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would preclude the other definitions discussed earlier that do not relate to physical matter.

There is no controlling case law construing “a material” in § 271(c) in this factual context, but there are a number of court decisions that are instructive. There are two Federal Circuit cases which involve an allegation that the provision of software satisfied the requirement for contributory infringement, but it does not appear in either case that the involved software was electronically transmitted. Both cases were presented to the Court on review of jury verdicts finding contributory infringement. The first case is *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321 (Fed. Cir. 2009). In that case, Lucent argued that Microsoft’s software product, a calendar “date-picker” tool, contributorily infringed a method for displaying information in fields covered by its ‘356 patent. Microsoft argued that the “material or apparatus” was the entire Outlook software package, which had substantial non-infringing uses. The Court rejected this argument because the specific feature, the date-picker tool, was suitable only for the infringing use covered by the method claims and that inclusion within the larger Outlook program did not change the date-picker’s ability to infringe. *Id.* at 1321. In so ruling, the Court observed that “if, instead of selling Outlook with the date-picker, Microsoft had offered the date-picker for sale *as a separate download* to be used with Outlook, there would be little dispute that Microsoft was contributing to infringement of the Day patent.” *Id.* at 1320 (emphasis added). Thus, the Court appeared to suggest that electronic transmissions of software would fall within at least one of the statutory categories of “a material or apparatus” and thereby provide a basis for contributory infringement.

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Microsoft also argued on appeal that its software product was not a “material or apparatus” under 35 U.S.C. § 271(c), based on the Supreme Court’s decision in another case involving Microsoft, *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007). In *Microsoft*, the Supreme Court held that the export of a “golden disk” of software did not constitute export of a “component” under a different provision of the patent statute, 35 U.S.C. § 271(f). The *Lucent* Court, noting that Microsoft relied on *Microsoft* “without further analysis,” held that the Supreme Court in *Microsoft* did not address the issue of what constituted a material or apparatus for purposes of 35 U.S.C. § 271(c), and *Lucent* did not comment on the issue further.⁴⁶

In the lower court, the issue was framed in terms of “component” rather than “a material or apparatus,” with Microsoft relying on the Supreme Court’s decision in *Microsoft*. The lower court rejected that argument because the Supreme Court did not purport to reach 35 U.S.C. § 271(c). The lower court also noted that “The dispute over the ‘356 patent involves method claims and commercial sales of software copies, not apparatus claims and foreign distribution of software ‘in the abstract.’” *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.Supp.2d 1016, 1039 (S.D. Cal. 2008) (citing *Microsoft*, 127 S. Ct. at 1727, as “distinguishing the abstract software code at issue from computer-readable copies, such as those ‘inserted into a CD-ROM drive or downloaded from the Internet’”). Thus, it appears that the district court distinguished the computer readable Outlook software copies in the *Lucent* dispute as substantively distinct from software “in the abstract” that was involved in the *Microsoft* case. As noted above, the Supreme

⁴⁶ See also *Arris Group, Inc. v. British Telecommunications PLC*, 639 F.3d 1368 (Fed. Cir. 2011) (citing *Lucent* and finding an Article III case or controversy exists arising from allegations of contributory infringement).

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Court's analysis in *Microsoft* indicates that for Section 271(f), software cannot be a component of a patented invention until it is in a form that can be installed or executed on a computer, *i.e.*, on a CD or downloaded from the internet. 550 U.S. at 449, 451, but is not dispositive of the meaning of "a material or apparatus" under § 271(c) as it was decided under § 271(f), and turned on the particular text and legislative history of that subsection of Section 271, which are different than those for subsection c.

The other Federal Circuit case is *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010). In that case, i4i's '449 patent claimed an improved method for editing documents containing mark-up languages like XML. i4i sued Microsoft for infringement by making, using, selling, offering to sell, and/or importing Word products capable of processing or editing Custom XML. A jury found Microsoft guilty of willful infringement. i4i presented three theories of liability: direct, contributory, and induced infringement. The jury returned a general verdict which did not require separate findings on the different theories. On appeal, Microsoft argued the trial judge erred in his contributory infringement instructions because he used the term "component" rather than "material or apparatus." The Federal Circuit rejected that argument, stating that the difference in language did not make a difference in that case, noting that the parties' used the terms interchangeably and their argument had not turned on whether Word's XML editor was a "component" rather than a "method or apparatus." The Court concluded that "there was sufficient evidence before the jury for it to conclude that the relevant 'material or apparatus' was the custom XML editor, not all of Word." *Id.* at 849.

In *Ricoh Co., Ltd. v. Quanta Computer, Inc.*, 550 F.3d 1325 (Fed. Cir. 2008), the Court held that the sale of software containing instructions to perform a patented method

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does not infringe a patented method under 35 U.S.C. § 271(a). The Court compared the situation to *Microsoft v. ATT*, which it cited for the proposition that “software is not a component of a patented device within the meaning of 35 U.S.C. § 271(f) until it is reduced to a machine-readable copy.” *Id.* at 1335 (citing *Microsoft*, 127 S. Ct. at 1753-55).

Further, there is one district court case which held that electronic copies of software did not constitute “a material or apparatus,” based on *Microsoft v. AT&T*. See *Veritas Operating Corp. v. Microsoft Corp.*, 562 F.Supp.2d 1141, 1275 (W.D.Wash. 2008). On the other hand, as Align notes, a California district court held that an electronic catalog was a physical “product” within the meaning of Section 271(g) finding *Microsoft v. AT&T* instructive on this point:

In *Microsoft*, the issue before the court was whether software is a combinable “component” for purposes of section 271(f). [127 S.Ct.] at 1755. The court stated that software “abstracted from a tangible copy” is simply abstract information. *Id.* Only when expressed and stored as machine-readable object code, e.g. burned on a CD-ROM or written to a server hard drive such that it is capable of being downloaded from the internet, does software become an actual, physical component amenable to combination. *Id.* at 1756. The court held that “a copy of Windows [software], not Windows in the abstract, qualifies as a ‘component’ under § 271(f).” *Id.*

CNET Networks, Inc. v. Etilize, Inc., 528 F. Supp.2d 985, 994 (N.D. Cal. 2007).

Thus, the *Lucent* and *i4i* cases involve contributory infringement of software in a combinable form, which provide some indication as to whether digital data sets that are at issue here may be considered to contributorily infringe under Section 271(c). The Supreme Court’s decision in *Microsoft* is instructive that software cannot be a “component” under § 271(f) unless it is in a form that can be read by and combined with

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a computer regardless of whether it is “delivered by CD-ROM or some other means capable of interfacing with the computer,” 550 US at 451, but is not dispositive of the meaning of “a material or apparatus” under § 271(c) as it was decided under § 271(f).

In addition, the Commission has previously found contributory infringement with respect to software that meets certain method steps in *Hardware Logic*. Inv. No. 337-TA-383, 1997 WL 665006, ID at *94. The Commission determined not to review the ID and thereby found a violation of Section 337. Notice (Oct. 2, 1997). The involved software was imported both on a CD and via electronic transmission. *Id.* at * 95. However, the issue of whether the software was a “material or apparatus” under Section 271(c) was not raised in that investigation.

In view of the guidance from these courts and these definitions, we affirm the ALJ’s finding of contributory infringement of the Group I claims because electronic transmissions of digital data qualify as “a material or apparatus” within the meaning of 35 U.S.C. § 271(c).⁴⁷

⁴⁷ This conclusion applies to all contributory infringement allegations in this investigation.

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2. Group II Claims (Claims 31 and 32 of the ‘325 patent⁴⁸; Claims 1 and 4-8 of the ‘863 patent; Claims 1, 3, 7, and 9 of the ‘666 patent; Claims 1, 3, and 5 of the ‘487 patent)

The Group II claims are directed to methods of generating digital data sets. The digital data sets at issue here are generated by CCPK in Pakistan prior to their electronic transmission to the United States. *See* ID at 472-73. Specifically, CCPK provides the initial data set it obtains from CCUS to the CCPK computer platform and manipulates the data set into final and intermediate positions. It is alleged that CCPK’s process of generating final and intermediate data sets in Pakistan practices the Group II claims, and the subsequent transmission of the generated data sets to CCUS constitutes a violation under Section 337(a)(1)(B)(ii). That provision concerns violations related to the importation of articles “made, produced, processed, or mined” using a process covered by a U.S. Patent.

a. The ID

For the ‘325 patent, the ALJ found that CCPK independently practices claims 31 and 32. ID at 512-13, 514-15. As to the ’863 patent, the ALJ found that CCPK practices claim 1. ID at 694-97. The ALJ further found that CCPK practices dependent claims 4-8 in Pakistan by producing the digital data sets. ID at 709, 714, 722, 725, 729. As to the ‘666 patent, the ALJ found that CCPK practices claims 1, 3, 7, and 9. ID at 655, 659,

⁴⁸ Align includes these claims in both Group II and Group IV. Align includes the claims in Group II because the ALJ found that CCPK independently infringes when it produces the digital data sets abroad and provides them to CCUS. ID at 512-13. The ALJ also found that CCUS provides the data sets to a computer, which would place the claims in Group IV. *Id.* (The ALJ did not make a factual finding that CCPK and CCUS therefore infringe in concert but that appears to be the implication.) As noted in our claim construction section, we understand “provide” to include conveying by electronic transfer. Therefore, these claims can be analyzed with CCUS as the sole infringer when it electronically transfers the data to the computer and also with CCPK as a joint infringer when it electronically transfers the data set to CCUS.

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666, 669. As to the '487 patent, the ALJ found that CCPK practices claims 1, 3, and 5. ID at 607, 609, 612.

The ALJ found the Respondents imported digital data sets that were made in Pakistan using the entire process of the Group II claims. Based on this, he concluded that Respondents violated 19 U.S.C. § 1337(a)(1)(B)(ii). *See* ID at 550, 624, 670, 732. We affirm, adopting the ALJ's analysis finding that the claim limitations are met. We analyze the other requirements of Section 337 as follows.

b. Parties' Arguments

The Respondents have argued that the requirements of Section 337(a)(1)(B)(ii) are not met, *i.e.*, that there is no article that is “made, produced, processed, or mined” within the meaning of the statute as part of their arguments that there is no “article.” Respondents point out that the Federal Circuit used the term “processes” as part of its analysis in *Bayer* that held that a physical product is required under Section 337 or § 271(g). Resps. Add. Sub. at 7.

Align argues that the plain meaning of “processed” must include “data processing on a computer.” Align Add. Sub. at 17. Align reports the following dictionary definitions of the verb “process,” *inter alia*,: “to prepare by or subject to a special process or method” (WEBSTER'S NEW WORLD DICTIONARY (1988)(where the noun “process” means a particular method of doing something, generally involving a number of steps or operations); “to treat or prepare by some particular process, as in manufacturing” (RANDOM HOUSE DICTIONARY (1987) (where the noun “process” means “a systematic series of actions directed to some end”). Align states that none of these definitions is limited to processes that use physical items. *Id.* at 18. Align continues that contemporary

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dictionary definitions and dictionary definitions contemporaneous with the enactment of [the process patent provision of] Section 337(a) in 1940 are similar. *Id.* at 18-19.

Align suggests that “processed” and “process” in subsection (ii) [of Section 337(a)(1)(B)] must be given the same meaning, and must be coextensive with any patented process. *Id.* at 20. Align argues that the close proximity of these terms in the statute provides a strong indication that they should be accorded the same meaning, and the meaning of either should inform the other. *Id.* at 20 (citing *Hall v. United States*, 132 S. Ct. 1882, 1891 (2012); *Brown v. Gardner*, 513 U.S. 115, 118 (1994)). Align concludes that “process” refers to any process that is claimed in a valid and enforceable U.S. patent, and that “processed” refers to the use of any patented process. *Id.* at 20.

Align further reasons that because “articles” may be digital data, subsection (ii) must contemplate processes that create digital data. *Id.* at 21. Align argues that a statutory term must be read in its context and with a view to its place in the overall statutory scheme. *Id.* at 21 (citing *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 644 (Fed. Cir. 2011) (citing *Davis v. Mich. Dep’t of Treasury*, 489 U.S. 803, 809 (1989)); *King v. St. Vincent’s Hosp.*, 502 U.S. 215, 221 (1991)); see also *id.* at 22 (citing cases for the proposition that terms in related provisions have similar interpretations).

Align asserts that the term “process” as used in Title 35 includes data processing, and that is informative here. *Id.* at 22. Align argues that the Supreme Court in *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972), interpreted the term “process,” which is defined in 35 U.S.C. § 100(b), to mean “a mode of treatment of certain materials to produce a given result. It is an act or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” *Id.* at 23 (quoting *Gottschalk*

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(quoting *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).⁴⁹ Align urges that data processing satisfies this definition because it is “an act” or “a series of acts.” *Id.* Align argues that “process” in § 271(c) and (g) also includes data processing. *Id.* at 24-24. With respect to § 271(g), Align relies on *CNET*, 528 F. Supp.2d at 993, which distinguishes *Bayer*, and explains that a data file is a product of a patented process where practicing each step of the method leads directly to the creation of the [data file]. *Id.* at 25.

Align argues that precedent confirms a broad reading of subsection (ii). *Id.* at 26. Align remarks that the Federal Circuit has referred to Section 337 as conferring rights on “process patent holders” and not on a subset thereof. *Id.* (citing *Kinik Co. v. ITC*, 362 F.3d 1359, 1362-63 (2004); *Zoltek Corp. v. United States*, 672 F.3d 1309, 1322 (Fed. Cir. 2012)). Align relates that the Commission’s references to the process patent provision are in accord. *Id.* at 26 (citing *Certain Methods of Making Carbonated Candy Products*, Inv. No. 337-TA-292, Notice of Termination (March 8, 1990); *Certain Plastic Encapsulated Integrated Circuits*, Inv. No. 337-TA-315, 1992 ITC LEXIS 738, n.138 (Nov. 1992)).

Align asserts that the legislative history of Section 337 dictates that “processed” include the practice of all types of patented process claims, although Align maintains that there is no need to consult the legislative history because of the plain meaning of the term. *Id.* at 27 (*Darby v. Cisneros*, 509 U.S. 137, 147 (1993)). Align relates how the process patent amendment to Section 337 was intended to overrule the CCPA’s decision

⁴⁹ We note that the Court in *Gottschalk* ultimately decided not to resolve whether computer programs were patentable, instead leaving the question to Congress. 409 U.S. at 72-73.

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in *In re Amtorg*, 75 F.2d 826 (CCPA 1935), and how a Congressional proponent of the legislation explained that it would include “all of the products and articles and the importation of articles produced on which there is a patent.” 86 Cong. Rec. H3783 (daily ed. Apr. 1, 1940) (statement of Rep. Wolcott). *Id.* at 29. Align argues that the legislative language was directed to the practice of any process covered by a valid and enforceable U.S. patent, and was not meant to otherwise limit the scope of the provision. *Id.* at 30.

The IA submits that the term “processed” in Section 337(a)(1)(B)(ii) includes data processing by a computer. IA Add. Sub. at 9. The IA argues that neither the plain language nor the legislative history of the statute supports limiting the term “processed” to any specific type of processing, much less excluding data processed by a computer. *Id.*

The IA further argues that the plain language of the statute distinguishes articles that are “processed” from three other types of articles (i.e., articles that are “made,” articles that are “produced,” and articles that are “mined.”) *Id.* The IA argues that the plain and ordinary meaning of “processed” includes “data processing,” and that a claim for a process may include data processing by a computer. *Id.*

The IA asserts that the legislative history also supports interpreting the term processed in this manner, and that nothing in the legislative history supports a limiting construction. *Id.* at 10 (citing *Amgen v. ITC*, 902 F.2d 1532 (Fed. Cir. 1990)).

The IA agrees with Complainant that “processed” in Section 337(a)(1)(B)(ii) includes data processing in view of *Gottshalk v. Benson*, 409 U.S. 63, 70 (1972), discussing the term “process” in the patent context, and *Zoltek Corp. v. United States*, 672 F.3d 1309, 1322 (Fed. Cir. 2012), discussing the process patent provision of Section 337. IA Add. Sub. Reply at 8. The IA asserts that Katz’s reliance on *Bayer* and *NTP* for

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the meaning of “processed” in Section 337 is misplaced because those cases interpret § 271(g) rather than Section 337. *Id.* at 8-9.

Mr. Katz argues that the term “processed” in Section 337(a)(1)(B)(ii) does not include data processing by a computer. *Id.* at 15. Mr. Katz reasons that “processed” cannot include data processing by a computer where data is the only product because data, information, and electronic transmissions do not qualify as articles under *Bayer* and *NTP*. *Id.* at 16. Mr. Katz argues that the court in *Bayer* held that § 271(g) was “concerned solely with physical goods that had undergone manufacture” and “for a product to have been ‘made by a process patented in the United States’ it must have been a physical article that was ‘manufactured’ and that the production of information is not covered.” *Id.* at 16 (quoting *Bayer*, 340 F.3d at 1373; also citing *NTP*, 418 F.3d at 1323-24).

c. Analysis

Section 337(a)(1)(B)(ii) provides as follows:

(a) Unlawful activities; covered industries; definitions

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

...

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that--

...

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337.

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We assess whether data processing results in something “processed” within the meaning of the statute.

The four statutory terms in the list of Section 337(a)(1)(B)(ii), “made, produced, processed, or mined,” represent four different kinds of methods by which goods are created. “Made” is the past participle of “to make” which means “to produce by a combination of parts, or by giving a certain form to a portion of matter; to construct, frame, fashion, bring into existence.”⁵⁰ SHORTER OXFORD ENGLISH DICTIONARY (1933). Something that is “made” thus has the meaning of having been assembled or shaped. “Produced” is the past participle of “to produce” meaning “to compose or bring out (a work of literature); to work up from raw material (material objects).” *Id.* Something that is “produced” is therefore composed or worked. “Processed,” the term in question, is the past participle of “to process” which means “2. to treat by a special process; e.g., to reproduce (a drawing, etc.) by a mechanical or photographic process.” *Id.* The noun form of “process,” in turn, means “6. A continuous and regular action or succession of actions taking place or carried out in a definite manner. . . b. A particular method of operation in any manufacture. . . “ *Id.*⁵¹⁵² These definitions support the conclusion that

⁵⁰ The Federal Circuit in *Bayer* found “made” in § 271(g) to mean “manufactured.” *See Bayer*, 340 F.3d at 1372.

⁵¹ Other contemporaneous dictionaries are in accord. *See* WEBSTER’S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE (2d. ed. 1937) (“2.To subject to some special process or treatment. . . b. To subject (esp. raw material) to a process of manufacture, development, preparation for the market, etc.; to convert into marketable form . . . c. To make usable, marketable, or the like . . . d. To produce or copy by photomechanical methods; to develop, fix, wash, and dry, or otherwise treat”); FUNK & WAGNALLS NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE (1938) (“2.To produce, as illustrations, by a process, especially by photoengraving: used chiefly in the past participle. 3. To treat by a process; specif. to heat, by steam or otherwise, so as to cook or sterilize”).

