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encountered difficulties in “the task of developing an automated system that includes reliable and efficient decision making algorithms and techniques for automatically determining an ideal finish position of the teeth.” *Id.* at 1313 (Emphasis added by Federal Circuit).

The Federal Circuit also found that the specification did not suggest or even allow for human adjustment of the computer-calculated “finish tooth position.” Moreover, the Federal Circuit noted that during prosecution of a patent related to the Ormco patents-in-suit, the patentee had distinguished a certain prior art reference by emphasizing its reliance on an operator for the decision making process and made a statement that the “present invention of applicants is directed toward the most complete and fully automated method for orthodontic appliance design and manufacture made.” Based on the disclosure of the specification and the arguments made during prosecution in the related patent regarding the “present invention,” the Federal Circuit held that certain of the claims at issue were properly limited to require automatic determination of “finish tooth positions.” *Ormco II*, 498 F.3d at 1314-1316.

As noted *supra*, and in contrast with *Ormco II*, the specification of the ‘880 patent merely indicates that fabrication of all of the appliances prior to the outset of treatment is one preferred embodiment. The claims of the ‘874 patent included the phrase “at the outset of treatment” that was used to distinguish those claims from the prior art. Moreover, unlike the patentees in *Ormco II*, the applicants for the ‘874 patent did not make broad statements regarding what was required by the “present invention” during prosecution. (JX-0016 at 272-275) As a result, I find that *Ormco II* is inapposite.

I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is sufficient to understand the meaning of the terms construed in this section. *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (“In

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most situations, an analysis of the ~~intrinsic~~ evidence alone will resolve any ambiguity in a disputed claim term. In such ~~circumstances~~, it is improper to rely on extrinsic evidence.”)

Based upon all of the foregoing, I ~~find~~ that the proper construction for the term “predetermined series of dental incremental position adjustment appliances,” as used in asserted claim 1, is “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.”

D. The ‘487 Patent

1. Level of Ordinary Skill in the Art

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 patents in suit. Based upon the similarities between the teachings of the ‘325 patent and the ‘487 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the ‘325 patent and the ‘487 patent, I ~~find~~ that one of ordinary skill in the art at the time of the invention of the asserted claims of the ‘487 patent has the same knowledge and expertise as one of ordinary skill in the art for the ‘325 patent.

Like the ‘325 patent, the ‘487 patent discusses orthodontic principles (*see, e.g.*, JX-0007 at 1:20-42) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions. (JX-0007 at 3:3-8, 5:35-38). The ‘487 patent does not, however, delve into the intricacies of the practice of orthodontics. (*See id.*) As in the

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'325 patent, the focus of the '487 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-0007 at 3:45-8:31) The '487 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. (JX-0007 at 5:19-8:31) Based on the similarities between the disclosures of the '325 patent and the '487 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 '487 patent is different than one of ordinary skill in the art for the '325 patent.

2. "treatment plan"

The term "treatment plan" appears in asserted claims 7, 8 and 9.

Align's position: Align asserts that this term should be construed as "a strategy formulated to reposition a patient's teeth." Align contends that Staff's proposed construction, which is generally consistent with Align's, improperly requires that the patient be an orthodontic patient. Align says that there is no requirement in the intrinsic record that the patient be an Orthodontist's patient; rather, the patient can be a dental patient or the patient of any other practitioner licensed to prescribe dental treatment using incremental repositioning dental appliances.

Align avers that Respondents argue they do not infringe claims of the '487 patent because the phrase "treatment plan" should be construed to require that an orthodontist or clinician formulate the treatment plan. (Citing RPHB at 119-120, 220-21, 226, 233) Align says that Respondents stated "No Construction Proposed" in the SRJCCC for this phrase, and cannot, therefore, advance this new construction now. (Citing Tr. at 8:4-16) Align continues that neither

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Respondents nor Dr. Mah cite to any supporting intrinsic evidence. Align contends that such a construction is nonsensical in view of the intrinsic record. Align says that the “treatment plans” of the asserted claims refer to “intermediate digital data sets” that represent “intermediate arrangements of the patient’s teeth.” Align continues that neither the ‘487 or ‘874 patents disclose, much less require, that an orthodontist plan out the treatment or prepare the digital models used to create the aligners; rather, they teach that most of the treatment planning is done by a technician interacting with a computer and following established protocols. (Citing JX-0006 at 10:12–15; JX-0007 at 5:29-32; JX-0003 at 12:33-38; CX-1150C at Q. 242, 251, 316) Align says that Respondents ignore the intrinsic evidence (as they must), and instead piece together their new construction based on unsupported statements from Dr. Mah along with an irrelevant argument regarding unauthorized practice of dentistry. (Citing RPHB at 107) Align contends that such extrinsic evidence is of little value in view of the clear intrinsic record. (Citing *Advanced Fiber Techs. Trust v. J&L Fiber Servs.*, 674 F.3d 1365, 1375 (Fed. Cir. 2012))

Align contends that despite electing not to provide a definition for “*treatment plan*” in the SRJCCC, Respondents again seek to now construe it to require that an orthodontist or clinician formulate the treatment plan in their post-hearing brief. (Citing RIB at 87-91) Align says that Staff agrees that this construction is unsupported. (Citing SIB at 72) Align says that in their post-hearing briefing, Respondents assert they do not infringe claims of at least the ‘487 and ‘874 Patents because “[t]he plain and ordinary meaning of ‘treatment plan’ is the course of treatment devised by the treating dentist or orthodontist.” (Citing RIB at 91) Align asserts that because Respondents stated “No Construction Proposed” in the SRJCCC for this phrase, they cannot advance this new construction now. (Citing Tr. at 8:4-9:4) Align says that Respondents’ new construction has already been excluded. (Citing *See, e.g.,* RX-0129C at Q. 32) Align

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continues that Staff agrees that Respondents' new construction is precluded. (Citing SIB at 72, 109)

Align contends that Respondents also did not cite to any supporting intrinsic evidence in their Prehearing Brief (citing RPHB at 107, 220-21), and thus should not be heard to cite to Align's provisional application (CX-1252) now. Waiver notwithstanding, Align contends that Respondents' construction such a construction is nonsensical in view of the intrinsic record.

Align says that Claim 7 of the '487 Patent recites:

7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein ...

(Citing JX-0007 at 11:26-35) Align continues that the recited "treatment plan" includes "a plurality of intermediate digital data sets" that represent "intermediate arrangements of the patient's teeth." (Citing *id.*) Align reasons that it is clear that the recited "treatment plans" are simply the product of the claimed process. Align continues that Claim 1 of the '874 patent is similar. (Citing JX-0006 at 32:37-56) Align says that Staff agrees. (Citing SIB at 73, 109)

Align says that "intermediate digital data sets" are also the product of exemplary embodiments of the processes taught by the '487 and '874 Patents. (Citing JX-0007 at 5:57-61; JX-0006 at 10:12-15, 19:9-11, 27:36-50) Align continues that the '487 and '874 patents teach that treatment planning is done on a computer by a user (*e.g.*, a "treatment plan designer") following established protocols. (Citing JX-0006 at 12:4-8) Align says that neither the '487 nor '874 patents disclose, much less require, that the user be an orthodontist; rather, the '874 Patent specifically provides for a system where a clinician can review the treatment plan that has already been prepared *via* a "viewer application," as cited above. (Citing JX-0006 at 27:36-50)

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Align asserts that the provision of this “viewer application” would make no sense if the orthodontist was operating the system.

Align contends that Respondents’ citation to Align’s provisional application 60/050,342 (CX-1252) is irrelevant. Align says that while it does indicate in some instances that an orthodontist may utilize the disclosed system, it does not teach that only an orthodontist may use it. Align continues that the claims of the ‘487 or ‘874 patents also do not preclude an orthodontist from creating the “treatment plan”—they are just not limited to such a situation. Align says that the provisional application also states that an “operator” may use the disclosed system. (Citing CX-1252 at 9:13, 20, 24, 10:23, 28)

Align asserts that despite Respondents’ citation to my instruction that I was “going to be focusing on treatment plan as it is used in the patent,” Respondents argue that extrinsic evidence should dictate the meaning of “treatment plan,” citing testimony from Jarrett Pumphrey and Willis Pumphrey, excluded Mah testimony (Citing RIB at 88 (“The evidence presented at the hearing shows...”); RX-0129C at Q. 32 (Excluded)), and an out-of-context quote from Dr. Valley. Align continues that Respondents fail to cite to their own documents which specify that they—not their orthodontists—prepare “treatment plans.” (Citing CX-0055 (“ClearCorrect maps out a complete treatment plan . . .”); CX-0090C at 28 (“a [DPS] sheet is used to make a treatment plan. . . .”); CX-078 at 64-68 (Treatment plan paperwork shipped with each phase)) Align concludes that to the extent extrinsic evidence is relevant it cuts against Respondents’ position.

Respondents’ Position: In the Second Revised Joint Claim Construction Chart, Respondents did not propose a construction for this term. In their post-hearing briefing, Respondents contend that the plain and ordinary meaning of “treatment plan” is the course of treatment devised by the treating dentist or orthodontist.

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Respondents say that the claims of the '487 patent involve the phrases "planning orthodontic treatment" and "orthodontic treatment plan." Respondents continue that the parties have differing views concerning these phrases. Respondents say that one of Align's expert witnesses, Dr. Valley, testified there are "many ways of defining treatment plan." (Citing Tr. at 804:14-15) Respondents continue that Align's other expert witness, Mr. Beers, testified that treatment plan was a "tough" phrase to define. Respondents say that I offered a more pragmatic approach, stating the phrase would be defined by its use in the patent: "Because you seem to be going all over the lot, several of you have tried this, but I am telling you that I am going to be focusing on treatment plan as it is used in the patent" (Citing Tr. at 704:24-705:3) and "I've also already told you I think the patent is what's important and the use of the term in the patent is what's important." (Citing Tr. at 805:5-6)

Respondents contend that the plain and ordinary meaning of this phrase should apply. Respondents say Align's expert has testified that a treatment plan is a document prepared by a Clinician, and not a dental lab such as CCUS or Align, for use in treating patients. Respondents continue that the evidence presented at the hearing shows that to one skilled in the art, a "treatment plan" is a systematic approach to correction or improvement of malocclusion which takes into account the patient's chief complaint and preferences, a clinical problem list, complicating factors, prognosis, clinical experience, and the Clinician's judgment relating to this items. Respondents say that one skilled in the art would understand that a treatment plan means a comprehensive plan and timing for management of the malocclusion which may include, but is not limited to, detailed biomechanical treatments with various orthodontic appliances, adjunctive therapies such as surgery, restorations or other dental care, re-evaluation, retention, referrals to other health professionals, and observation as indicated.

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Respondents say ~~that~~ Align attempts to establish the 1997 priority date for the '487 patent through Dr. Valley's witness statement. (Citing CX-1247C at Q. 115) Respondents continue that Dr. Valley testifies ~~that~~ the '487 patent does indeed claim priority to the earlier application. (Citing *id.*) Respondents say that the provisional application contains an express statement of how the treating orthodontist prepares the treatment plan. Respondents continue that in the "summary of the invention," the application states "[u]sing treatment planner software, the orthodontist then creates a series of intermediate treatment states." (Citing CX-1252-007) Respondents say that the "detailed description of the invention" likewise describes how the orthodontist partitions a digital model of the patient's teeth, manipulates the model to create a "goal state" of the patient's teeth, and then creates "intermediate states" that correspond "to progressive stages of teeth movement between the initial and goal states." (Citing CX-1252-008) Respondents contend that while the '487 patent is itself silent about who prepares the treatment plan, the original application from which it was derived expressed that the orthodontist prepares all the planning for the orthodontic treatment.

Respondents assert that the disclosures in Align's provisional application are consistent with the other evidence presented at the hearing. Respondents say that Jarrett Pumphrey testified that the treating doctor prepares the treatment plan and dental labs like CCUS do not. (Citing Tr. at 350:15-351:13) Respondents continue that Dr. Willis Pumphrey testified that neither OrthoClear, Align, nor CCUS prepare treatment plans:

Because the doctor that produces the treatment plan, to treat the person that treats the patient is me. OrthoClear, Align, and ClearCorrect, they are dental labs. They don't treat patients, you know. At least we don't at ClearCorrect. We definitely don't treat patents.

(Citing Tr. at 415:4-11) Respondents say that Dr. Pumphrey added that treatment by the physician is a matter of law and industry standard. (Citing Tr. at 415:12-14) Respondents

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contend that for almost a century, virtually all states ~~have~~ prohibited corporations from practicing health care professions that require state licensure, ~~such~~ as medicine and dentistry. Respondents say that all states generally outlaw any interference by ~~un~~licensed people or entities with dentists' independent clinical judgment and patient ~~care~~ and courts repeatedly uphold the state laws. (Citing *Semler v. Oregon State Bd. of Dental Examiners*, 294 U.S. 608, 611 (1935) ("That the state may regulate the practice of dentistry, prescribing the qualifications that are reasonably necessary, and to that end may require licenses and establish supervision by an administrative board, is not open to dispute... We have held that the state may deny to corporations the right to practice, insisting upon the personal obligation of individuals"))

Respondents contend that there are two primary reasons why business corporations cannot practice medicine or dentistry. Respondents say that only people can obtain the medical licenses needed to practice. Respondents continue that permitting business corporations to practice medicine or dentistry would threaten physicians' bonds with patients and risk care motivated by profit rather than purely medical decision-making.

Respondents aver that California, the state in which Align Technology, Inc. is headquartered, has typical statutes outlawing the corporate practice of medicine. (Citing CAL BUS. & PROF. CODE § 1625.1(a)) Respondents say that unlicensed practice is, in some circumstances, a criminal offense. (Citing *id.* at § 1701.1) Respondents contend that California courts recognize that "[i]t is an established doctrine ~~that~~ a corporation may not engage in the practice of such professions as law, medicine or dentistry." (Citing *Cal. Physicians Serv. v. Aoki Diabetes Research Inst.* 163 Cal. App. 4th 1506, 1514 (Cal. App. 2008, rev. denied) (quotation omitted)) Respondents say that as described in CAL BUS. & PROF. CODE § 2400 "Corporations and other artificial legal entities shall ~~have~~ no professional rights, privileges, or

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powers.” Respondents continue that the evidence Align itself submitted demonstrates how Align frequently counsels investors about how Align is subject to various state laws concerning dentistry. (Citing CX-1201-013 (“As a participant in the health care industry we [Align] are subject to extensive and frequently changing regulation under many other laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business.”))

Respondents contend that the plain and ordinary meaning of “treatment plan” is the course of treatment devised by the treating dentist or orthodontist. Respondents say that this meaning is consistent with the provisional patent application to which the ‘487 patent claims priority, the witness testimony, applicable state law, and Align’s own representations about its compliance with state law. Respondents continue that Align attempts to expand the plain and ordinary meaning of the phrase by suggesting that a treatment plan can be prepared by anyone. Respondents conclude that Align’s broad interpretation is inconsistent with its provisional application, the witness testimony and state law.

Respondents assert that the CCPK operators do not “create treatment plans.”

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Respondents assert that Align effectively offers nothing to contradict the plain and ordinary meaning of “treatment plan.” Respondents say that One of Align’s expert witness, Dr.

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Valley, testified there are “many ways of defining treatment plan.” (Citing Tr. at 804:14-15)

Respondents continue that Align’s other expert witness, Mr. Beers, testified that treatment plan was a “tough” phrase to define. (Citing Tr. at 551:21) Respondents aver that Align offers only three of CCUS’s documents that state the phrase “treatment plan” to support Align’s request for a modification of “treatment plan’s” plain and ordinary meaning. (Citing CIB at 39)

Respondents say that these items were addressed at the hearing and Align has no response to the witness testimony explaining:

You know, I would say that for the documents that we send to doctors, if we have labeled them treatment plan, it is just so they can kind of think with how that’s supposed to fit into their treatment plan. It is not actually a plan of treatment similar to anything like what a doctor would plan.

(Citing Tr. at 351:19-25)

Staff’s Position: Staff asserts that this term should be construed to mean “a strategy formulated for repositioning an orthodontic patient’s teeth.” Staff asserts that because Respondents originally proposed no construction for “treatment plan” and I excluded Dr. Mah’s opinion that a “treatment plan” is only planned by a Clinician (citing RX-0129C, Q. 162), Respondents are precluded from arguing this as a proposed construction. Staff adds that its proposed construction, which does not materially differ from Align’s proposed construction, is consistent with the plain language of the claims and disclosures in the specification. Staff says that claim 1 recites in pertinent part: “A method of *planning orthodontic treatment of a patient.*” (Citing JX-0007 at 10:61-63 (emphasis added)) Staff continues that the specification discloses, “[t]he present invention is related generally to the *field of orthodontics*, and more particularly to a system and method for gradually repositioning teeth.” Staff says that any arguments to the contrary by Respondents should be rejected.

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Construction to be applied: “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”

The plain language of claim 7 requires an “orthodontic treatment plan” and provides details regarding what is required by that orthodontic treatment plan. Specifically, claim 7 requires:

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-0007 at 11:26-35 (emphasis added))

Respondents have waived the right to offer a construction for the term “treatment plan.” Respondents did not propose a construction for “treatment plan” in the Second Revised Joint Claim Construction Chart. (SRJCCC at 8 (“No construction proposed.”)) In their post-hearing briefing, however, Respondents contend that the plain and ordinary meaning of “treatment plan” is “the course of treatment devised by the treating dentist or orthodontist.” (RIB at 87-91) Because Respondents failed to disclose this construction in the Second Revised Joint Claim Construction Chart, Respondents have waived the right to argue that this construction should be adopted. Assuming *arguendo* that Respondents had not waived this argument, I find nothing in the intrinsic record to support their construction.

The plain language of claim 7 provides clear guidance for the meaning of “treatment

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plan.” Claim 7 first identifies the purpose of the “treatment plan,” saying it is “for repositioning a patient’s teeth using incremental tooth repositioning appliances.” Claim 7 continues to provide that the treatment plan “resides on a computer readable storage media” and comprises “a plurality of intermediate digital data sets.” (JX-0007 at 11:26-35) Thus, the plain language of claim 7 explains that the “treatment plan” for repositioning a patient’s teeth includes a plurality of digital data sets that can be stored on computer readable storage media.

Claim 7 continues to explain that the intermediate digital data sets “represent[] intermediate arrangements of the patient’s teeth.” Claim 7 also explains that the “intermediate arrangements” represent “different orthodontic treatment stages as the patient’s teeth are moved from an initial arrangement toward a final arrangement.” Claim 7 says that the final arrangement “represent[s] the patient’s teeth in a desired or prescribed arrangement.” (JX-0007 at 11:26-35) Thus, the plain language of claim 7 provides that the “treatment plan” represents tooth arrangements from an initial arrangement toward a final arrangement. Based on the foregoing, it is clear that the plain language of claim 7 defines a “treatment plan” as “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.”

This meaning finds support in the use of the term “treatment plan” in the specification for the ‘487 patent. The term “treatment plan” appears in the specification twice and only within a single paragraph. The specification provides:

Next, the digital model is segmented into one model for each tooth (step 344). Each tooth is then matched against a model associated with a prior scan developed at the beginning of the *treatment plan* (step 346). The matching process is based on matching corresponding points between the current scan and the prior scan of the teeth. In most cases, the teeth segmented from the current scan retain the shapes determined at the beginning of the *treatment plan*, and the matching process is easy because the models should be similar to each other.

