

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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.



## PUBLIC VERSION

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 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

## PUBLIC VERSION

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.

## PUBLIC VERSION

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

## PUBLIC VERSION

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

PUBLIC VERSION

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.

## PUBLIC VERSION

### 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

## PUBLIC VERSION

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 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

## PUBLIC VERSION

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.



## PUBLIC VERSION

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,

## PUBLIC VERSION

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 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

## PUBLIC VERSION

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

## PUBLIC VERSION

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.

### 3. Secondary Consideration of Non-Obviousness

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

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

## PUBLIC VERSION

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

Respondents argue that Dr. Valley’s remaining two contentions likewise fail.

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

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

## PUBLIC VERSION

Respondents aver that Align made no mention of computer modeling or digital data sets.

According to Respondents, these were the factors Align considered critical three years before the Federal Circuit rejected them as “secondary considerations” in *Ormco I*. Respondents argue that only now does Align assert that the digital files are Align’s alleged reasons for its “commercial success.”

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

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

PUBLIC VERSION

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

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

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



## PUBLIC VERSION

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

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

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

## PUBLIC VERSION

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

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

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

PUBLIC VERSION

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

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

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

## PUBLIC VERSION

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

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

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

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

Align asserts that Respondents' wrongly assert that Align's method of creating visual images of tooth arrangements is not recited in the asserted claims. Align says that its claims specifically recite a method for creating visual images based on digital data sets representing substantially accurate shapes of a patient's actual teeth. (Citing JX-0003 at 27 (2:27-53))

Respondents say that as Dr. Valley opined that these images may be used as a diagnostic tool between the clinician and the patient and support the commercial success of Align's inventions.

(Respondents say that CX-1254C at ¶¶ 228-230, at 83-84; CX-1247C at Q. 496-497) Align disagrees with Respondents' reliance on a single 10-K to claim that Align never acknowledged either "computer modeling" or the use of "digital data sets" as being commercially beneficial.

Align says that this 10-K actually discusses the benefits of being able to (i) "visualize treatment," (ii) determine a "likely outcome," and (iii) produce highly customized aligners in volume.

(Citing CX-1266 at 7, 11)

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

## PUBLIC VERSION

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

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

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

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

## PUBLIC VERSION

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

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

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

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

## PUBLIC VERSION

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

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

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

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



## PUBLIC VERSION

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

Specifically, Dr. Valley testifies that:

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

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

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

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

**PUBLIC VERSION**

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

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

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

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

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

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

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

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

## PUBLIC VERSION

or to explain which features of the claims actually “solved the problem of having a human operator attempt to manually divide a larger tooth movement into small, precise movements.”

(*Id.*)

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

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

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

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

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

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

## PUBLIC VERSION

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

### C. The ‘880 Patent

#### 1. Anticipation

##### a. Claim 1

Asserted claim 1 teaches:

A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:

- a) obtaining a digital data set representing an initial tooth arrangement;
- b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;
- c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and
- d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

(JX-0002 at 22:12-29)

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<sup>16</sup> This does not, however, weigh against a finding of infringement.

## PUBLIC VERSION

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

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

## PUBLIC VERSION

difference between the claim and the prior art.

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

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

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

## PUBLIC VERSION

predetermined series of dental incremental position adjustment appliances” (‘880 claim 1).

(Citing RIB at 86-87)

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

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

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

## PUBLIC VERSION

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

(Citing G.R. 8.2)

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

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

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

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



## PUBLIC VERSION

In Section IV.B.1.a, *supra*, I also find that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirety of the treatment. I incorporate and reaffirm that finding and rationale here. As a result, I also find that Lemchen does not disclose "fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement" as required by claim 1.

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

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

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

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

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

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

**b. Claim 3**

Claim 3 depends from claim 1 and teaches:

A method as in claim 1, wherein the step of obtaining a digital data set representing a repositioned tooth arrangement comprises:

defining boundaries about at least some of the individual teeth; and

moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set.

(JX-002 at 22:33-41)

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

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

## PUBLIC VERSION

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

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

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

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

## 2. Obviousness

### a. Claim 1

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

## PUBLIC VERSION

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

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

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

## PUBLIC VERSION

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

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

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

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

## PUBLIC VERSION

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

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

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

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

## PUBLIC VERSION

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 '880 patent. In section IV.C.1, *supra*, I noted that even if I had found that Lemchen incorporated the *entirety* of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '880 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '880 patent.

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

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

## PUBLIC VERSION

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

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the 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 the asserted claims of the '880 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the



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

**b. Claim 3**

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

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

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

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

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

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

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

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

#### **D. The '487 Patent**

##### **1. Anticipation**

###### **a. Claim 1**

Claim 1 teaches:

A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:

receiving an initial digital data set representing an initial arrangement of the patient's teeth;

producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;

producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement.

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

## PUBLIC VERSION

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

Respondents incorporate the section addressing the preamble of Claim 1 of the '325 Patent.

Respondents say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment:

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

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

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

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

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

## PUBLIC VERSION

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

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

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

## PUBLIC VERSION

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

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

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

## PUBLIC VERSION

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

(Citing Ground Rule 8.2)

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

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

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

## PUBLIC VERSION

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

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

Assuming, *arguendo*, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement," as required by claim 1.

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

### **b. Claim 3**

Dependent claim 3 recites:

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

## PUBLIC VERSION

fabrication of shell appliances for a corresponding treatment stage.

(JX-007 at 11:10-13)

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

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

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

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

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

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

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



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

**c. Claim 5**

Claim 5 teaches:

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

(JX-007 at 11:19-22)

**Respondents' Position:** The Respondents incorporate Disclosure Category 9.

Respondents contend that Disclosure Category 9 discloses the subject matter of claim 5.

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

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

## PUBLIC VERSION

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

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

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

### d. Claim 7

Claim 7 teaches:

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

wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

(JX-007 at 11:26-35)

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

## PUBLIC VERSION

Respondents incorporate the section addressing the preamble of Claim 1 of the '325.

Respondents say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment. (Citing RX-103C at 16.)

Respondents incorporate Disclosure Categories 1, 5, and 7.

Respondents assert that Disclosure Category 2 discloses “the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth.”

Respondents contend that Disclosure Categories 7 and 10 disclose “wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.”

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

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

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

## PUBLIC VERSION

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

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

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

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

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

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

## PUBLIC VERSION

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

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

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

### e. Claim 8

Claim 8 teaches:

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

(JX-007 at 11:36-39)

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

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

## PUBLIC VERSION

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

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

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

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

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

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

### **f. Claim 9**

Claim 9 teaches:

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

## PUBLIC VERSION

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

(JX-007 at 11:40-44)

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

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

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

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

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

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

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

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

## **2. Obviousness**

### **a. Claim 1**

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

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



## PUBLIC VERSION

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

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

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

## PUBLIC VERSION

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

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

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

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

## PUBLIC VERSION

comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now.

(Citing Ground Rule 8.2)

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

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

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

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

## PUBLIC VERSION

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

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

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, Wu and the knowledge of one 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, Nahoum, or Wu to follow the methods in the '487 patent. In section IV.D.1, *supra*, I noted that even if I had found that Lemchen incorporated the *entirety* of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '487 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '487 patent.

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

## PUBLIC VERSION

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

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

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

## PUBLIC VERSION

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

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

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

### **b. Claim 3**

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

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

## PUBLIC VERSION

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

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

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

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

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

## PUBLIC VERSION

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

### **c. Claim 5**

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

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

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

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

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



## PUBLIC VERSION

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

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

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

**d. Claim 7**

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

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

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

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

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

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