⁵² Modern, contemporary definitions are in accord. In fact, the Sixth Edition (2007) of the SHORTER OXFORD ENGLISH DICTIONARY has an example relating to data as a specific case of the generic definition: “Subject to or treat by a process or in a processor; spec. (a) reproduce . . . (b) preserve . . . (c) operate on (data) using a computer; (d) puree or liquidize (food) in a food processor....”

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“processed” is the result of treatment or change through a fixed series of actions.

“Mined” refers to extraction from the earth. *Id.*

Thus, the term “processed” refers to something that has been subjected to a treatment or change according to a series of actions, in contradistinction to “made” which generally refers to something assembled from parts and in contradistinction to “produced” which generally refers to something that is “composed” (if it is a literary composition) or “worked” (if it is a material object). These are all ways that something may be the result of a patented process. Thus it appears that by using the phrase “made, produced, processed, or mined under, or by means of a process covered by the claims of a valid and enforceable United States patent,” Congress was trying to comprehensively cover all ways in which a method patent can be infringed.

The legislative history is consistent with this understanding of the statute. Section 337(a)(1)(B)(ii) is the reenactment of former Section 337a. Congress explicitly gave the Commission this jurisdiction in 1940 to overturn the CCPA’s decision in *In re Amtorg*, 75 F.2d 826 (CCPA 1935), where the Court held that the importation of a phosphate rock mined abroad by a process that was patented in the United States did not constitute an unfair trade practice. The legislative report states that “Since the Amtorg decision owners of American process patents are helpless to prevent the infringement abroad of their patent rights. This bill will give to them the same rights which the owners of product patents have.” S. Rep. 76-1903 at 4 (1940) (no emphasis in original). Moreover, the language of the amendment and this legislative history indicate that the legislation was not limited to the mining of phosphate rock at issue in *Amtorg*, but rather was intended to cover the full range of activity that may be covered by a patented process - -

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“made, produced, processed, [and] mined.” This is in keeping with prior Commission cases under the Tariff Act of 1922 and 1930.⁵³ Indeed, one Congressman explained that Section 337a would include “all of the products and articles and the importation of articles produced on which there is a patent.” 86 Cong. Rec. H3783 (daily ed. Apr. 1, 1940) (statement of Rep. Wolcott). *Id.* at 29.

Commission cases are in accord with the understanding that “processed” means treated. For example, in *Sucralose*, without differentiating between “made, produced,

⁵³ Section 337a was intended to overrule *In re Amtorg*, 75 F.2d 826, 22 CCPA 558 (1935), and to reinstate two prior CCPA decisions, *Frischer & Co. v. Bakelite Corporation*, 39 F.2d 247 (CCPA 1930) and *Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934).

In *Synthetic Phenolic Resin, Form C, and Articles Made Wholly or in Part Thereof* the Commission, under the Tariff Act of 1922, found unfair methods of competition in the importation of synthetic phenolic resin, Form C, and articles made wholly or in part thereof made abroad using patented processes. U.S. Tariff Commission, Report No. 3, at 15 (1930). One of the patents covered a method for making synthetic phenolic resin, Form C, and another covered a method of fusing synthetic phenolic resin material, Form C, together including material of different colors. In each case, the direct result of the patented process was a material which could then be used to make various articles, such as the imported products. The Commission recommended that the President issue an exclusion order, based in part on the recited process claims. The Court of Customs and Patent Appeals subsequently affirmed the Commission. *Frischer & Co. v. Bakelite Corporation*, 39 F.2d 247 (CCPA 1930), cert. denied sub nom. *Frischer & Co. v. Tariff Commission & Bakelite Corporation*, 282 U.S. 852 (1930).

In *Oxides of Iron Suitable for Pigment Purposes*, Inv. No.337-4 (Tariff Commission 1934)), the Commission, under the original Section 337 of the Tariff Act of 1930, found unfair methods of competition in the importation of iron oxide pigment made from iron ore using patented processes. The Commission recommended issuance of an exclusion order covering the subject imports: a yellow pigment directly produced by the patented process and a red pigment which was a dehydrated form of the yellow pigment. The Court of Customs and Patent Appeals subsequently affirmed the Commission in *In re Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934).

The Commission followed *Iron Oxides* in *Phosphate Rock*, Inv. No. 337-3. Tariff Commission 17th Annual Report at 41 (1933) and 18th Annual Report at 41 (1934). In that investigation, the Commission found unfair methods of competition based on the importation of phosphate rock or apatite which had been processed (concentrated) by a method covered by the claims of two patents. The imported phosphate rock appears to have been the direct product of the patented process. The Court of Customs and Patent Appeals subsequently reversed the Commission’s determination in *Phosphate Rock* in *In re Amtorg*, 75 F.2d 826, 22 CCPA 558 (1935), thereby also overruling *Northern Pigment* and *Frischer*

After conducting hearings on the impact of *In re Amtorg* in 1938, Congress passed former section 337a (former 19 U.S.C. § 1337a) to overrule that decision, providing:

The importation for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims of any unexpired valid United States letters patent, shall have the same status for purposes of section 1337 of this title as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

54 Stat. 724 (July 2, 1940). This statute was intended to overrule the CCPA’s decision in *In re Amtorg*.

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[or] processed,” the Commission found that the chemical treatment or transformation of sucrose to sucralose by the substitution of chlorine atoms for hydroxyl groups satisfied the requirements of Section 337(a)(1)(B)(ii). Similarly, data processing can infringe a method claim in the United States under 35 U.S.C. § 271(a). *See, e.g., SiRF Technology, Inc. v. ITC*, 601 F.3d 1319, 1329 (Fed. Cir. 2010) (a method of receiving global positioning system (GPS) satellite signals). Further, a claim for a process may include data processing by a computer where the claim is not directed to a purely abstract idea. *See Bilski v. Kappos*, 130 S. Ct. 3218, 3228-29, 3231 (2010) (discussing business method patents). Accordingly, the Commission agrees with Align and the IA that the plain meaning of “processed” includes data processing on a computer. This is the plain meaning in modern parlance, and is consistent with the historical meaning of “process” as a mode of treatment, as explained below.

As we explained in detail above, the *Bayer* case, relied on by Respondents, interpreted the meaning of 35 U.S.C. § 271(g). The meaning of Section 337 was not directly before the Court in *Bayer*. To the extent it commented on Section 337(a)(1)(B)(ii), it addressed the term “made” which appears in § 271(g). Consistent with this definition, the Court in *Bayer* found “made” in § 271(g) to mean “manufactured.” It did not address the meaning of “processed” in Section 337. *Bayer*, 340 F.3d at 1372. As *Bayer* states, the language of Section 337 indicates that it has a broader scope than § 271(g). *Id.* at 1374 n.9. *Bayer*, in construing the term “made,” concluded that information in that case was not “made.” *Id.* at 1371. However, while § 271(g) may be limited to products that are “made,” Section 337 may be broader in scope because it also covers articles that are “processed” and “mined” (and perhaps also

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“produced” depending on the sense of the word). Further, even to the extent that the process patent jurisdiction of Section 337 is similar to that of § 271(g), the obtaining of the information in *Bayer* is different than the “process[ing]” of the digital data sets representative of teeth here. In *Bayer*, the information was obtained by applying substances to cell lines in order to determine whether the agent is an inhibitor or an activator. *Id.* at 1369. That was simple information because the agent was either an inhibitor or an activator. However, here the digital data sets are more complex, are directly representative of teeth, and are “processed” or treated through a series of interpolations, in a manner analogous to physical manipulation of a mold of teeth. Indeed, Respondents have argued in defense to violation that the claimed processes are anticipated or rendered obvious by physical analogs from the 1940s. *See, e.g.,* Resps. Sub. at 12. While we do not find that the prior art taught the same interpolation technique, we find that the art of processing of the digital data is analogous to the art of processing of plaster casts of teeth which had been physically manipulated since at least the 1940’s in the treatment of patients. *See* U.S. Patent No. 2,467,432. The digital data set of teeth is treated or manipulated in the same manner as a plaster cast of teeth.

We therefore conclude that digital data are “articles” that are “processed” within the meaning of Section 337(a)(1)(B)(ii). Because CCPK practices the method of the Group II claims, CCUS and CCPK satisfy the elements of Section 337(a)(1)(B)(ii) in the sale for importation, importation, and sale after importation of the subject digital data sets and treatment plans.

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3. Group III Claims (Claims 7-9 of the '487 patent)

The Group III claims are directed to treatment plans (*i.e.*, a series of digital data sets) on a storage medium.

a. Direct Infringement

i. The ID

The ALJ found that the intermediate digital data sets produced by CCPK meet each and every limitation of claim 7 when they are stored on CCPK or CCUS computers, servers, or other forms of “computer readable storage media.” ID at 616. However, the ALJ proceeded to analyse the activity with respect to the requirements of Section 337: “This does not, however, end the inquiry. The Commission has explained that “section 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to ‘articles that -- infringe.’ *We also interpret the phrase ‘articles that – infringe’ to reference the status of the articles at the time of importation.* Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337.” ID at 619 (quoting *Certain Electronic Devices With Image Processing Systems, Components Thereof, And Associated Software*, Inv. No. 337-TA-724, Comm’n Op. (Dec. 21, 2011) (emphasis in ID)).” The ALJ found that at the time of importation, the accused digital data sets do not meet each and every limitation of claim 1 and thus do not directly infringe that claim because they are electronically transmitted and thus do not reside on “storage media,” as required by the claims, at the time of importation. ID at 619. Because the ALJ found no direct infringement of claim 7 at the time of importation, he found no direct infringement of dependent claims 8 and 9. ID at 620, 622.

ii. Parties’ Arguments

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Align argues that Respondents waived their noninfringement arguments because these arguments did not appear in their pre-hearing brief, but appeared for the first time in their post-hearing brief. Align Pet. at 7. Align argues that the ALJ therefore abused his discretion in finding no infringement. *Id.*

Align also argues that there is a sale for importation, *i.e.*, CCPK sells its data sets to CCUS, and that at the time this sale occurs, the data sets are residing on CCPK's storage medium. *Id.* at 8-9. Align further argues that the act of importation includes the act of putting the electronically transmitted data on a storage medium. *Id.* at 9. Align further asserts that the policy underlying the 724 decision is not implicated here because this is a not situation where, as there, an imported article arrives in a non-infringing state and is later transformed into an infringing article by some separate post-importation step such that it would not be fair to say that the product infringes "as imported." *Id.* at 10.

The Respondents respond that neither the workstation nor the computer is imported. Resps. Resp. at 3. The Respondents argue that it does not matter whether there is a sale for importation or sale after importation because the law, as embodied by the 724 decision, requires infringement at the time of importation. *Id.* at 4.

The IA argues that Respondents waived their non-infringement arguments because they were not included in the pre-hearing brief. IA Resp. at 4. However, to the extent that the arguments were not waived before the ALJ, the IA agrees with Respondents. *Id.* at 4-6.

iii. Analysis

The Commission affirms and adopts the ALJ's finding that there is no direct infringement of the Group III claims at the time of importation, as set forth in the ID at

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617-623. In raising certain non-infringement arguments for the first time in their post-hearing brief, Respondents did fail to comply with ALJ's Ground Rule 8.2, which requires that all arguments appear in the pre-hearing brief. Although the ALJ would have been entitled to find waiver based thereon, his decision not to do so is generally reviewed for abuse of discretion and for whether it is contrary to law. *Cf.* 19 C.F.R. §210.43 (standard for petition for review). The ALJ in his management of the case considers the interests of justice, prejudice to the parties, and whether a finding of violation of Section 337 would be contrary to law. Here, the ALJ chose not to find waiver of the *Electronic Devices* (724) argument (*i.e.*, that there is no direct infringement at the time of importation) and we find no abuse of discretion in his finding. See ID at 619 (finding elements not met). Furthermore, while Align argues prejudice, there is no reason why Align could not have asserted indirect infringement of the Group III claims in the complaint and before the ALJ, which Align failed to do.

Therefore, we affirm the ALJ's finding of no direct infringement of the Group III claims.

b. Contributory Infringement

The ALJ did not address the issue of contributory infringement of the Group III claims. See ID at 616-19; Align Pet. at 11.

Align acknowledges that it did not argue contributory infringement before the ALJ. In its petition for review, Align raises contributory infringement for the first time and asks to be excused from waiver: Align argues that "Respondents' failure to timely raise the 'computer-readable storage media' argument prejudiced Align; if Align had known that Respondents disputed the 'computer readable storage media' limitation,

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Align would have developed and asserted a contributory infringement theory.” Align Pet. at 11.

Respondents counter that Align never alleged contributory infringement and thereby waived the argument. Resps. Resp. at 4. Respondents argue that even if Align did not waive the argument, “the ALJ’s findings on induced infringement are fatal to any finding of contributory infringement.” *Id.* at 5.⁵⁴

Align had full opportunity to assert indirect infringement of the Group III claims in the complaint and before the ALJ. The Commission has not in the past allowed parties to assert new theories of infringement after the taking of evidence, when the ALJ has certified the record and rendered a final initial determination on violation. *See* 19 C.F.R. § 210.14(c) (amendment of pleadings may be granted when theory asserted during the taking of evidence). Even in the 724 investigation when the Commission found that there was no importation of an article that directly infringes, the Commission did not allow the parties to assert new theories of indirect infringement. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Pub. 4374 (February 2013). The Commission has therefore determined to consider Align’s new theory of indirect infringement of the Group III claims to be waived.

⁵⁴ The ALJ found that there was no induced infringement with respect to claims 1 and 3 of the ‘880 patent because Align failed to show that CCPK possessed the requirement intent. ID at 589. Claim 1 of the ‘880 patent is in Group I and claim 3 of the ‘880 patent is in Groups I and IV. Respondents argue elsewhere that there is the same intent requirement for contributory infringement as for induced infringement, an argument we reject. Resps. Pet. at 56 (“The intent required to show contributory infringement is at least as high, if not higher, than the standard for induced infringement.”) (citing *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060, 2067-68 (2011)). Align did not petition for review with respect to inducement, nor did it raise the issue in either of its briefs on review.

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4. Group IV Claims (Claims 1- 3, 11, 13-14, 21, 30-35, 38-39 of the '325 patent; Claims 1 and 3 of the '880 patent; Claim 1 of the '511 patent; and Claims 1, 2, 38-39, 41, and 62 of the '874 patent)

The Group IV claims are directed to methods of producing dental appliances starting with the images of the patient's teeth which are exported to Pakistan, manipulated abroad, and then imported. The final digital data sets are imported and the dental appliances are constructed by CCUS in the United States after importation.

a. Direct Infringement (Combining Foreign and Domestic Conduct and the Applicability of Section 271(g))

i. The ID

The ALJ found that CCPK and CCUS act in concert to practice the Group IV claims (although the ALJ found that claims 21 and 30 of the '325 patent and claim 1 of the '880 patent are also practiced independently by CCUS and claims 31 and 32 of the '325 patent are also practiced independently by CCPK).⁵⁵

As to the '325 patent, the ALJ found that CCPK and CCUS jointly practice every limitation of claims 1, 11, 21, 30, 33, 34, 35, and 38. ID at 477, 490-91, 503, 505, 517, 518, 523, 529.⁵⁶ As noted above, the ALJ found that CCUS also independently practices

⁵⁵ Claims 21 and 30 of the '325 patent and claim 1 of the '880 patent fall in Group IV if practiced by CCUS and CCPK together and fall in Group I if practiced independently by CCUS. Similarly, claims 31 and 32 of the '325 patent fall in Group IV if practiced by CCUS and CCPK together and fall in Group II if practiced independently by CCPK.

⁵⁶ The ALJ stated that CCUS practices dependent claim 2, ID at 478, but since he found that claim 1, from which claim 2 depends, was practiced by the concerted efforts of CCUS and CCPK, it appears that he meant to state that CCUS practices the additional limitation of claim 2 and that CCUS and CCPK together practice claim 2. Similarly, the ALJ found that CCUS practices dependent claim 39, where the practice should be joint. ID at 530. The ALJ appears to have made an analogous misstatement for certain claims with respect to CCPK, finding that CCPK practices dependent claim 3. ID at 484. It appears that he meant to state that CCPK practices the additional limitation of claim 3 but that CCUS and CCPK together practice claim 3. Similarly, the ALJ found that claim 13 is "substantively identical" to claim 3, ID at 492, and that CCPK practices claim 14, 31, 32. ID at 496, 513, 515. It appears that he meant to state that claim 31 is also jointly practiced and that claims 14 and 32 are jointly practiced based on the practice of the independent claims.

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claims 21 and 30 of the '325 patent. ID at 502-03, 504-05. As to the '880 patent, the ALJ found that CCPK and CCUS practice every limitation of claims 1 and 3. ID at 571-72, 577. The ALJ found that CCUS also independently practices claim 1 of the '880 patent. ID at 571. As to the '511 patent, the ALJ found that CCPK and CCUS practice every limitation of claim 1. ID at 638. As to the '874 patent, the ALJ found that CCPK and CCUS practice every limitation of claims 1, 2, 38, 39, 41, and 62. ID at 747, 748, 750-01, 753, 755-56, 758. The ALJ found that CCUS also independently practices claim 62 of the '874 patent. ID at 758.⁵⁷

With respect to the Group IV claims, the ALJ found a violation under 19 U.S.C. § 1337(a)(1)(B)(ii), *see* ID at 550-51, 592-93, 639, 758-59. He also found a violation under 35 U.S.C. § 271(g), apparently holding that infringement under 35 U.S.C. § 271(g) can serve as a predicate for a violation under 19 U.S.C. § 1337(a)(1)(B)(i), notwithstanding *Kinik v. ITC*, 362 F.3d 1359, 1363 (Fed. Cir. 2004) (defenses of § 271(g) do not apply to Section 337(a)(1)(B)(ii)). *See* ID at 432. For those claims which were jointly infringed (by CCPK's acts abroad and CCUS's acts in the United States), the ALJ held that foreign and domestic conduct may be combined by using 35 U.S.C. § 271(g) as a basis for direct infringement (with some claimed method steps performed prior to importation) and that this direct infringement could serve as a predicate for contributory infringement.

The ALJ suggested that infringement under section 271 of the Patent Act is limited to acts within the United States but that Section 337 is different because “[t]he purpose of section 337 from its inception was to provide relief to United States industry

⁵⁷ The ALJ found that CCPK practices the additional elements of dependent claims 2, 28, 39, and 41. Thus, by implication, CCUS and CCPK jointly practice these claims because they jointly practice claim 1 from which they depend.

