. 1.
providing to the computer system the digital model of the patient's dentition;	CX-1252 at 3:25-28, 4:30-5:23, 8:1-7, 10:1-8, Fig. 1.
providing to the computer system a digital model set representing a final tooth arrangement;	CX-1252 at 4:1-3, 8:10-12:17, Fig. 1.
producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets.	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6; 16:9-11, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 6 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated the Lemchen, claim 6 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 6 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions." According to Dr. Valley's unrebutted testimony, Lemchen does not disclose, or teach or suggest, calculating positions-in-between. (CX-945, 1:55-2:1; 2:54-57; 3:16-24; CX-1247C at Q. 184-185) As a result, I find that Lemchen does not disclose "producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets," as required by claim 6.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. Lemchen describes "generating digital information" regarding the initial "malocclused teeth." Kesling was originally filed in 1943, and the patent issued in 1949, before the concept of digital data existed. As Dr. Valley testified credibly, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 6.

e. Asserted Claim 7

Claim 7 states:

> 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)

Respondents' position: Respondents incorporate Disclosure Category 4, discussed *supra* with respect to the second element of claim 4.

Align's position: Regarding the priority date for claim 7 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 7 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.,* 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra.*

'863 Claim Element	Dec. 4, 1998 Priority Date
7. A method as in claim 6, wherein the step of providing a digital model set representing a final tooth arrangement comprises:	*See* claim 6, above
defining boundaries about at least some of the individual teeth on a visual image provided by the computer system; and	CX-1252 at 9:16-28, 10:10-21, Fig. 1.
moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.	CX-1252 at 4:1-3, 10:23-11:9, 11:25-12:3, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 6 to be anticipated and invalid, I could still find that claim 7 is valid. Since, however, I have found claims 1 and 6 to be valid and ***not*** anticipated the Lemchen, claim 7 is necessarily valid, because it depends from claim 1 via claim 6 and necessarily contains all of

the elements of claims 1 and 6. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 and dependent claim 6 are anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 7 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information which defines the shape and location of each malocclused tooth in the patient's jaw," generating a mathematical model of the tooth and jaw, and then calculating the respective "finish positions" for each tooth. (CX-0945 at 1:55-62) Lemchen discloses that the generation of digital information may be accomplished through digital video scanning. (CX-0945 at 2:59) Lemchen, thus, discloses defining boundaries about at least some of the individual teeth on a visual image provided by the computer system, which the first element of claim 7 requires. Lemchen, however, does not disclose moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set as the second element of claim 7 requires. Although Lemchen teaches generating a digital data set representing teeth in their "final" position, Lemchen does not disclose the specific details of how to generate a "final" digital data set.

Kesling was originally filed in 1943, and the patent issued in 1949, before the concept of digital data existed. According to Dr. Valley's unrebutted testimony, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64) As a result, I find that Kesling does not disclose "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," as required by claim 7.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claims 1 and 6, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the elements of claim 7.

f. Asserted Claim 8

Asserted claim 8 recites:

> 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)

Respondents' position: Respondents incorporate Disclosure Category 7, discussed *supra* with respect to the second element of claim 1.

Align's position: Regarding the priority date for claim 8 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 8 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.*, 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra*.

'863 Claim Element	Dec. 4, 1998 Priority Date
8. 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.	CX-1252 at 12:20-14:26

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and claim 6 to be anticipated and invalid, I could still find that claim 8 is valid. Since, however, I have found claims 1 and 6 to be valid and ***not*** anticipated the Lemchen, claim 8 is necessarily valid, because it depends from claim 1 via claim 6 and necessarily contains all of the elements of claims 1 and 6. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 8 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions." As Dr. Valley testified credibly, Lemchen does not disclose, or teach or suggest, calculating positions-in-between. (CX-945, 1:55-2:1; 2:54-57; 3:16-24; CX-1247C at Q. 184-185) As a result, I find that Lemchen does not disclose "determining positional differences between the initial digital model and the final digital model and interpolating said differences," as required by claim 8.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. As described, *supra*, Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position."