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(JX-0007 at 8:38-47 (emphasis added)) The portion of the specification from which this quote is taken discusses an optional process whereby mid-treatment information—*i.e.*, a scan of the patient's teeth taken in the middle of the treatment—is incorporated into the final positioning process. (JX-0007 at 8:32-37) Thus, the quoted portion of the specification explains that a scan is developed at the “beginning of the treatment plan,” and the shape of the teeth from that scan are matched to the shape of the teeth from a scan taken in the middle of the treatment. This is consistent with the meaning of the term “treatment plan” that is evident in claim 7—the treatment plan includes digital data sets representing tooth arrangements progressing from an initial tooth arrangement (e.g., a scan developed at the beginning of the treatment plan) toward a final tooth arrangement.

Limiting the definition of “treatment plan” to “the course of treatment devised by the treating dentist or orthodontist” as proposed by Respondents in post-hearing briefing would conflict with the language of claim 7 and the specification. First, claim 7 already addresses the role of the “treating dentist or orthodontist,” disclosing that the final arrangement of the patient's teeth can be based on a prescription. Specifically, claim 7 says that the final arrangement “represent[s] the patient's teeth in a *desired or prescribed* arrangement.” (JX-0007 at 11:34-35 (emphasis added)) Thus, claim 7 is not limited to final arrangements that are prescribed; rather, claim 7 also contemplates final arrangements that are “desired.”

Limiting the definition of “treatment plan” as proposed by Respondents would also conflict with the specification. The specification distinguishes between actions of a “user” to generate the treatment plan and the actions of the “treating professional.” Specifically, the specification says that:

FIG. 3 shows a process 200 for producing the incremental position

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adjustment appliances for subsequent use by a patient to reposition the patient's teeth. As a first step, an initial digital data set (IDDS) representing an initial tooth arrangement is obtained (step 202). The IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using X-rays, three dimensional X-rays, computer-aided tomographic images or data sets, or magnetic resonance images, among others. The teeth data may be generated by a destructive scanner, as described in the incorporated-by-reference U.S. application Ser. No. 09/169,276, filed Oct. 8, 1998.

The IDDS is then manipulated using a computer having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. More specific aspects of this process will be described in detail below.

Individual tooth and other components may be segmented or isolated in the model to permit their individual repositioning or removal from the digital model. After segmenting or isolating the components, ***the user will often reposition the tooth in the model by following a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition one or more teeth based on a visual appearance or based on rules and algorithms programmed into the computer.*** Once the user is satisfied, the final teeth arrangement is incorporated into a final digital data set (FDDS) (step 204). The FDDS is used to generate appliances that move the teeth in a specified sequence.

(JX-0007 at 5:17-44 (emphasis added)) Clearly the specification allows that a "user" may operate the software to generate the final digital data set, while the role of the "treating professional" is to provide a prescription or other written specification. The specification does not require that the "treating professional" necessarily operates the software to generate the final digital data set. Moreover, this portion of the specification teaches that instead of relying on a prescription from the treating professional, the user can "alternatively" reposition the teeth based on a visual appearance or rules or algorithms programmed into the computer. This is further evidence that the inventors did not intend to provide a limitation beyond the clear meaning of the term "treatment plan."

Respondents' arguments based on U.S. Provisional Application No. 60/050342 were not

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raised in their pre-hearing brief (*see* RPHB at 107), and have been waived. Nevertheless, even if these arguments had not been waived, they are incorrect. Although the provisional application does teach that an orthodontist can operate the software to generate final digital data sets and intermediate digital data sets, this is merely one embodiment. The provisional application also contemplates users other than orthodontists operating the software, saying that: “[t]he orthodontist or *other operator* may further simplify the identification process by marking the physical replica prior to scanning.” (CX-1252 at CX1252-13 (emphasis added)) The provisional application states that “[t]he current version of treatment planning software functions to automatically calculate, for each state, a physically realizable (i.e. collision-free) movement path. However, it also permits the orthodontist or *other operator* to guide the computer in several ways.” (*Id.* at CX1252-017 (emphasis added))

The provisional application actually contemplates users without orthodontic training operating the software:

The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, *the component manipulation software can assist a computer operator, lacking orthodontic training*, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and teeth-moving dynamics, can simply use the component identification and manipulation software as a tool and disable or otherwise ignore the advice.

(*Id.* at CX1252-015 (emphasis added)) Clearly the provisional application teaches not only an embodiment in which an orthodontist operates the software; but it includes one in which a user “lacking orthodontic training” operates the software. I find nothing in the provisional application to evidence a clear intention of the inventors to limit the meaning of “treatment plan” to the embodiment in which the orthodontist operates the software. *See i4i Ltd. P’ship v. Microsoft*

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Corp., 598 F.3d 831, 843 (Fed. Cir. 2010) (quoting *Liebel-Flarshiem Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

Respondents' argument that California law requires that a "treatment plan" be created by a dentist or orthodontist lacks any relevance to this issue. As noted above, limiting the claims as proposed by Respondents would conflict with the plain language of the claims and the specification. The Federal Circuit has explained that extrinsic evidence shall not be used to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999). Reference to California law on the unlicensed practice of dentistry epitomizes this principle. The claim makes clear that a "treatment plan" is the object of the claim and what is obtained by practicing the claim (*i.e.* the successive digital data sets that represent arrangements of a patient's teeth from an initial arrangement toward a final arrangement). There is nothing in the claims or specification that suggests abandoning the guidance of the claims themselves and looking to a legal definition related to the practice of the profession contemplated in California law.

I also find that Align's proposed construction is incorrect. The Federal Circuit has explained that "claims are construed as an aid to the decision-maker, by restating the claims in non-technical terms." *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1360 (Fed. Cir. 2008)(citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998)). Here, Align's construction essentially replaces the word "treatment plan" with "strategy." This fails to provide any more context or clarification for understanding claim 7 than the original claim language, and Align cites no support from the claims or specification for its proposed construction. (CIB at 89-90) Defining treatment plan merely as a "strategy formulated . . ." also would conflict with the language of the claim, which requires that the "treatment plan" include

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digital data sets. (JX-0007 at 11:29-31) The ordinary meaning of a “strategy” would not necessarily include the creation of digital data sets. Moreover, as noted above, the claims make clear that a “treatment plan” is the object of the claim and what is obtained by practicing the claim (*i.e.* the successive digital data sets that represent arrangements of a patient’s teeth from an initial arrangement toward a final arrangement).

I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is sufficient to understand the meaning of the terms construed in this section. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (“In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.”)

Based upon all of the foregoing, I find that the proper construction for the term “treatment plan,” as used in asserted claim 7, is “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.”

E. The ‘511 Patent

1. Level of Ordinary Skill in the Art

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 patents in suit. Based upon the similarities between the teachings of the ‘325 patent and the ‘511 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the ‘325 patent and the ‘511 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the

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'511 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

The '511 patent is directed at a computer implemented method of defining tooth-moving appliances, which is the same field as that of the '325 patent. (JX-001, 1:23-24) The '511 patent discusses orthodontic principles. (*see, e.g.* JX-001, 3:23-30) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions (JX-001, 3:59-62); but the '511 patent focuses on the methods used to computationally generate a planned path for repositioning a patient's teeth from an initial to a final position and for segmenting that path into a plurality of treatment segments. (JX-001, 1:32-67, 2:34-39) The invention of the '511 patent then generates a plurality of appliances that will be used to reposition the patient's teeth in successive arrangements. (JX-001, 2:1-12) The '511 patent describes a system that can be used to augment a computational or manual process using a designer (human or automated) to finely tune the performance of the aligners and to facilitate direct aligner manufacturing under numerical control. (JX-001, 2:45-57, 11:4-19)

2. "computer-implemented method"

The term "computer-implemented method" appears in the preamble to asserted claim 1.

Align's position: Align contends that the proper construction for this term is "A method implemented wholly or in part using a computer."

Align asserts that this phrase needs no construction because the terms are easily understandable words with ordinary meanings, and there is no explicit definition of "computer-implemented method" or disclaimer of the scope of this phrase in the '511 patent. (Citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed. Cir. 2002)) Nevertheless, Align says it has provided a clarifying construction of this term that is proper in view of the '511

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patent's description of user interaction with the described methods and systems. (Citing JX-001, at 4:36-50) Align argues that Respondents have improperly advanced a *new* construction for this phrase in their *Prehearing Brief* that is markedly different from that they proposed in the *SRJCCC*, which also now seeks to expand the limitation to every element. Align reasons that Respondents' new construction has been waived, and as a result Align does not address it, other than to note that it is similarly unsupported.

Respondents' Position: In the *SRJCCC*, Respondents contended that the proper construction for this term is "a computer automated creation process in which each step is a computer program module for execution on one or more conventional digital computers, and where the data comprises signals corresponding to physical objects or activities external to the computer system, and the process causes a physical transformation of the signals which represent the physical objects or activities."

In their initial Post-Hearing Brief, Respondents assert that a person with ordinary skill in the art would understand a "computer-implemented method" to require "an automated process carried out by computer programs." Respondents assert that the context of the '511 Patent makes this clear. Respondents say, for example, the "detailed description" of the invention states: "The computational steps of the process are advantageously implemented as computer program modules for execution on one or more conventional digital computers." (Citing JX-001, at 3:35-38) Respondents continue that the summary states, that the "apparatus of the invention can be implemented as a system, or it can be implemented as a computer program product, tangibly stored on a computer-readable medium, having instructions operable to cause a computer to perform the steps of the method of the invention." Respondents add that there are no teachings in the patent that suggest anything other than an automated process carried out by

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computer programs. Respondents conclude that this limitation does not mean a manual method carried out with the assistance of a computer; but rather requires that each step be computationally implemented on a computer. The Respondents contend that this phrase should be construed to mean: a computer automated creation process in which each step is a computer program module for execution on one or more conventional digital computers.

Staff's Position: Staff is of the view that the term should be given its "Plain and ordinary meaning."⁶

Staff contends that the term "computer-implemented method" requires no construction. Staff disagrees with Respondents' proposed construction, which requires the process to be a "computer automated creation process in which each step is a computer program module." Staff says that the patent specification contemplates user intervention, thus conflicting with Respondents' requirement of a "computer automated" process. (Citing JX-001 at 4:36-39) Staff adds that Respondents have not cited any support for the language "and where the data comprises signals corresponding to physical objects or activities external to the computer system, and the process causes a physical transformation of the signals which represent the physical objects or activities."

The Staff also disagrees with Complainant's proposed construction to the extent it allows a "computer implemented method" to cover methods that use computers in a tangential manner.

Construction to be Applied: "a method accomplished using a computer"

The plain language of asserted claim 1 teaches:

⁶ Staff's assertion of "plain and ordinary meaning," without further elaboration, does not rise to the level of a proposed construction. See, e.g., *O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 411 F. Supp. 2d 1008, 1037 (N.D. Iowa 2006); *Certain Semiconductor Integrated Circuits and Products Containing Same*, Inv. No. 337-TA-665, Order No. 19 (April 8, 2009).

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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) Taken in context, the language of the claim is clear that the method for segmenting an orthodontic treatment into segments is to be accomplished using a computer. The claim further teaches the foregoing three elements as “comprising” the method. “Comprising” is a term of art which, when used in claim language, means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.

Genentech, Inc. v. Chiron Corporation, 112 F.3d 495, 501 (Fed. Cir. 1997) (*Genentech*) (citing *In re Baxter*, 656 F.2d 679, 686 (CCPA 1981)). Thus, a method that satisfies asserted claim 1 must contain the listed elements; but it may contain additional, unnamed elements.

The parties agree that asserted claim 1 requires the use of a computer to accomplish the method. Respondents, however, urge a specific and very narrow construction that is neither taught nor suggested by the language of asserted claim 1⁷. In addition, Respondents offer only two brief references from the patent to support their position. For the reasons set forth, *infra*, I find that the two references offered by Respondents, when considered in context, do not support

⁷ While Respondents, in their post-hearing brief, have omitted some of the restrictive language they included in their proposed construction in the SRJCCC, it is clear from their argument that they continue to take the position that the use of the computer requires a wholly automated process carried out by computer programs and that the limitation does not allow for an interactive method carried out with the assistance of a computer.

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their position.

The patent specification is informative. The Detailed Description, referring to Figure 1, states “[t]he process 100 includes the methods, and is suitable for the apparatus, of the present invention, as will be described. The computational steps of the process are advantageously implemented as computer program modules for execution on one or more conventional digital computers.” (JX-001, 3:36-39) The specification describes acquiring data in the form of “a mold or scan of a patient’s teeth or mouth tissue,” and says the step “generally involves taking casts of the patient’s teeth and gums, and may also involve taking wax bites, direct contact scanning, x-ray imaging, tomographic imaging, sonographic imaging, and other techniques ...” It concludes “[f]rom the data so obtained, a digital data set is derived that represents the initial ... arrangement of the patient’s teeth and other tissues.” (JX-001, 3:39-50)

The specification provides that the final position of the teeth “can be received from a clinician in the form of a prescription, can be calculated from basic orthodontic principles, or can be extrapolated computationally from a clinical prescription.” (JX-001, 3:59-63) The Detailed Description goes on to describe that with a specification of final positions and a digital representation of the teeth, the final position and surface geometry of each tooth can be specified to form a complete model of the teeth at the desired end of treatment. It concludes that the result of this step is a set of digital data structures that represents an orthodontically correct repositioning of the modeled teeth. (JX-001, 3:64-4:6)

Finally, the specification describes that having both a beginning and final position for each tooth, the process defines a tooth path for the motion of each tooth, and the tooth paths are segmented. The segments are calculated so that each tooth’s motion with a segment stays within threshold limits of linear and rotational translation. (JX-001, 4:7-18)

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While the description of Figure 1 in the specification clearly describes use of a computer to accomplish this method, it also describes:

At various stages of the process, and in particular after the segmented paths have been defined, the process can, and generally will, interact with a clinician responsible for the treatment of the patient (step 160). Clinician 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 process 100 are implemented. The client process is advantageously programmed to allow the clinician to display an animation of the positions and paths and to allow the clinician to reset the final positions of one or more of the teeth and to specify constraints to be applied to the segmented paths. If the clinician makes any such changes, the subprocess of defining segmented paths (step 150) is performed again.

(JX-001, 4:36-50) Thus, the specification anticipates direct interaction with the computer by a clinician who may reset the final position(s) of teeth and specify constraints to be applied to segmented paths.

The Detailed Description then provides that the segmented tooth paths and associated tooth position data are used to calculate clinically acceptable appliance configurations that will move the teeth on the defined treatment path in the steps specified by the path segments. Nevertheless, even at this stage, the specification allows for interactions and “even iterative interactions” with the clinician (step 160). (JX-001, 4:51-56, 4:63-65)

The process ends at the manufacturing step, “in which appliances defined by the process are manufactured, or electronic or printed information is produced that can be used by a manual or automated process to define appliance configurations or changes to appliance configurations⁸.” (JX-001, 5:1-6) Clearly, the specification contemplates human intervention and interaction with the computer during the segmentation process as well as the manufacturing

⁸ Further references to human interaction in the manufacturing stage can be found at JX-001, 8:66-9:14.

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process. Respondents have not identified any language in claim 1 that justifies excluding these disclosed embodiments.

Additionally, limiting claim 1 to preclude human intervention and interaction would conflict with claim 6, which depends from claim 1. Claim 6 requires “[t]he method of claim 1, further comprising: displaying the segmentation to a user; and receiving input from the user changing the segmentation.” (JX-001 at 11:40-42.) Because claim 6 explicitly contemplates user interaction with the “computer implemented method” of claim 1, construing claim 1 to preclude user intervention would directly conflict with the user intervention contemplated in claim 6.

In order to give the asserted claim its broadest, reasonable interpretation⁹, I conclude that, while the process clearly requires the use of one or more computers to accomplish the method of asserted claim 1, it also allows for additional elements such as interaction – even iterative interaction – by a clinician or other person. I, therefore, reject the narrower interpretation offered by Respondents.

Based upon all of the foregoing, I find that the proper construction for the term “computer implemented method” as used in asserted claim 1, is “a method accomplished using a computer.”

F. The ‘863 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,

⁹ See *Genentech, supra*, at 499.

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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 '863 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 patents in suit. Based upon the similarities between the teachings of the '325 patent and the '863 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '863 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '863 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Similar to the '325 patent, the focus of the claims of the '863 patent is the method used to generate the digital models of dental positioning appliances used for orthodontic treatment. (*See, e.g.*, JX-0005 at R1:57-2:4; JX-005 at 13:65-14:60) The '863 patent incorporates by reference U.S. Patent No. 5,975,893 ("the '893 patent").¹⁰ (JX-0005 at 2:20-25) The incorporated '893 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. (*See, e.g.*, '893 patent at 6:50-56) As in the '325 patent, the '863 patent describes fabricating a plurality of

¹⁰ The '863 patent, which was filed on October 29, 2001, is a continuation-in-part of U.S. Patent No. 6,398,548 ("the '548 patent"), which was filed December 17, 1999. The '548 patent, in turn, is a continuation-in-part of the '893 patent, which was filed on October 8, 1997. Both the '863 patent and '893 patent claim priority to the same provisional application 60/050,342, which was filed on June 20, 1997. *See* JX-0005 at 1:6-28.

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dental incremental position adjustment appliances based on the digital data sets. (*See, e.g.*, ‘893 patent at 6:56-62) The ‘863 patent teaches providing a digital model of an attachment device, and positioning the digital model of the attachment device on the digital model of the dental positioning appliance. (*See, e.g.*, JX-0005 at R2:1-4 and 12:46-60)

Similar to the ‘325 patent, the ‘863 patent contemplates a treating professional (an orthodontist) providing a prescription that identifies final tooth positions (*see, e.g.*, ‘893 patent at 6:1-11), but does not delve into the intricacies of the practice of orthodontics. For example, the ‘863 patent states that it would be possible to provide software which could interpret a prescription from a treating professional in order to generate digital data representing a final tooth arrangement. (*Id.*) Based on the similarities between the ‘325 patent and the ‘863 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the ‘863 patent is the same as one of ordinary skill in the art for the ‘325 patent.

2. “distinct successive incremental dental positional appliance”/“successive incremental dental positional appliance”

The term “distinct successive incremental dental positional appliance”/“successive incremental dental positional appliance” appears in asserted claim 1.

Align’s position: Align asserts that this term should be construed as “one of a series of appliances to be worn for incrementally positioning teeth.” Align contends that the ‘863 patent describes how the repeating use of “successive appliances comprising new configurations eventually move the teeth through a series of intermediate configurations to a final desired configuration.” (Citing JX-0005 at 2:10-20) Align argues that its construction follows this description and clarifies the term by construing it to mean “one of a series.”

Align contends that Respondents are wrong in their argument that Align cannot seek a construction that covers sets of appliances “fabricated after the outset of treatment,” citing the

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prosecution history of the '874 patent. (Citing RPHB at 217) Align contends that Respondents confuse the concept of (i) a ~~single~~ "set" of appliances (one upper and one lower) used at one treatment stage with (ii) a ~~series~~ of appliances for successive treatment stages. Align asserts that, during the prosecution of the '874 patent, Align distinguished prior art that "teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance) ..." (Citing JX-0016 at 274) Align says that its statement that the prior art "teaches making one set of appliances at a time" refers to one upper appliance and one lower appliance corresponding to a single treatment stage. Align argues that Respondents have also not explained how the prosecution of the '874 patent can affect the asserted claims of the other patents. Align continues that Respondents arguments are further improper for the '863 patent because the statements to which Respondents refer were made after the '863 patent issued.