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from unfair acts, including infringement of United States patents by goods manufactured abroad.” ID at 429-430 (citing *Lannom Mfg. Co., Inc. v. U.S.I.T.C.*, 799 F.2d 1572, 1580 (Fed. Cir. 1986)). The ALJ stated that: “The Commission made clear, however, that a violation of section 337 does not depend upon a violation of section 271, ...” *Id.* at 430 (citing *Certain Hardware Logic Emulation Systems*, Inv. No. 337-TA-383, Comm’n Op. (March 1998)). The ALJ rejected the IA’s argument that infringement must occur pursuant to 35 U.S.C. § 271(a) and cannot be premised on 35 U.S.C. § 271(g). *Id.* The ALJ found that “*NTP v. RIM* is not controlling on this point.” *Id.* The ALJ stated that “I reaffirm my finding that the parties’ arguments regarding the territorial limitations found in *NTP v. RIM* to apply to 35 U.S.C. § 271 are irrelevant to whether or not Respondents violate 19 U.S.C. § 1337(a)(1)(B)(i) or (ii).” *Id.* at 431.

The ALJ found that there is no requirement that the direct infringement occur prior to importation, and articles that contributorily infringe prior to importation may be the subject of Commission remedial orders. *Id.* The ALJ stated that “infringe” also includes 35 U.S.C. § 271(g). ID at 432-34. The ALJ held that while the defenses of 35 U.S.C. § 271(g) do not apply to investigations under Section 337(a)(1)(B)(ii), 35 U.S.C. § 271(g) may still as a basis for violation under Section 337(a)(1)(B)(i). ID at 434.

ii. Parties’ Arguments

The Respondents argue that the ALJ improperly combined foreign and domestic conduct to find infringement of method claims. Resp. Pet. at 11.⁵⁸ The Respondents

⁵⁸ The Respondents argue (in a footnote) that it does not appear that the ALJ relied on 271(g) to find infringement, and that 271(g) cannot be a basis for a finding of infringement under Section 337. Resp. Pet. at 10 n.1 (citing *Kinik Co. v. Int’l Trade Comm’n*, 362 F.3d 1359 (Fed. Cir. 2004) (holding that the defenses under §271(g) do not apply in Section 337 proceedings)). However, the ALJ held that § 271(g) was a basis for a finding of infringement (which Align argues allows the ALJ to combine foreign and

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quote the Federal Circuit in *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005):

We therefore hold that a process cannot be used ‘within’ the United States as required by section 271(a) unless each of the steps is performed within this country.

Id. Respondents further quote *Research in Motion* that, “if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability . . .” *Id.* (citing *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 836 (2002)). Respondents therefore conclude that there can be no infringement under § 271(a) if *any part* of a step is performed outside of the U.S. *Id.*

Respondents state that there would be no infringement finding absent the ALJ’s errors of law. *Id.* (citing ID at 477, 491, 503, 505, 518, 527, 571, 577 and 747). The Respondents argue that even in the limited instances in which the ALJ found that one Respondent practiced all claim limitations, he still relied on combined conduct to find infringement. For example, Respondents acknowledge that the ALJ found that CCUS performed all of the limitations of two independent claims—claim 21 of the ‘325 patent and claim 1 of the ‘880 patent—but argue that the ALJ expressly noted that CCUS and CCPK “act in concert to practice claim 21 of the ‘325 patent.” *Id.* (discussing ID at 503; 566-71).

domestic conduct), ID at 434. Respondents may be basing their statement on the fact that the ALJ also held that contributory infringement may occur through the combination of foreign and domestic conduct. *See* ID at 434 and n.31. The Respondents further assert that, if 271(g) did apply in Section 337 investigations, it would not apply in a case of “divided infringement” where part of the process is performed in the United States. *Id.* (citing *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 813 F.Supp.2d 602, 613-14 (D. Del. 2011)).

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Conversely, the Respondents acknowledge that the ALJ found that CCPK itself practices each claim limitation of claim 31 of the '325 patent, claim 1 of the '863 patent, claim 1 of the 487 patent, and claims 1 and 7 of the '666 patent, but argue that the ALJ improperly combined CCPK's conduct with that of CCUS. Respondents state that throughout his ID, the ALJ consistently found that CCUS performed the step of providing data sets when it sent the initial data sets to CCPK or otherwise provided the initial scan to it, discussing ID at 475, 498-90, 530, but the Respondents assert that Align argued that when the data set is received in both the United States and Pakistan, Align alleges a joint process that does not occur entirely within Pakistan or the United States.

The Respondents argue that the ALJ erred when he impermissibly combined the Respondents' independent conduct to find "concerted" infringement. The Respondents refer to *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (*en banc*), and argue that liability for induced infringement requires direct infringement by a single actor.

The Respondents state that the ALJ combined the Respondents' acts to find direct infringement, citing the Respondents' "concerted efforts" or acts "in concert" as support for his infringement conclusions. *See* Resp. Pet. at 9 (referring to ID at 477, 491, 503, 571, and 747 for "concerted efforts" findings and ID at 505, 518, 522, 527 and 577 for "in concert" findings. The Respondents further argue that the ALJ accepted and approved the testimony of Align's lone infringement expert, Andrew Beers, who likewise relied on combined acts to opine about infringement. *Id.* (citing Tr. 541:14 to 555:9 for his testimony about the independent claims of the '325, '880, '487, '863 and '666 patents and 583:21 to 586:13 for his testimony about the '511 and '874 patents; ID at 434-35).

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Align argues that the ALJ did not “improperly combine foreign and domestic conduct” to find infringement. Align notes that Respondents cite *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) for the proposition that, to find infringement of a process claim under 35 U.S.C. § 271(a), all of the claimed steps must be performed in the United States. Align Resp. to Resps. at 7. However, Align counters that this proposition does not apply to other parts of 35 U.S.C. § 271 such as § 271(g). *Id.* at 8.

Align states that the ITC has instructed that “infringe” includes “all forms of infringement,” which would include § 271(g) claims. *Id.* (citing *Certain GPS Chips, Assoc. Software and Sys. and Prods. Containing Same*, Inv. No. 337-TA-596, 2010 ITC LEXIS 582, at *81 (Mar. 2010)). Align argues that while it is true that the court has found that the defenses of § 271(g) do not apply in the context of a violation under 337(a)(1)(B)(ii), this finding is inapplicable to Align’s present assertions. *Id.* (discussing ID at 432–34). Align argues that both 35 U.S.C. § 271(a) and 35 U.S.C. § 271(g) infringement is “direct infringement” for purposes of Section 337(a)(1)(B)(i). Align Resp. to IA at 5-6. Align states the Federal Circuit has repeatedly confirmed that infringement under 35 U.S.C. 271(g) is a form of direct infringement. *Id.* at 5. Align cites district court precedent for the proposition that infringement under § 271(g) may serve as a basis for indirect infringement under 271(b) or (c). *Id.*

Align argues that the IA has conceded that the holding of *Kinik* is limited to the [non]application of the § 271(g) defenses to Title 19. Align Resps. to IA Pet. at 9.

Align further argues that the Federal Circuit recently confirmed in *Akamai* that the process steps of the asserted claims do not have to be performed by a single entity for §

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271(g) infringement. *Id.* (citing *Akamai*, 692 F.3d at 1306). Align asserts that no one advances a theory involving multi-actor performance of method steps under 35 U.S.C. § 271(a). *Id.* at 4.

With respect to the Group IV claims, Align argues that Respondents violate 337(a)(1)(B)(i) when they import, sell for importation, or sell after importation, digital data sets made by CCPK according to the steps of various claims, and CCUS then creates aligners based on the digital data. *Id.* at 5. Align argues that these are the imported digital data sets that contributorily infringe under 35 U.S.C. § 271(c), and the ultimate sale, offer for sale, or use of the manufactured aligners by CCUS is a direct infringement under 35 U.S.C. § 271(g). *Id.* at 5-6. Align argues that Respondents' arguments are again irrelevant, as the asserted basis is § 271(g), not § 271(a).⁵⁹ *Id.*

The IA argues against the ALJ's legal conclusion that claims under 35 U.S.C. § 271(g) are cognizable as direct infringement before the Commission, and any infringement determinations based thereon. The IA notes that in *Kinik*, the Federal Circuit "affirm[ed] the Commission's ruling that the defenses established in § 271(g) are not available in § 1337(a)(1)(B)(ii) actions." 362 F.3d at 1363. The IA submits that *Kinik's* holding regarding section 271(g)'s defenses indicates that section 271(g) infringement claims are also not cognizable as direct infringement before the Commission. Furthermore, the IA argues that Congress enacted 35 U.S.C. § 271(g)'s process patent provisions at the same time, and within the same act, in which it incorporated the Commission's separate process patent authority into 19 U.S.C. 1337(a)(1)(B)(ii), and argues that had Congress intended to incorporate the process patent

⁵⁹ See also Align's Response to Staff's *Petition*, Issues A and B.

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standards of 35 U.S.C. § 271(g) into the Commission’s authority regarding process patents, it could have done so explicitly. *Id.* (citing *See Abrasive Products*, Inv. 337-TA-449, Comm’n Op. Affirming ALJ Order No. 40 at 3); *Amgen, Inc. v. Int’l Trade Comm’n*, 565 F.3d 846, 851 (Fed. Cir. 2009) (“In *Kinik* . . . this court explained that § 271(g) provided a new right and remedy in the district court, but held that the Tariff Remedy of exclusion based on practice of a patented process was unchanged.”). The IA states that OUII is not aware of any post-*Kinik* Commission opinions that have adopted an infringement theory based on § 271(g). The IA states that in *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, the ALJ’s Final ID discussed the legal standards for infringement, referring in passing to §§ 271(a) and 271(g), ID at 93–94 (Feb. 17, 2006), but the Commission re-characterized the infringement determination as one that should be assessed pursuant to Section 337(a)(1)(B)(ii). *Rubber Antidegradants*, Inv. 337-TA-533, Comm’n Op. at 2, 9 n.2 (Jul. 24, 2006), vacated on other grounds, 511 F.3d 1132 (Fed. Cir. 2007).⁶⁰

The IA states that CCUS and CCPK are not independent entities, because, according to the IA, the overwhelming evidence does not support ClearCorrect’s contention. IA Resp. at 16. Nevertheless, the IA agrees with the Respondents that the ALJ erred in his finding to the extent that the ID combined foreign and domestic conduct to find infringement of method claims under either 35 U.S.C. § 271(a) or § 271(g). IA Resp. at 16 n.3 (citing IA Pet. 4–10).

⁶⁰ The IA notes that, according to the Complainant, infringement of the following claims was based on 35 U.S.C. § 271(g): claims 1, 2, 3, 11, 13, 14, 30, 33, 34, 35, 38, and 39 of U.S. Patent No. 6,217,325; claim 3 of U.S. Patent No. 6,722,880; claim 1 of U.S. Patent No. 6,471,511; and claims 1, 2, 38, 39, 41, and 62 of U.S. Patent No. 7,134,874.

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iii. Analysis

The ALJ found a violation with respect to the Group IV claims under Section 337(a)(1)(B)(ii) and Align argues that the ALJ also found violation under 35 U.S.C. § 271(g). The pertinent questions are whether there is violation under Section 337(a)(1)(B)(ii), whether 35 U.S.C. § 271(g) is applicable to Section 337 as an alternative theory propounded by Align, and if so, whether § 271(g) would cover the Group IV claims.

First, we find that the ALJ erred in finding a violation of Section 337(a)(1)(B)(ii) with respect to the Group IV claims because the imported digital data sets are not the end product of the Group IV claims, which disclose methods for fabricating dental appliances. Therefore, because the Group IV claims are directed to fabricating dental appliances, the last claim step is not performed prior to importation as required by Section 337(a)(1)(B)(ii).

Second, we find that Align is mistaken when it argues that infringement under 35 U.S.C. § 271(g) can form the basis for a finding of violation of Section 337(a)(1)(B)(i). Align argues that 35 U.S.C. § 271(g) is included in the term “infringe” in Section 337(a)(1)(B)(i). It is a well-established canon of statutory construction that a specific provision governs over a general provision. *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. —, —, 132 S. Ct. 2065, 2068 (2012) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384, 112 S. Ct. 2031, 119 L.Ed.2d 157 (1992)). The existence of Section 337(a)(1)(B)(ii), which specifically defines violations of Section 337 based on the importation of articles produced by a patented process, persuades us that violations of Section 337 based on process of manufacture

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claims should not be addressed under Section 337(a)(1)(B)(i) read in conjunction with § 271(g). Section 337(a)(1)(B)(ii) is a special provision which governs over the general provision of Section 337(a)(1)(B)(i). Therefore, violation premised on the importation (or sale after importation) of articles produced by a patented process should be analyzed under Section 337(a)(1)(B)(ii) rather than Section 337(a)(1)(B)(i). *See id.*

The Court in *Kinik Co. v. ITC*, explained that the Process Patent Amendments which created Section 271(g) were not intended to change existing remedies at the Commission. 362 F.3d 1359, 1362-63 (Fed. Cir. 2004) (holding that the statutory defenses to infringement under 35 U.S.C. 271(g) were not available as defenses to Section 337(a)(1)(B)(ii) at the Commission) (“However, § 9006(c) of the Process Patent Amendments Act, *supra*, states the intent to preserve all existing remedies, as elaborated in the Senate Report.”) Indeed, the Federal Circuit in *Kinik* stated that “It was explained [in the legislative history] that § 271(g) was intended to provide ‘patent owners the new right to sue for damages and seek an injunction in Federal district court.’” 362 F.3d 1359, 1362 (Fed. Cir. 2004) (quoting S. Rep. No. 100–83 at 27 (1987)). Thus, § 271(g) was intended to serve as a supplement in district courts analogous to the practice at the Commission, and the re-enactment of Section 337a as Section 337(a)(1)(B)(ii) was intended to govern practice at the Commission regarding process patents. Further, the Court in *Kinik* did not apply the defenses of § 271(g) to Section 337(a)(1)(B)(ii). If § 271(g) applied, then the defenses would apply. They do not.

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Because § 271(g) does not apply to Section 337, we need not address the indirect infringement allegations regarding Group IV claims.⁶¹ In conclusion, we find no violation with respect to the Group IV claims.

D. Invalidity

The only claims which the Respondents specifically cite for anticipation and obviousness, as exemplary claims to represent the entire ID, are claims 1, 37, and 38 of the '325 patent. Resps. Pet. at 48 n.80 (“The ALJ made this finding throughout the *ID*. For example, he applied this finding in claims 1, 37, & 38 of the '325 Patent.”).⁶² Since Respondents failed to make a specific case for any of the other claims, the Commission has determined that they have waived any similar arguments with respect to those claims.⁶³

⁶¹ Parenthetically, we note that even if § 271(g) applied to the Commission, it is our view that § 271(g) only applies to imported products made abroad by patented processes. We have not been briefed with any case, and we have not found any case, in which the Federal Circuit has applied § 271(g) to conduct that is entirely domestic (*i.e.*, with no importation).

⁶² Claim 37 of the '325 patent was not asserted in this investigation.

⁶³ Although the Respondents do not make separate arguments for each of the asserted claims, the Respondents appear to argue that each of the 40 asserted claims is anticipated or obvious, and adopt, for the purposes of their invalidity analysis, a uniform characterization of the asserted claims as involving a five-step process for making aligners: (1) a digital representation of the patient's existing teeth arrangement is created; (2) the representation is digitally modified to allow each individual tooth to be manipulated; (3) 3D graphics software is used to move the virtual teeth to the desired (final) position; (4) virtual intermediate tooth arrangements are created (by interpolation between the initial and final positions); and (5) physical molds are created to form aligners. Resps. Pet. at 39. We note that some of the claims are directed to digital data sets, but the Respondents argue invalidity in generic terms (*i.e.*, not differentiating the asserted claims), arguing with respect to what they characterize as the patentee's method (above) for manufacturing dental appliances.

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1. Prior art at issue

a. U.S. Patent No. RE35,169 (“Lemchen”)

Lemchen, entitled “Method for Determining Orthodontic Bracket Placement,” discloses a method for determining orthodontic bracket placement on a maloccluded⁶⁴ tooth to correct the malocclusion by repositioning of the tooth to a “finish” position. Lemchen was originally filed on January 24, 1989, and is prior art to all patents-in-suit. Lemchen’s disclosed method includes the steps of: (1) generating digital information which defines the shape and location of the maloccluded tooth in the patient’s jaw, from which digital information a mathematical model of the tooth and jaw is generated; (2) calculating the “finish” position of the maloccluded tooth or teeth from the digitized information, with respect to their positions in the model; (3) calculating the correct placement of a bracket from the digitized information; (4) modifying the bracket in view of the patient’s physical deviations from the statistical averages; and (5) forming an archwire (force-producing attachment) for the brackets. Also, the method may be used on one or more teeth in the same dental arch, as well as for both dental arches with respect to malocclusion between them. CX-945 (Lemchen), Abstract, 2:48-4:16.

Further, the method may generate the digital information in a variety of ways, including electromechanically, using laser scanning, sonic ranging, digital video scanning, or magnetically. *Id.* The method may also use computer-aided design (“CAD”) techniques to generate the mathematical model, and the repositioning may be done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist.

⁶⁴ Malocclusion is faulty contact between upper and lower teeth when the jaw is closed.

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Id. Also, Lemchen specifically refers to Figs. 1 and 3 of U.S. Patent No. 2,467,432 (“Kesling”) as prior art examples, respectively, of a physical embodiment of the mathematical model and a manual step of physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. *Id.* at 3:7-15, 25-40.

b. U.S. Patent No. 2,467,432 (“Kesling”)

Kesling, entitled “Method of Making Orthodontic Appliances and of Positioning Teeth,” discloses a method for providing removable tooth positioning appliances (*i.e.*, aligners) which are adapted to be used to maintain or bring the teeth of the user into a predetermined ideal or desirable position without the necessity for the use of metallic bands, wires, or any other prior art appliance. Kesling was originally filed July 23, 1943, and is prior art to all patents-in-suit. The disclosed method includes the steps of: (1) generating a physical model, *e.g.*, a cast, of the teeth to be repositioned; (2) removing the teeth to be repositioned from the model; (3) resetting the teeth in their desired positions; (4) generating a new model of the repositioned teeth; and (5) using the new model, generating a tray for taking an impression of the repositioned teeth which is used to form the removable tooth positioning appliance to be worn by the user. CX-944 (Kesling), 1:1-8, 2:43-4:70. Fig. 1 of Kesling illustrates a plaster model of an upper and lower jaw and shows the condition of the patient’s teeth prior to the beginning of treatment. *Id.* at Fig. 1, 2:7-9. Fig. 3 illustrates a similar plaster cast and shows the teeth after they have been dissected from the cast, and reset upon the same base to show the ideal position in which they are finally to be positioned. *Id.* at Fig. 3, 2:15-21.