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. Kesling was originally filed in 1943, and the

patent issued in 1949, before the concept of digital data existed. According to Dr. Valley's unrebutted testimony, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claims 1 and 6, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 8.

2. Obviousness

a. Asserted claim 1

Respondents assert that their arguments regarding obviousness for the '863 patent apply whether the Court adopts Align's, Respondents', or the Staff's claim constructions. Respondents incorporate Disclosure Categories 1, 7, and 8, discussed *supra*, together with knowledge of one of ordinary skill addressed in claim 1 of the '325 patent. Respondents also incorporate the section addressing the preamble of claim 1 of the '325 patent together with knowledge of one of ordinary skill in the art. In that section, Respondents asserted two separate combinations in their post-hearing briefing— (1) Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; and (2) Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art.

Respondents argue that claim 1 is further rendered obvious in light of U.S. Patent No. 4,793,803 ("Martz") and the knowledge of one of ordinary skill in the art. Respondents assert that Martz discloses a method of producing dental positioning appliances. (Citing CX-0941 at

5:4-14) Respondents contend that Martz also discloses a model of a patient's dentition. (Citing CX-0941 at 3:50-52, 3:65 – 4:5) Respondents also submit that Martz further discloses the production of a plurality of models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model. (Citing CX-0941 at 3:65 -4:5; at 5: 4-14) Respondents claim that Martz also discloses the provision of attachment devices to the models of the patient's dentition. (Citing CX-0941 at 5: 33-45; at. 7:36-41) Respondents argue that these disclosures show that the claimed invention was obvious.

Respondents argue that claim 1 is also rendered obvious in light of the asserted '511 patent and the knowledge of one of ordinary skill in the art. Respondents assert that the '511 patent discloses the production of digital models of dental positioning appliances. (Citing JX-0001 at 6:10-17) Respondents contend that the '511 patent also discloses the provision of a digital model of a patient's dentition. (Citing JX-0001 at 3:40-50; 5:60-66) Respondents submit that the '511 patent also discloses the production of a plurality of models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model. (Citing JX-0001 at 4:51-57; JX-0001 at 9:2-35; JX-0001 at flowcharts) Respondents submit that the '511 patent further discloses the provision of a digital model of an attachment device positioned on a modified digital model of the patient's dentition. (Citing JX-0001 at 8:47 - 50; JX-0001 at 9:2 – 11 & 9:25-28)

Align's position: Align says that Respondents argue that all of the asserted claims of the '863 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align argues that Respondents' arguments fail for a myriad of reasons. First, Align asserts that this particular combination was disclosed for the first time in the JSCI, as explained in Align's Motion in Limine No. 4, and is therefore improperly raised now. Second, Align contends that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Third, Align submits that these references, in any combination, fail to disclose all the elements of the asserted claims of the '863 patent. (Citing CIB Sec. IV.F.2.a, IV.F.4) Fourth, Align asserts that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Sec. IV.F.2.b) Fifth, Align maintains that both Lemchen and Kesling were considered by the USPTO during the re-examination of the '863 patent, further confirming that the asserted claims of the '863 patent are valid over these references. (Citing Sec. IV.F.4) Sixth, Align argues that secondary considerations support a finding of non-obviousness. (Citing Sec. IV.F.2.c)

Align says that Respondents identified several other combinations in the JSCI. Align asserts that none were properly raised in Respondents' Prehearing Brief, and have been waived. (Citing CIB Sec. IV.F.2) Align asserts that, regardless, no combination of the prior art discloses all elements of the asserted claims of the '863 patent. (Citing CIB Secs. IV.F.2.a, IV.F.4; CDX-150-CDX-155) Align says that Respondents assert that other prior art renders Align's asserted claims obvious in the most general way. Align asserts, however, that Respondents have not disclosed any obviousness combination involving this art. Thus, Align argues that there are no

allegations, much less a *prima facie* case, for Align to address. Align says that Dr. Mah treats these additional prior art references in a particularly cursory manner. (Citing RX-0113C at Q. 81-82, 85-86) Align argues that each of these references fails to disclose numerous claim elements.