Respondents' Position: Respondents contend that the plain and ordinary meaning of this phrase should apply, and that there is no basis to conclude that any meaning other than the plain and ordinary meaning should apply. In the infringement section of its post-hearing brief, however, Respondents assert that one skilled in the art would understand the second element of claim 1 would require that all of the "plurality" of "modified digital models" progress successively from the initial tooth arrangement to the final tooth arrangement and be produced prior to active treatment. (RIB at 120)

Staff's Position: Staff asserts that this term should be construed to mean "one of a series of dental appliances for repositioning teeth." Staff contends that, because Respondents contend that the plain and ordinary ~~meaning~~ should apply, they have effectively taken the position that no construction of this claim term is necessary. (Citing Order No. 9) Staff notes that, nonetheless, Respondents argue that one of ordinary skill in the art would understand that the claim element

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reciting these claim terms would require that all of the “~~plurality~~ of modified digital models” progress successively from the initial tooth arrangement to the final tooth arrangement. (Citing RPHB at 186-187) Staff asserts that Respondents’ arguments appear to be based on Dr. Mah’s opinions, which the ALJ has excluded. (Citing RX-0129C at Questions 118 and 120) As such, Staff is of the view that Respondents are precluded from presenting those arguments.

Staff contends that, even if permitted, Respondents’ new claim construction appears to conflict with the plain language of the claim, which recites in pertinent part, “a plurality of modified digital models, wherein the modified models represent successive *treatment stages of an orthodontic treatment.*” (Citing JX-0005 at 1:57-67 (emphasis added by Staff)) Staff argues that Respondents’ proposed construction requires that all of the “plurality” of “modified digital models” progress from the initial tooth arrangement to the final tooth arrangement, i.e. a phase-based process would not fall within the scope of the claim. (Citing RIB at 187) Staff asserts that the claim clearly recites “stages” of an orthodontic treatment, wherein the modified models represent successive stages of orthodontic treatment, as opposed to the overall orthodontic treatment. As such, Staff is of the view that, if considered, Respondents’ claim construction should be rejected.

Construction to be Applied: “a single, separate appliance to be used during a particular interval for repositioning teeth”

The plain language of claim 1 discloses a method for producing digital models of dental positioning appliances, and provides details regarding what is required by that method.

Specifically, claim 1 requires, in pertinent part:

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

providing a digital model of a patient’s dentition;

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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;

...

(JX-0005 at R1:55-2:4¹¹ (emphasis added)) The parties dispute the meaning of “successive” and whether or not the phrase “successive” includes *all* successive appliances to be used in treatment.

Respondents offered “plain and ordinary meaning” as a construction for the term “distinct successive incremental dental positional appliance” in both the Second Revised Joint Claim Construction Chart and its post-hearing brief, and offered no construction beyond that comment. (SRJCCC at 8; RIB at 119) Assertion of “plain and ordinary meaning,” without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int’l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 411 F. Supp. 2d 1008, 1037 (N.D. Iowa 2006); *Certain Semiconductor Integrated Circuits and Products Containing Same*, Inv. No. 337-TA-665, Order No. 19 (April 8, 2009).” In Order No. 9, in the instant investigation, I stated that a party, who offered “plain and ordinary meaning” as a construction in the SRJCCC, would be precluded from offering another construction at a later point in the investigation.

Nevertheless, in the non-infringement section of its post-hearing brief, when referring to the limitation of the second element of asserted claim 1, Respondents argue that they do not infringe this limitation because, “[b]ased on the context of the patent and related prosecution history, one skilled in the art would understand that this limitation would require that *all* of the ‘plurality’ of ‘modified digital models’ progress successively from the initial tooth arrangement

¹¹ See Ex Parte Reexamination Certificate (“the Reexamination Certificate”) appended to the ‘863 patent. The designation “R” will be used to refer to the Reexamination Certificate.

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to the final tooth arrangement and be produced *prior* to active treatment.” (RIB at 120 (emphasis added)) Respondents continue that “[a] final tooth arrangement can only be a projection at the treatment stage prior to active treatment.” (Citing RX-0129C, Q. 120) Respondents also argue that “this means that the Clinician does not determine the successive tooth arrangements that are required until after treatment has begun.” (RIB at 120)

Because Respondents failed to previously disclose any construction for this term, Respondents have waived the right to propose any construction for this term anywhere in its post-hearing briefing. Respondents have attempted to overcome the waiver of that right by offering a backdoor construction for this term in the non-infringement section of their post-hearing brief. In ruling on Align’s first motion *in limine*, I excluded that portion of Question 120 of Dr. Mah’s testimony, upon which Respondents rely to support their waived argument on construction. Respondents’ disingenuous attempt to recover their waived argument is rejected.

Nevertheless, assuming *arguendo* that Respondents had not waived their argument that the limitation of the second element of asserted claim 1 means that “all of the plurality of modified digital models progress successively from the initial tooth arrangement to the final tooth arrangement and be produced prior to active treatment,” I find that nothing in the intrinsic record even hints at such a restrictive construction.

The claims themselves conflict with Respondents’ construction, and provide substantial guidance regarding the meaning of the term “distinct successive incremental dental positioning appliance.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). The first limitation of the second element of claim 1 recites, in pertinent part, “producing a *plurality* of ... digital models.” This language only requires that two or more digital models be produced. *See Apple v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1379 (Fed. Cir. 2012); *see also August*

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Technology Corp. v. Camtek, Ltd., 655 F.3d 1278 (Fed. Cir. 2011). The remainder of claim 1 does not change this meaning. In pertinent part, the second limitation of the second element recites that, “the ... models represent successive treatment stages.” The third limitation of the second element then recites that “*each* modified *model* ... is to be used in fabrication of *a* distinct successive incremental dental positioning appliance associated with *the respective* treatment *stage of that* modified *model*.” (JX-0005 at R1:63-67 (emphasis added)) Nothing in these limitations in any way requires a specific *total* of models required to be produced before the fabrication of dental positioning appliances. Rather, they explain the one-to-one *ratio* that one digital model (representing a single “treatment stage”) is used to fabricate one dental appliance. This arises from the use of the word “each” to clarify that a single model is used to fabricate “a distinct” (i.e. single and separate) dental appliance associated with a particular treatment stage.

Although, the Federal Circuit has stated that “an indefinite article ‘a’ or ‘an’ in patent parlance carries the meaning of ‘one or more’ in open-ended claims containing the transitional phrase ‘comprising,’” there is an exception when the patentee evinces a clear intent to limit the article ‘a’ to receive a singular interpretation. *KJC Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2010). As noted above, claim 1 clearly and specifically requires that one digital model be used to fabricate a single dental positioning appliance associated with a particular treatment interval. Based upon all of the foregoing, I find that the language of the second element provides a limitation on the article “a” such that it refers to a single, separate dental appliance as opposed to the normal use of the article to represent one or more dental appliances.

In addition, the specification and prosecution history of the ‘863 patent describe replacing

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attachment devices mid-treatment or placing new attachment devices throughout treatment. (JX-005 at 7:61-64; CX-1251 at 212) This description, which is not limited to a preferred embodiment, teaches away from Respondents' restrictive construction of fabricating all of the dental appliances prior to the outset of treatment, and is not inconsistent with the view that claim 1 requires that one digital model and corresponding appliance be used during one particular treatment stage.

Found nowhere in claim 1 is the additional temporal requirement of "a series" of dental positioning appliances, as Align's and Staff's constructions introduce. Rather, this limitation is added by claim 57, which depends from claim 1. Specifically, claim 57 recites, "[a] method as in claim 1, further comprising providing the produced plurality of modified digital models for use in fabricating *a series* of successive dental positioning appliances." (JX-0005 at R6:15-18 (emphasis added))

The doctrine of claim differentiation is applicable here. The doctrine of claim differentiation, stems from "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1368-69 (Fed. Cir. 2005). There is a presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim, and the presumption is "especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim." *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

The only meaningful difference between claim 57 and claim 1 is the use of the term "a series." Claim 57 recites producing a plurality of modified digital models for use in fabricating "*a series*" of successive dental positioning "*appliances*" (plural), while claim 1 recites producing

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a plurality of modified digital models, wherein “*each modified model*” is used to fabricate a “*a distinct*” successive incremental dental positioning “*appliance*” (singular). Claim 1 does not describe fabricating *a series* of dental repositioning appliances after the production of a plurality of digital models.

Use of the term “successive” in conjunction with the terms “distinct” and “incremental” in claim 1 does not change the meaning of the plain language of the claim to require “a series.” Claim 1 associates “a distinct successive incremental dental appliance” with a corresponding treatment stage, which as discussed above, is a single interval in orthodontic treatment that uses a single fabricated dental repositioning appliance derived from a single digital model. If one assumes that claim 1 requires using one digital model to produce “one of a series” of dental appliances, then either claim 57 would be rendered superfluous or it would render that portion of claim 1 superfluous. *InterDigital Communications, LLC v. Int’l Trade Comm’n*, 690 F.3d 1318, 1324-25 (Fed. Cir. 2012); *Aristocrat Technologies Australia Pty Ltd. v. Int’l Game Technology and IGT*, 709 F.3d 1348, 1355-56 (Fed. Cir. 2013). Either result is incorrect.

Respondents’ prosecution history estoppel arguments, once again, are ill-considered. Respondents rely on arguments that Align made during prosecution of the ‘874 patent to assert that the claims of the ‘863 patent should be interpreted to require that all appliances to be used in treatment be fabricated before treatment begins. The arguments ascribed to Align by Respondents were based on claim language that is not present in asserted claim 1 of the ‘863 patent. Like the claims of the ‘325 patent discussed in Section III.B.2, *supra*, claim 1 of the ‘863 patent does not include the phrase “at the outset of treatment.” (See JX-0005 at R1:57-67) For the reasons explained in in Section III.B.2, *supra*, which I reaffirm here, because claim 1 does not include the phrase “at the outset of treatment,” arguments made during prosecution of the

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'874 patent regarding the phrase "at the outset of treatment" are not relevant to determining the scope of the claims of the '863 patent.

Based upon all the foregoing, I find that the proper construction for the term "distinct successive incremental dental positional appliance" as used in asserted claim 1 is "a single, separate appliance to be used during a particular interval for repositioning teeth."

G. The '874 Patent

1. Level of Ordinary Skill in the Art

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 patents in suit. Based upon the similarities between the teachings of the '325 patent and the '874 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '874 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '874 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Similar to the '325 patent, the '874 patent is directed to a method to use a computer to create a plan for repositioning an orthodontic patient's teeth. (JX-006, Abstract, and 1:29-31) The '874 patent discusses orthodontic principles (*see, e.g.*, JX-006, 1:32-2:25) and contemplates involvement by a clinician (JX-006, 16:19-33, 22:26-28, 30:40-54) and a prescription by an orthodontist. (JX-006, 17:17-20) Similar to the '325 patent, the focus of the '874 patent is a computer implemented method and related program for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions.

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(See, e.g., JX-006, 32:37-39, 37:18-22) The '874 patent discusses, in detail, the manipulation of digital data to prepare the treatment plan. (JX-006, 10:12-32:14)

2. "computer-implemented method"

The term "computer-implemented method" appears in asserted claim 1.

Align's position: Align contends that the proper construction for this term is "A method implemented wholly or in part using a computer."

Align refers to its argument regarding this same term as it appears in the '511 patent.

(See section III.E.3, *supra*)

Respondents' Position: The Respondents refer to their argument regarding this phrase in relation to the '511 patent and contend that this phrase should be construed to mean the same as it does in the '511 Patent.

Staff's Position: Staff notes that the term "computer-implemented method" also appears in the '511 patent, and the parties agree that the term should be construed consistently between the patents. Staff contends that this term requires no construction. Staff adds that, rather than provide clarity, the constructions proposed by the private parties introduce confusion into the analysis. Thus, Staff disagrees with Complainant's proposed construction to the extent it allows a "computer implemented method" to cover methods that use computers in a tangential manner. Staff also disagrees with Respondents' proposed construction, which requires the process to be a "computer automated creation process in which each step is a computer program module." Staff reiterates that this requirement is inconsistent with the intrinsic evidence. Staff contends that Respondents' proposed addition of the language "and where the data comprises signals corresponding to physical objects or activities external to the computer system, and the process

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causes a physical transformation of the signals which represent the physical objects or activities” is also unsupported.

Staff argues that, where, as here, the terms are ordinary, simple English words, they mean what they say absent an indication that their use has been altered. (Citing *Philips*, 415 F.3d at 1313) Staff asserts that there is no indication, and the private parties have pointed to nothing suggesting that, the use of the terms has been altered beyond their plain and ordinary meaning. Staff concludes that there is nothing in the patent specification or prosecution history that shows that the patentees clearly assigned any specialized meaning to or otherwise narrowed the meaning of “computer-implemented method.”

Staff is of the view that the term “computer-implemented method” requires no construction beyond its plain and ordinary meaning.

Construction to be Applied: “a method accomplished using a computer”

The plain language of asserted claim 1 teaches a computer implemented method for segmenting an orthodontic treatment path into segments, when it states:

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

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

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

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

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

(JX-006, 32:37-56) Taken in context, the language of the claim is clear that the method for creating a treatment plan is to be accomplished using a computer. The claim teaches use of an initial digital data set that represents the teeth in their initial positions and the data produced by scanning the patient's teeth or a physical model of the teeth. In the second and third elements, the claim calls for "generating" a set of intermediate positions for movement of the teeth while moving toward final positions and then "generating" successive appliances to accomplish the repositioning of the teeth from the initial positions to the final positions. These three elements clearly intend for the treatment plan to be accomplished using a computer. As in the '511 patent, asserted claim 1 of the '874 patent uses the term "comprising" in its preamble. "Comprising" is a term of art which, when used in claim language, means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. *Genentech, Inc. v. Chiron Corporation*, 112 F.3d 495, 501 (Fed. Cir. 1997) (*Genentech*) (citing *In re Baxter*, 656 F.2d 679, 686 (CCPA 1981)). Thus, a method that satisfies asserted claim 1 must contain the listed elements; but it may contain additional, unnamed elements.

The parties agree that asserted claim 1 requires the use of a computer to accomplish the method, and they each refer to or reiterate their arguments in section III.E.3, *supra*, related to the '511 patent to support their proposed construction to be applied to this term in the '874 patent.

The patent specification is informative. In the Background of the Invention, the inventor notes that the invention "relates generally to the field of orthodontics and, more particularly, to computer automated development of an orthodontic treatment plan and appliance." (JX-006,

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1:29-31) In the Summary of the Invention, the inventor makes clear that there are multiple ways in which a computer may be used in this context. The inventor states:

In one aspect, the invention relates to the computer-automated creation of a plan for repositioning an orthodontic patient's teeth. A computer receives an initial digital data set representing the patient's teeth at their initial positions and a final digital data set representing the teeth at their final positions. The computer uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.

In some implementations, the initial data set includes data obtained by scanning a physical model of the patient's teeth, such as by scanning a positive impression or a negative impression of the patient's teeth with a laser scanner or a destructive scanner...

(JX-006, 3:7-19) The inventor continues:

In other embodiments, the computer applies a set of rules to detect collisions that will occur as the patient's teeth move along the treatment paths... The computer also can be used to detect improper bite occlusions that will occur as the patient's teeth move along the treatment paths. Other embodiments allow the computer to render a three-dimensional (3D) graphical representation of the teeth at any selected treatment step. The computer also can be used to animate the graphical representation of the teeth to provide a visual display of the movement of the teeth along the treatment paths.

(JX-006, 3:34-47)

Respondents' proposed construction, which requires the process to be a "computer automated creation process in which each step is a computer program module," improperly narrows the scope of the claim. While it is clear that the computer implemented method includes some automated features, as discussed, *supra*, the Summary of the Invention and the Detailed Description of the Invention both allow for some user interaction beyond mere automation. For example, the specification notes "some embodiments allow the user to modify the underlying digital data set by repositioning a tooth in the 3D graphical representation." (JX-006, 3:51-53)

Other examples include, "[d]eveloping an orthodontic treatment plan for a patient involves

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manipulating the IDDS [Initial Digital Data Set] at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images.”

(JX-006, 10:12-15) Figure 3 of the ‘874 patent illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS [final digital data set] on the computer.

(JX-006, 12:4-6) The specification clearly contemplates a combination of automated processes along with user input and interaction to create the treatment paths for a patient’s teeth. (*See, e.g.*, JX-006, 12:11-44; 12:53-62

The specification describes segmenting the teeth in a 3D model and details the methods for both human-assisted segmentation (*e.g.* using tools such as a “saw” (JX-006, 13:3-23) and an “eraser” (JX-006, 13:36-51)) and automated segmentation, in which the includes a subsystem that performs automatic or semi-automatic segmentation of the 3D dentition model into models of individual teeth (JX-006, 14:20-25). Other examples of automatic and human-assisted features abound in the specification. (JX-006, 14:39-22:4, 22:41-23:31) Clearly the ‘874 patent does not limit a computer implemented method to a fully automatic scenario; it includes interactive uses as well.

Additionally, limiting claim 1 to preclude human intervention and interaction would conflict with claims 32, 37, 45, 46, 47, 51, 53, 72 and 76, all of which depend from claim 1. For example, dependent claim 45, which depends from claim 1 via dependent claim 42, comprises receiving an instruction from a human user to modify the graphical representation of the teeth and modifying the graphical representation in response to the instruction. Dependent claim 46 depends from claim 45 and teaches modifying the selected data set in response to instruction from the user. Claim 53, which depends from claim 42, teaches “further comprising receiving an input signal from a 3D input device controlled by a human user and using the input signal to alter the

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orientation of the teeth in graphical representation.” Finally, claim 72, which depends from claim 1 via dependent claim 71, comprises displaying at least two different sets of intermediate treatment positions to a user and allowing the user to select one of the sets for use in treating the patient’s teeth. Clearly, the use of the term “computer-implemented method” in independent claim 1 does not limit itself to a fully automated system. (JX-006, 35:17-20, 35:21-23, 35:45-48, and 36:50-53)

In order to give the asserted claim its broadest, reasonable interpretation¹², I conclude that, while the process clearly requires the use of one or more computers to accomplish the method of asserted claim 1, it also allows for interaction with a human user. I, therefore, reject the narrower interpretation offered by Respondents.

Based upon all of the foregoing, I find that the proper construction for the term “computer implemented method” as used in asserted claim 1, is “a method accomplished using a computer.”

3. “treatment plan”

The term “treatment plan” appears in asserted claim 1.

Align’s position: Align says that this term is discussed in CIB Sections IV.D and VII.A.1 in the discussion of the ‘487 patent. Align argues that its construction is proper for the reasons advanced in those sections.

In its argument regarding the ‘487 patent, Align contends that this term should be construed as “a strategy formulated to reposition a patient’s teeth.” Align says that Staff’s proposed construction, which is generally consistent with Align’s, improperly requires that the patient be an orthodontic patient. Align asserts that there is no requirement in the intrinsic record that the patient be an Orthodontist’s patient; rather, the patient can be a dental patient or the

¹² See *Genentech, supra*, at 499.

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patient of any other practitioner licensed to prescribe dental treatment using incremental repositioning dental appliances.