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c. U.S. Patent No. 6,471,511 (“the ’511 patent”)

The ’511 patent, entitled “Defining Tooth-Moving Appliances Computationally,” is asserted by Align in this investigation and discloses a method and corresponding apparatus for segmenting an orthodontic treatment path, *i.e.*, repositioning of trouble teeth to a “finish” position, into clinically appropriate substeps to perform correct repositioning using tooth-moving appliances. The ’511 patent was originally filed June 20, 1997. The disclosed method includes the steps of: (1) acquiring a mold of the patient’s teeth and tissue using a variety of methods including direct contact scanning and imaging that provides information about the structure of the teeth, jaw, gums, and other orthodontically relevant tissue; (2) deriving a digital data set from the mold and the orthodontic information that represents the initial arrangement of the patient’s teeth and other tissues; (3) processing the digital data set to segment extraneous elements, *e.g.*, individual tooth crowns, hidden surfaces, and root structures, from each other; (4) calculating the desired final position of the teeth, *i.e.*, the end result of orthodontic treatment, using a clinical prescription such that the final position and surface geometry of each tooth can be specified; (5) using the beginning and finish teeth positions, defining a tooth path for the motion of each tooth which is optimized so that the teeth are moved in the quickest fashion with the least amount of duplicative back-and-forth tooth movement to bring the teeth to their desired final positions; (6) segmenting the tooth paths so that each tooth’s position within a segment stays within threshold limits of linear and rotational translation; and (7) using the segmented tooth paths and associated tooth position data to calculate and make clinically acceptable appliance configurations (or successive changes in appliance configuration) that will move the teeth on the defined

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treatment path in steps specified by the path segments. Also, the method discloses that the appliances can be braces, polymeric shells, or other forms of orthodontic appliance.

JX-1 (“the ‘511 patent”), Abstract, Fig. 1, 3:22-4:67.

2. Anticipation

Respondents contend that Lemchen incorporates Kesling and anticipates the asserted claims of the ‘325 patent.

a. Relevant Law

A patent is presumed valid, and a party challenging validity has the burden of proving invalidity by clear and convincing evidence. *See* 35 U.S.C. § 282; *Iron Grip Barbell Co., v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004). A patent claim is invalid as anticipated if “the invention was known or used by others, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, [.]” 35 U.S.C. § 102(a). Anticipation requires that a single prior art reference discloses each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379-80 (Fed. Cir. 2003). The Federal Circuit has held that “[m]aterial not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document.” *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (*citing Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069 (Fed. Cir. 1997)).

b. Does Lemchen Incorporate Kesling In Whole or In Part?

A threshold issue is whether Kesling is fully incorporated by reference into

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Lemchen.⁶⁵ At the hearing, respondents contended that asserted claims 1-3, 11, 13-14, 21, 30-35, and 38-39 of the '325 patent, where claim 1 is representative, are anticipated by Lemchen, which they purported fully incorporates Kesling by reference.

ID at 108, 148-68. The two passages in Lemchen incorporating Kesling read:

Thus, in many applications of the preferred embodiment, a complete “model”, as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of [Kesling].

Id. at 145 (citing Lemchen, 3:10-15).

In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced [Kesling].

Id. (citing Lemchen, 3:35-40).

However, the IA and Align argued that Kesling was not fully incorporated by reference into Lemchen by these passages. *Id.* at 128-38, 139-42.

Reviewing the relevant precedent, the ALJ found that “[t]o incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.” ID at 142 (citing *Advanced Display*, 212 F.3d at 1282 (citing *In Re Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973))). The ALJ noted, however, that the Federal Circuit and its predecessor have limited incorporation to the portions of the external reference that are specifically identified in the incorporation language of the host

⁶⁵ Also at issue is whether the ALJ properly limited the evidentiary use of certain expert reports from the *Ormco* litigation. *See infra*.

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document. *Id.* at 143-44 (citing *Zenon Environmental, Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1379 (Fed. Cir. 2007); *In re Saunders*, 444 F.2d 599, 600 (C.C.P.A. 1971).

Applying the relevant case law, the ALJ found that the incorporation language of Lemchen identifies with detailed particularity what specific material it incorporates from Kesling and clearly indicates where the material is found, *i.e.*, Figs. 1 and 3 of Kesling. *Id.* Accordingly, the ALJ concluded that Lemchen does not incorporate Kesling beyond Figs. 1 and 3 of Kesling. *Id.* Further, even assuming *arguendo* that Lemchen incorporates fully by reference Kesling, the ALJ still found no anticipation because each and every limitation of claim 1 of the '325 patent is not disclosed by Lemchen and Kesling. *Id.* at 146.

Respondents contend that the ALJ clearly erred on the threshold issue of whether Lemchen fully incorporates Kesling. Respondents' Pet. at 36-38. They argue that language in a patent such as "[r]eference is made to" can be sufficient to indicate to one of ordinary skill in the art that the referenced material is *fully incorporated* [into] the host document." *Id.* at 36 (citing *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009) (emphasis added)). They argue that Lemchen uses similar language and makes clear that it is referring to the "methods of treatment" in the prior art, and not just the figures in stating: "In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model I the finish position." *Id.* (citing Lemchen, 3:35-40). They further argue that it is important to consider the entirety of the incorporated document to properly understand its teachings, particularly because Kesling is small and only contains one page of figures and approximately 3.5 pages of text. *Id.* at

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38 (citing *In re Hughes*, 550 F.2d 1273, 1275-76 (C.C.P.A. 1977)). They submit that Figs. 1 and 3 of Kesling are substantively discussed repeatedly throughout the first two pages of the reference, and are essentially omitted only from the claim section and the listing of the prior art. *Id.*

Align points out that Lemchen only briefly refers to two *figures* from Kesling. Align's Resp. at 21 (emphasis added). Align argues that these references to Figs. 1 and 3 of Kesling are used only as examples of *models*, and that Lemchen does not state that the *entire* disclosure of Kesling or any of its *particular* methods are incorporated. *Id.* (emphasis added). Complainant submits that Lemchen's use of the language "in the above referenced [Kesling]" is merely citing Lemchen's prior reference to Fig. 1 of Kesling. *Id.* Align also contends that Lemchen's use of the language "methods of treatment" merely refers to different methods of treating a patient with brackets and archwires – not the removable appliance disclosed by Kesling. *Id.* (emphasis added).

The Commission has determined to affirm the ALJ's finding that Lemchen does not incorporate Kesling in its entirety, as set forth in the ID at 142-48. Incorporation by reference requires the host document to "identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents." *See Advanced Display Sys.*, 212 F.3d at 1282. Lemchen specifically discloses that the "physical embodiment of such a [digital] model is shown, for example, in FIG. 1 of [Kesling]." This passage thus refers to a model of a patient's jaw structure in Kesling that is found solely in Fig. 1 of Kesling, thereby obviating any need to view other portions of Kesling to understand the incorporated subject matter. Further, Lemchen specifically discloses that this physical model is shown, "for example, [in] FIG. 3 in the

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above-referenced [Kesling].” *Id.* at 3:39-40. Again, based on this specific language of Lemchen, this refers to a model of a patient’s jaw structure, this time with the teeth repositioned in the finish position, that is found solely in Fig. 3 of Kesling.

The patents in the precedent cited by Respondents used different language than the patent here which clearly indicates what subject matter is incorporated and where it can be found. In both *Callaway Golf* and *Hughes*, the material to be incorporated was designated more broadly. *See Callaway Golf*, 576 F.3d at 1346; *Hughes*, 550 F.2d at 1275-76. Further, in *Mobile Devices* the incorporation by reference language was not in dispute. *See Certain Mobile Devices, Associated Software, and Components Thereof (“Mobile Devices”)*, Inv. No. 337-TA-744, Final ID, 2011 WL 6916539, at *103-04 (Dec. 20, 2011).

c. Comparison of Exemplary Claimed Process to Prior Art

The ALJ found that Lemchen describes “generating digital information” regarding the initial “maloccluded teeth,” and then determines their respective “finish positions.” *Id.* at 146-47. The ALJ found that Lemchen discloses calculating positions on the teeth for bracket placement, and completes movement of the teeth with traditional brackets and archwires, not polymeric shell, *i.e.*, removable, appliances. *Id.* (citing CX-495 at 1-2, CX-1247C at Q. 186). However, he found that Align’s expert (Dr. Valley) credibly testified that Lemchen does not disclose, teach, or suggest calculating positions-in-between. *Id.* (citing CX-945 at 1-3, CX-1247C at QQ. 184-85). As a result, the ALJ found that Lemchen does not disclose “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement,” as required by exemplary claim 1 of

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the '325 patent. *Id.* Based on the foregoing, the ALJ found that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by claim 1 of the '325 patent. *Id.* at 147.

The ALJ further found that the incorporation of Figs. 1 and 3 of Kesling, as well as its full incorporation, into Lemchen does not disclose these limitations of claim 1. *Id.* He noted that Kesling was originally filed in 1943 and issued in 1949, before the concept of digital data existed. *Id.* Also, he found that Dr. Valley testified credibly that Kesling “does not disclose, teach, or suggest, or even remotely contemplate” the use of computers or digital technology. *Id.* (citing CX-1247C at QQ. 141-42, 564-71, 574-77). He also found that Kesling describes making tooth arrangements by (1) using a plaster mold of teeth, (2) separating the plaster teeth with a saw, and (3) reassembling the plaster teeth in wax into their assumed positions. *Id.* at 148 (citing CX-944 at 3).

In addition, the ALJ found that Dr. Valley testified credibly that Kesling only contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. *Id.* (citing CX-1247C at QQ. 144-45, CX-944 at 5). He further found that Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. *Id.* Rather, he found that Kesling discloses manually making an appliance using tools, supplies, and materials, including by, *inter alia*, (1) articulating the plaster cast; (2) taking an impression of the teeth of the plaster

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cast; and (3) making a mold filled with the appliance material. *Id.* (citing CX-944 at 3-4, CX-1247C at Q. 146).⁶⁶

Based on the foregoing, the ALJ concluded that respondents failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates independent claims 1, 11, 21, 31, 33, 35, and 38 of the '325 patent. *Id.* at 148. Based on his non-anticipation finding with respect to these asserted independent claims, he also found that asserted dependent claims 2-3, 13-14, 30, 32-34, and 39 are not anticipated by Lemchen. *Id.* at 148-171.

The Respondents argue that, once it is correctly found that Lemchen fully incorporates Kesling by reference as respondents argue, Lemchen anticipates the asserted claims of the '325 patent. Resps. Pet. at 39-48. Specifically, Respondents submit that Kesling teaches the following: (1) creating a model of the teeth in their existing position (citing Kesling, 2:7-9); (2) methods for modifying the initial model to allow the teeth to be individually manipulated (citing Kesling, 3:30-49); (3) methods for moving the modeled teeth to the desired location (citing Kesling, 3:49-64); (4) creating intermediate tooth arrangement models between the existing tooth arrangement model and the desired arrangement (citing Kesling, 2:50-3:1); and (5) a plurality of successive or intermediate

⁶⁶ The ALJ observed that, in previous litigation, the Federal Circuit found that the asserted claims of certain Align patents describing systems and methods for incrementally repositioning teeth, U.S. Patent Nos. 6,554,611 ("the '611 patent") and 6,398,548 ("the '548 patent"), are rendered invalid in view of prior art showing use of such systems and methods by orthodontists. *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1302 (Fed. Cir. 2006). Respondents asserted *Ormco's* findings, especially Dr. Diane Rekow's (expert for Align in the litigation) expert reports from that litigation from Dr. Diane Rekow (Align's expert in that litigation), as proof of the knowledge of one of ordinary skill in the art and invalidity of the patents at issue here. *Id.* at 187 (also at 201, 219-20, 380, 397). However, the ALJ ruled that respondents' evidentiary exhibits (RX-102C and RX-103C) that contained the expert reports from *Ormco*, which included reports on the issue of the asserted combination of Lemchen and Kesling, were limited in evidentiary use to show only that Align took an inconsistent position in *Ormco*. *Id.* at 187 (also at 201, 219-20, 380, 397); *see also* Tr. at 20-21 (granting-in-part Align's motion in limine to exclude the reports as hearsay).

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tooth positions and the fabrication of a series of appliances based on the intermediate tooth positions as recited by claim 1 of the '325 patent.

Align submits that the ALJ correctly concluded that, even assuming *arguendo* that Lemchen fully incorporates Kesling, this combination does not render any of the asserted claims obvious because it still does not disclose all elements of the claims. Align Resp. to Resps. at 23-29. Align submits that, contrary to respondents' contention, the claimed feature of determining intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement is completely absent from Kesling and Lemchen. *Id.* at 24-25 (citing CX-1247C at QQ. 137-62; CX-1254C, ¶ 62-65 at 21-23, ¶67 at 24-25, Tr. at 790-93). Specifically, Align contends that Kesling does not disclose, *inter alia*, the following claimed features: (1) digital data sets or models of a dentition; (2) intermediate or successive tooth arrangements based on initial and final positions; (3) fabricating a dental appliance, or controlling a fabricating machine, based on a digital data set; or (4) numerous other elements. *Id.* at 25. Rather, Align contends, Kesling only discloses a *reactive* process, done *one step at a time*, where subsequent appliances are created by repeating the process for making the first. *Id.* at 24 (emphasis added).

The Commission affirms the ALJ's finding and adopts the ALJ's reasoning, as set forth in the ID at 142-48 and 168-69, that Lemchen does not anticipate claim 1 or 38 of the '325 patent.⁶⁷ Lemchen does not teach interpolation or how to create successive appliances. ID at 149 (citing CX-945 at 1-3, CX-1247C at QQ. 184-85). Further, we

⁶⁷ Further, although Respondents have not petitioned with specificity with respect to other claims, the Commission adopts the ALJ's findings in the ID that Respondents have not proven that the remaining claims of the patents in suit are anticipated by Lemchen, whether or not it incorporates Kesling.

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agree with Align that Lemchen does not discuss defining or moving tooth boundaries. We agree with the ALJ that this combination, even assuming *arguendo* that Kesling is fully incorporated into Lemchen, still fails to disclose the claimed feature of mathematical interpolation.

3. Obviousness

a. Relevant Law

Under 35 U.S.C. § 103(a), a patent is valid unless “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” See 35 U.S.C. § 103(a). Once claims have been properly construed, “[t]he second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of non-obviousness” (also known as “objective evidence”). See *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1354 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

The Supreme Court rejected a “rigid approach” to prove obviousness, that requires an express “teaching, suggestion, or motivation to combine references,” in favor of a non-formalistic approach that considers other factors, *e.g.*, demands of the market and the technical community, interrelated teachings of multiple patents, background knowledge of one skilled in the art, inferences and creative steps one skilled in the art would employ, etc. See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). All of these

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factors may be considered by the court to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *Id.* at 417-21.

b. Combination of Lemchen and Kesling for all Asserted Claims

The ALJ found that Lemchen combined with Kesling would not render obvious any asserted claim of the '325 patent. *Id.* at 181-223. Focusing on the motivation to combine references, the ALJ found that the mention of Kesling in Lemchen would be adequate to cause a person of ordinary skill in the art to consider both references in combination. *Id.* at 182. However, the ALJ found that Kesling “does not disclose, or teach or suggest, or even remotely contemplate” the use of computers or digital technology, and Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. *Id.*

The Respondents submit that the only difference between Kesling and the claimed subject matter of the asserted patents is the use of digital data. *Resps. Pet.* at 41. They submit that the mere application of modern electronics to existing subject matter is commonplace and obvious to one skilled in the art. *Id.* (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”); *Western Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1370 (“Our conclusion of obviousness was based in part on the reasoning that applying modern electronics to older mechanical devices has been commonplace in recent years.”); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) (the

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Court rejecting arguments that such incorporation, *i.e.*, applying modern electronics to a prior art mechanical device, would have been beyond the ability of a person of ordinary skill in the art)).

Respondents argue that the record in this investigation demonstrates that the asserted claims are for digitally performing operations, such as interpolation, which were previously performed in an analog manner and therefore are invalid as obvious. Resps. Sub. at 12. Respondents assert that the technology at issue is easy to understand, and that the fact that analog methods were performed to accomplish the same steps to make aligners cannot be meaningfully disputed. *Id.* at 12. Respondents point to the *Ormco* litigation in which the Federal Circuit held claims of other of Align's patents to be invalid, and argue that "[t]hese holdings, discussed in greater detail in Respondents' petition for review, conclusively demonstrate that analog and digital methods of designing and manufacturing aligners predated Align's asserted claims." *Id.* at 13 (citing *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1313-18 (Fed. Cir. 2007)).

Respondents discuss the Kesling analog system, *Id.* at 13-14, and cite the expert report from the *Ormco* litigation for the proposition that the only difference between Kesling and the claimed subject matter is the use of digital technology. *Id.* at 14 (RX-103C at 2). Respondents argue that Lemchen taught the use of 3D graphics to move the virtual teeth to the desired position. *Id.* at 15 (citing CX-945 at 2:66-3:6). Respondents argue that each individual step of the claimed methods was known and performed both manually and digitally prior to the claimed invention. *Id.* at 17-19 (citing RX-103C at 2).

Respondents argue that Dr. Rekow's expert report in the *Ormco* litigation and Dr. Mah's testimony set forth the motivation to combine. *Id.* (citing RX-103C at 2; RX-113 Q.95).

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Align asserts that its inventions are not simply computerized versions of prior art systems. Align Sub. at 14. Align states that Respondents never submitted any evidence that the asserted claims merely recite manual methods using modern electronics. *Id.* at 14-15. Align argues that one significant difference between Align's asserted claims and the prior art is Align's inventive concept of determining intermediate or successive states based on the initial and desired final states. *Id.* at 15. Align continues that Dr. Valley, Align's expert, explained why this is fundamentally different from the prior art. *Id.* at 16 (citing, CX-1247C at Q.141, 144-45, 183-85, 293-95, 304-06, 335-38, 410, 412, 414-15, 418-22, 440-41, 443-44; CX-1254C ¶¶ 65, 82, 126, 149-50, 194; Tr. at 791:21-793:5, 794:3-795:17).

Align argues that Kesling describes a reactive process, done one step at a time based on the position of the teeth, and repeated, and that Kesling's method is not based on the initial and final positions. *Id.* at 16 (citing ID at 147; CX-1247C at Q.144-45; CX-1254C at ¶ 65; Tr. at 790:9-791:20). Align argues that Respondents do not dispute this and that Dr. Rekow testified in the *Ormco* litigation only that Kesling moved the teeth by incremental amounts. *Id.* at 16-17 (citing RX-103C at 13).⁶⁸ Align asserts that the prior art fails to disclose other limitations of other claims either in digital or physical form, e.g., "interpolation," which is recited in claim 14 of the '325 patent, claim 8 of the '863 patent, and claims 3, 7, and 9 of the '666 patent.

Align contends that the authority relied on by Respondents is readily distinguishable. *Id.* at 18. Align argues that *Leapfrog Enters. v. Fisher-Price, Inc.*, 485

⁶⁸ Regarding the *Ormco* expert reports, Align submits that the ALJ was correct to limit respondents' use of these reports. Align Resp. to Pet. at 30-31. Align submits that only relevant, reliable, and material evidence is admissible in Commission proceedings. *Id.* (citing 19 C.F.R. § 210.37(b)).

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F.3d 1157 (Fed. Cir. 2007), is distinguishable because Align's invention is not merely an old system with new parts. Align argues that *Western Union Co. v. MoneyGram Payment Sys.*, 626 F.3d 1361 (Fed. Cir. 2010), is distinguishable because Align's inventions are not merely an upgrade to an old or existing system. Align argues that Respondents have no support (except citation to Dr. Rekow's report in the *Ormco* litigation) for their claim that Lemchen taught intermediate tooth arrangements and that applying digital technology to prior art was obvious to one of ordinary skill in the art. *Id.* at 8.