Align argues that U.S. Patent No. 4,793,803 ("Martz") (CX-0941) does not disclose, *inter alia*: (i) digital data sets or models (citing CX-1247C at Q. 331-333; CX-1254C ¶¶ 146-147 at 57-58); (ii) intermediate or successive tooth arrangements based on initial and final positions (citing CX-1247C at Q. 335-338; CX-1254C ¶¶ 149-150 at 58-60; Tr. at 794:3-795:17); or (iii) numerous other claim elements (citing CX-1247C at Q. 330, 344-346; CX-1258 at 22-28). In its reply brief, Align argues that any obviousness combination involving the Martz patent has been waived because it was not disclosed in Respondents' PreHearing Brief. Align also argues that the Martz patent cannot render any of the claims obvious under any combination. (Citing CIB at Sec. IV.F.4.d)

Align argues that its '325 patent, '511 patent, '666 patent, '880 patent, '874 patent and '487 patent do not render any claim of the '863 patent obvious. (Citing CDX-0122) First, Align asserts that Respondents have no element-by-element analysis supporting such a contention. Second, Align contends that the other patents do not qualify as prior art given that: (i) the '863 patent's priority date is December 4, 1998 and (ii) all were commonly assigned to Align when filed. (Citing JX-0011 at 14-15; JX-0016 at 57-60; JX-0017 at 28-29; JX-0014 at 3-5; 35 U.S.C. § 103(c)). In its reply brief, Align further argues that Respondents fail to specify any combination involving the '511 patent, and any such combination would be waived because it was not specifically identified in Respondents' PreHearing Brief. (Citing CIB Sec. IV.H.2.a)

Staff's position: Staff says that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the asserted claims of the '325 patent are also made with respect to the

asserted claims of the '863 patent. Staff's submits that their discussion of obviousness with respect to the '325 patent applies equally here. (Citing SIB Section IV.E.2)

Staff asserts that, in view of my ruling precluding Respondents from relying on any claim charts disclosing combinations of prior art that allegedly render the asserted claims of the '325 patent (and the '863 patent) invalid for obviousness, the record is devoid of any evidence showing clearly and convincingly how and where any combination of prior art discloses each and every element of the asserted claims of the '325 patent (and the '863 patent). (Citing Hearing Tr. at 19:11-25)

Staff contends that, even if Respondents were to argue that the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill) renders the asserted claims of the '325 patent (and the '863 patent) invalid for obviousness, Staff is of the view that Respondents cannot meet their burden of clear and convincing evidence. Staff avers that, like the testimony alleging anticipation, the testimony alleging obviousness provided by Dr. Mah is merely conclusory. (Citing RX-0113C at Q. 114-121) Thus, Staff submits that Dr. Mah's testimony does not cure the lack of any claim charts (or other evidence) explaining clearly and convincingly how and where the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill) disclose, teach, or suggest each and every element of the asserted claims of the '325 patent (and the '863 patent).

In sum, Staff argues that there is a lack of evidence demonstrating clearly and convincingly that any of the asserted claims of the '325 patent (and the '863 patent) are rendered invalid for obviousness by the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill).

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that any of the asserted claims of the '863 patent are rendered obvious by the cited prior art. Respondents have asserted four separate combinations in post-hearing briefing: (1) Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; (2) Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art; (3) Martz and the knowledge of one of ordinary skill in the art; and (4) the asserted '511 patent and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 3.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '325 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 60-67) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 49) Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief."

Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations were waived, including: (1) Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; (2) Martz and the knowledge of one of ordinary skill in the art; and (3) the asserted '511 patent and the knowledge of one of ordinary skill in the art. Nevertheless, assuming *arguendo* that Respondents had not waived their right to assert those combinations, I would find that Respondents have not met their burden to show by clear and convincing evidence that the following combinations render the asserted claims obvious: (1) Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; and (2) Martz and the knowledge of one of ordinary skill in the art. I find that the third combination of the '511 patent and the knowledge of one of ordinary skill in the art renders the asserted claims of the '863 patent obvious.

In order to prevail on their claim that the asserted claims of the'863 patent are invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling and/or Nahoum discloses all of the limitations of the asserted claims. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003). Equally important is the requirement that the Respondents establish by clear and convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. *See PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in

their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '863 patent. In section IV.G.1, *supra*, I noted that even if I had found that Lemchen incorporated the entirety of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '863 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '863 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling and/or Nahoum. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 103, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. I found in section IV.G.1.a that Lemchen does not in any way disclose, or

hint at, producing digital models that represent successive treatment stages and which are used to fabricate distinct successive incremental dental positioning appliances. I found that Lemchen only discloses calculating a finish position for the teeth, and that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment.

I also found in section IV.G.1.a that Kesling does not disclose, teach, suggest, or even remotely contemplate the use of computers or digital technology. I found that Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

The Nahoum reference is an article reprinted from the New York State Dental Journal, Vol. 20, No. 9, pp. 385-390 (November, 1964). It describes a method for constructing dental appliances by vacuum forming thermoplastics using plaster model(s) of a patient's teeth. Nahoum says that the appliance can be fabricated to move teeth. The Nahoum method contemplates a plaster model of a patient's teeth, cutting the teeth from the model with a saw or fissure burr, repositioning the teeth into the model using wax, and vacuum forming the appliance over the altered model. Nahoum includes a description of making an adjustment in two or more phases in which partial and progressive adjustments are made in each appliance. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '863 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person

having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '863 patent.

Turning to the combination of Martz with the knowledge of one of ordinary skill in the art, I find that Martz describes a method of forming dental positioners using plaster casts of teeth and wax setups of plaster teeth, similar to Kesling. (CX-0941 at 3:50-4:15) Specifically, Martz discloses that a dentist first makes plaster casts of the upper and lower teeth in their original positions and then makes duplicate plaster casts which are mounted in a device known as an "articulator." The articulator allows the casts to be moved and manipulated in a way which simulate the actual jaw movements of the patient. To prepare a positioner, a technician cuts apart the plaster casts with a saw. Plaster teeth are then arranged into desired positions and held in place by wax. (*Id.*) Similar to Kesling, Martz does not disclose, teach, suggest, or remotely contemplate the use of computers or digital technology. Therefore, Martz does not disclose a digital model of a patient's dentition, or a plurality of digital models where each digital model represents a successive orthodontic treatment stage.

I find, too, that Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Martz. Here, Respondents simply make a conclusory statement that claim 1 is rendered obvious in light of Martz and the knowledge of one of ordinary skill in the art. Respondents do not cite to any evidence showing how the knowledge of one of ordinary skill in the art would fill in any claim elements that are allegedly not disclosed in Martz. Also, beyond simply providing citations, Respondents do not explain how the disclosure of Martz reads on any of the elements of the '863 patent.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '863 patent are

disclosed or suggested by Martz in combination with the knowledge of a person of ordinary skill in the art at the time of the invention.

Finally, turning to the '511 patent, it was filed on October 8, 1998 and issued as a patented on October 29, 2002. The '863 patent was filed on October 29, 2001 and issued as a patent on March 16, 2004. Providing the chart below, Align argues that the '863 patent claims a priority date to December 4, 1998.

'863 Claim Element	Dec. 4, 1998 Priority Date
1. A method for producing digital models of dental positioning appliances, said method comprising:	CX-1252 at 3:25-28, 4:30-5:23, 5:5-16, 8:1-7, 8:10-28, 10:1-8, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6
providing a digital model of a patient's dentition;	CX-1252 at 3:25-28, 4:30-5:23, 8:1-7, 10:1-8, Figs. 1, 5.
producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6.
providing a digital model of at least one attachment device; and	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.
positioning the digital model of the attachment device on at least some of the plurality of modified digital models.	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.