Align notes that, in their non-infringement argument, Respondents attempt to offer a new construction for this term which would require that an orthodontist or clinician formulate the treatment plan. Align asserts that Respondents cannot advance their new construction, because it has been excluded. (Citing Tr. at 8:4-9:4; and RX-0129C at Q. 32) Align says that Respondents stated “No Construction Proposed” in the SRJCCC for this phrase, and cannot, therefore, advance a new construction now. (Citing Tr. at 8:4-16)

Align contends that Respondents also did not cite to any supporting intrinsic evidence in their Prehearing Brief (citing RIB at 107, 220-21), and thus should not be heard to cite to Align’s provisional application (CX-1252) now. Waiver notwithstanding, Align contends that Respondents’ construction is nonsensical in view of the intrinsic record. Align recites the relevant portion of claim 7 of the ‘487 Patent and notes that the term “treatment plan” includes “a plurality of intermediate digital data sets” that represent “intermediate arrangements of the patient’s teeth.” (Citing JX-0006, 32:37-56) Align reasons that it is clear that the recited “treatment plans” are simply the product of the claimed process. Align adds that Claim 1 of the ‘874 patent is similar. (Citing JX-007, 11:26-35)

Align continues that neither the ‘487 or ‘874 patents disclose, much less require, that an orthodontist plan out the treatment or prepare the digital models used to create the aligners; rather, they teach that most of the treatment planning is done by a technician interacting with a computer and following established protocols. (Citing JX-006, 10:12-15; JX-007, 5:29-32; JX-003, 12:33-38; and CX-1150C, Qs. 242, 251, 316) Align says that Respondents ignore the intrinsic evidence and piece together a new construction based on unsupported statements from

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Respondents' expert Dr. Mah along with an irrelevant argument regarding unauthorized practice of dentistry. (Citing RIB at 107) Align contends that such extrinsic evidence is of little value in view of the clear intrinsic record. (Citing *Advanced Fiber Techs. Trust v. J&L Fiber Servs.*, 674 F.3d 1365, 1375 (Fed. Cir. 2012))

Align asserts that “intermediate digital data sets” are also the product of exemplary embodiments of the processes taught by the ‘487 and ‘874 Patents. (Citing JX-007, 5:57-61; JX-006, 10:12-15, 19:9-11, 27:36-50) Align continues that the ‘487 and ‘874 patents teach that treatment planning is done on a computer by a user (*e.g.*, a “treatment plan designer”) following established protocols. (Citing JX-006, 12:4-8) Align says that neither the ‘487 nor ‘874 patents disclose, much less require, that the user be an orthodontist; rather, the ‘874 Patent specifically provides for a system where a clinician can review the treatment plan that has already been prepared *via* a “viewer application,” as cited above. (Citing JX-006, 27:36-50) Align asserts that the provision of this “viewer application” would make no sense if the orthodontist was operating the system.

Align contends that Respondents' citation to Align's provisional application 60/050,342 (CX-1252) is irrelevant. Align says that while it does indicate in some instances that an orthodontist may utilize the disclosed system, it does not teach that only an orthodontist may use it. Align continues that the claims of the ‘487 or ‘874 patents also do not preclude an orthodontist from creating the “treatment plan”—they are just not limited to such a situation. Align says that the provisional application also states that an “operator” may use the disclosed system. (Citing CX-1252 at 9:13, 20, 24, 10:23, 28)

Align asserts that despite my instruction that I would “be focusing on treatment plan as it is used in the patent,” Respondents argue that extrinsic evidence should dictate the meaning of

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“treatment plan,” citing testimony from Jarrett Pumphrey and Willis Pumphrey, the excluded testimony of Dr. Mah. (Citing RIB at 88; and RX-129C at Q. 32 (Excluded)), and “an out-of-context quote from Dr. Valley.” Align adds Respondents fail to cite to their own documents which specify that they—not their orthodontists—prepare “treatment plans.” (Citing CX-055 (“ClearCorrect maps out a complete treatment plan . . .”); CX-090C at 28 (“a [DPS] sheet is used to make a treatment plan. . . .”); and CX-078 at 64-68 (Treatment plan paperwork shipped with each phase))

Respondents’ Position: The Respondents contend that this phrase should be construed to mean the same thing as it does in the ‘487 Patent. Accordingly, that discussion, *supra*, is incorporated here.

Discussing construction for the ‘487 patent, Respondents contend that the plain and ordinary meaning of “treatment plan” should apply. Respondents rely heavily on extrinsic evidence in their argument, reciting testimony of witnesses such as Dr. Valley, Mr. Beers, and Jarrett Pumphrey. Respondents argue that California law precludes the creation of a treatment plan, because it would amount to the unlawful practice of dentistry pursuant to Section 1625.1(a) of the California Business and Professions Code.

Respondents also say that I offered a “pragmatic approach”, stating the phrase would be defined by its use in the patent. (Citing Tr. at 704:24-705:3, and 805:5-6)

Respondents argue that one skilled in the art would understand that a treatment plan means a comprehensive plan and timing for management of the malocclusion which may include, but is not limited to, detailed biomechanical treatments with various orthodontic appliances, adjunctive therapies such as surgery, restorations or other dental care, re-evaluation, retention, referrals to other health professionals, and observation as indicated.

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Respondents now contend that the plain and ordinary meaning of “treatment plan” is “the course of treatment devised by the treating dentist or orthodontist.” Respondents say that this meaning is consistent with the provisional patent application to which the ‘487 patent claims priority, the witness testimony, applicable state law, and Align’s own representations about its compliance with state law. Respondents continue that Align attempts to expand the plain and ordinary meaning of the phrase by suggesting that a treatment plan can be prepared by anyone. Respondents conclude that Align’s broad interpretation is inconsistent with its provisional application, the witness testimony and state law.

Respondents assert that Align effectively offers nothing to contradict the plain and ordinary meaning of “treatment plan.” Respondents aver that Align offers only three of CCUS’s documents that state the phrase “treatment plan” to support Align’s request for a modification of “treatment plan’s” plain and ordinary meaning. (Citing CIB at 39) Respondents say that these items were addressed at the hearing and Align has no response to the witness testimony explaining:

You know, I would say that for the documents that we send to doctors, if we have labeled them treatment plan, it is just so they can kind of think with how that’s supposed to fit into their treatment plan. It is not actually a plan of treatment similar to anything like what a doctor would plan.

(Citing Tr. at 351:19-25)

Staff’s Position: Staff asserts that this term should be construed to mean “a strategy formulated for repositioning an orthodontic patient’s teeth.” Staff asserts that because Respondents originally proposed no construction for “treatment plan” and I excluded Dr. Mah’s opinion that a “treatment plan” is only planned by a Clinician (citing RX-0129C, Q. 162), Respondents are precluded from arguing this as a proposed construction. Staff adds that its proposed construction, which does not materially differ from Align’s proposed construction, is

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consistent with the plain language of the claims and disclosures in the specification. Staff says that claim 1 recites in pertinent part: “A method of *planning orthodontic treatment of a patient.*” (Citing JX-0007 at 10:61-63 (emphasis added)) Staff continues that the specification discloses, “[t]he present invention is related generally to the *field of orthodontics*, and more particularly to a system and method for gradually repositioning teeth.” Staff says that any arguments to the contrary by Respondents should be rejected.

Construction to be Applied: “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.”

Respondents did not propose a construction for “treatment plan” in the SRJCCC. In their post-hearing briefing, however, Respondents contend that the plain and ordinary meaning of “treatment plan” is “is the course of treatment devised by the treating dentist or orthodontist.” (RIB at 138, and 87-91) I have repeatedly and consistently held that assertion of “plain and ordinary meaning,” without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int’l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 411 F. Supp. 2d 1008, 1037 (N.D. Iowa 2006); *Certain Semiconductor Integrated Circuits and Products Containing Same*, Inv. No. 337-TA-665, Order No. 19 (April 8, 2009).” In Order No. 9, in the instant investigation, I stated that a party, who offered “plain and ordinary meaning” as a construction in the SRJCCC, would be precluded from offering another construction at a later point in the investigation. Because Respondents failed to disclose this construction in the SRJCCC, Respondents have waived the right to argue that this construction should be adopted.

Because Respondents failed to previously disclose any construction for this term,

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Respondents have waived the right to propose any construction for this term anywhere in its post-hearing briefing. Respondents have attempted to overcome the waiver of that right by offering a backdoor construction for this term in the non-infringement section of their post-hearing brief. In ruling on Align's first motion *in limine*, I excluded that portion of Question 120 of Dr. Mah's testimony, upon which Respondents rely to support their waived argument on construction. Respondents' disingenuous attempt to recover their waived argument is rejected.

Nevertheless, assuming *arguendo* that Respondents had not waived their argument, I find nothing in the intrinsic record to support their proposed construction.

The parties all agree that the construction for "treatment plan" should be the same in the '874 patent as it is in the '487 patent. Align and Staff agree with each other that the construction for this term should be a strategy formulated to reposition a patient's teeth. Align and Staff only disagree on whether or not the word patient should be modified by the descriptor "orthodontic," a point that I find not material here.

Asserted claim 1 describes a computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set initial tooth positions to a set of final tooth positions. The method entails first receiving an initial data set obtained by scanning the patient's teeth or a physical model thereof. Then the method teaches generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions. Finally, the method requires generating a plurality of successive appliances to receive and reposition teeth from the initial positions toward the final positions.

As in the '487 patent, asserted claim 1 of the '874 patent begins, in the first element, with the receipt of "an initial digital data set" representing the teeth at their initial positions. The second element of claim 1 teaches "generating a set of intermediate positions" toward which the

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teeth will move, and the ~~third element~~ requires “generating a plurality of successive appliances ... to receive and reposition teeth.”

The specification offers ~~additional~~ enlightenment, when it describes, “[d]eveloping an orthodontic treatment plan for a ~~patient~~ involves manipulating the IDDS [Initial Digital Data Set] at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images.” (JX-006, 10:12-15) Figure 3 of the ‘874 patent illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS [final digital data set] on the computer. (JX-006, 12:4-6) The specification clearly contemplates a combination of automated processes along with user input and interaction to create the treatment paths for a patient’s teeth, which are represented by digital data sets. (*See, e.g.*, JX-006, 12:11-44; 12:53-62) Additionally, dependent claim 46, which depends from claim 1 via claims 45 and 42, teaches modifying the selected data set in response to instruction from the user. (JX-006, 35:21-23)

Based upon the foregoing, I find that the term “treatment plan” shall be construed in accordance with its plain and ordinary meaning to be, “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.”

I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is ~~sufficient~~ sufficient to understand the meaning of the terms construed in this section. *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (“In most situations, an analysis of the ~~intrinsic~~ intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such ~~circumstances~~ circumstances, it is improper to rely on extrinsic evidence.”)

IV. INVALIDITY AND OTHER DEFENSES

A. Applicable Law

It is the respondent's burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1380 (Fed. Cir. 2008). "Under the patent statutes, a patent enjoys a presumption of validity, see 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence[.]" *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006). The clear and convincing standard was recently reaffirmed by the Supreme Court. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S.Ct. 2238 (2011) (upholding the Federal Circuit's interpretation of 35 U.S.C. § 282).

The clear and convincing evidence standard placed on the party asserting the invalidity defense requires a level of proof beyond the preponderance of the evidence. Although not susceptible to precise definition, "clear and convincing" evidence has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that the truth of a factual contention is 'highly probable.'" *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (citing *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed.Cir.1988)).

"When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job[.]" *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Therefore, the challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed.Cir.1990).

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1. Anticipation

“A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.” *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted).

2. Obviousness

Section 103 of the Patent Act states:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a) (2008).

“Obviousness is a question of law based on underlying questions of fact.” *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include: “(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness.” *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are often referred to as the “*Graham* factors.”

The critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417-418 (2007). In *KSR*, the Supreme Court rejected the Federal Circuit's rigid application of the teaching-suggestion-motivation test. The Court stated that “it can be

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important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.* at 418. The Court described a more flexible analysis:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. . . . As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id.

Since *KSR* was decided, the Federal Circuit has announced that, where a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, “the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, . . . and would have had a reasonable expectation of success in doing so.” *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

In addition to demonstrating that a reason exists to combine prior art references, the challenger must demonstrate that the combination of prior art references discloses all of the limitations of the claims. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010) (upholding finding of non-obviousness based on the fact that there was substantial evidence that the asserted combination of references failed to disclose a claim limitation); *Velandar v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (explaining that a requirement for a finding of obviousness is that “all the elements of an invention are found in a combination of prior art references”).

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B. The '325 Patent

1. Anticipation

a. Claim 1

Asserted claim 1 teaches:

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

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

presenting a visual image based on the initial data set;

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

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

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

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

(JX-0003 at R1:29-48)

Respondents' Position: Respondents state in their brief that, to avoid repetition they have identified 10 corresponding categories of disclosures made by U.S. Patent No. RE 35,169 ("Lemchen") and, as incorporated, U.S. Patent No. 2,467,432 ("Kesling"). Respondents say that the categories are used to identify common disclosures applicable to claims with similar subject matter. For ease of reference, categories 1, 3, 4, 5, 7, 9, and 10 are identified in section IV.B, *infra*, addressing anticipation of Claim 1 of the '325 patent. Category 2 is identified in section IV.F, *infra*, addressing Claim 1 of the '666 patent. Category 6 is identified in section IV.H,

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infra, addressing Claim 38 of the '874 patent. Category 8 is identified in section IV.G, *infra*, addressing Claim 1 of the '863 patent.

Respondents argue that each of the asserted claims of the '325 patent 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. Respondents say that their 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.

Respondents assert that when a document is "incorporated by reference" into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein. (Citing *Telemac Cellular Corp. v. Topp Telecom Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001)) Respondents say that material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. Respondents continue that incorporation by reference is accomplished by citing such material in a manner that makes clear that the material is effectively part of the host document. (Citing Robert L. Harmon et al., *Patents and the Federal Circuit* 125-26 (10th ed. 2011))

Respondents contend that Kesling is incorporated by reference into Lemchen. Respondents say that Kesling is specifically identified. Respondents aver that the referenced figures cannot be understood in isolation. Respondents say that the referenced figures require the context of Kesling's disclosures to be understood. Respondents conclude that Kesling disclosures are necessarily incorporated into Lemchen, because they are necessary to understand the manual three dimensional modeling that Lemchen teaches digitally. (Citing RX-0113C at Q. 45 & 47)

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Respondents argue that Dr. Lemchen expressly incorporated the disclosures of Kesling to explain that the digital three-dimensional model that they disclosed was the same as the manual 3-D model created by Dr. Kesling in Kesling. (Citing CX-0945 at 3:43 – 46) Respondents say that Align's present expert, Dr. Valley, disagrees with Align's former expert, Dr. Rekow on this issue. Respondents say that one skilled in the art would understand that this statement necessarily incorporates the entire disclosure of Kesling because Figure 1 in isolation does not explain the significance of the displayed model; rather, it is only in the context of the entire disclosure that the significance of the model displayed in Figure 1 as a representation of the patient's teeth prior to treatment is understood.

Respondents contend that Dr. Lemchen also expressly incorporated the disclosure of Kesling to explain their three dimensional modeling methodology. (Citing CX-0945 at 3:36 – 40) Respondents say that the inventors stated that FIG. 3 was one example of a repositioned tooth arrangement. Respondents argue that one skilled in the art would understand that this same method would apply equally to the intermediate or successive tooth arrangements that are described in Kesling. Respondents continue that this is because the methodology is the exact same for all successive tooth arrangements from the initial position to the final position. Respondents add that intermediate or successive tooth arrangements are inherent in tooth modeling because one cannot model tooth movement accurately without including the intermediate steps. Respondents say that one skilled in the art would understand that this statement necessarily incorporates the entire disclosure of Kesling because Figure 3 in isolation does not explain the significance of the displayed model. Respondents continue that it is only in the context of the entire disclosure that the significance of the model displayed in Figure 3 as a

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representation of the patient's teeth as a ~~modified~~ tooth arrangement is understood. (Citing RX-0113C at Q. 47-48)

According to Respondents, Dr. Lemchen and Dr. Andreiko expressly stated that the three-dimensional modeling methods that they invented, using software, "may be derived by conventional means for the particular method of treatment elected by the orthodontist." (Citing CX-0945 at 3:25 – 26) Respondents continue that inventors similarly stated in their detailed description that there "are a number of methods of treatment commonly used by the orthodontist." (Citing CX-0945 at 3:43 – 46) Respondents reason that Lemchen expressly recognizes that its methods may be used with different types of orthodontic treatment. Respondents contend that one skilled in the art would understand that other treatment methods, such as the aligner treatment method disclosed in Kesling could be used with the digital methods disclosed in Lemchen. (Citing RX-0113C at Q. 49) Respondents say that one skilled in the art would understand that the methods of Kesling were not limited to brackets (which are custom fabricated in the disclosed methods to conform to the surface of the teeth) and arch wires; rather, the incorporation of the disclosures of Kesling and the other statements concerning other treatment methods makes it clear that the methodology of Lemchen applies beyond brackets and archwires. (Citing RX-0113C at Q. 49)

Respondents aver that Kesling's disclosures are limited to methods for making aligners based on a series of 3-D tooth models. Respondents say that one skilled in the art would understand the incorporation of Kesling to ~~mean~~ that the methods of Lemchen would apply to aligners, the appliance expressly described in Kesling. Respondents continue that one skilled in the art would understand that the modeling of ~~teeth~~ movement is the same, regardless of the type of appliance used. (Citing RX-0113C at Q. 51)

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Respondents argue that each and every step of the claimed processes is described or embodied, either expressly or inherently, in Lemchen. Respondents say that the evidence establishes that there are no differences between the claimed invention and Lemchen, as viewed by one skilled in the art. Respondents say that there is no evidence in the prosecution histories that the PTO considered that Lemchen incorporated Kesling, despite Align's contentions in the *Ormco II* litigation. Respondents assert that it is well settled that the scope of patent claims does not change between an infringement analysis and an invalidity analysis and Align cannot now contend that the scope of the asserted claims is less for the invalidity analysis.

Respondents contend that claim 1 of the '325 Patent is broadly directed to the fabrication of "tooth repositioning appliances." Respondents say that under its plain language, this claim is not limited to removable appliances and no party has requested the construction of this phrase and its plain meaning applies here. Respondents say that Align has suggested that there is a distinction between removable and fixed appliances; but this is an improper attempt to apply an undisclosed claim construction and this argument should be rejected here.

Respondents argue that the subject matter of the preamble of claim 1 is disclosed in the prior art reference. Respondents say Kesling expressly discloses a plurality of tooth arrangements, the use and fabrication of a series of dental appliances, and 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)

According to Respondents, Lemchen discloses a digital method for three dimensional modeling of teeth movement that was the same as the manual method disclosed in Kesling. (Citing RX-0113C at Q. 39-40) Respondents say that this digital modeling includes intermediate or successive tooth arrangements. (Citing RX-0113C at Q. 41) Respondents continue that

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Lemchen discloses methods for the fabrication of multiple custom appliances based on the three dimensional modeling. (Citing RX-0113C at Q. 42) Respondents say that Lemchen also discloses using positive models generated from digital data. (Citing RX-0113C at Q. 42-43)

Respondents aver that Align previously recognized that “[c]apitalizing 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) 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)

Respondents assert that Lemchen discloses the first element of claim 1. (Citing CX-0945 at 2:54 – 63) Respondents say that Dr. Lemchen specifically discloses that his method generates “accurate digital information” defining the teeth locations. (Citing CX-0945 at 2:55 –57) Respondents continue that Dr. 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 disclosed in Kesling. (Citing CX-0945 at 3:43 – 46) Respondents say that Align previously recognized that Lemchen developed a digital representation of the physical model of an initial tooth arrangement described by Kesling. (Citing RX-103C at 16) Respondents identify these disclosures as “disclosure category 1.”