The IA argues that the testimony provided by Respondents' expert Dr. Mah is merely conclusory and does not make up for the deficiency with respect to the claimed knowledge of one of ordinary skill or the alleged motivation to apply any digital technology. IA Sub. at 8 (citing RX-113C at QQ.114-121).

The IA asserts that the use of digital data is not the only difference between Kesling's teachings and the subject matter of the asserted claims. *Id.* at 9. The IA states that the ALJ found that Kesling contemplated a reactive process, and that Lemchen does not disclose or teach calculating positions in between. *Id.* (citing ID at 146-47).

The Commission affirms the ALJ's findings, and adopts the ALJ's reasoning, as set forth in the ID at 180-82 and 203-206, that Respondents have not proven that claim 1 or claim 38 of the '325 patent is obvious.⁶⁹ Kesling and Lemchen do not teach the interpolation of digital data sets, and Respondents have not cited any substantive evidence of record to support the defense that the asserted claims are an obvious

⁶⁹ Further, although Respondents have not petitioned with specificity with respect to other claims, the Commission explicitly adopts the ALJ's findings in the ID that Respondents have not proven that the remaining claims of the patents in suit are anticipated or rendered obvious by Lemchen, whether or not it incorporates Kesling.

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application of digital technology. Respondents point only to the expert report of Dr. Rekow, Align's expert, from the *Ormco* litigation, which the ALJ held could only be used for impeachment purposes in this investigation, and the testimony of Dr. Mah, which the ALJ found to be conclusory and unsupported. Therefore, Respondents have not met their burden of proof.

c. Combination of the '511 Patent and Knowledge of One of Ordinary Skill in the Art (for the asserted claims of the '863 patent)

At issue is whether respondents waived their arguments with respect to, *inter alia*, the combination of the asserted '511 patent and knowledge of one of ordinary skill in the art.⁷⁰ The ALJ found that Respondents failed to set forth any specific combination and thus waived their argument. ID at 349-50. However, the ALJ made the finding in the

⁷⁰ In a contingent petition for review, Align asserts that the ALJ erred in finding that the '863 patent is not entitled to a priority date of December 4, 1998, based on claiming priority to the '881 provisional application, and notes that this issue was not disputed at the hearing. Align's Pet. at 40-41. Align submits that the ALJ's factual finding was incorrect because the '881 provisional application incorporates by reference the '080 patent application, which incorporates the '342 provisional application. *Id.* (citing CX-1253 at 4, '893 patent). Accordingly, Align asserts that the '881 provisional application does incorporate by reference the disclosure of the '342 provisional application to provide sufficient support for asserted claims 1 and 4-8 of the '863 patent, and therefore the '863 patent is entitled to a priority date of December 4, 1998. *Id.* (citing CX-1247C at QQ. 91-97; CX-1254C at 13). Align thus contends that ALJ's findings on this issue should be reversed.

The IA agrees with Align and submits that the ALJ does not adequately explain why a claim to a Dec. 4, 1998, priority date requires the incorporation by reference of an application filed on Jun. 20, 1997, thereby warranting review by the Commission on this issue. IA's Pet. at 7-8.

Respondents disagree with Align and submit that Align did not meet its burden for establishing an earlier priority date for the '863 patent than its filing date on the face of the patent. Respondents' Pet. at 18 (citing *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008) (patentee has the burden to establishing an earlier priority date than on the face of the patent to overcome a prima facie case of invalidity)).

We agree with Align and the IA that the relevant priority date for the '863 patent is Dec. 4, 1998, because it has an adequate disclosure based on the incorporation by reference of the '342 provisional application. Nevertheless, the ALJ's determination of the priority date was harmless error in view of the ALJ's finding that the '511 patent is prior art to the '863 patent regardless of whether the '863 patent may claim priority to Dec. 4, 1998. *See* ID at 355.

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alternative that, if Respondents did not waive this combination, the combination would render the asserted claims of the '863 patent obvious. ID at 350.

At the hearing, Respondents contended that the asserted claims 1 and 4-8 of the '863 patent are obvious in view of various combinations of prior art including the asserted '511 patent and the knowledge of one of ordinary skill in the art. *Id.* at 344-45. The ALJ noted that respondents do mention “knowledge of one of ordinary skill in the art” in their pre-hearing brief (section 3.5.2.2), but found that the invalidity arguments in their brief amount to a general discussion of eleven separate references with no element-by-element discussion of how those eleven references would be combined to render the asserted claims of the asserted patents obvious. *Id.* at 349 (also at 180); *see also* sections 4.1.2.2, 5.5.2.2, 6.5.2.2, 7.5.2.2, and 8.5.3.2 of Respondents' Pre-Hearing Br. (RPHB). He found rather that Respondents' pre-hearing brief only included a general reference to a “claim chart” that they would produce at the hearing. *Id.* The ALJ found that this general reference to a future claim chart is inadequate 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. *Id.* (citing RPHG at 60-67). Accordingly, the ALJ granted Align's motion in limine number 6 and excluded the claim charts that were not specifically cited in respondents' pre-hearing brief as required by his Ground Rule 8.2.⁷¹ *Id.* (citing Tr. at 18-20).

In addition, although he noted that respondents discussed these eleven different prior art references in their pre-hearing brief at section 3.5.2.2, the ALJ found that they

⁷¹ ALJ's Ground 8.2 states that “[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.” *See* Order No. 2 (Apr. 2, 2012).

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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. *Id.* (citing RPHB at 49). Having identified only these specific combinations, the ALJ found that any other combinations were waived including the combination of the asserted '511 patent and the knowledge of one of ordinary skill in the art. *Id.* at 350.

Respondents contend that their excluded claim chart was disclosed to Align as part of respondents' discovery responses and it was an exhibit to respondents' invalidity expert report. Resps. Pet. at 54. They also argue that their pre-hearing brief provided their contentions that all asserted claims were obvious and discussed the prior art in particular detail, including identifying where the disclosed subject matter was located in the prior art references. *Id.* (citing RPHB at 48-67, 97-106, 127-36, 146-54, 174-83, 205-17, 240-48). They further submit that under *Certain Mobile Devices, Associated Software, and Components Thereof* ("Mobile Devices"), Inv. No. 337-TA-744, Final ID, 2011 WL 6916539, at *103-04 (Dec. 20, 2011), their detailed disclosure complies with the ground rules and does not waive their invalidity defenses.

Complainant contends that the ALJ correctly found waiver because respondents failed to disclose this argument in their pre-hearing brief in violation of his Ground Rule 8.2. *Id.* at 30 (citing ID at 349-50).

The Commission affirms and adopts the waiver, exclusion, and limitation determinations made by the ALJ set forth in the ID at 349-50. Invalidity is an affirmative defense. 35 U.S.C. § 282. Respondents' pre-hearing briefing on invalidity states only the following with respect to the '511 patent:

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8.5.3 Obviousness under 35 U.S.C. § 103(a)

The Respondents['] contentions concerning obviousness described above are incorporated here. During the hearing, the Respondents intend to introduce a chart prepared by Dr. Mah that shows where each element of each asserted claim is found in the prior art reference.

* * *

8.5.3.2 The following prior art references in combination with the knowledge of one of ordinary skill in the art, and with other prior art where specifically referenced.

* * *

8.5.3.2.13 U.S. Patent No. 6,471,511 (Chishti)

Align claims a priority date of December 4, 1998 [for the '863 patent]. This priority date makes the other asserted patents prior art as to the '863 [patent]. Each of the other asserted patents discloses the following: 1) methods for producing digital models used to generate orthodontic appliances; 2) methods for providing a digital model of a patient's dentition; 3) methods for producing a plurality of digital dentition models that represent successive orthodontic treatment stages from initial to final that are used to fabricate appliances; 4) presenting a visual image of the digital model; 5) manipulating the visual image to reposition the teeth; and 6) defining boundaries around individual teeth. These patents also disclose the use of attachment devices. One skilled in the art would also understand the use of attachment devices in light of these references.

RPHB at 205, 214.

The ALJ's Ground Rule 8.2 states, with respect to pre-hearing briefs, that "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn[.]" See Order No. 2. The Commission agrees with the ALJ that Respondents' general, broad reference to the prior art as disclosing the claimed features, along with a claim chart to be purportedly presented later at the hearing does not serve to satisfy this rule. Align had no notice prior to the hearing of what arguments were to be made with respect to the asserted prior art such as: (1) where exactly in the prior art are the claim

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features disclosed; (2) what evidence would be presented; and (3) what motivation to combine such knowledge and the prior art would be presented that would lead to the claimed invention. The Commission thus affirms the ALJ's determination that Respondents' argument with respect to the '511 patent was waived and to exclude the claim chart at issue.

E. Estoppel Defense (Including Defense of Implied License or Patent Exhaustion)

Respondents argue in their petition for review that Align is estopped from asserting the patents-in-suit against them by reason of Align's withdrawal of a prior lawsuit in Texas in which Align asserted United States Patent No. 6,554,611 (the '611 Patent) and Align's issuance of a statement, which Respondents regard as a covenant not to sue (the so-called "Texas Covenant") at the time that Align withdrew its Texas lawsuit.

The ALJ, in Order No. 20, found that the Respondents had waived their right to assert a defense of estoppel or patent exhaustion because it was not previously raised in their response to the original complaint, and, assuming arguendo that the defenses were not waived, that there was no implied license of the patents-in-suit. Order. No. 20 at 23. The ALJ found that the instant situation is distinguished from the patent exhaustion cases relied on by Respondents, *TransCore* and *Leviton*, because Respondents have not established that the '880 patent and '511 patents are necessary to practice the '611 patent. *Id.* at 25 (citing *TransCore LP v. Electronic Transaction Consultants Corp*, 563 F.3d 1271, 1279 (Fed. Cir. 2009); *General Protecht Group, Inc. v. Leviton Manufacturing Co.*, 651 F.3d 1355, 1361 (Fed. Cir. 2011)). The ALJ further found that *Leviton* was not

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applicable with respect to the Texas Covenant because the asserted patents are not continuations of the '611 patent. *Id.*

The Respondents argue that the ALJ erred in his finding because the Respondents pleaded the affirmative defense of estoppel as their “Fourth Affirmative Defense” in their response to the Complaint. Resp. Pet. at 31. Respondents’ Fourth Affirmative Defense stated:

Because of proceedings in the U.S. Patent and Trademark Office during the prosecution of the application that resulted in U.S. Patent Nos. 6,685,469, 6,394,801, 6,398,548, 6,722,880, 6,629,840, 6,699,037, 6,318,994, 6,729,876, 6,602,070, 6,471,511 or 6,227,850--as shown by the prosecution histories--Align is estopped from construing the claims of these patents in a way that would cause any valid claim thereof to cover or include any products that are or have been manufactured, used, sold, offered for sale, or imported by ClearCorrect, or any process used by ClearCorrect to manufacture its products.⁷²

The Respondents argue that the Fourth Affirmative Defense does not relate to prosecution estoppel, as noted by the ALJ, because the Respondents had pleaded prosecution history estoppel as a separate defense. Resp. Pet. at 32. The Respondents further argue that they could not have waived their affirmative defense of estoppel because Align was on notice of the defense based on Align’s interrogatories that sought the basis of the estoppel defense. *Id.*

Align argues that the Fourth Affirmative Defense referred to by the Respondents was unrelated to the alleged defense of implied license or patent exhaustion. Align Resp. to Pet. at 10. Rather, Align argues that this affirmative defense refers exclusively to prosecution histories and claim construction. *Id.*

⁷² Response of ClearCorrect Operating, LLC to Complaint under Section 337 of the Tariff Act of 1930, as amended; Inv. 337-TA-833 (CX-1021).

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Align contends that neither *TransCore* nor *Leviton* are applicable here because unlike in *TransCore* and *Leviton*, Align never asserted the '611 patent against Respondents nor did they receive consideration in exchange for the agreement. *Id.* at 17. Align argues that to establish patent exhaustion, an accused infringer must show that the product sold substantially embodies the patented invention, and that Respondents cannot establish that its products embody the '611 patent claims or that there was an authorized sale. Align Resp. to Resps. at 18-19.

The Commission has determined to affirm and adopt the ALJ's finding that the Respondents had waived their right to assert implied license and patent exhaustion because they were not asserted in their response to Align's complaint. ID at 1-2; Order No. 20. The Commission requires that the affirmative defenses be pleaded with as much specificity as possible in the response to the complaint. 19 C.F.R. § 210.13(b) The Fourth Affirmative Defense upon which the Respondents base their defense of estoppel with respect to implied license and patent exhaustion is instead solely directed to Align's prosecution of the patents-in-suit before the USPTO and does not even reference the '611 patent upon which its defense is based.

Aside from waiver, the Commission has determined to affirm the ALJ's findings in Order No. 20 that the facts of the current case differ from those in *TransCore* and *Leviton* because in the Texas action, Align withdrew its complaint without a settlement agreement and Respondents provided no consideration. Order No. 20 at 25. Further, although the patents at issue are derived from a common provisional application, the resulting claims are not necessarily exhausted by operation of the '611 patent at issue in the withdrawn Texas suit.

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F. Domestic Industry - - Economic Prong

The ALJ found that Respondents waived the right to contest domestic industry and found that Align established the economic prong of the domestic industry requirement. ID at 766-67. He concluded that Align made a significant investment in plant and equipment and significant employment of labor and capital in the United States. Specifically, the ALJ found that Align spends money on rent for a research facility and hires employees who perform research and development. *Id.* at 767. The evidence shows that Align employs over [[

]], and has paid approximately [[

]] ID at 767 (citing CX-1237C at Q 32). Align has a corporate headquarters in San Jose, California, [[]]
CX-1237C, QQ.25-52. Align [[]] for its San Jose facility, [[]]
]] ID at 766 (citing CX-1237C at Q. 27.).

Respondents argue that the ALJ erred in not allowing them to cross-examine Align's witness. Respondents' Pet. at 69. We affirm and adopt the ALJ's findings that Respondents waived this issue before the ALJ by stipulating that it would not contest domestic industry (either prong), and that Align has established that it met the economic prong of the domestic industry requirement.⁷³ ID at 766-67; Tr. at 46-48, 72-79, 619-624.

G. Domestic Industry - - Technical Prong

As stated above, the ALJ found that Respondents waived the right to contest domestic industry. He found that Align's Invisalign system satisfied representative

⁷³ We clarify that the economic prong was proven under 19 U.S.C. § 1337(a)(3)(A) and (B).

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claims of all the asserted patents except the ‘666 patent based on Dr. Kuo’s Witness Statement. ID at 771-795.⁷⁴

1. The ‘487 Patent

The Respondents petitioned for review of the ALJ’s finding that Align satisfied the technical prong of the domestic industry requirement based on their claim construction argument that a “treatment plan” (in claim 7) can be made only by a clinician. Resps. Pet. at 68. Because we affirm the ALJ’s claim construction, we affirm the ALJ’s finding that the technical prong is satisfied for the ‘487 patent.

2. The ‘863 Patent

Respondents argued in their petition that Align does not make digital models of actual dental appliances, and only makes digital models of teeth. Resps. Pet. at 68. Align responds that this argument was waived because it was not presented in a claim construction chart in a timely fashion, that the ALJ correctly held that the preamble of claim 1 is not limiting, and that Align’s digital models of the teeth should be considered negative models of the aligners. Align Resp. to Pet. at 52-53. We find that Respondents waived any technical prong argument for this patent. Tr. at 46-48, 72-79, 619-624.

3. The ‘666 Patent

Pursuant to the claim chart set forth in the ID at 784-85, the ALJ found that Align had not made a *prima facie* showing that it practiced claim 7 of the ‘666 patent. ID at 787-88. The ALJ found that Dr. Kuo’s witness statement did not provide any evidence

⁷⁴ The Commission adopts the ALJ’s finding that the technical prong is satisfied for those patents for which there is no petition for review.

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that Align's process includes the step of "interpolating positional differences between the initial and final position of teeth." ID at 788.

Align contends that the ALJ's exclusion of factual evidence as "impermissible expert testimony" caused the ALJ to improperly rule that Align had failed to establish the technical prong of the domestic industry requirement with respect to the '666 patent. Align. Pet. at 13. Align argues that had the ALJ retained the factual testimony regarding Align's process, while striking only Dr. Kuo's conclusion, the evidence would have supported that Align's process includes "the step of interpolating positional differences between the initial and final position of teeth." *Id.* The Complainant cites the Commission's prior holding in *Certain Video Graphics Display Controllers & Prods. Containing Same*, Inv. No. 337-TA-412, Order No. 53 (Jan. 20, 1999) and a district court holding in *LaSalle Bank Nat'l Ass'n v. Nomura Asset Capital Corp.*, 2004 U.S. Dist. LEXIS 18599 (S.D.N.Y. Sept. 13, 2004) as support for the proposition that a witness's factual testimony should remain admissible even where the court determines that opinion testimony should be excluded. Align. Pet. at 16.

The IA submits that the ALJ erred in its finding that although Dr. Kuo's witness statement does not recite the exact words from the allegedly missing limitation, "his statement describes the step in sufficient detail to make a *prima facie* showing that Align practices claim 7 of the '666 patent." IA Pet. at 11. Specifically, the IA argues that the computer software, as described in Dr. Kuo's statement, "interpolates positional differences between the initial and final position of teeth" when computer software is used by Align technicians to "generate a plan wherein a tooth path is determined for motion of each tooth from an initial position to a final position." *Id.* at 11.

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The IA further argues that the ID's finding with respect to the '666 patent contradicts the finding that Align met its burden to make a *prima facie* showing that it practiced claim 1 of the '511 patent. IA Pet. at 12. The IA argues that the testimony that supported finding that Align practiced claim limitation "calculating a segmentation of the aggregate tooth paths" of the '511 patent should also satisfy the *prima facie* showing that Align practices the "step of interpolating positional differences between the initial and final position of teeth." *Id.*

The Respondents argue that Dr. Kuo's Witness Statement was the only evidence Align cites for its practice of the fourth element of claim 7 describing "interpolating positional differences" between teeth in different positions. Resps. Resp. at 5. The Respondents contend that the ALJ properly excluded Dr. Kuo's improper opinion testimony because he was never disclosed as an expert. *Id.* As such, the Respondents argue that since the relevant part of the statement was excluded, no other evidence supports the practice of "interpolation" limitation.