As a threshold matter, I find that Align has not demonstrated that all elements of claim 1 of the '511 patent are entitled to the asserted priority date. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305 (Fed. Cir. 2008).

The '881 Provisional Application does not appear to incorporate by reference the '342 Provisional Application. It only states, "A full description of an exemplary repositioning appliance is described in co-pending U.S. application Serial No. 08/947,080, filed October 1997, which is herein incorporated by reference for all purposes." (CX-1253 at 4) U.S. application

Serial No. 08/947,080 eventually issued as U.S. Patent No. 5,975,893 ("the '893 patent"). Although the '893 patent claims the priority from the '342 Provisional Application, the '342 Provisional Application was not itself incorporated into the '881 Provisional Application. Thus, Align improperly cites to disclosure from the '342 Provisional Application to support the December 4, 1998 priority date for the preamble and first two elements of claim 1. Align has not shown that the '342 Provisional Application is actually incorporated into the '881 Provisional Application.

Moreover, even if the '863 patent does sufficiently claim a priority date to December 4, 1998, Align has still not shown that the '511 patent does not qualify as prior art under 35 U.S.C. § 102(a) which recites:

> A person shall be entitled to a patent unless—
>
> (a) ***The invention was known or used by others***, or patented or described in a printed publication in this or a foreign country, ***before the invention thereof by the applicant*** for patent

35 U.S.C. § 102(a) (emphasis added). The filing date of the '511 patent, October 8, 1998, is before December 4, 1998, the date to which Align attempts to claim priority. Also, the '511 patent and the '863 patent do not have identical inventive entities (although they do have Chishti as a common inventor). *In re Hubbell*, 709 F.3d 1140, 1143 (Fed. Cir. 2013). The inventors of the '511 patent include Chishti, Pavlovskaia, Bala, and Freyburger, while the inventors of the '863 patent include Phan, Chishti, and Miller. Because the '511 patent was known or used by "others" before Align's claimed December 4, 1998 priority date, I find that the '511 patent qualifies as prior art under § 102(a).

I turn to the issue of whether or not the substance of the '511 patent reads on the asserted claims of the '863 patent. The '511 patent is entitled "Defining Tooth-Moving Appliances

Computationally" and describes a computer-implemented method for segmenting an orthodontic treatment path in the process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement, and fabricated appliances for the treatment segments. (JX-001 at 1:32-35; 11:4-20)

I find that the '511 patent discloses "providing a digital model of a patient's dentition" as required by the first element of claim 1. The '511 patent reveals producing a digital data set that represents the initial arrangement of the patient's teeth and other tissues. (JX-001 at 3:47-50)

The '511 discloses "producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment," as taught by the second element of claim 1. The '511 patent reveals repositioning a patient's teeth from an initial tooth arrangement to a final tooth arrangement by making a series of incremental position adjustments. (JX-001 at 1:44-47) The '511 patent also reveals providing digital models of the shape and material of each of a sequence of appliances to be applied to a patient. (JX-001 at 2:4-7) The '511 patent discloses computationally defining aligner geometries and shapes. (JX-001 at 2:55-57; 2:65-67; Fig. 6) The '511 patent also discloses that the computational steps of the process are advantageously implemented as computer program ***modules*** for execution on one or more conventional digital computers. (JX-001 at 3:35-38) The '511 patent reveals defining tooth paths for each tooth, after having both a beginning position and a final position for each tooth. (JX-001 at 4:7-12) As discussed above, the '511 patent discloses that the clinican interaction can be implemented using a client process programmed to receive tooth positions ***and models***, as well as path information from a server computer or process in which other steps of the process are implemented. (JX-001 at 4:39-43)