Respondents argue that Lemchen also discloses the second element of claim 1 by disclosing the use of commercially available computer-aided design software to create visual images of digital three-dimensional models. (Citing CX-0945 at 2:66 – 3:6) Respondents say

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that Align previously recognized that the CAD system described by Lemchen presented visual images based on the initial data set and successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen disclosed visual images based on the initial data set. (Citing *Ormco II* at 498 F.3d 1315) Respondents identify these disclosures as “disclosure category 2.”

Respondents contend that Lemchen discloses the third element of claim 1 by expressly noting 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* at 498 F.3d 1315) Respondents identify these disclosures as “disclosure category 4.”

According to Respondents, Kesling discloses the fourth element of claim 1 by disclosing modeling a final tooth arrangement. (Citing CX-0944 at 2:50 – 3:1) 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.

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(Citing RX-103C at 16; *Ormco II* at 498 F.3d 1315) Respondents identify these disclosures as “disclosure category 5.”

Respondents contend that Kesling discloses the fifth element of claim 1 by disclosing the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions. (Citing CX-0944 at 2:50 – 3:1) Respondents say that Kesling describes the necessity of making a plurality of appliances as obvious. (Citing CX-0944 at 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-0945 at 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-0113C at Q. 59) Respondents say that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-0113C at 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

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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* at 498 F.3d 1315) Respondents identify these disclosures as “disclosure category 7.”

Respondents assert that Kesling discloses the sixth element of claim 1 by disclosing “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-0944 at 1:1-6) Respondents say that figure 7 shows that a “tooth positioning appliance,” similar to an aligner, was disclosed. (Citing CX-0944 at 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.

Respondents say that Kesling discloses that a cast of the teeth in their initial position is created using traditional methods (citing CX-0944 at 2:43 – 49) and then each individual tooth is manually sectioned out by an operator using a scroll saw. (Citing CX-0944 at 3:30 – 43) Respondents continue that 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-0944 at 3:30 – 60) Respondents say that a positive model of the teeth in their new position is made. (Citing CX-0944 at 3:61 – 64 & Figure 3) Respondents continue that the aligners are then fabricated by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. CX-0944 at 3:65 – 4:70. Respondents reason that the incorporated disclosures of Kesling demonstrate methods for producing a series

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of polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements. Respondents conclude, as a result, that Kesling expressly discloses intermediate or successive models representing tooth positions, the use and fabrication of a series of dental appliances, and using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement.

Respondents say that Dr. Lemchen discloses methods that include controlling a fabrication machine. (CX-0945 at 5:4 –8) Respondents continue that the inventors also describe the use of a “laboratory model of the tooth” Respondents add that the inventors expressly noted that while they referred to a single tooth, their invention “may be utilized with some or all of the teeth in a given arch” (Citing CX-0945 at 5:21 – 24) Respondents assert 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 contend that 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) Respondents identify these disclosures as “disclosure category 10.”

Respondents assert that the transfer of digital data was disclosed in Lemchen. Respondents say that Dr. 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 identify these disclosures as “disclosure category 9.”

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Respondents disagree with Align's argument that Respondents have waived their invalidity defenses. Respondents say that contrary to Align's assertions, Respondents' Pre-Hearing Brief provided Respondents' contentions that all asserted claims were obvious and discussed the prior art in particular detail, identifying where the disclosed subject matter was located in the prior art references. (Citing RPHB at 48-67, 97-106, 127-136, 146-154, 174-183, 205-217, & 240-248) Respondents say that in *Certain Mobile Devices*, Inv. No. 337-TA-744, Final I.D., 2011 WL 6916539, at *103-04 (Dec. 20, 2011), the Respondent's failed to discuss certain of the prior art at all, but the ALJ addressed the defenses on the merits and did not hold the defenses waived. *Id.* Respondents assert that Align has long known that the Respondents have asserted the combination of Lemchen and Kesling with the knowledge of one of ordinary skill and there is no waiver.

Respondents also disagree with Align's arguments that *Ormco Corp. v. Align Tech., Inc.* is irrelevant. (Citing *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1302 (Fed. Cir. 2006) ("*Ormco I*") Respondents say that clinicians have long used series of removable tooth positioning devices, such as the aligners at issue here, to treat patients. Respondents say that in *Ormco I*, the Federal Circuit considered several of Align's patent claims to series of orthodontic aligners. (*Ormco I. at* 463 F.3d 1302) Respondents continue that the Federal Circuit considered the systems claimed in United States Patent No. 6,554,611 (the '611 Patent) and United States Patent No. 6,398,548 (the '548 Patent), the asserted claims of which the Federal Circuit found invalid as obvious based on the past use of such series of aligners by orthodontists. (Citing *id.*) Respondents argue that the findings in the *Ormco I* case are relevant here because it is also indisputable that methods for making such aligners existed in the prior art. Respondents say that if the apparatus existed before Align's patents, there can be no question but that methods for

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making the apparatus existed before Align’s patents. Respondents say that the series of prior art appliances that were addressed by the Federal Circuit were obviously fabricated by a method for making such a series.

Respondents say that Align’s argument appears to be based solely on the fact that in *Ormco I*, Align was a defendant accused of infringing Ormco’s patent claims directed to methods for fabricating aligners. Respondents say that Align does not dispute that the subject matter of a series of appliances that was at issue in *Ormco I* is the same subject matter at issue here. Respondents assert that Align’s methods for making these series of aligners were at issue in *Ormco I*. Respondents continue that Align’s methods were held to infringe claims asserted by Ormco and the scope of the disclosures of the prior art does not change based on who is the defendant. Respondents say that the Federal Circuit’s findings in *Ormco I* related to series of aligners and methods for manufacturing those aligners are relevant here.

Respondents say that the question in this investigation is whether the prior art disclosed digital methods to manufacture such series of aligners or, alternatively, whether such methods would have been obvious to one skilled in the art, which is the same issue that was addressed in *Ormco I*. Respondents say that it is instructive, by way of example, to compare the elements of the asserted claim 1 of the ‘880 Patent to the elements of the invalidated system claims to show how closely related the claims asserted here are to the apparatus claims invalidated in the *Ormco I* litigation:

Claim 1 of the ‘880 Patent (JX-0002)	Invalidated Claim 1 of the ‘611 Patent (the sequence of elements 2 and 3 has been switched)
A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:	A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:

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<p>a) obtaining a digital data set representing an initial tooth arrangement;</p>	<p>a first appliance having a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;</p>
<p>b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;</p>	<p>a final appliance having a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement;</p>
<p>c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and</p>	<p>one or more intermediate appliances having geometries selected to progressively reposition the teeth from the first intermediate arrangements to successive intermediate arrangement;</p>
<p>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.</p>	<p>and instructions which set forth that the patient is to wear the individual appliances in a predetermined order which will progressively move the patient's teeth toward the final arrangement, a package, said package containing said first appliance, said one more [sic] intermediate appliances and said final appliance, wherein the appliances are provided in a single package to the patient.</p>

(Citing *Ormco I* 463 F.3d at 1302) Respondents assert that invalidated claims 1 and claim 11 of the '548 Patent are similar. (Citing *id.* at 1303) Respondents say that this comparison demonstrates how closely related the subject matter is between the invalidated apparatus claims and the asserted method claims.

Respondents assert that it is also apparent from the foregoing chart that Align is simply claiming the application of modern electronics (the use of "digital data") to the subject matter of the orthodontic appliances that existed in the prior art. Respondents say that is improper under well settled precedent. Respondents continue that the application of modern electronics to orthodontic appliances pre-dates the asserted claims in the prior art by several years.

Respondents disagree with Align's incorporation by reference arguments. Respondents say that the standard for determining incorporation is straightforward: "the host document must

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identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.” (Citing *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009)) Respondents continue that the Federal Circuit has taken a practical approach in determining whether a host document incorporates a reference. (Citing *id.*) Respondents assert that when the statements in the Lemchen reference are considered light of the Federal Circuit’s standard for determining incorporation, it is clear that the Lemchen reference incorporates the entire Kesling patent.

Respondents say that the first reference to the Kesling patent provides:

The mathematical model may be as detailed as the particular circumstances require, dependent only upon the quantity of digitized information generated in the prior step. Thus, 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-0945 at 3:6 – 15) Respondents continue that Dr. Lemchen also stated:

There are a number of **methods of treatment commonly used by the orthodontist**. Each method takes different factors into account with varying degrees of emphasis. As utilized in the present invention, the orthodontist provides a description of the desired results, which is prescribed for reaching the finish position of each individual tooth relative to adjacent teeth, opposing teeth, supporting bony foundations and soft tissue, and the entire cranial-facial complex. Utilizing standard statistical tooth position data, the repositioning of the teeth is calculated to provide a mathematical model of the finish position. **In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position.** See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432.

(Citing CX-0945 at 3:25–40 (emphasis added)) Respondents conclude that the only reasonable conclusion is that Lemchen intended to incorporate the entire Kesling reference.

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Respondents say that Lemchen uses language “in the above referenced U.S. Pat. No. 2,467,432” that is very similar to the language that the Federal Circuit has held incorporates the entire reference (“reference is made to”). Respondents continue that Lemchen makes it clear that he is referring to the “methods of treatment” in the prior art, and not just the figures in abstract: “In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position.” Respondents argue that this statement expressly describes the methods disclosed by Kesling and is not limited to the abstract figures.

Respondents say that Courts have held that it is important to consider the entirety of the incorporated document to properly understand its teachings:

The reason for requiring the consideration of the whole reference, . . . is that . . . when ‘all of the disclosures in a reference’ are considered, the overall suggestion to emerge from the prior art reference may be contrary to that which might appear from an isolated portion of the reference.”

(Citing *In re Hughes*, 550 F.2d 1273, 1275-76 (CCPA 1977)) Respondents reason that this rule prevents a party from misrepresenting the substance of a prior art reference by limiting the amount of incorporation. Respondents argue that this is precisely what Align is attempting to do.

Respondents say that this rule especially makes sense in light of the Kesling reference. Respondents say that the Kesling reference is small, it contains one page of figures and approximately three and one half pages of text. (Citing CX-0945) Respondents say that figures 1 and 3 are substantively discussed repeatedly throughout the first two pages, essentially omitted only from the claim section and the listing of prior art. (Citing CX-0945) Respondents say that Align’s attempt to carve up the portions of Kesling that are incorporated is directly contrary to the settled law that seeks to avoid misunderstanding the teachings of the prior art. Respondents conclude that I should find that the Lemchen reference has incorporated the Kesling patent.

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Respondents argue that Align's reliance upon an overruled Initial Determination shows the fallacy of their argument. Respondents say that the Commission overruled my finding in the cited Initial Determination that a referenced document was not incorporated, holding: "when considering incorporation by reference, the proper focus is on material and content rather than semantics and typographical errors." (Citing *Certain MEMS Devices*, Inv. 337-TA-700, Commission Determination, 2011 WL 7592771, at *16-18 (USITC November 2011))

Respondents say that I should reject Align's argument here.

Respondents say that Align has described the method for making aligners as a process with essentially five steps:

Aligners are generally made in a five-step process: (1) a digital representation of a patient's existing tooth arrangement is created; (2) the representation is digitally modified to allow the virtual teeth to be individually manipulated; (3) 3D graphics software is used to move the virtual teeth to the desired position; (4) virtual intermediate tooth arrangement models are created between the existing tooth arrangement and the desired arrangement; and (5) physical molds are created from these digital representations in order to form aligners.

Respondents argue that this description highlights the inconsistency between Align's infringement contentions and its invalidity contentions. According to Respondents, to find infringement, Align is forced to characterize the Respondents' methods one way; but to avoid invalidity, Align argues that there are differences between its claims and the prior art and characterizes its claims differently. Respondents assert that there is no difference between the five steps identified by Align and the methods disclosed in Lemchen and in the incorporated Kesling.

Respondents disagree with Align's current position that Kesling did not disclose "intermediate or successive tooth arrangements based on initial and final positions."

Respondents say that the evidence relied upon by Align for this assertion is Dr. Valley.

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Respondents say that As Dr. Rekow explained, contrary to Align's contentions here, the incremental movements are based on obtaining the desired final position. Respondents say that Dr. Valley conceded that Dr. Rekow was "much more of an expert than I am in this area." (Citing Tr. at 760:19-761:1) Respondents argue that Align is improperly attempting to create a new, undisclosed claim construction to avoid the prior art disclosures.

Respondents say that the only difference between Kesling's teachings and the claimed subject matter, is the use of digital data. Respondents continue that It is not surprising that Dr. Kesling did not disclose digital methods, because he patented his invention in the 1940s.

Respondents say that as Dr. Rekow opined in the *Ormco II* case that:

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

(Citing RX-103C at 2)

Respondents say that in its litigation with *Ormco*, Align recognized that Lemchen had developed a digital method based on the Kesling physical method. Respondents continue that Dr. Rekow recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement. (Citing RX-103C at 16) Respondents argue that Lemchen's disclosures confirm that Dr. Rekow's opinion is correct.

Respondents assert that Lemchen's disclosures demonstrate that there is no difference between the five steps identified by Align and the methods disclosed in Lemchen and in the incorporated Kesling. Respondents say that Lemchen taught creating a digital representation of a

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patient's existing tooth arrangement. (Citing CX-0945 at 2:54 – 63) Respondents continue that Lemchen taught digitally modifying the model to allow the virtual teeth to be individually manipulated and taught that the use of commercially available computer-aided design software to create digital three-dimensional models was well known in the art. (Citing CX-0945 at 2:66–3:6) Respondents say that Lemchen describes scanning and modeling the movement of each individual tooth, and expressly noted 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 continue that Dr. Rekow confirms this in her description of Lemchen's teachings: “To accomplish these operations mathematically, individual teeth had to be segmented from digital data representing a plurality of teeth.” (Citing RX-103C at 16) Respondents say that Lemchen taught the use of 3D graphics software to move the virtual teeth to the desired position. Respondents continue that Lemchen taught the use of conventional CAD software create 3D models to move the teeth to their desired position. (Citing CX-0945 at 2:66 – 3:6) Respondents continue that Dr. Rekow confirms this in her description of Lemchen's teachings. (Citing RX-103C at 16) Respondents say that The Federal Circuit 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 Lemchen taught creating virtual intermediate tooth arrangement models between the existing tooth arrangement and the desired arrangement. Respondents say that Lemchen disclosed that his method “produces appropriate force magnitudes at various stages of treatment to move the tooth to its ideal position.” (Citing CX-

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0945 at 2:37-38) Respondents continue that the uncontroverted testimony establishes that one skilled in the art would understand that the “various stages of treatment” refers the successive stages of treatment typical in orthodontic treatment. (Citing RX-0113C at Q. 57) Respondents say that Dr. Rekow confirms that “Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen” and that this “model is the mathematical representation of the physical model described by Kesling in 1949.” (Citing RX-103C at 16)

Respondents argue that it is undeniable that Kesling taught intermediate successive tooth arrangements as part of the disclosed 3D modeling method. (Citing CX-0944 at 2:50 – 3:1) Respondents say that the modeling of teeth movement is the same regardless of the type of appliance that is to be used. (Citing RX-0113C at Q. 25) Respondents contend that Lemchen taught that creating physical molds from digital models to make appliances. Respondents say that Lemchen taught 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-0945 at 5:4–8) Respondents continue that Lemchen also describes the use of a “laboratory model of the tooth” in the disclosed methods for fabricating an appliance. (Citing CX-0945 at 4:63–67) Respondents reason that this physical tooth model is to be fabricated by the disclosed methods. Respondents add that, 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-0945 at 5:21–24) Respondents argue that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated, and Dr. Rekow confirms that references cited in the Lemchen article expressly address using CAD/CAM

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to fabricate positive models of modified tooth arrangements based on digital data. (Citing RX-103C at 17-26)

Respondents argue that Align identifies additional subject matter that it now contends that Lemchen/Kesling incorporated reference does not disclose. Respondents say that Kesling discloses polymeric shell appliances. (Citing CX-0944 at 2:38 – 42 & Figure 7) Respondents continue that Lemchen disclosed the use of polymeric shell appliances as part of the referenced “indirect” method of bracket application. (Citing CX-0945 at 4:6 –12) Respondents add that Lemchen discloses the subject matter of threshold limits. (Citing CX-0945 at 2:37 – 38 & RX-0113C at Q. 58) Respondents say that Lemchen also discloses substantially accurate shapes of a patient’s teeth:

The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the maloccluded tooth with respect to the patient’s jaw.

(Citing CX-0945 at 2:54 – 63) Respondents continue that Lemchen discloses the use of attachment devices in his digital three-dimensional modeling: “The structural adhesive is initially a moldable putty which easily takes on the contour of the dental surface to which the appliance will be fixed (Citing CX-0945 at 4:56–60) Respondents add that Lemchen discloses the use of brackets which are devices that attach appliances to teeth. (Citing CX-0945 at 3:55 – 4:2)

Respondents disagree with Align’s argument that this combination was disclosed to the PTO. Respondents say that there is no evidence in the prosecution history that Align ever disclosed that the Kesling teachings were combined with the Lemchen reference. Respondents continue that there is no evidence in the prosecution history that the PTO ever considered the

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combination of these references. Respondents reason, as a result, that the PTO was never informed of this incorporated reference that is the key to the invalidity analysis.

Align's Position: Align asserts that Respondents' invalidity case relies on a cursory, 25-page statement of Dr. Mah that fails to undertake the most basic analyses, such as comparing the asserted claims on an element-by-element basis with the prior art or providing specific citations to the alleged disclosures of the prior art he identifies, rendering it, as noted by the presiding ALJ, "conclusory," (Citing Tr. at 643:24-644:6, 649:8-14) Align says that Respondents' Prehearing Brief provides no more specificity. (Citing RPHB at 48-67, 97-106, 127-136, 146-154, 174-183, 205-217, 240-248) Align continues that Respondents' failure to introduce an element-by-element comparison of the prior art with Align's asserted claims is *fatal* to their invalidity defenses. (Citing *Certain Mobile Devices*, Inv. No. 337-TA-744, Final I.D., 2011 WL 6916539, at *103-04, *103 n.33 (Dec. 20, 2011)) Align says that neither Respondents nor their expert have explained how the prior art meets, *inter alia*, any of the constructions for the disputed claim terms. Align asserts that Respondents cannot legitimately contend that any of Align's claims are invalid.

Align says that Respondents contend that *all* of the asserted claims are anticipated by U.S. Patent No. RE 35,169 ("Lemchen"), including "as incorporated" U.S. Patent No. 2,467,432 ("Kesling"). Align asserts 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. Align continues that even if Kesling is somehow deemed to be fully incorporated in Lemchen, 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.

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Align argues that *Ormco I* is irrelevant to the validity of the patents-in-suit because it addressed different patents, claims, limitations, and prior art. Align says that Dr. Rekow's reports from *Ormco I* (Citing RX-0102C; RX-0103C) are only available to possibly show "prior inconsistent positions" (Citing Tr. at 20:5-21:21) and Respondents cannot, therefore, use them to bolster their invalidity theories. Align continues that even if they could, the Rekow reports do not support Respondents' invalidity theories. (Citing CX-1247C at Q. 274, 622-627; CX-1254C ¶ 274 at 97; Tr. at 801:6-802:13)

Align asserts that as depicted in CDX-0288 and shown on the face of the patents (and reexam certificates), almost every reference cited by Respondents was *already* considered by the USPTO, and determined to *not* preclude issuance of the claims. (Citing JX-0001 at 2; JX-0002 at 2; JX-0003 at 1-2, 21-26; JX-0004 at 1-2; JX-0005 at 1-2, 26-31; JX-0006 at 1-4; JX-0007 at 1-5; CX-1250 at 257) Align continues that the USPTO has repeatedly approved the claims over Lemchen and Kesling.