Respondents further disagree with the IA's comparison of the contested limitation to the '511 patent as flawed because "interpolate" is understood to mean, "To estimate a value of (a function or series) between two known values." Resps. Resp. at 7 (citing THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 915 (4th ed. 2000)). The Respondents argue that Align offered no evidence that its technicians estimate values when they "generate tooth paths" or "calculate a segmentation of tooth paths." *Id.*

The sole limitation that the ALJ found was not satisfied was the step of "interpolating positional differences between the initial and final position of teeth" of claim 7 of the '666 patent. ID at 788. We agree that the ALJ did not abuse his discretion

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with respect to excluding Dr. Kuo's concluding opinion. *See* ID at 188. However, the IA is correct to point out that the ALJ relied on Dr. Kuo's Witness Statement (and only on his Witness Statement) as evidence in finding that Align satisfied the technical prong with respect to the '511 patent. ID at 784 (citing CX-1235, Qs. 20-23). The IA is therefore correct that this same evidence (from the Witness Statement as opposed to the trial testimony) may be relied on to satisfy the technical prong with respect to the '666 patent. In our view, this same statement is equally applicable to the limitation at issue in the '666 patent. CX-1235, Q. 22 [[

]] Therefore, Align has put forth sufficient evidence to show that it practices claim 7 the '666 patent. We therefore reverse the ALJ's finding that Align has not satisfied the technical prong of the domestic industry requirement with respect to the '666 patent.

4. The '325 patent, the '880 patent, the '511 patent, and the '874 patent

The ALJ found that Align established the technical prong of the domestic industry requirement with respect to the '325 patent, the '880 patent, the '511 patent, and the '874 patent for the reasons set forth in the claim charts of the ID at 771-72, 776-77, 782, 793. None of the parties petitioned for review of satisfaction of the technical prong with respect to these patents, and we adopt the ALJ's findings with respect thereto.

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IV. REMEDY, THE PUBLIC INTEREST, AND BONDING

A. Remedy

1. The Recommended Determination

The ALJ did not recommend the issuance of an exclusion order. Recommended Determination (“RD”) at 797. Instead, the ALJ recommended the issuance of a cease and desist order against CCPK and CCUS that prohibits importation (electronically or otherwise) into the United States of certain digital models, digital data, and treatment plans (for use in making dental appliances), citing Inv. No. 337-TA-383, *Certain Hardware Logic Emulation Systems and Components Thereof*, Comm’n Op. at 28 (March 1998). RD at 802. The ALJ found the presence of a “rolling” inventory in the United States because CCUS imports digital data sets on a daily basis and pays on average \$3000/day based on a monthly payment of approximately \$85,000 to CCPK. *Id.* at 803.

The ALJ observed that the Commission has granted cease and desist orders directed to electronic transmission of software in previous investigations. *Id.* at 803 (citing *Hardware Logic*). The ALJ also observed that the Commission has issued a cease and desist order against a foreign entity, Kinik Co. of Taipei, Taiwan, in *Certain Abrasive Products*, Inv. No. 337-TA-449, Comm’n Op. (May 9, 2002).

2. Parties’ Arguments

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Align does not seek an exclusion order, and argues that the Commission should adopt the ALJ's recommendation for issuance of a cease and desist order.⁷⁵ Align Sub. at 20; Align Reply Sub. at 10. Align proposes that the language of any such order should encompass the principals and managing employees of both Respondents. Align Sub. at 20. Align argues that the Commission should issue a cease and desist order against CCPK because CCUS is at least the second company with which personnel of CCPK have worked, and an order against CCPK would better enable Align to file an enforcement action should CCPK continue its infringing conduct. Align Reply Sub. at 10.

Respondents argue that typically the complainant must prove commercially significant inventories of infringing products in the United States to justify a cease and desist order. Resps. Sub. at 19 (citing *Certain Cigarettes & Packaging Thereof*, USITC Pub. 3366, Inv. No. 337-TA-424 (Nov. 2000)). Respondents state that here there are no "inventories" of digital information at issue. *Id.* Respondents argue that the evidence does not show significant inventories of the orthodontic appliances either. *Id.*

Further, Respondents discuss the possible types of electronic communications (including telephone calls) and argue that "any cease and desist order should therefore be written narrowly to avoid excessive peripheral litigation about what transmissions and activities are prohibited." *Id.* at 20; Respondents Reply Sub. at 10. Respondents agree

⁷⁵ Align argued to the ALJ that the imposition of a "commercially significant inventory" requirement for issuing a cease and desist order would leave no practical mechanism to prevent importation in the absence of an exclusion order. Align Post-Hrg. Reply Br. at 94. Align cited the Commission Opinion in *Hardware Logic* for the notion that the purpose of issuing a cease and desist order that includes electronic transmissions is to prevent relief from being meaningless. *Id.* Align argued that the Commission has previously issued a cease and desist order against a foreign respondent in an analogous situation where that respondent's domestic distributor maintained a commercially significant inventory in the U.S. *Id.* at 96 (citing *Certain Toner Cartridges*, Inv. No. 337-TA-740, Comm'n Op. at 7-8 (Oct. 5, 2011) (citing *Certain Abrasive Products*, Inv. No. 337-TA-449, Comm'n Op. at 7-8 (May 2, 2002))).

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with the IA that any cease and desist order should not include CCPK. Respondents Reply Sub. at 10.

The IA agrees with the ALJ's recommendation that the issuance of an exclusion order is not appropriate in this case. IA Sub. at 10. The IA states that the Commission has previously considered and rejected requests that exclusion orders cover electronic transmissions. *Id.* (citing *Hardware Logic*, Comm'n Op. at 19-20).

The IA agrees with the ALJ's recommendation to issue a cease and desist order to CCUS. *Id.* at 11. The IA asserts that the ALJ correctly determined that CCUS has a commercially significant inventory in the United States. *Id.* at 11 (citing *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 73 (June 3, 2009)). The IA states that the ALJ determined that CCUS pays CCPK approximately \$3000.00 per day, based on a monthly payment of \$85,000.00, and that this rolling daily inventory of \$3000.00 worth of digital data sets is sufficient to find that CCUS has a commercially significant inventory in the United States.

The IA disagrees with the ALJ's recommendation that a cease and desist order should be directed to CCPK because, as a matter of prudence, the Commission does not issue cease and desist orders to foreign companies that do not have a domestic inventory because it would not have an effective means of enforcing such an order. *Id.* at 12. The IA cites Commission precedent for the proposition that it is Commission practice to issue cease and desist orders only to domestic respondents, particularly in light of the difficulty of enforcing such orders against foreign entities, that cease and desist orders may ultimately be enforced by the Commission in U.S. district courts, and that it is

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inappropriate to issue one unless a party in the United States can be compelled to do some act or refrain from doing some act. *Id.* (citing *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, Comm’n Op. at 25 (July 1997); *Certain Wear Components and Products Containing Same*, Inv. No. 337-TA-644, Comm’n Op. at 22-23 (Nov. 24, 2009)); IA Reply Sub. at 10.

3. Analysis

The appropriate remedy in this case (and the only remedy requested) would be cease and desist orders directed to CCUS and CCPK.

As noted by the IA, the Commission typically imposes cease and desist orders against Respondents with domestic inventories because the ultimate mechanism for dealing with noncompliance is in district courts.⁷⁶ *See* 19 U.S.C. § 1337(f)(2). The ALJ found that CCUS had a “rolling” inventory of digital data sets that make up particular phases of patients’ treatment provided by CCPK to CCUS on a daily basis, which are then used by CCUS to manufacture aligners. ID/RD at 803. Although Respondents dispute whether these digital data sets may constitute inventory, the Commission nonetheless has authority to issue a cease and desist order for any violation found because the presence of a U.S. inventory is not a statutory requirement.

The Commission has issued cease and desist orders against a foreign respondent in several investigations. In *Abrasive Products*, the Commission issued a cease and desist order against Kinik Co. of Taipei, Taiwan, because the U.S. distributor, Rodel,

⁷⁶ If a person violates a cease and desist order, the Commission, in an enforcement proceeding, may replace the cease and desist order with an exclusion order, 19 U.S.C. § 1337(f)(1), or impose a penalty “of not more than the greater of \$100,000 or twice the domestic value of the articles entered or sold on such day in violation of the order.” 19 U.S.C. § 1337(f)(2). The Commission may also bring a civil action in the U.S. District Court for the District of Columbia for a mandatory injunction. *Id.*

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Inc., was not a respondent. *Abrasive Products Made Using a Process for Making Powder Preforms and Products Containing Same*, Inv. No. 337-TA-449, Comm'n Op. at 7-8 (May 9, 2000). The Commission intended to thereby bind the domestic distributor through an order directed against the foreign respondent. *Id.* The Commission also issued cease and desist orders against foreign respondents in *Certain Toner Cartridges and Components Thereof*, Inv. No. 337-TA-740. In that investigation, the Commission explained that Ninestar Tech was the same company as Ziprint, both domestic companies, and that Ninestar Tech was a subsidiary of Ninestar Image Int'l., of China, which shared a headquarters with Ninestar, also of China. In *Lighting Control Devices*, the Commission issued a cease and desist order against a foreign respondent, where a domestic reseller held the foreign manufacturers' inventories for resale in the United States, Inv. No. 337-TA-776, Comm'n Op. at 26-27 (Nov. 8, 2012).

Here, unlike *Abrasive Products*, there is a domestic respondent, CCUS. With regard to the business relationships between respondents in connection with the infringing imports, which was considered in *Toner Cartridges*, Respondents contend that CCPK is independent of CCUS. The ALJ's findings, however, show that CCPK and CCUS engage in concerted activities to produce aligners for distribution in the United States through CCPK's production of digital data sets and treatment plans that are transmitted to CCUS as set forth in the detailed findings of the ALJ in the ID.

The Commission has therefore determined that the issuance of a cease and desist order would be the appropriate remedy for the violation of Section 337 if the issuance of such an order is not precluded by the public interest factors. We consider the public interest factors in the following section.

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B. The Public Interest

1. Parties' Arguments

Respondents argue that a cease and desist order would harm the public welfare. Resps. Public Interest Sub. at 2. Respondents state that in 2010, Align declared that any doctor who did not buy at least ten cases a year from Align and take the continuing education Align dictated would be stricken from Align's customer rolls and would not be sold any clear aligners. *Id.* Respondents state that Align's misconduct was addressed generally in the class action suit Case No. 3:10-cv-2010, *Leiszler v. Align Technology, Inc.*, in the United States District Court for the Northern District of California, which Align settled two years ago. *Id.* Respondents state that Dr. Willis Pumphrey founded ClearCorrect because he could not buy aligners from Align after it bought OrthoClear's assets. *Id.*

Respondents state that Align received a letter from the FDA during 2010 advising that Align had failed to disclose reports of important side effects to patients using its Invisalign system, including allergic reactions to the product. *Id.* (citing the FDA letter at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm234578.htm>). *Id.* at 4. Respondents further state that Align concedes in its SEC filings that its manufacturing operations are located outside the United States. *Id.*

Align argues that cease and desist orders would not be adverse to the public interest, discussing each of the public interest factors. Align Public Interest Sub.at 2-5. Align argues that Respondents rely on vague and unauthenticated statements of doctors, that the record is closed, and that Respondents' public interest statement was untimely. Align Reply Sub. at 10.

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The IA states that Respondents do not assert any concerns that would contradict Align's assertion that the teeth positioning systems at issue are elective and not part of an essential life-saving device. IA Sub. at 12-13. The IA notes that Align attests that it has adequate capacity to service patients who want clear removable teeth positioning appliances, and that conventional braces still constitute 90% of the treatments for malocclusion. *Id.* at 13 (citing Align's Public Interest Comments at 5). As to competitive conditions in the United States economy, the IA asserts that Respondents' exit from the market would not diminish competition in the overall U.S. orthodontic market because providers and consumers would continue to have choices in the overall orthodontic market. *Id.* at 12-13. The IA notes that Align's technology makes up 10% of the orthodontic market, and that Respondents make up 10% of that market share or 1% of the overall orthodontic market. *Id.* at 12. As to the production of like or directly competitive articles in the United States, the IA notes Align's assertion that it can replace the articles covered by the cease and desist order. *Id.* at 14 (citing Align's Public Interest Comments at 4). As to United States consumers, the IA is of the view that a cease and desist order would not harm United States consumers, and that the fact that some consumers may have to pay a higher price does not outweigh the protection of intellectual property. *Id.* (citing *Certain Telecommunications Chips*, Inv. No. 337-TA-337, Comm'n Op. at 40-41 (August 1993)).

2. Analysis

After considering the record and the parties' arguments, the Commission finds that the evidence pertaining to the statutory public interest factors does not indicate that

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cease and desist orders should not be issued. However, the Commission determines to include an exemption in the cease and desist orders for existing ClearCorrect patients.

Respondents' arguments with respect to effects on public health and welfare warrant analysis both with respect to that factor and potential impact on U.S. consumers.⁷⁷ The record indicates that Align is fully capable of providing its products to all doctors seeking incremental orthodontic appliances for their patients. There is no indication that Align continues to refuse to sell to dentists after settling the class action. Indeed, Respondents note that this issue was addressed in the settlement of that litigation. Also, conventional braces account for the large majority of orthodontic treatments in the United States. As for Align's citation for failure to report side effects in 2010, the record does not reflect any continuing failure to provide such reports to the FDA or that the use of Align's products for orthodontic treatment may adversely impact patients' health. Therefore, the effects of the orders on the public health and welfare and on U.S. consumers do not indicate that the orders should not issue.

The potential effects of the orders on U.S. consumers (and possibly public health and welfare), however, warrant an exemption for activities related to treatment of patients who have already begun treatment with ClearCorrect's aligners. As the Commission has recognized in certain investigations relating to cellular telephones, *see, e.g., Personal Data and Mobile Communications Devices and Related*, Inv. No. 337-TA-710 (Exclusion Order), the Commission may balance the public interest to accommodate the needs of

⁷⁷ Respondents submitted letters from dentists on their behalf, in support of the Commission not issuing a remedial order. Resps. Sub., Attachment 13. These letters request that the dentists be allowed to continue to give their patients the option of ClearCorrect aligners. The Commission has considered these letters in considering the effect on U.S. consumers. As set forth herein, the Commission has determined that Align's system and traditional braces are both acceptable alternatives to ClearCorrect's aligners.

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U.S. consumers who require repair and replacement of existing devices. Given the ongoing nature of orthodontic treatment, we do not place a time limit on these exemptions. However, certifications and compliance reporting requirements apply to all such continuing treatments throughout the duration of treatment for existing patients. Thus, the Commission exempts repair and replacement of existing appliances from the scope of the cease and desist orders, and activities relating to treatment of patients who have already contracted for treatment with ClearCorrect as of April 10, 2014. (The one-week grace period from issuance of this order is intended to allow time for the cease and desist orders to be communicated to orthodontists and dentists.) This exemption is subject to reporting to the Commission and to a certification requirement.

As to competitive conditions in the United States economy, the record reflects that Align is able to manufacture sufficient dental appliances to meet U.S. demand for this specific type of aligner for orthodontic treatment. Moreover, the record reflects that traditional dental appliances are the predominant choice for the treatment of malocclusions and there is no indication of any adverse impacts of the cease and desist orders on these traditional appliance treatments.

As to the production of like or directly competitive articles, the record indicates that the predominant mode of orthodontic treatment in the United States is traditional braces. The record provides no indication that the orders will have any adverse effect on production of orthodontic appliances in the United States.

The Commission has therefore determined that there would be no adverse effect on the public health and welfare, competitive conditions in the U.S. economy, the

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production of like or directly competitive articles in the United States, or U.S. consumers such that the orders (with the exemption discussed above) should not be issued.

C. Bonding

The ALJ did not recommend the issuance of a bond during the period of presidential review. RD at 810.

Align states that it “does not seek review” of the ALJ’s finding that no bond is appropriate. *Id.* The IA notes that Align has not requested any bond before the Commission. IA Reply Sub. at 9.

As there is no request for a bond, the Commission has determined not to require a bond during the Presidential review period.

V. CONCLUSION

For the foregoing reasons, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the ID of the ALJ and to issue a cease and desist order against CCUS and CCPK.

By order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: April 9, 2014

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DISSENTING VIEWS OF COMMISSIONER DAVID S. JOHANSON

It is a question of first impression whether the electronic transmission of digital data into the United States constitutes importation of an “article” within the meaning of Section 337(a)(1)(B) of the Tariff Act of 1930. The Commission majority broadly interprets the statute to allow it to exercise jurisdiction and find a violation by treating electronic transmission of data as an “article.” As this interpretation does not address Congress’s delegation of authority to the Commission, ignores Section 337’s remedial scheme, and contradicts the federal courts’ interpretation of “articles,” I respectfully dissent.¹

1. The Commerce Clause of the United States Constitution empowers Congress to “regulate commerce with foreign nations” and to “lay and collect taxes, duties, imposts, and excises.” U.S. Const. Art. I, § 8, cl. 1-3. Under that authority, Congress has passed into law numerous federal statutes, including the Tariff Act of 1930, as amended. Section 337 was originally enacted as Section 316 of the Tariff Act of 1922, one of the so-called “flexible tariff” provisions of that Act. As a trade act, Section 337 is not meant to remedy every unfair act in every context, but rather is directed to remedy those acts in the context of the statutory framework established by Congress for importation into the customs territory of the United States.² Thus, Section 337 is not the international extension of our patent, copyright, and

¹ Align bears the burden of proof under the Administrative Procedure Act to show that electronic transmissions are “articles” within the meaning of Section 337. 5 U.S.C. § 556(d) (“Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.”). Specifically, Align has the burden of showing Congress intended to cover digital transmissions under Section 337. Align has failed to meet that burden.

²As discussed below, Align and the majority assert Section 337 is a remedial statute and should be broadly construed. But the legislative history makes clear that the only part of Section 337 that should be broadly construed is “unfair methods of competition and unfair acts” in Section 337(a)(1)(A), not the portion of the statute at issue here. *See, e.g.*, Report, S. Rep. 67-595 at 3 (1922), 62 Cong. Rec. 5879 (1922). Indeed, the “unfair competition” part of the statute was

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trademark laws, but has restrictions that stem from the fact that it is, first and foremost, a trade law. *See, e.g., Schaper Mfg. Co. v. ITC*, 717 F.2d 1368, 1373 (Fed. Cir. 1983) (rejecting broader construction of the domestic industry requirement); *Corning Glass Works v. ITC*, 799 F.2d 1559, 1566 (Fed. Cir. 1986) (rejecting broader construction of the injury requirement); *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1355 (Fed. Cir. 2008). Indeed, the statute provides that the remedies it permits are in addition to other provisions of law. 19 U.S.C. 1337(a)(1). Thus, Section 337 provides a customs remedy in addition to the remedies that can be obtained from the courts. Align is currently seeking relief from the courts.³

Section 337's requirements—and in particular, what it means to be an imported “article”—therefore must be informed by Congress's understanding of the scope of the enacted United States trade laws. The ITC is a creature of statute and must find authority for its actions in its enabling statute. *See Vastfame Camera, Ltd. v. ITC*, 386 F.3d 1108, 1112 (Fed. Cir. 2004). It therefore is simply incorrect to say that the Commission has broad authority except as expressly limited by Congress. Absent clear indications to the contrary, it makes little sense to interpret Section 337 in a way that differs from the interpretation of other trade statutes. Besides lying closer to Congress's intent, a consideration of the trade laws in unison reduces the

never at issue here as this case was brought under the specific patent provisions of Section 337(a)(1)(B). I further note that denominating a statute as “remedial” does not permit an agency or tribunal to add to a statute. *Fortin v. Marshall*, 608 F.2d 525, 529 (1st Cir. 1979) (citing *United Shoe Workers of America, AFL-CIO v. Bedell*, 506 F.2d 174, 187 (D.C. Cir. 1974); *U.S. EEOC v. AIC Security Investigations, Ltd.*, 55 F.3d 1276, 1282 (7th Cir. 1995) (“A liberal construction does not mean one that flies in the face of the structure of the statute.”). It is argued that the term “that infringe” which follows “articles” in Section 337(a)(1)(B)(i) modifies “articles” so that the term covers electronic transmissions. However, a modifier narrows its subject; it does not broaden it.