Align says that Kesling (CX-0944) generally discloses tooth positioning appliances made manually using tools and equipment available in the 1940s (*e.g.*, plaster and wax). (Citing CX-1247C at Q. 142-143; CX-1254C ¶ 63 at 21-22) Align says that its inventive concept of determining intermediate states based on the initial and final states is absent from Kesling. (Citing CX-1247C at Q. 144-145; CX-1254C ¶ 65 at 23) Align continues 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 at Q. 144-145; CX-1254C ¶ 65 at 23; Tr. at 790:9-791:20) According to Align, Kesling makes one appliance at a time. Kesling does not disclose a proactive method of determining intermediate tooth positions at the outset

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based on both the initial and final positions. (Citing CX-1247C at Q. 144-145; CX-1254C ¶ 65 at 23)

Align asserts that Kesling does not disclose, *inter alia*: (i) digital data sets or models of a dentition (citing CX-1247C at Q. 141-143; CX-1254C ¶¶ 62-63 at 21-22); (ii) intermediate or successive tooth arrangements based on initial and final positions (citing CX-1247C at Q. 141, 144-145; CX-1254C ¶ 65 at 23; 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 at Q. 141, 146-147; CX-1254C ¶ 67 at 24-25); or (iv) numerous other elements (citing CX-1247C at Q. 137-162; CX-1258 at 2-8).

Align asserts that Lemchen (CX-0945) discloses a method for determining orthodontic bracket placement. (Citing CX-0945 at 1:55-2:8) Align says that Lemchen is directed to a single fixed appliance used for the duration of a patient's treatment, not a removable appliance. (Citing *id.*; CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33; CX-1264 at 5) Align continues that Lemchen's disclosure is limited to the idea of treating a patient with the single set of brackets. (Citing CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33) Based on this, Align contends that the concept of intermediate digital data sets or tooth arrangements is, therefore, absent from, and irrelevant to, Lemchen. (Citing CX-1247C at Q. 183-185; CX-1254C ¶ 82 at 29-30) Align avers that Lemchen teaches away from the use of intermediate arrangements. (Citing CX-1247C at Q. 225-227; CX-1254C ¶ 97 at 34-35)

Align concludes that Lemchen does not disclose, *inter alia*: (i) intermediate or successive digital data sets or tooth arrangements (citing CX-1247C at Q. 183-185; CX-1254C ¶ 82 at 29-30); (ii) polymeric shell appliances (citing CX-1247C at Q. 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

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sets (citing CX-1247C at Q. 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 at Q. 183, 190-191; CX-1254C ¶¶ 90-91 at 32-33); (v) threshold limits (citing CX-1247C at Q. 233-235; CX-1254C ¶ 105 at 39-40); (vi) interpolation or movements of equal sizes (citing CX-1247C at Q. 236-238; CX-1254C ¶ 106 at 40); (vii) substantially accurate shapes of a patient's teeth in a modified arrangement (citing CX-1247C at Q. 239-240; CX-1254C ¶ 108 at 41); (viii) attachment devices (citing CX-1247C at Q. 241-243; CX-1254C ¶ 109 at 41-42); or (ix) numerous other elements of the asserted claims (citing CX-1247C at Q. 275-277; CX-1258 at 9-15).

Align disagrees with Respondents' claim that Lemchen incorporates the entire disclosure of Kesling. Align asserts 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.) Align says that a "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)) Align continues 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 asserts that Lemchen only briefly refers to two figures from Kesling. (Citing CX-0945 at 3:14-15, 3:35-40) Align says that these are references to FIGS. 1 and 3 as examples of **models**, nothing else. Align continues 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

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Lemchen cites these FIGS as examples of what models look like and does not otherwise address Kesling or the relationship between the FIGS. (Citing CX-1247C at Q. 249, 251-258; CX-1254C ¶¶ 112-117 at 42-46) Align adds that Kesling FIGS. 1 and 3 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 says that 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 disagrees and asserts 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. (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 explains that plaster tooth arrangements were commonly known and used. (Citing CX-1247C at Q. 264-265; CX-1254C ¶ 117 at 45-46)

Align alternatively argues 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)

Align disagrees with Respondents’ ‘325 patent invalidity positions as wholly unsupported and insufficient to meet their high burden. Align says that Respondents have no particular evidence to support their invalidity case because no claim charts explaining where each claimed element is shown in the cited references are in evidence. (Citing Tr. at 19:11-20:4, 651:14-653:25) Align continues that the prior art also fails to disclose all elements of any of the asserted claims of the ‘325 patent, individually or under any combination, as explained above. (Citing

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CX-1247C at Q. 606, 610; CX-1258) Align adds that none of the prior art discloses, *inter alia*, “a plurality of digital data sets” or “controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement.” (Citing *id.*)

Align disagrees with Respondents’ argument that all of the asserted claims of the ‘325 patent are anticipated by Lemchen and “as incorporated,” Kesling and asserts that Respondents’ argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Align contends that Respondents’ argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described above. Alternatively, Align asserts that even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of the asserted claims.

Align argues that because Respondents did not introduce evidence that even attempts an element-by-element comparison of the prior art with Align’s asserted claims, their arguments fail. (Citing *Certain Mobile Devices*, Inv. No. 337-TA-744, Final I.D., 2011 WL 6916539, at *103-04, *103 n.33 (Dec. 20, 2011)) Align asserts 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, for that matter, Align’s or Staff’s proposed constructions; rather, 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 says that Respondents’ failure to address claim construction is likewise fatal to their invalidity defenses.

Align says that the USPTO considered Lemchen and Kesling during the prosecution of the ‘874 and ‘487 patents and the reexaminations of the ‘863 and ‘325 patents. (Citing JX-0006

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at 1-2; JX-0007 at 1-2; JX-0005 at 26-27; JX-0003 at 21, 22.) Align asserts that Respondents' anticipation defense fails as a matter of law because it relies on the assumption that Lemchen incorporates the full disclosures of Kesling, which is wrong. Align says that the majority of Kesling is completely unrelated to FIG. 1 or FIG. 3. Align says that this illustrates that Respondents' mantra that reading such portions of Kesling is somehow necessary to understand "the significance of" FIGS. 1 and 3 is incorrect.

Align says that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets. (Citing CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33) Align disagrees and says that the "methods of treatment" in Lemchen refer to different methods of treating a patient with brackets and archwires – not aligners. (Citing CX-1247C at Q. 215-219; CX-1254C ¶ 98 at 35-36; Tr. at 798:7-799:25) Align disagrees with Respondents' argument that "modeling of teeth movement is the same, regardless of the type of appliance used." (Citing CX-1247C at Q. 221-222; CX-1254C ¶ 99 at 37) Align explains that the anchorage needs and, therefore, the biomechanics of tooth movement, vary depending on the type of appliance used. (Citing CX-1247C at Q. 221-222; CX-1254C ¶ 99 at 37)

Align says that Respondents' "element-by-element" analysis should be wholly rejected under GR 8.2 because it was not disclosed in Respondents' Align continues that the "disclosure categories" consist of mischaracterizations of Lemchen and Kesling that are largely unsupported by anything other than attorney argument. Align adds that the disclosure categories do not address numerous elements of the asserted claims. Align argues that Respondents' methodology is flawed by failing to apply their disclosure categories consistently with the methodology used by Align's expert.

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Align says that Respondents fail to establish that Lemchen discloses presenting a visual image based on a data set; rather, the portion of Lemchen cited by Respondents merely discusses CAD generally and does not indicate that a visual image is presented in Lemchen's method. Align continues that Respondents quote *Ormco II* at 498 F.3d 1312, claiming that "Align successfully argued . . . that one skilled in the art would understand that Lemchen disclosed visual images based on the initial data set[.]" Align disagrees, explaining that *Ormco II* does not contain *Align's* characterizations of Lemchen.

Align disagrees with Respondents' identification of "disclosures relating to manipulation of the image to reposition teeth." Align says that Respondents fail to establish that Lemchen discloses manipulating an image to reposition teeth because they do not cite to any portion of Lemchen supposedly disclosing manipulating an image to reposition teeth. Rather, Align says that Respondents rely on Dr. Rekow's report (RX-103C), which refers to teeth being "*digitally* manipulated," but not manipulated *visually* in an image. (Citing *Id.* at 46) Align continues that Lemchen merely discusses "the *calculation* of the 'finish' position," not *visual manipulation* of teeth. (Citing CX-0945 at 3:16-18; Tr. at 765:21-766:18)

Align also disagrees with Respondents' identification of "disclosures relating to the final digital data set." Align says that Respondents cite the Rekow report (RX-103C) and contend that Align has now taken a contrary position regarding the disclosures of Kesling. Align says that Respondents fail to substantiate their contention that Lemchen discloses "producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image." Align says that Respondents do not cite any portion of Lemchen or explain where this is allegedly disclosed; rather Respondents rely on the Rekow report (RX-103C), which merely

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indicates that, in Lemchen, finish positions of teeth are *calculated*, not observed in an image.

(Citing *Id.*; Tr. at 765:21-766:18)

Align disagrees with Respondents' identification of "disclosures relating to generating the intermediate tooth arrangements or digital models." 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." 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 at Q. 144-145; CX-1254C ¶ 65 at 23) Align explains 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. (Citing *Id.*; Tr. at 790:9-791:20) Align says 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 at Q. 144-145; CX-1254C ¶ 65 at 23) Align says 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 asserts that one of ordinary skill in the art would understand Lemchen as simply indicating that repositioning teeth into the finish position may involve using software. (Citing CX-1247C at Q. 236-238; CX-1254C at ¶ 106 at 40) Align contends that Lemchen does not disclose the concepts of treatment segments, interpolation, or equal-sized translational movements between tooth positions. (Citing CX-1247C at Q. 236-238; CX-1254C at ¶ 106 at 40)

Align disagrees with Respondents' claim that 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

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intermediate steps from an initial position to the desired position.” (Citing RIB at 50) Align contends that the concept of intermediate digital data sets or tooth arrangements is absent from, and irrelevant to, Lemchen. (Citing CX-1247C at Q. 183-185; CX-1254C ¶ 82 at 29-30) Rather, Align says that Lemchen is limited to the idea of treating a patient with a single set of brackets (citing CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33) and teaches *away* from using intermediate arrangements (citing CX-1247C at Q. 225-227; CX-1254C ¶ 97 at 34-35). Align continues that the Rekow Report does not indicate that Lemchen discloses intermediate steps or incorporates Kesling.

Align says 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 RIB at 58, 86) Align disagrees, saying that nowhere in Disclosure Category 7 do Respondents actually contend that the prior art discloses intermediate or successive digital data sets. (Citing RIB at 49-51) Align says that the prior art does not disclose these elements. (Citing CX-1247C at Q. 141-145, 183-185; CX-1254C ¶¶ 62-63, 65, 82 at 21-23, 29-30; Tr. at 791:21-793:5)

Align says that Respondents identify purported disclosures “relating to digital models of attachment devices.” Align says that Respondents mischaracterize Lemchen. Align explains that Lemchen does not disclose attachment devices or digital models thereof. (Citing CX-1247C at Q. 241-243; CX-1254C ¶ 109 at 41-42)

Align says that Respondents identify purported “disclosures relating to the transferring of digital data sets.” Align says that the portion of Lemchen relied on by Respondents merely indicates that digitized information is “utilized,” not transferred.

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Align says that Respondents identify purported “disclosures relating to the fabrication of the appliances.” Align contends 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.” (Citing RIB at 51) Align disagrees, saying 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 says 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 again disagrees, saying that Kesling discloses using dental materials, tools, and an articulating device, not a fabrication machine. (Citing CX-0944 at 3:65-4:70, Fig. 4; CX-1247C at Q. 153; CX-1254C ¶ 72 at 26) Align says that 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 continues 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 at Q. 209-210; CX-1254C ¶ 109 at 41-42) Align adds that Respondents inexplicably cite to the Rekow Report’s discussion of other “references cited by Lemchen.” (Citing RIB at 52) Align says that these other alleged references are not in evidence and, thus, cannot support Respondents’ invalidity defense.

Align asserts that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, “presenting a visual image based on the initial data set” (‘325 claims 1, 31); “manipulating the visual image to reposition individual teeth in the visual image” (‘325 patent claim 1); “producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image” (‘325 patent claims 1, 31); “intermediate digital data

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sets” (‘325 patent claims 1, 31); “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets” (‘325 patent claim 1); “defining boundaries about at least some of the individual teeth” (‘325 patent claims 3, 13); “successive digital data sets” (‘325 patent claims 11, 35); “fabricating appliances based on at least some of the produced digital data sets” (‘325 patent claim 11); “determining positional differences . . . and interpolating said differences” (‘325 patent claim 14); digital data sets representing “substantially accurate shapes of the patient’s actual teeth” (‘325 patent claims 30, 32, 35); “fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation” (‘325 patent claim 33); “the appliances are fabricated based on individual ones of at least a corresponding plurality of the produced digital data sets” (‘325 patent claim 39). (Citing RIB at 45-61) Align says 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 continues that Respondents also misapply their “disclosure categories” with respect to at least claims 11, 31, and 38 of the ‘325 patent. Align adds that the USPTO considered Lemchen and Kesling during the reexamination of the ‘325 patent, further demonstrating that the asserted claims are not anticipated. (Citing JX-0003 at 21, 22)

Staff’s Position: Staff argues that the evidence does not demonstrate clearly and convincingly that any of the Asserted Claims of the ‘325 patent (or any of the other Asserted Patents) 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).

Staff asserts that Lemchen does not incorporate the entirety of Kesling. Staff says that

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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 continues 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 adds 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 contends 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 patents in suit) is anticipated by Lemchen and, “as incorporated,” Kesling. (Citing CX-1247C at Q. 561-571; CX-1258 at 1-14) Staff says 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 continues 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 says that Respondents’ technical expert Dr. Mah provides only conclusory testimony about the subject matter of the prior art and the ‘325 patent (and the other patents in suit); but does not provide a detailed discussion of how and where Lemchen and, “as incorporated,” Kesling disclose, teach, or suggest each and every element of the Asserted Claims

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of the '325 patent (or any of the other patents in suit). (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 patents in suit, but the ALJ has excluded that claim chart (Citing Tr. at 18:13-19:25 (excluding RX-0124 and RX-0113C at Q. 110)) According to Staff, the record contains no 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 says that the PTO considered both Lemchen and Kesling during: (i) prosecution of the '487 patent, (ii) prosecution of the '874 patent, (iii) reexamination of the '325 patent, and (iv) reexamination of the '863 patent, and the PTO still approved all of the asserted claims of the patents in suit. (Citing CX-1247C at Q. 135 and 177; JX-0003; JX-0005; JX-0006; JX-0007)

Staff concludes that there is a lack of evidence demonstrating clearly and convincingly that any of the Asserted Claims of the '325 patent (or the other patents in suit) are anticipated by Lemchen and, "as incorporated," Kesling.

Staff agrees with Complainants' argument that Respondents have failed to meet their burden of proving that all of the asserted claims of the patents in suit are anticipated or rendered obvious because Respondents have failed to provide, *inter alia*, an element-by-element comparison of the prior art with the asserted claims of the patents in suit. Staff says that Respondents, in their Post-Hearing Brief, attempt to make up for shortcomings by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '325 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

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continues that Even if Respondents' comparison of their prior art references with the Asserted Claims of the '325 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff avers 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 by the ALJ. Staff continues that Respondents' allegations of obviousness also include Nahoum (RX-0096), but Respondents further fail to show how one of ordinary skill in the art would have been motivated to combine Nahoum in any manner. 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 element of the Asserted Claims of the '325 patent.

Analysis and Conclusions: After thorough review of the evidence and arguments presented, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling.

In *Advanced Display Systems*, the Federal Circuit treated the issue of a rejection for anticipation in which the single reference "expressly incorporates a particular part" of another reference. *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272 (Fed. Cir. 2000). The court said, at page 1282, "[m]aterial not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document." (Citing *Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069, 44 USPQ2d 1336, 1339-40 (Fed. Cir. 1997)) The court went on to explain, "[t]o incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is

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found in the various documents.” (Citing *In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (C.C.P.A. 1973); *see also In re Saunders*, 444 F.2d 599 (C.C.P.A. 1971))

Whether material has been incorporated by reference into a host document, and the extent to which it has been incorporated, is a question of law. (*Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006)) In making that determination, “the standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity.” *Advanced Display Systems*, 212 F.3d at 1283.

Incorporation by reference and anticipation are separate inquiries. While incorporation by reference is a question of law, anticipation is a question of fact. The Federal Circuit has held “if incorporation by reference comes into play in an anticipation determination, the court's role is to determine what material in addition to the host document constitutes the single reference. The factfinder's role, in turn, is to determine whether that single reference describes the claimed invention.” *Id.*

The first issue, therefore, is what, if anything, was specifically identified and incorporated by reference in Lemchen. In *Zenon Environmental*, the court considered the scope of incorporation by reference in a patent that said,

The vertical skein is not the subject matter of this invention and any prior art vertical skein may be used. Further details relating to the construction and deployment of a most preferred skein are found in the parent U.S. Pat. No. 5,639,373, and in Ser. No. 08/690,045, the relevant disclosures of each of which are included by reference thereto as if fully set forth herein.

Zenon Environmental, Inc. v. United States Filter Corporation, 506 F.3d 1370, 1379 (Fed. Cir. 2007). The Federal Circuit panel disagreed with the trial court's finding that the foregoing

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language incorporated by reference the entire disclosures of the referenced patents. The court stated:

The plain language expressly limits the incorporation to only relevant disclosures of the patents, indicating that the disclosures are not being incorporated in their entirety. Moreover, the plain language indicates that the subject matter that is being incorporated by reference pertains to the details relating to the construction and deployment of a vertical skein. Thus, we must look, as one reasonably skilled in the art would, to the grandparent patents to determine what the patentees meant by details relating to the construction and deployment of a vertical skein.

Id.

In *Saunders*, the court reviewed a patent denial issued by the Patent Office Board of Appeals, based upon the theories of anticipation and obviousness. The subject matter of the patent was a family of methods for preparing cellular polyurethane foam by what the court characterized as a “one shot” technique. (*Saunders*, 444 F.2d at 600) In connection with the anticipation issue, the court examined incorporating language that said,

The above-described siloxane-oxyalkylene block copolymers can be prepared in accordance with the procedures described and claimed in the copending application of D. L. Bailey and F. M. O'Conner, Serial No. 417,935, filed December 14, 1953.

Id. at 603.

The court found that the incorporation by reference was limited to the specific method of making surfactants of this general type in which the oxyalkylene chains were composed entirely of one type of oxyalkylene, and would not expressly indicate that other compounds which the Bailey reference also taught how to make could also be employed as surfactants in the applicant's process. *Id.*

Applying the foregoing principles to the case at bar, I examine the reference in Lemchen, which states:

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Thus, in many applications of the preferred embodiment, a complete “model”, at the 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.

(CX-945, 3:10-15) I note that this quote from Lemchen, similar to the language in *Saunders*, does not specifically indicate that Kesling is incorporated by reference. Rather, the allusion in Lemchen to Figure 1 in Kesling is used as an example in the prior art of a physical model representing the replication of the upper and lower dental arches and associated jaw structure of a patient, which the invention of Lemchen would generate mathematically using digitized information in a computer. (CX-944, Figure 1)

Similarly, Lemchen’s nod to Figure 3 in Kesling represents an example in the prior art of a manually created model of a patient’s teeth in the finish position, and which Lemchen teaches could be generated mathematically by its invention. Lemchen states:

In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in a finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432.

(CX-945, 3:35-40; and CX-944, Figure 3)

Following the rationale of *Advanced Display Systems* and *Saunders*¹³, supra, I find that the foregoing language from Lemchen identifies with detailed particularity what specific material it incorporates from Kesling and clearly indicates where that material is found, to wit: Figures 1 and 3 of Kesling. As in *Saunders*, however, I find that the reference in Lemchen does not extend beyond Figures 1 and 3 of Kesling.

¹³ Neither Lemchen nor *Saunders* contains an expression that the relevant language is “incorporated by reference.” This does not appear to be required as long as the context indicates such an intent. Inasmuch as, the court in *Saunders* inferred such an intent, I draw the same inference in Lemchen, the language of which is similar to that of *Saunders*.

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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 United States Patent and Trademark Office during the re-examination of the '325 patent. (JX-003 at 21-22 (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.¹⁴ *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Respondents, however, have failed to meet the 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.

Lemchen describes “generating digital information” regarding the initial “maloccluded 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 “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement,” as required by exemplary claim 1.

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

¹⁴ Lemchen and Kesling were also considered by the United States Patent and Trademark Office during the re-examination of the '863 patent (JX-005 at 26-27 (Re-Exam References Cited)) and during prosecution of the '874 patent (JX-006 at 1-2 (References Cited)) and the '487 patent (JX-007 at 1-2). The same heightened burden applies for those patents as well.

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over the entirety of the treatment. (CX-945, 1:56-62; 3:55-63; CX-1247C at Q. 190) As a result, I also find that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by exemplary 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. 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. 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)

Dr. Valley also testified credibly that Kesling only contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. (CX-1247C, Qs. 144-145; CX-944, 5:22-32) Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Rather, Kesling discloses manually making an appliance using tools, supplies, and materials, including, inter alia, (i) articulating the plaster

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cast; (ii) taking an impression of the teeth of the plaster cast, and (iii) making a mold filled with the appliance material. (CX-944, 3:65-4:58; CX-1247C at Q. 146)

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 claims 1, 11, 21, 31, 33, 35, and 38 of the '325 patent. Because Respondents have failed to meet their burden to prove by clear and convincing evidence that the asserted independent claims are anticipated by Lemchen, I find that the asserted dependent claims (claims 2, 3, 13, 14, 30, 32, 33, 34 and 39) also are not anticipated by Lemchen.

b. Claim 2

Claim 2 recites:

A method as in claim 1, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

(JX-003 at 15:33-36)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of claim 2 by disclosing that a digital data set representing an initial tooth arrangement is generated by scanning a model of the patient's teeth. (Citing CX-0945 at 2:54 – 63)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 2 is valid. Since, however, I have found claim 1 to be valid and *not* anticipated by Lemchen, claim 2 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1.

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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 2 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen discloses "generating digital information" regarding the initial "maloccluded teeth." (CX-945, 1:55-61; 3:16-24). Lemchen specifically discloses

The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the maloccluded 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.

(CX-945, 2:54-60) Lemchen does not, however, reveal generating the initial data regarding maloccluded teeth from a physical model of the patient's teeth as shown in Kesling. Rather it uses Kesling to illustrate what a model of the upper and lower dental arches looks like. Lemchen actually teaches away from using a physical model such as that in Kesling, when Lemchen states:

Utilizing standard statistical tooth position data, the repositioning of the teeth is calculated to provide a mathematical model of the finish position. In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432. However, this procedure did not take into account the individual finish position desired related to the cranial-facial base.

In the present method, this 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. An "ideal" finish position is not based upon statistical averages and takes into account the variation and physical characteristics of the individual patient. Therefore, it is preferable that, the program be utilized to provide a customized finish position for the particular patient, so as to make the finish position ideal for the patient, rather than attempting to have the patient duplicate the statistically average position.

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(CX-945, 3:32-53) The foregoing discussion teaches away from use of the physical model. Rather, it forwards an approach that uses scanning of the patient's actual teeth to take into account the individual finish position related to the cranial-facial base. Lemchen endorses taking into account "the variation and physical characteristics of the individual patient." Thus, Lemchen with the incorporation of Kesling, does not reveal "data obtained by scanning a physical model of the patient's teeth."

c. Claim 3

Claim 3 recites:

A method as in claim 2, 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-003 at 15:37-43)

Respondents' Position: Respondents say that Lemchen also discloses the subject matter of claim 3. Respondents continue that Align successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen disclosed manipulating visual images to reposition individual teeth in the visual image. (Citing *Ormco II* at 498 F.3d 1315)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 both claim 1 and claim 2 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claims 1 and 2 to be valid and *not* anticipated Lemchen,

claim 3 is necessarily valid, because it depends from claim 1 via claim 2 and necessarily contains all of the elements of claims 1 and 2. See *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that claims 1 and 2 are anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 3 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

Claim 1 teaches "manipulating the visual image to reposition individual teeth in the visual image." (JX-003 at R1:29-48) Assuming, *arguendo*, that Lemchen disclosed this limitation, because this limitation discusses moving "individual" teeth, Lemchen would necessarily disclose defining boundaries around those teeth in order to move those teeth in the image. As a result, I find that if claims 1 and 2 were anticipated by Lemchen, claim 3 would be anticipated by Lemchen.

d. Claim 11

Asserted claim 11 teaches:

A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:

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

providing a final digital data set representing a final tooth arrangement;

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

fabricating appliances based on at least some of the produced digital data sets.

(JX-003 at 16:19-34)

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Respondents' Position: Respondents contend that, like claim 1, the preamble and first and second elements of claim 11 are disclosed by Lemchen and Kesling. Respondents assert that the third element of claim 11 is disclosed by Kesling because the Kesling reference discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions. (Citing CX-0944 at 2:50 – 3:1) Respondents say that the Kesling reference describes the necessity of making a plurality of appliances as obvious. (Citing CX-0944 at 2:50 – 3:1) Respondents say that, as described above, Lemchen discloses a digital method of performing the manual method disclosed in Kesling.

Respondents assert that Lemchen and Kesling disclose the fourth element of claim 11. Respondents say Lemchen discloses methods that include controlling an appliance fabrication machine (Citing CX-0945 at 5:4 –8) Respondents say that Lemchen also describes the use of a “laboratory model of the tooth . . .” and note 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-0945 at 5:21 – 24) Respondents assert 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 in order to produce appliances.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In section IV.B.1, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen only describes “generating digital information” regarding the initial “maloccluded teeth,” and then determining their respective “finish positions,” Lemchen does not disclose “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements

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progressing from the initial tooth arrangement to the final tooth arrangement,” as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell 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 entirety of the treatment. As a result, I find that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 11 requires, *inter alia*,

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

fabricating appliances based on at least some of the produced digital data sets.

(JX-003 at 16:27-34) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 11.

e. Claim 13

Dependent claim 13 recites:

A method as in claim 11, wherein the step of providing a digital data set representing a final tooth arrangement comprises:

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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 final data set.

(JX-003 at 16:39-46)

Respondents' Position: Respondents argue that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 13.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 11 to be anticipated and invalid, I could still find that claim 13 is valid. Since, however, I have found claim 11 to be valid and *not* anticipated by Lemchen, claim 13 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 11 is anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 13 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling. Claim 11 merely teaches "providing a final digital data set representing a final tooth arrangement." (JX-003 at 16:24-25) Unlike claim 1, claim 11 does not teach manipulating a visual image to move "individual" teeth. 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 13.

f. Claim 14

Dependent claim 14 recites:

A method as in claim 11, 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-003 at 16:47-50)

Respondents' Position: Respondents argue that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 14.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 11 to be anticipated and invalid, I could still find that claim 14 is valid. Since, however, I have found claim 11 to be valid and *not* anticipated by Lemchen, claim 14 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 11 is anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 14 of the '325 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, and does not discuss interpolating differences between an initial position and a final position (*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 14.

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g. Claim 21

Claim 21 teaches:

A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising:

providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;

controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and

producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement.

(JX-003 at R1:65-R2:14)

Respondents' Position: According to Respondents, Claim 21 of the '325 Patent is noteworthy, because it claims a method for fabricating a single appliance. Respondents say that because the prior art taught methods for fabricating polymeric appliances that formed a shell over the individual teeth using digitally modified teeth arrangements, this independent claim is anticipated by Lemchen and, as incorporated, Kesling for the reasons discussed above. Respondents say that Lemchen and Kesling disclose the third element of claim 21 because Kesling discloses a method for producing aligners by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-0944 at 3:65 – 4:70) Respondents reason that the incorporated disclosures of Kesling demonstrate methods for producing a series of polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements. Respondents say that Lemchen discloses methods that include controlling a fabrication machine. (Citing CX-0945 at 5:4 –8)

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Respondents continue that Lemchen also describes the use of a “laboratory model of the tooth . . .” and as notes that while it referred to a single tooth, the invention “may be utilized with some or all of the teeth in a given arch” (Citing CX-0945 at 5:21 – 24) Respondents conclude 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 assert that claim 21 does not include any limitation relating to a series of appliances. Respondents say that Lemchen discloses generating a repositioned tooth arrangement, such as a desired final tooth arrangement. (Citing CX-0945 at 2:54 – 63)

Respondents continue that Lemchen discloses references that teach controlling a fabrication machine to make positive models of teeth. (Citing CX-0945 at 5:4 –8) Respondents say that Kesling discloses making a polymeric shell appliance as a negative of the positive models created using the disclosed methods. (Citing CX-0944 at 3:65 – 4:70) Respondents argue that these facts demonstrate 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 treats all claims above in its discussion of claim 1.

Staff’s Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: Asserted claim 21 requires, *inter alia*:

providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;

controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement;

producing the polymeric shell dental appliance as a negative of the positive model

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(JX-0003 at R2:1-9) As noted above regarding claim 1 in section IV.B.1.a, *supra*, Lemchen is limited to the idea of treating a patient with a single set of brackets, not with polymeric shell appliances. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 21.

h. Claim 30

Claim 30 depends from claim 21 and teaches:

A method as in claim 21, wherein the digital data set represents substantially accurate shapes of the patient's actual teeth in the modified tooth arrangement.

(JX-003 at R2:24-26)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of Claim 30. Respondents say that Lemchen specifically discloses that his method generates "accurate digital information" defining the teeth locations. (Citing CX-0945 at 2:55 –57)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 21 to be anticipated and invalid, I could still find that claim 30 is valid. Since, however, I have found claim 21 to be valid and *not* anticipated by Lemchen, claim 30 is necessarily valid, because it depends from claim 21 and necessarily contains all of the elements of claim 21. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 21 is anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 30 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

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Lemchen discloses generating digital information that defines the shape and location of a maloccluded tooth and determining the desired position of that tooth after treatment. (CX-945 at 1:56-62) Lemchen explains that the digital information defining the shape and location of the maloccluded tooth is “accurate.” (CX-945 at 2: 54-57) Thus, I find that Lemchen with the incorporation of Kesling, reveals that “the digital data set represents substantially accurate shapes of the patient's actual teeth in the modified tooth arrangement.”

i. Claim 31

Claim 31 teaches:

A method for facilitating a tooth repositioning dental treatment of a patient by use of a series of successive tooth positioning appliances, including producing a plurality of digital data sets representing a plurality of tooth arrangements and providing a plurality of the digital data sets to a fabrication operation for fabricating the treatment, said method comprising:

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

presenting a visual image based on the initial data set;

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

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

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

and providing a plurality of the produced intermediate digital data sets to a fabrication operation to facilitate the tooth repositioning dental treatment of the patient with a series of successive tooth repositioning appliances.

(JX-003 at R2:27-50)

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Respondents' Position: Respondents contend that Lemchen anticipates Claim 31 of the '325 Patent. Respondents say that the subject matter of the preamble and claim elements 1-5 of claim 31 are disclosed in the prior art as explained above. Respondents assert that claim element 6 is disclosed by Lemchen. Respondents say that Lemchen discloses 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 assert that claim 31 is directed to the fabrication of a series of successive tooth repositioning appliances and is not limited to aligners or removable appliances. Respondents say that Dr. Rekow opined that Lemchen taught "[f]ull three-dimensional modeling in orthodontic treatment planning" (Citing RX-0103C at 16) Respondents continue that Dr. Rekow opined that Lemchen taught a digital method of the physical method taught by Kesling. (Citing RX-0103C at 16.) Respondents argue that it is clear 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) Respondent argue that these facts demonstrate 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 treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

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Analysis and Conclusions: In section IV.B.1.a, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen only describes “generating digital information” regarding the initial “maloccluded teeth,” and then determining their respective “finish positions,” Lemchen does not disclose “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement,” as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell 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 entirety of the treatment. As a result, I find that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 31 requires, *inter alia*,

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

(JX-003 at R2:43-46) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 31.

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j. Claim 32

Claim 32 depends from claim 31 and teaches:

A method as in claim 31, wherein the produced digital data sets represent substantially accurate shapes of the patient's actual teeth.

(JX-003 at R2:51-53)

Respondents' Position: Respondents say that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 32. Respondents allege that claim 32 is anticipated by Lemchen/Kesling because Lemchen specifically discloses that his method generates “accurate digital information” defining the teeth locations. (Citing CX-0945 at 2:55 –57) Respondents continue that these facts demonstrate 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 treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 31 to be anticipated and invalid, I could still find that claim 32 is valid. Since, however, I have found claim 31 to be valid and *not* anticipated by Lemchen, claim 32 is necessarily valid, because it depends from claim 31 and necessarily contains all of the elements of claim 31. See *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 31 is anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 32 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling. Lemchen discloses generating digital information that defines the shape and location of a maloccluded tooth and determining the desired position of that tooth after treatment. (CX-945 at

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1:56-62) Lemchen explains that the digital information defining the shape and location of the maloccluded tooth is “accurate.” (CX-945 at 2: 54-57) Thus, I find that Lemchen with the incorporation of Kesling, reveals that “the produced digital data sets represent substantially accurate shapes of the patient's actual teeth.”

k. Claim 33

Claim 33 depends from claim 31 and teaches:

A method as in claim 31, further comprising fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-003 at R2:54-57)

Respondents’ Position: Respondents say that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 33.

Align’s Position: Align treats all claims above in its discussion of claim 1.

Staff’s Position: Staff treats all claims above in its discussion of 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 31 to be anticipated and invalid, I could still find that claim 33 is valid. Since, however, I have found claim 31 to be valid and *not* anticipated by Lemchen, claim 33 is necessarily valid, because it depends from claim 31 and necessarily contains all of the elements of claim 31. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 31 is anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 33 of the ‘325 patent is anticipated by Lemchen with the incorporation of Kesling.

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In section IV.B.1.a, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen only describes “generating digital information” regarding the initial “maloccluded teeth,” and then determining their respective “finish positions,” Lemchen does not disclose “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement,” as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell 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 entirety of the treatment. As a result, I find that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 33 requires, *inter alia*,

fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-003 at R2:54-57) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 33.

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I. Claim 34

Claim 34 teaches:

A method as in claim 33, wherein fabricating the successive tooth repositioning appliances comprises fabricating polymeric shell appliances.

(JX-003 at R2:58-60)

Respondents' Position: Respondents contend that Lemchen and Kesling disclose the subject matter of claim 34. Respondents aver that this claim element is similar to the element in Claim 21 of the '325 patent. Respondents say that Kesling teaches a method for producing aligners by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-0944 at 3:65 – 4:70) Respondents continue that Lemchen discloses methods that include controlling a fabrication machine. (Citing CX-0945 at 5:4 –8)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 both claims 31 and 33 to be anticipated and invalid, I could still find that claim 34 is valid. Since, however, I have found claims 31 and 33 to be valid and *not* anticipated by Lemchen, claim 34 is necessarily valid, because it depends from claim 31 via claim 33 and necessarily contains all of the elements of claims 31 and 33. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 31 and 33 are anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 34 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling. As

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noted above regarding claim 1, Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. As a result, I find that Lemchen does not disclose the limitations of claim 34.

m. Claim 35

Claim 35 teaches:

A method for fabricating a plurality of successive dental incremental position adjustment appliances, said method comprising:

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

providing a final digital data set representing the final tooth arrangement;

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;

controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and

producing the successive dental appliances as negatives of the positive models.

(JX-002 at R2:61-R3:11)

Respondents' Position: Respondents assert that Lemchen anticipates Claim 35 of the '325 Patent. Respondents say that the subject matter of the preamble and all claim elements are disclosed in the prior art as explained above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: in section IV.B.1, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen

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only describes “generating digital information” regarding the initial “maloccluded teeth,” and then determining their respective “finish positions,” Lemchen does not disclose “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement,” as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell 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 entirety of the treatment. As a result, I find that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 35 requires, *inter alia*,

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;

controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and

producing the successive dental appliances as negatives of the positive models.

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(JX-003 at R3:1-11) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 35.

n. Claim 38

Claim 38 teaches:

A method for fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances for repositioning at least some of a patient's teeth, said method comprising:

providing an initial digital data set representing substantially accurate shapes of the patient's actual teeth in an initial tooth arrangement;

providing a final digital data set representing substantially accurate shapes of the patient's actual teeth in a final tooth arrangement;

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital datasets represents substantially accurate shapes of the patient's actual teeth in a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;

and fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets.

(JX-003 at R3:21-R4:19)

Respondents' Position: Respondents contend that Lemchen anticipates also Claim 38 of the '325 Patent. Respondents say that the subject matter of the preamble and claim elements 1-4 of claim 38 are disclosed in the prior art as explained above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In section IV.B.1, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen

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only describes “generating digital information” regarding the initial “maloccluded teeth,” and then determining their respective “finish positions,” Lemchen does not disclose “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement,” as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell 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 entirety of the treatment. As a result, I find that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 38 requires, *inter alia*,

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represents substantially accurate shapes of the patient’s actual teeth in a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets.

(JX-003 at R4:8-19) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 38.

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o. Claim 39

Claim 39 depends from claim 38 and teaches:

A method as in claim 38, wherein the appliances are fabricated based on individual ones of at least a corresponding plurality of the produced digital data sets.

(JX-003 at R4:20-22)

Respondents' Position: Respondents continue that the subject matter of claim 39 is disclosed by Lemchen and Kesling as explained above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 38 to be anticipated and invalid, I could still find that claim 39 is valid. Since, however, I have found claim 38 to be valid and *not* anticipated by Lemchen, claim 39 is necessarily valid, because it depends from claim 38 and necessarily contains all of the elements of claim 38. See *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that claim 38 is anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 39 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

Claim 38 teaches "fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets." (JX-002 at R4:16-19) Assuming, *arguendo*, that Lemchen disclosed this limitation, because this limitation discusses fabricating appliances based on the produced digital data sets, Lemchen would necessarily disclose fabricated based on individual ones of at least a

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corresponding plurality of the produced digital data sets. As a result, I find that if claim 38 were anticipated by Lemchen, claim 39 would be anticipated by Lemchen.

2. Obviousness

a. Claim 1

Respondents' Position: Respondents assert that Align's expert in a previous litigation, Dr. Rekow, stated that:

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

RX-103C at 2. Respondents contend that the related nature of the subject matters and the problems addressed made the combination obvious. Respondents continue that this is especially true given the internal references between Lemchen and Kesling. Respondents assert that Dr. Rekow also stated that the Lemchen reference and the Kesling reference were combined based on her analysis of the references in the Lemchen patent. Respondents say that Dr. Rekow's report states that Lemchen's methods for digital 3-D modeling was a representation of Kesling's physical 3-D modeling. (Citing RX-103C at 16) Respondents argue that each asserted claim is obvious in light of the identified prior art references with the knowledge of one of ordinary skill.