³ The parties are involved in a civil action in the Southern District of Texas, which has been stayed during the Commission investigation. *Align Technology, Inc. v. ClearCorrect, Inc., ClearCorrect Operating, LLC, and ClearCorrect Holdings, LLC*, No. 4:11-cv-00695 (Jury Demanded), Order (May 10, 2012).

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possibility of inconsistent or contradictory treatment of different imports. Therefore, to understand Section 337, it is important to consider, for example, the Harmonized Tariff Schedule of the United States (HTSUS). Indeed, Section 337 specifically references the HTSUS. *See* 19 U.S.C. § 1337(m) (defining the United States to mean the customs territory of the United States as defined in general note 2 of the HTSUS).⁴

Under the HTSUS, tangible items are subject to tariff⁵ as has always been the case with the customs laws of the United States. This comports with the plain understanding of the term in the context of the statute; namely, “articles” are physical things.⁶ *See Dolan v. United States*

⁴ The Commission routinely requires the complainant to provide the applicable HTS number for the articles subject to a Section 337 investigation.

⁵ The dutiable lists or schedules of the Tariff Act of 1930, set forth in Title I, were replaced in 1963 by the Tariff Schedule of the United States, (the “TSUS”), Pub. L. 87-456. The legislative history of the TSUS includes the Tariff Classification Study Submitting Report, which accompanied the proposed revisions to the tariff laws. In that Report, the Commission wrote “General headnote 5 sets forth certain intangibles which, under various established customs practices, are not regarded as articles subject to treatment under the tariff schedules.” *Id.* at 18. In this connection, the original TSUS explicitly excepted electricity from the scope of the tariff schedules. General headnote 5(c). The TSUS was in turn replaced by the Harmonized Tariff Schedule of the United States (“HTSUS”), pursuant to the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418 § 1206, 102 Stat. 1151, codified at 19 U.S.C. § 3006. The HTSUS includes a heading for electrical energy but provides that electrical energy shall enter duty free and is not subject to entry under Section 484 of the Tariff Act of 1930; rather, the HTSUS provides that electrical energy is subject to entry under regulations to be prescribed by the Secretary of the Treasury. *Compare* HTSUS 2716 with HTSUS General Headnote 3(e)(iii) and Headnote 6(b) to Chapter 27. While the amendments subsequent to 1930 to the tariff schedules may or may not be relevant to the interpretation of Section 337, it is clear that the original tariff schedules only included tangible items and that the HTSUS excludes telecommunications transmissions and business data as intangibles (and even excludes electric energy from the entry requirements of Section 484 of the Tariff Act of 1930).

⁶ When looking to the plain meaning of “article” based on a reliance on certain dictionary definitions from 1922 to 1930 at the time of the enactment of Section 337 as the Supreme Court requires us to do, it must not be viewed in the abstract. Rather, one should look to the statute when read in the context of other trade laws to determine which definition fits within that context. *Dolan v. United States*, 546 U.S. at 486. Under that analysis “article” means a tangible good. Numerous definitions were submitted to support a “plain meaning” construction of the

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Postal Service, 546 U.S. 481, 486 (2006) (“The definition of words in isolation, however, is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis.”). In fact, the only clear reference to Customs’ authority to regulate electronic transmission of digital data strongly suggests Congress did *not* intend for Section 337 to remedy electronic transmissions. Congress explicitly exempted electronic transmissions as a good from the tariff schedule. *See* HTSUS General Headnote 3(e) (“For the purposes of general note 1 – (ii) telecommunication transmissions ... are not goods subject to the provisions of the Tariff schedule.”). Thus, Congress has specifically limited Customs’ authority to regulate or lay and collect taxes, and/or duties on electronic transmissions. *Id.* There is nothing in the legislative history of Section 337 to suggest that the Commission’s authority exceeds Customs’ in this regard.

term “article,” and the majority of such definitions suggest some tangible quality (or are at best ambiguous): (1) “Something considered by itself and as apart from other things of the same kind or from the whole of which it forms a part; also, a thing of a particular class or kind; as, an *article* of merchandise; salt is a necessary article” (Harris, Webster’s New International Dictionary of the English Language at 131, G. & C. Merriam Co. (1924)); (2) “A particular object or substance; a material thing or class of things; as, an *article* of food” (Funk, New Standard Dictionary of the English Language, Funk & Wagnalls Co. at 162 (1929)); (3) “a particular thing; item” (Webster’s New International Dictionary, 2d. Edition (1927)); (4) “a particular thing” (Funk & Wagnall’s Concise Standard Dictionary of the English Language, 2d. Edition (1929) and Fowler, H. W., Concise Oxford dictionary of Current English, 2d. Edition (1929)); (5) “a particular object or substance; a material thing or class of things” (Funk & Wagnall’s College Standard Dictionary of the English Language, 1st edition (1929)). Relatedly, the Federal Circuit relied on a definition of “article” in Webster’s Third New International Dictionary (a more recent edition of Webster’s) in interpreting 35 U.S.C. § 271(g), which was enacted in 1988. “Article” is there defined as “one of a class of *material things* . . . *piece of goods*; COMMODITY.” *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 n.4 (Fed. Cir. 2003) (emphasis added by Federal Circuit).

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Other related trade laws also have been limited to tangible goods. For example, under the previous countervailing duty law, Section 303 of the Tariff Act of 1930 (now repealed), the term “merchandise” was limited to tangible items. *See Preliminary Affirmative Countervailing Duty Determination: Certain Computer Aided Software Engineering Products from Singapore*, International Trade Administration, Department of Commerce (Commerce), 55 *Fed. Reg.* 1596 (January 17, 1990). In that case, Commerce rejected the argument that the imported software should be analyzed exclusively in terms of its (intangible) intellectual property and be considered merchandise under Section 303. Commerce concluded that it is the tangible medium, and not the intangible software, which can give the imported goods their characteristics as merchandise under Section 303. There, software on a tangible medium was an article or “merchandise,” but electronic transmission of software would not have been. Section 303 was, like Section 337, part of Title III of the Tariff Act of 1930. It specifically referenced an “article or merchandise.” The use of the terms article and merchandise interchangeably suggests they should be afforded the same meaning, and both appear in the same provision of the Tariff Act of 1930. Again, there is no indication in the legislative history that Congress intended to construe “article” differently in Section 337 as compared to the rest of Title 19. In sum, there is nothing in related trade acts to suggest inclusion of anything other than tangible articles.

2. There are additional indications within Section 337 itself that support an interpretation of “articles” that does not include electronic transmissions. Congress created Section 337 to remedy unfair practices in the importation of goods and provided specific remedies—central of which is exclusion from entry. The statute’s references to “entry”⁷ are

⁷ Citations to interpretations of terms in unrelated statutes or cases that generally concern the term “importation” and “articles of commerce” untied to Section 337 offer little guidance. *See*

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found in eight of the fourteen subsections of Section 337 and provide various remedies directed toward articles specifically: exclusion from entry and seizure and forfeiture orders. *See* 19 U.S.C. § 1337(d), (e), (i), (j) (*e.g.*, “articles concerned” be excluded from entry; “attempted entry”; and “denial of entry”). This focus on how “articles” obtain “entry” into the United States is no accident. The concern with entry reflects Congress’s explicit choice to attack the problem of articles that violate Section 337 through established Customs entry procedures (*i.e.*, Section 484 of the Tariff Act of 1930 (19 U.S.C. § 1484) and associated Customs regulations 19 U.S.C. § 1484(c)(1) (Entry)).⁸ It is this remedial scheme that was adopted in Section 337.

That scheme contemplates only tangibles as “articles.” Electronic transmissions do not arrive at ports of entry, are incapable of being held in Customs custody, cannot be presented to Customs, and therefore can never be refused or denied entry. An exclusion order directed against electronic transmissions could not only have no effect within the context of Section 337—it simply would make no sense as it would not be enforced. Moreover, to define “articles” as including electronic transmissions would render much of Section 337 meaningless because the definition cannot be applied to all or part of eight of the fourteen subsections of Section 337. *See United States v. Ron Pair Enterprises, Inc.* 489 U.S. 235, 242 n.5 (1989) (a definition should be

Cedar Rapids Community School Dist. V. Garret F. ex rel. Charlene F., 526 U.S. 66, 78 n.10 (1999).

⁸ The procedure may be briefly described as follows: Once merchandise arrives at a port of entry, it is regarded as imported and comes under Customs’ custody. In order to obtain release from Customs’ custody into the “United States,” *i.e.*, the customs territory of the United States, the importer must “make entry,” *i.e.*, present certain documentation to Customs so that Customs may determine whether the merchandise may be admitted into the customs territory of the United States and, if admissible, what duties, if any, are applicable. It is a hallmark of this process that both the merchandise and entry documentation are presented to Customs before Customs may permit the merchandise to enter the customs territory of the United States. 19 U.S.C. § 1484(c)(1) (Entry); *see, generally, Ernesto F. Rodriguez, Inc. v. United States*, 65 Cust. Ct. 163, C.D. 4072 (1970); *United States v. Mussman & Shafer*, 40 C.C.P.A. 108 (1953); *Wilcon v. United States*, 13 Cust. Ct. 96, C.D. 876 (1944).

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consistent with and give effect to the entire statute). For example, Section 337(i) discusses “attempted entry” of the article. It makes little sense to say electronic data is the subject of “attempted entry”—it was either transmitted or it was not. This provision only reasonably applies to attempts to import physical goods. Congress has chosen not to regulate electronic transmissions or other forms of data⁹ through Custom’s entry procedures. An interpretation of “article” that captures that which Congress expressly denied Customs from regulating would be entirely inconsistent with the remedial scheme of Section 337 established by Congress.

In addition, the term “article” should be construed to have the same meaning throughout the statute, regardless of the remedy. *See Sullivan v. Stroop*, 496 U.S. 478, 484 (1990) (“The substantial relation between the two programs presents a classic case for application of the ‘normal rule of statutory construction that “identical words used in different parts of the same act are intended to have the same meaning’.”) (citations omitted). It would be improper to define “article” differently depending on whether one is referring to an exclusion order or a cease and desist order. Indeed, to define “article” in such a way that a separate regime is created for electronic transmissions consisting of only select portions of Section 337 would run afoul of the remedial framework established by Congress. For example, cease and desist orders may be issued “in lieu of” exclusion orders. The legislative history makes clear that cease and desist orders were added to provide a less draconian remedy than exclusion orders, and our reviewing court has referred to cease and desist orders as a “softer remedy” than exclusion orders. *Textron, Inc. v. USITC*, 753 F.2d 1019, 1029 (Fed. Cir. 1985); *see* S. Rep. 93-1298 at 198 (1974). This is laid out by the language of the statute, which provides that cease and desist orders can be

⁹ HTSUS General Headnote 3(e)(ii) and (iii) (emphasis added) (2012). For the purposes of general note 1 the following are also exempt: (ii) telecommunication transmissions...(iii) records, diagrams and **other data** with regard to any business, engineering or exploration operation whether on paper, cards, photographs, blueprints, tapes or **other media**.

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replaced with exclusion orders. If “articles” were defined to include electronic transmissions, such replacement would not be possible. Indeed, that provision demonstrates that the definition of “articles” for Section 337(f) must be the same as the rest of the statute; otherwise the provision for replacement would be rendered a nullity and read out of the statute.¹⁰ Due to the nature of electronic data transmissions, for example, an exclusion order’s requirement that goods be “permitted entry” if a respondent posts a bond makes little sense when such transmissions cannot be subject to the Customs entry and other port requirements. If issuing an exclusion order against electronic data is incompatible with this scheme then, according to the express statements of the statute, cease and desist orders solely based upon electronic transmissions should not issue either.

3. The federal courts also have provided significant guidance on the meaning of the term “article” that strongly suggests that it should not include intangibles for the purposes of the importation requirement.

In *Bayer v. Housey*, the Federal Circuit analyzed Section 337, stating that Section 337 does not cover intangibles.¹¹ 340 F.3d at 1374. In *Bayer*, the question before the Federal Circuit

¹⁰ Critically, this does *not* prevent the Commission from including electronic transmissions within the scope of a cease and desist order, as in *Hardware Logic*, in order to prevent circumvention of its remedial orders after it has already found a violation of Section 337. This possibility is based on the Commission’s broad remedial authority. It does not depend on whether electronic transmissions are “articles.”

¹¹ Multiple courts are in accord. For example, in interpreting the term “article” in a previous Tariff Act, the Supreme Court held that it “applied to almost every separate substance or material, whether as a member of a class, or as a particular substance or commodity.” *Junge v. Hedden*, 146 U.S. 233, 238 (1892). The Court of Customs and Patent Appeals (the “C.C.P.A.”), the predecessor to the Federal Circuit, explained that the term “articles” is used hundreds of times in most tariff statutes, with narrower or broader meanings, but that in providing a dutiable list in Title I of the Tariff Act of 1930, it means, in a broad sense, “any provided-for substance, material or thing of whatever kind or character.” *United States v. Eimer & Amend*, 28 CCPA 10, 12 (1940). Thus, according to the C.C.P.A., the dutiable schedule of the Tariff Act of 1930

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was whether the term “a product which is made by a [patented] process” in 35 U.S.C. § 271(g) includes information as a result of that process. The court held that it does not. To arrive at that conclusion, the court looked to Section 337 as section 271(g) “was designed to provide new remedies to supplement existing remedies from the International Trade Commission (“ITC”) under 19 U.S.C. § 1337 (2000).”¹² *Id.* at 1373. Indeed, in expanding infringement to include section 271(g), Congress “recognized the availability of redress from the ITC, but noted that the remedies available thereunder were insufficient to fully protect the owners of process patents.” *Id.* at 1374. The court stated that the “legislative history suggests that section 271(g) was intended to address the same ‘articles’ as were addressed by section 1337, but to add additional rights against importers of such ‘articles.’” *Id.* at 1374. It then stated:

We recognize that section 1337 covers both articles that were “made” and articles that were “produced, processed, or mined.” While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

Id. at 1374 n.9. While the Federal Circuit decision concerned section 271(g), that decision was based on the court’s understanding that Section 337 does not cover intangible information. Indeed, in the absence of that understanding, there would be little or no basis for the Court’s holding regarding section 271(g), thereby indicating that this discussion should not be discounted as dicta.

represents the broadest possible sense of the term “article.” As noted above, the schedule lists tangible goods.

¹² The court specifically noted Section 337(a)(1)(B)(ii) (referring to “articles that – are made, produced, processed or mined under . . .”), but also referred to Section 337(a)(1)(A) (referring to “unfair acts in the importation of articles”). *Id.* at 1373-74. The court had previously noted that the term “article” refers to “one of a class of material things . . . piece of goods: commodity.” *Id.* at 1372 n.4.

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The Federal Circuit further clarified that the creation of electronic data cannot be considered to be “manufactured” or a “product” under section 271(g) in *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1323-24 (Fed. Cir. 2005). In that case, the plaintiff argued that, while *Bayer* might address electronic data in the abstract, the defendant’s intangible e-mail packets were actually “manufactured” and “imported” due to the specific packaging of the data by the defendant. *Id.* The court disagreed, holding that “transmission of information ... does not entail the manufacturing of a physical product,” so section 271(g) did not apply. Similarly, the complainant in this case cannot escape the requirements of Section 337 through the argument that the respondent’s data is packaged in any specific format and so is “manufactured.”

The Federal Circuit also has suggested that “articles” are limited to “tangible articles” in interpreting the portion of Section 337 dealing with the domestic industry requirement. Under Section 337(a)(3), “an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent,” certain investments. The court interpreted this language in several cases this year. In *Interdigital Communications, LLC v. International Trade Commission*, 707 F.3d 1295 (Fed. Cir. 2013) (opinion on denial of rehearing), the court extensively examined the legislative history of Section 337(a)(3).¹³ The court held that the domestic industry requirement is met by goods manufactured outside the United States as long as there is substantial investment in licensing in the United States. *See id.*

¹³ The court restated this point in *Motiva* holding that licensing programs only meet the need that there be “articles protected by the patent” when those programs “encourage adoption and development of articles that incorporated... patented technology.” *Motiva, LLC v. International Trade Commission*, 716 F.3d 596, 600 (Fed. Cir. 2013). In *Motiva*, the Federal Circuit relied not only on *Interdigital* but also on *John Mezzalingua Assocs. v. Int’l Trade Comm’n*, 660 F.3d 1322 (Fed. Cir. 2011) in which it noted that the “Commission is fundamentally a trade forum, not an intellectual property forum” and holding that “litigation expenses directed at preventing instead of encouraging *manufacture of articles* incorporating patented technology does not satisfy the domestic industry requirement of Section 337.” *Id.* at 600 (emphasis added).

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at 1303-04. But the court also held that licensing activity only meets the domestic industry requirement if there are “articles protected by the patent.” *Id.* at 1300-04. The court held that the legislative history made clear “that a sufficiently substantial domestic industry will need to license its technology *to a manufacturer somewhere*; they do not say that the manufacturer must be domestic.” *Id.* at 1303 n.4 (emphasis added). This suggests that the “articles protected by the patent” are physical articles manufactured somewhere. Recently, in *Microsoft Corp. v. Int’l Trade Comm.*, 731 F.3d 1354, 1362 (Fed. Cir. 2013)(emphasis added), the court noted that “[a] company seeking section 337 protection must therefore provide evidence that its substantial domestic investment ... relates to an *actual article* that practices the patent, regardless of whether or not that article is *manufactured* domestically or abroad.”

In sum, the Federal Circuit has indicated an “article protected by the patent” under Section 337(a)(3) is a physical good—and specifically a good that can practice the patent. Indeed, it is difficult to see how abstract data can be said to be “practicing the patent.” The key point is that the word “article” appears both in the domestic industry requirement of Section 337(a)(3) and in the importation requirement of Section 337(a)(1)(b). Accordingly, the same word found in adjoining statutory sections should be given the same meaning. *See Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2004-05 (2012) (“[I]t is a ‘normal rule of statutory construction’ that ‘identical words used in different parts of the same act are intended to have the same meaning’.”). It is contrary to canons of statutory construction to construe the “articles” being “protected” one way and the “articles” causing the harm another way.