Respondents assert that the preamble of claim 1 is obvious in light of the prior art references. Respondents say 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

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the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design.

(Citing RX-0102C at 6) Respondents continue 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) Respondents say that this evidence shows the knowledge of one skilled in the art. Respondents say that combined with the disclosures of the prior art identified in the anticipation section addressing the preamble to Claim 1 of the ‘325 patent, the preamble is obvious.

Respondents say that Lemchen discloses that the “repositioning is done mathematically by appropriate software programs which may be derived by conventional means” (Citing CX-0945 at 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-0113C at Q. 59) Respondents say that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-0113C at Q. 59)

Respondents say that Dr. Lemchen also expressly incorporated the disclosure of Kesling to explain his 3-D modeling methodology. (Citing CX-0945 at 3:36 – 40) Respondents conclude that Lemchen stated that FIG. 3 was one example of a repositioned tooth arrangement. Respondents say that one skilled in the art would understand that this same method would apply equally to the intermediate or successive tooth arrangements that are described in Kesling. (Citing RX-0113C at Q. 48) Respondents aver that the methodology is the same for all successive tooth arrangements from the initial position to the final position. (Citing RX-0113C

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at Q. 48) Respondents add that intermediate or successive tooth arrangements are inherent in tooth modeling. (Citing RX-0113C at Q. 48) Respondents explain that one cannot model tooth movement accurately without including the intermediate steps. (Citing RX-0113C at Q. 48)

Respondents say that the figures in Kesling demonstrate that a “tooth positioning appliance,” similar to an aligner, was disclosed. (Citing CX-0944 at Fig. 7) Respondents continue that Kesling expressly discloses: intermediate or successive models representing tooth positions, the use and fabrication of a series of dental appliances, using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-0113C at Q. 33)

Respondents assert that Dr. Lemchen discloses methods that include controlling a fabrication machine. (Citing CX-0945 at 5:4–8) Respondents say 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-0945 at 5:21 – 24) Respondents contend that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated. (Citing RX-0113C at Q. 43)

Respondents assert that Nahoum also taught methods for fabricating series of successive aligners in the 1960s. Respondents say that Dr. Nahoum taught methods for fabricating a series of aligners by vacuum forming thermoplastics over positive models. (Citing RX-0096) Respondents continue that one skilled in the art would understand, in light of this reference, the following subject matter: an initial tooth arrangement; a projected final tooth arrangement;

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intermediate or successive tooth positions; the use or fabrication of a series of dental appliances; and producing a positive model of a tooth arrangement. (Citing RX-0113C at Q. 88-89)

Respondents assert that Dr. Lemchen expressly stated that the three-dimensional modeling methods, using software, “may be derived by conventional means for the particular method of treatment elected by the orthodontist.” (Citing CX-0945 at 3:25 – 26) Respondents say that Lemchen similarly stated in the detailed description that there “are a number of methods of treatment commonly used by the orthodontist.” (Citing CX-0945 at 3:43 – 46) Respondents conclude that Lemchen expressly recognizes that its methods may be used with different types of orthodontic treatment and one skilled in the art would understand that other treatment methods, such as the aligner treatment method disclosed in Kesling could be used with the digital methods disclosed in Lemchen. (Citing RX-0113C at Q. 49)

Respondents argue that one skilled in the art would understand that the methods of Kesling were not limited to brackets (which are custom fabricated in the disclosed methods to conform to the surface of the teeth) and arch wires. (Citing RX-0113C at Q. 49) Rather, Respondents assert that the incorporation of the disclosures of Kesling and the other statements concerning other treatment methods makes it clear that methodology disclosed in Lemchen applies beyond brackets and archwires. (Citing RX-0113C at Q. 49) Respondents say that Kesling disclosures are limited to methods for making polymeric shell appliances based on a series of three-dimensional tooth models. (Citing RX-0113C at Q. 49) Respondents contend that one skilled in the art would understand the incorporation of Kesling to mean that the methods of Lemchen would apply to polymeric shell appliances, the orthodontic appliance expressly described in Kesling. (Citing RX-0113C at Q. 49) Respondents conclude that one

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skilled in the art would also understand that the modeling of teeth movement is the same, regardless of the type of orthodontic appliance used. (Citing RX-0113C at Q. 51)

Respondents say that Dr. Lemchen also disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, “where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion.” (Citing CX-0945 at 5:15 –20) Respondents assert that these disclosures render the claim obvious.

Align’s Position: Align asserts that Respondents’ *Prehearing Brief* raises obviousness, but does not identify which claims are allegedly obvious. Align concludes that any obviousness contentions are waived. Respondents say that a *prima facie* showing requires clear and convincing evidence that: a particular combination of prior art discloses all elements of a claim; and one of ordinary skill in the art would have some reason to make the combination. Align argues that Respondents’ evidence fails on both requirements for every asserted claim.

Align says that Respondents generally refer to a combination of Lemchen, Kesling, and “the knowledge of one of ordinary skill in the art.” Align argues that this combination fails to disclose all elements of any of the asserted claims. Align says that Respondents’ Prehearing Brief did not identify any other combinations with particularity; rather, Respondents simply presented a “jumble of references,” which the presiding ALJ recognized is insufficient to identify a combination. (Citing Tr. at 652:8-13) Align concludes that any other combinations are waived. Align asserts that none of the prior art, in *any* combination, discloses all elements of any of the asserted claims.

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Align contends that there is no evidence that one of ordinary skill in the art at the time of the inventions would have been motivated to combine *any* of the identified references in *any* manner. Align says that Respondents refused, throughout this Investigation, to identify particular motivations to combine and I limited Respondents to motivations purportedly identified by the Rekow reports of November 10, 2008 (RX-0103C) and May 18, 2004 (RX-0102C) (the use of which was also limited to “showing that prior inconsistent positions were taken by Align in previous litigation”). (Citing Tr. at 16:19-17:23; 20:5-21:21) Align continues that these reports provide no motivation to combine the prior art asserted here, and I noted that Respondents face an “uphill struggle” to identify any motivation to combine specific references within these reports. (Citing Tr. at 16:19-17:23)

Align argues that the evidence shows that one of ordinary skill in the art would *not* have been motivated to combine prior art directed to removable appliances (*e.g.*, Kesling) with prior art directed to fixed appliances (*e.g.*, Lemchen) because the knowledge and understanding of the capabilities of these different types of appliances was vastly different. (Citing CX-1247C at Q. 165-166, 280-281, 318-319, 349-350, 427-428, 452-453, 577; CX-1254C ¶ 77 at 27-28, ¶ 121 at 47)

Align disagrees with Respondents’ argument that all of the asserted claims of the ‘325 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 Respondents’ argument fails because 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 these references, in any combination, fail to disclose all the elements of any

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asserted claim, as discussed above. 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). Align says that secondary considerations support a finding of non-obviousness.

Align asserts 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, 98-106, 128-136, 146-154, 175-183, 205-217, 240-248) Align says that the record is devoid of evidence supporting obviousness.

Align asserts that Respondents fail to even identify what combination of prior art they rely on for each asserted claim; rather, consistent with their practice throughout the Investigation, 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.” Align says that Respondents also fail to contend that certain claims are obvious at all, including for example, for claim 14 of the ‘325 patent, where Respondents simply state:

Mr. Beers identifies common evidence that he contends covers this limitation as Evidence Category 7. CX-1150C at Q. 198. Respondents incorporate Disclosure Category 7 with the knowledge of one of ordinary skill as described addressing Claim 1 of the ‘325.

(Citing RIB at 68)

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) Align says that this position is also waived under GR 8.2 because it was not specified in Respondents’ *Prehearing Brief*. Align continues that Respondents do not assert that there was a

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motivation to combine any specific prior art other than Lemchen and Kesling. Align adds 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 at Q. 165-166, 280-281, 318-319, 349-350, 427-428, 452-453, 577; CX-1254C ¶ 77 at 27-28, ¶ 121 at 47.)

Align says that Respondents improperly rely on the Federal Circuit's decision in *Ormco I*, which addressed different patents and unrelated claims. (Citing *In re Dillon*, 892 F.2d 1554, 1565 (Fed. Cir. 1989)) Align continues that Respondents improperly rely on *Ormco I*'s discussion of prior art devices made by Dr. Truax that are not in evidence here.

Align asserts that the *Ormco II* opinion only provides Ormco inventors' characterizations of Lemchen, in the form of statements made during the prosecution of an Ormco patent. (Citing *Ormco II*, 498 F.3d at 1314-15) Align explains that the Federal Circuit does not adopt these characterizations of Lemchen, but merely references them in the context of construing Ormco's patent claims.

Align says that Respondents improperly rely on Dr. Rekow's Reports from the *Ormco* litigation because Respondents failed to show that prior statements *by Dr. Rekow*, an independent expert, are attributable to Align. Align says that I ruled that the Rekow Reports "will not be accepted as expert testimony" here. (Citing Tr. at 20:5-21:21) Align concludes that Respondents cannot use the Reports to bolster their invalidity theories. Alternatively, Align says that the Reports do not support Respondents' contentions regarding the prior art. Align says that the cited portions of RX-0102C simply confirm that Lemchen is directed to a fixed appliance that includes brackets. (Citing RX-0102C at 7-8)

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Align says that Respondents reference Nahoum in regards to claim 1 of the '325 patent (Citing RIB at 64-65) Align contends that any obviousness combination involving Nahoum has been waived because it was not disclosed in Respondents' PreHearing Brief.

Staff's Position: Staff says 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 (or any Asserted Patent) invalid for obviousness (citing Tr. at 19:11-25), 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 other patents in suit).

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 other patents in suit) invalid for obviousness, Respondents cannot meet their burden of clear and convincing evidence. Staff says that, like the testimony alleging anticipation, the testimony alleging obviousness provided by Dr. Mah is merely conclusory. (Citing RX-0113C at Q. 114-121) Staff concludes, as a result, 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 (or any of the other patents in suit). Staff says that, in sum, there is a lack of evidence demonstrating clearly and convincingly that any of the asserted claims of the '325 patent (or the other patents in suit) are rendered invalid for obviousness by the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill).

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Analysis and Conclusions: 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 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, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

In order to prevail on their argument that claim 1 of the ‘325 patent is invalid as obvious,

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Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling discloses all of the limitations of the claim 1. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velandar 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 of 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 '325 patent. In section IV.B.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 claim 1 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 1 of the '325 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

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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)

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, 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 entirety of the treatment.

Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. 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)

Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Rather, Kesling discloses manually making an appliance using tools, supplies, and materials, including, inter alia, (i) articulating the plaster cast; (ii) taking an impression of the teeth of the plaster cast, and (iii) making a mold filled with the appliance material. (CX-944, 3:65-4:58)

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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. (RX-096, ALGN0001447) Nahoum includes a description of making an adjustment in two or more phases in which partial and progressive adjustments are made in each appliance. (RX-096, ALGN0001448) 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 '325 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 '325 patent.

b. Claim 2

Respondents' Position: Respondents assert that dependent claim 2 is obvious in light of the identified prior art discussed above and the knowledge of one of ordinary skill in the art. Respondents say that the disclosures of Lemchen demonstrate that a digital data set representing an initial tooth arrangement is generated by scanning a model of the patient's teeth (Citing CX-0945 at 2:54 – 63)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

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

Assuming *arguendo* that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 2 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.b, *supra*, I found that Lemchen does not reveal generating the initial data regarding maloccluded teeth from a physical model of the patient's teeth as shown in Kesling. In the interest of brevity, I will not repeat the discussion in section IV.B.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. 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 2 of the '325 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 2 of the '325 patent.

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c. Claim 3

Respondents' Position: Respondents assert that dependent claim 3 is obvious in light of the identified prior art discussed above and the knowledge of one of ordinary skill in the art. Respondents say that Align successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen disclosed manipulating visual images to reposition individual teeth in the visual image. (Citing *Ormco II* at 498 F.3d 1315)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 1 and 2 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 claims 1 and 2 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 via claim 2 and necessarily contains all of the elements of claims 1 and 2. See *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that claims 1 and 2 are rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 3 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.c, *supra*, I found that if Lemchen anticipated claims 1 and 2, it would also anticipate claim 3. As a result, assuming *arguendo* that claims 1 and 2 are obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that

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claim 3 is obvious based on the rationale discussed in section IV.B.1.c.

d. Claim 11

Respondents' Position: Respondents assert that claim 11 is obvious in light of the identified prior art discussed above and the knowledge of one of ordinary skill in the art. Respondents say that the subject matter of the preamble is disclosed in the prior art, as explained regarding claim 1. Respondents say 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-0944 at 2:50–3:1) Respondents continue that Kesling describes the necessity of making a plurality of appliances as “obviously” necessary. (Citing CX-0944 at 2:50–3:1) Respondents add that Lemchen discloses methods that include controlling an appliance fabrication machine. (Citing CX-0945 at 5:4–8) Respondents continue 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-0945 at 5:21–24) Respondents conclude 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 in order to produce appliances and claim 11 is thus obvious.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not 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 and although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2,

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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 and any other combinations, including Nahoum with Lemchen, Kesling, 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 follow the methods in the '325 patent. In section IV.B.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 claim 11 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 11 of the '325 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. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in

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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.

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 entirety 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 11 of the '325 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 '325 patent.

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e. Claim 13

Respondents' Position: Respondents assert that the subject matter of claim 13 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 11 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 13 is valid. Since, however, I have found claim 11 to be valid and *not* rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 13 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 11 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 13 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.e, *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.B.1.e 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. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a

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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 13 of the '325 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 13 of the '325 patent.

f. Claim 14

Respondents' Position: Respondents assert that the subject matter of claim 14 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 11 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 14 is valid. Since, however, I have found claim 11 to be valid and *not* rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 14 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 11 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 14 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.f, *supra*) Although Lemchen teaches generating a digital data set

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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, and does not discuss interpolating differences between an initial position and a final position (*see* CX-945 at 3:44-54). In the interest of brevity, I will not repeat the discussion in section IV.B.1.f 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. 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 14 of the ‘325 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 14 of the ‘325 patent.

g. Claim 21

Respondents’ Position: Respondents assert that claim 21 is noteworthy because it claims a method for fabricating a single appliance. Respondents continue that, as explained above regarding claim 1, because the prior art taught methods for fabricating polymeric appliances that formed a shell over the individual teeth using digitally modified teeth arrangements, this independent claim is obvious in light of the prior art references with the knowledge of one of ordinary. Respondents say that Kesling teaches a method for producing aligners by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-0944 at 3:65 – 4:70) Respondents continue that the incorporated disclosures of Kesling demonstrate methods for producing a series of

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polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements. Respondents add that Lemchen discloses methods that include controlling a fabrication machine to provide a “machined” base conforming to tooth morphology. (Citing CX-0945 at 5:4–8) Respondents say that this and similar statements identified above expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on digital data.

Align’s Position: Align treats all claims above in its discussion of claim 1.

Staff’s Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents’ prehearing brief does not 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 and 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 and any other combinations, including Nahoum with Lemchen, Kesling, 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 of 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 ‘325 patent. In section IV.B.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 claim 21 of the ‘325 patent. Based upon

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that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 21 of the '325 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. 100, 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. 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. 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, I find that Nahoum does not in any way disclose use of computers

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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 21 of the '325 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 '325 patent.

h. Claim 30

Respondents' Position: Respondents assert that the subject matter of claim 30 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 21 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 30 is valid. Since, however, I have found claim 21 to be valid and *not* rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 30 is necessarily valid, because it depends from claim 21 and necessarily contains all of the elements of claim 21. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 21 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 30 of the '325 patent is rendered obvious by that combination.

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In section IV.B.1.h, *supra*, I found that if Lemchen anticipated claim 21, it would also anticipate claim 30. As a result, assuming *arguendo* that claim 21 is obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that claim 30 is obvious based on the rationale discussed in section IV.B.1.h.

i. Claim 31

Respondents' Position: Respondents assert that claim 31 is obvious in light of the identified prior art with the knowledge of one of ordinary skill in the art as explained regarding claim 1.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not 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 and 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 and any other combinations, including Nahoum with Lemchen, Kesling, 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 follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that

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Lemchen incorporated the *entirety* of Kesling by reference, those two references taken together would still not disclose each and every element of the claim 31 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 31 of the '325 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. 100, 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. 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.

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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 entirety 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 31 of the '325 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 '325 patent.

j. Claim 32

Respondents' Position: Respondents assert that the subject matter of claim 32 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 31 to be rendered obvious by the asserted prior art and invalid, I could still find

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that claim 32 is valid. Since, however, I have found claim 31 to be valid and *not* rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 32 is necessarily valid, because it depends from claim 31 and necessarily contains all of the elements of claim 31. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 31 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 32 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.j, *supra*, I found that if Lemchen anticipated claim 31, it would also anticipate claim 32. As a result, assuming *arguendo* that claim 31 is obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that claim 32 is obvious based on the rationale discussed in section IV.B.1.j.

k. Claim 33

Respondents' Position: Respondents assert that the subject matter of claim 33 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 31 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 33 is valid. Since, however, I have found claim 31 to be valid and *not* rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 33 is necessarily valid, because it depends from claim 31 and necessarily contains all of

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the elements of claim 31. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 31 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 33 of the '325 patent is rendered obvious by that combination.

Claim 33 requires, *inter alia*,

fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-003 at R2:54-57) Examining Nahoum in combination with Lemchen and Kesling, Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. 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 33 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, Nahoum, and the knowledge of a person 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 the those references to create the method claimed in the invention of the '325 patent.

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I. Claim 34

Respondents' Position: Respondents assert that the subject matter of claim 34 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 31 and 33 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 34 is valid. Since, however, I have found claims 31 and 33 to be valid and *not* rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 34 is necessarily valid, because it depends from claim 31 via claim 33 and necessarily contains all of the elements of claims 31 and 33. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that claims 31 and 33 are 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 34 of the '325 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. Nahoum and the knowledge of one of ordinary skill in the art do not fill these gaps. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance, as required by claims 34.

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 34 of the '325 patent are

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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 34 of the '325 patent.

m. Claim 35

Respondents' Position: Respondents assert that the subject matter of claim 35 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not 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 and 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 and any other combinations, including Nahoum with Lemchen, Kesling, 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 follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that Lemchen incorporated the *entirety* of Kesling by reference, those two references taken together

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would still not disclose each and every element of the claim 35 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 35 of the '325 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. 100, 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. 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.

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one bracket per tooth to be used over the entirety 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 35 of the ‘325 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 ‘325 patent.

n. Claim 38

Respondents’ Position: Respondents assert that the subject matter of claim 38 is obvious for the reasons discussed above.

Align’s Position: Align treats all claims above in its discussion of claim 1.

Staff’s Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents’ prehearing brief does not 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 and although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2,

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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 and any other combinations, including Nahoum with Lemchen, Kesling, 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 follow the methods in the '325 patent. In section IV.B.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 claim 38 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 38 of the '325 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. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in

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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. 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 entirety 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 38 of the '325 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

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those references to create the method claimed in the invention of the '325 patent.

o. Claim 39

Respondents' Position: Respondents assert that the subject matter of claim 39 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of 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 38 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 39 is valid. Since, however, I have found claim 38 to be valid and *not* rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 39 is necessarily valid, because it depends from claim 38 and necessarily contains all of the elements of claim 38. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 38 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 39 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.o, *supra*, I found that if Lemchen anticipated claim 38, it would also anticipate claim 39. As a result, assuming *arguendo* that claim 38 is obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that claim 39 is obvious based on the rationale discussed in section IV.B.1.o.