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Nor do prior decisions of this Commission compel a different interpretation of “articles.”¹⁴ For example, in *Hardware Logic*,^{15,16} the Commission determined to include electronic transmission of the respondents’ infringing software in a cease and desist order (but not an exclusion order). *Id.* at *11. Importantly, the allegedly infringing import was not an electronic transmission in that investigation, but rather a (tangible) emulation device system, which included software. It was argued that some systems were imported without software. It was also argued that some of the software was imported on a disk or electronically transmitted into the United States. As to the software imported as part of an infringing emulation system and on a disk, which clearly could be imported or excluded by Customs from importation, the

¹⁴ Most recently, in the related proceeding, *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), Public Comm’n Op. (Feb. 19, 2013), the Commission reaffirmed the holding of *Hardware Logic* that the Commission may craft its cease and desist orders and consent orders to prohibit the importation of electronic transmissions after a determination of violation. As the Commission noted in its submission to the Federal Circuit on appeal, the 562 investigation did not address whether an electronic transmission of digital data is an article in the context of violation. On page 7 of its opinion in *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), the Commission stated “[T]he Commission has held that it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States,” *Id.* (citing *Certain Hardware Logic Systems and Components Thereof* (“*Hardware Logic*”), Inv. No. 337-TA-383). The citation includes the following parenthetical as to the holding in *Hardware Logic*: “(stating that the Commission has the legal authority to issue a remedial order that covers electronic importations, and issuing a cease and desist order that covered electronic importation).” Thus, *Dental Appliances* confirms that the Commission’s broad authority to fashion a remedy (covering acts which might not themselves be a violation of the statute) can justify a cease and desist order addressing electronic transmissions in an appropriate case.

¹⁵ *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383, Commission Determination (U.S.I.T.C. 1998), 1998 WL 307240.

¹⁶ Similarly, in *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, the accused products were hardware with versions of source code. Final ID at 57 (May 9, 2005). In *Viruses*, the Commission stated that it was following *Hardware Logic*, and prohibiting electronic transmissions in the cease and desist order but not in the exclusion order. Comm’n Op. at 4-5 (Aug. 23, 2005).

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Commission entered an exclusion order covering those emulation systems found in violation. *See id.* at *7-9. But the Commission was concerned that its remedy could be circumvented if it did not preclude transmission of the software running those emulation systems. *Id.* at *15.

To avoid circumvention of its orders of a Section 337 violation—based on importation of physical articles—the Commission recognized that its remedial authority to issue cease and desist orders could cover electronic transmissions of data. *Id.* at *16. Put another way, the Commission’s remedy may go beyond merely stopping the actual violation that triggered the Commission’s jurisdiction and also include “reasonably related” acts that would result in circumvention of the Commission’s order. *See FTC v. Mandel Bros.*, 359 U.S. 385, 392-93 (1958) (permitting FTC to prohibit like and related acts of misbranding with amended wording of cease and desist order).¹⁷ But the fact that the Commission has broad remedial power does not expand the Commission’s ability to change activity that is not a violation of Section 337 into one that is. To the extent that others have interpreted the Commission as holding otherwise, those interpretations stretch that decision too far.¹⁸

4. While the majority carefully provides a thoughtful analysis of the statute and law to come to a contrary conclusion, I must respectfully disagree.

¹⁷ The language of Section 337 closely resembles the language of the FTC Act, 15 U.S.C. § 45.

¹⁸ One such interpretation is found in *Former Employees of Computer Sciences Corp. v. United States Secretary of Labor*, 414 F. Supp. 2d 1334 (C.I.T. 2006), but *cf. Woodrum v. U.S.*, 737 F.2d 1575 (Fed Cir. 1984) (Federal Circuit affirmed the CIT’s determination that the term “article,” under section 222(3) of the Trade Act of 1974, does not cover activity that fails to create or manufacture a tangible commodity, or transforming an existing product into a new and different article). This decision concerns whether former employees ought to receive certain benefits under 19 U.S.C. § 2272(a)(2)(A) (“Trade Adjustment Assistance”). In interpreting that statute the CIT characterized our decision in *Hardware Logic*, as holding that “software [is] an article of importation regardless of its mode of importation.” *Id.* at 1342. This 2006 decision is not binding on the Commission but is instead binding on the Department of Labor and appears inconsistent with other authority.

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The majority states that its “task is to determine whether the phrase ‘importation ... of articles’ encompasses this modern form of international commerce, or should be understood as limited to the kinds of international transactions in existence when the statute was first enacted” (at 54). To be sure, it is appropriate to apply a statute to new technology when that technology falls within the words of the statute. No one would argue that Section 337 is frozen to cover only items that existed in 1930. But we are also bound by the words of statute, and we should examine new technologies in light of the statute and regulations as written. The Supreme Court’s decision in *Fortnighly Corp. v United Artists Television, Inc.*, 392 U.S. 390 (1968), highlights this principle.

In *Fortnighly*, the owners of copyrighted motion pictures brought suit against community antenna television systems that acted as large antennas to receive television broadcasts for communities that had trouble picking up the broadcasts using standard household receivers. *See id.* at 391. The Supreme Court acknowledged that it “must read the statutory language of 60 years ago in the light of drastic technological change.” *Id.* at 396. But the Court did not divorce such a reading from the language of the statute and held that those transmissions could not be understood to violate the enumerated rights listed in the Copyright Act. *See id.* 400-01. In doing so, the Court rejected the argument that it “accommodate various competing considerations of copyright, communications, and antitrust policy,” stating “[w]e decline the invitation. That job is for Congress. We take the Copyright Act of 1909 as we find it.” *Id.* at 401.¹⁹ In this instance, extending the term “article” in Section 337 to cover electronic

¹⁹ Congress subsequently took up that job in enacting the Copyright Act of 1976 to cover such situations. *See WGN Continental Broadcasting Co. v. United Video, Inc.*, 693 F.2d 622, 624 (7th Cir. 1982).

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transmissions of digital data would be an over extension of the statute. *See Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1355 (“The ITC is a creature of statute, and must find authority for its actions in its enabling statute.”).

Moreover, based on its goals of preventing every type and form of unfair practice, the majority finds that electronic transmissions must be covered under Section 337 by holding that “the meaning of ‘articles’ extends to all imported items of commerce as to which a finding of infringement by a patent, trademark, copyright or protected hull design may be sustained (provided that all other requirements of the statute are met).” Op. at 42. But defining “article” in Section 337 in terms of what infringes raises the question of what the definition of “article” is.²⁰ This definition does not account for the numerous cases in which infringement is clearly demonstrated, but no violation of Section 337 is found based on additional statutory requirements contained in Section 337, *e.g.*, 1337(a)(2), (3). If there can be acts of infringement that do not yield a violation of Section 337, then one should avoid treating infringement and Section 337 as coextensive.

Indeed, the “other requirements of the statute” *also* use the term “article”; it does not appear only in the phrase “articles that infringe” in Section 337(a)(1)(B). It is also found in the phrases “exclusion of articles from entry,” § 337(d), “articles ... be seized,” § 337(i), “previously attempted to import the article,” § 337(i)(1)(A), and “consignee of any article,” § 337(i)(4). As explained above, those phrases lack clear meaning if “article” includes electronic transmissions. Thus, any interpretation focused solely on the phrase “articles that infringe” without consideration of those other uses of the word in this trade statute is improper.

²⁰ *See* n. 2 *supra*.

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Finally, an alternative definition of “article” that “encompasses such items as are bought and sold in commerce and that are imported into the United States, regardless of the mode of importation,” (Op. at 41) appears overly broad. In fact, there are things that are not “articles” under anyone’s definition, which “could be bought and sold”— for example a service.

Ultimately, I am sympathetic to protecting against all manner of unfair trade actions. The Commission, however, is bound by statute, and I am reluctant to broaden the definition of “article” as suggested by Align and the majority without an act of Congress.

5. In sum, the plain language of the statute, its interplay with other trade statutes, the lack of guidance in the statute’s legislative history, and the statute’s prior judicial interpretation all lead to the same place: Congress did not delegate to the Commission the authority to remedy importation of “articles” based only on electronic data transmitted into the United States. Under the facts in this investigation, the activities of the respondents may be unfair business practices and may even deserve a remedy in some other forum. But it is not clear that electronic transmissions of data are “articles” under Section 337, and absent such clarity the Commission should defer to Congress and should err on not assuming new powers. So far, Congress has not taken this step. *See Schaper Mfg. Co. v. International Trade Comm’n*, 717 F.2d at 1373 (“If, as appellants suggest, present-day ‘economic realities’ call for a broader definition to protect American interests (apparently including many of today’s importers) it is for Congress, not the courts or the Commission, to legislate that policy.”). For these reasons, I respectfully dissent and hold that due to a lack of importation of “articles” within the meaning of Section 337 there can be no violation of Section 337 in this investigation, and, therefore, do not join the remainder of the Commission’s opinion.

**CERTAIN DIGITAL MODELS, DIGITAL DATA, AND
TREATMENT PLANS FOR USE, IN MAKING
INCREMENTAL DENTAL POSITIONING ADJUSTMENT
APPLIANCES, THE APPLIANCES MADE THEREFROM,
AND METHODS OF MAKING THE SAME**

337-TA-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **April 10, 2014**.



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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

Inv. No. 337-TA-833

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDED DETERMINATION ON REMEDY AND BOND**

Administrative Law Judge Robert K. Rogers, Jr.

(May 6, 2013)

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Pursuant to the Notice of Investigation and Rule 210.42 of the Rules of Practice and Procedure of the United States International Trade Commission, this is the Administrative Law Judge's Final Initial Determination in the matter of Certain Digital Models, Digital Data, And Treatment Plans For Use, In Making Incremental Dental Positioning Adjustment Appliances Made Therefrom, And Methods Of Making The Same, Investigation No. 337-TA-833.

The Administrative Law Judge hereby determines that a violation of Section 337 of the Tariff Act of 1930, as amended, has been found in in the sale for importation and the importation into the United States of certain digital models, digital data sets, and treatment plans, and the sale of incremental dental positioning adjustment appliances made using the digital models, digital data sets, and treatment plans after importation thereof, in connection with U.S. Patent Nos. 6,217,325, 6,471,511, 6,705,863, 6,722,880, 7,134,874, and 8,070,487. Furthermore, the Administrative Law Judge hereby determines that a domestic industry in the United States exists that practices U.S. Patent Nos. 6,217,325, 6,471,511, 6,705,863, 6,722,880, 7,134,874, and 8,070,487.

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The following abbreviations may be used in this Initial Determination:

CPX	Complainant's physical exhibit
CDX	Complainant's demonstrative exhibit
CX	Complainant's exhibit
CIB	Complainant's initial post-hearing brief
CRB	Complainant's reply post-hearing brief
RPX	Respondents' physical exhibit
RDX	Respondents' demonstrative exhibit
RX	Respondents' exhibit
RIB	Respondents' initial post-hearing brief
RRB	Respondents' reply post-hearing brief
SIB	Commission Investigative Staff's initial post-hearing brief
SRB	Commission Investigative Staff's reply post-hearing brief
Dep.	Deposition
SRJCCC	Second Revised Joint Claim Construction Chart
JSCI	Joint Stipulation of Contested Issues
JX	Joint Exhibit
Tr. at	Transcript
CPHB	Complainant's pre-hearing brief
RPHB	Respondents' pre-hearing brief
SPHB	Commission Investigative Staff's pre-hearing brief

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I. BACKGROUND

A. Procedural History

On March 30, 2012, the Commission issued a Notice of Investigation in this matter to determine:

[W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same that infringe one or more of claims 1-3, 11, 13, 14, 21, 30-35, 38, and 39 of [U.S. Patent No. 6,217,325]; claim 1 of [U.S. Patent No. 6,471,511]; claims 1, 3, 7, and 9 of [U.S. Patent No. 6,626,666]; claims 1 and 4-8 of [U.S. Patent No. 6,705,863]; claims 1 and 3 of [U.S. Patent No. 6,722,880]; claims 1, 2, 38, 39, 41, and 62 of [U.S. Patent No. 7,134,874]; and claims 1, 3, 5, and 7-9 of [U.S. Patent No. 8,070,487], and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(See Notice of Investigation) The investigation was instituted upon publication of the Notice of Investigation in the *Federal Register* on April 5, 2012. See 77 Fed. Reg. 20648-49; 19 CFR § 210.10(b).

The complainant is Align Technology, Inc. (“Align”) 2560 Orchard Parkway, San Jose, CA 95131. The respondents are ClearCorrect Pakistan (Private), Ltd. (“CCPK”), Azia Cottage, 9-Kanal Park, Gulberg II, Lahore, Pakistan and ClearCorrect Operating, LLC (“CCUS”), 15151 Sommermeyer Street, Houston, TX 77041-5332. The Commission Investigative Staff of the Office of Unfair Import Investigations (“Staff”) is also a party in this investigation.

On January 2, 2013, I issued Order No. 17, an order that granted Align’s motion to strike CCUS’s and CCPK’s ninth affirmative defense directed to inequitable conduct.

On January 14, 2013, I issued Order No. 20, an order that denied CCUS’s and CCPK’s motion for summary determination and found that CCUS and CCPK waived any estoppel

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defense, including defenses based on implied license or patent exhaustion.

On February 4, 2013, I granted-in-part CCUS's and CCPK's Motion In Limine No. 4, finding that while Align can argue the doctrine of equivalents, they waived the right to rely on any evidence to show the doctrine of equivalents. (Tr. at 42:3-17)

An evidentiary hearing in this investigation was held on February 4-6, 2013.

B. The Private Parties

1. Align Technology, Inc.

Align is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in San Jose, California. (Corrected Complaint at ¶ 16)

2. ClearCorrect Operating, LLC.

CCUS is a corporation organized and existing under the laws of the state of Texas with its principal place of business in Houston, Texas. (CCUS Response to Corrected Complaint at ¶ 17)

3. ClearCorrect Pakistan (Private), Ltd.

CCPK is a corporation organized and existing under the laws of Pakistan with its principal place of business in Lahore, Pakistan. (CCPK Response to Corrected Complaint at ¶ 18)

C. Overview Of The Patents At Issue

U.S. Patent No. 6,217,325 ("the '325 patent") is entitled "Method and System for Incrementally Moving Teeth." (JX-003) It lists Muhammad Chishti, Apostolos Lerlos, Brian Freburger, Kelsey Wirth, and Richard Ridgley as the inventors. (*Id.*) It was filed on April 23, 1999 and issued on April 17, 2001 and is subject to a terminal disclaimer. (*Id.*) The '325 patent was the subject of an ex parte reexamination based on a request received on July 27, 2005. (*Id.*)

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A reexamination certificate issued on January 15, 2008. (*Id.*) The Abstract of the '325 patent states:

A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

(JX-003 at Abstract)

U.S. Patent No. 6,722,880 ("the '880 patent") is entitled "Method and System for Incrementally Moving Teeth." (JX-002) It lists Muhammad Chishti and Kelsey Worth as the inventors. (*Id.*) It was filed on January 14, 2002 and issued April 20, 2004 and is subject to a terminal disclaimer. (*Id.*) The Abstract of the '880 patent states:

A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

(JX-002 at Abstract)

U.S. Patent No. 8,070,487 ("the '487 patent") is entitled "System and Method for Positioning Teeth." (JX-007) It lists Muhammad Chishti and Andrew Beers as the inventors. (*Id.*) It was filed on October 31, 2007 and issued December 6, 2011 and is subject to a terminal disclaimer. (*Id.*) The Abstract of the '487 patent states:

Methods and apparatus fit a set of upper and lower teeth in a masticatory system by generating a computer representation of the masticatory system and computing an occlusion based on interactions in the computer

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representation of the masticatory system.

(JX-007 at Abstract)

U.S. Patent No. 6,471,511 (“the ‘511 patent”) is entitled “Defining Tooth-Moving Appliances Computationally.” (JX-001) It lists Muhammad Chishti, Elena I. Pavlovskaja, Gregory P. Bala, and Brian Freyburger as the inventors. (*Id.*) It was filed on October 8, 1998 and issued October 29, 2002, and is subject to a terminal disclaimer. (*Id.*) The Abstract of the ‘511 patent states:

Methods and corresponding apparatus for segmenting an orthodontic treatment path into clinically appropriate substeps for repositioning the teeth of a patient. The methods include providing a digital finite element model of the shape and material of each of a sequence of appliances to be applied to a patient; providing a digital finite element model of the teeth and related mouth tissue of the patient; computing the actual effect of the appliances on the teeth by analyzing the finite elements models computationally; and evaluating the effect against clinical constraints. The appliances can be braces, polymeric shells, or other forms of orthodontic appliance. Implementations can include comparing the actual effect of the appliances with an intended effect of the appliances; and identifying an appliance as an unsatisfactory appliance if the actual effect of the appliance is more than a threshold different from the intended effect of the appliance and modifying a model of the unsatisfactory appliance according to the results of the comparison. The model and resulting appliance can be modified by modifying the shape of the unsatisfactory appliance, by adding a dimple, by adding material to cause an overcorrection of tooth position, by adding a ridge of material to increase stiffness, by adding a rim of material along a gumline to increase stiffness, by removing material to reduce stiffness, or by redefining the shape to be a shape defined by the complement of the difference between the intended effect and the actual effect of the unsatisfactory appliance.

(JX-001 at Abstract)

U.S. Patent No. 6,626,666 (“the ‘666 patent”) is entitled “Method and System for Incrementally Moving Teeth.” (JX-004) It lists Muhammad Chishti, Apostolos Leros, Brian Freyburger, Kelsey Wirth, and Richard Ridgley as the inventors. (*Id.*) It was filed on January 8,

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2001 and issued on September 30, 2005 and is subject to a terminal disclaimer. (*Id.*) The

Abstract of the '666 patent states:

A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

(JX-004 at Abstract)

U.S. Patent No. 6,705,863 ("the '863 patent") is entitled "Attachment Devices and Methods for a Dental Appliance." (JX-005) It lists Loc Phan, Muhammad Chishti, and Ross Miller as the inventors. (*Id.*) It was filed on October 29, 2001 and issued on March 16, 2004 and is subject to a terminal disclaimer. (*Id.*) The '863 patent was the subject of an ex parte reexamination based on a request received on June 23, 2005. (*Id.*) A reexamination certificate issued on January 8, 2008. (*Id.*) The Abstract of the '863 patent states:

The present invention provides improved systems and methods for removably attaching a dental positioning appliance to the dental features of a patient during orthodontic treatment. These appliances function by applying force to specific surfaces of the teeth or dental features to cause directed movement. The application of force is improved by the use of one or more attachment devices which may be positioned on the teeth or dental features to provide the appropriate physical features. Specific design and location of these attachment devices may provide newly achievable and/or more effective repositioning forces, anchoring ability and appliance retention. The systems and methods of the present invention provide the design, production and use of such attachment devices with removable dental positioning appliances in orthodontic treatment.

(JX-005 at Abstract)

U.S. Patent No. 7,134,874 ("the '874 patent") is entitled "Computer Automated Development of an Orthodontic Treatment Plan and Appliance." (JX-006) It lists Muhammad

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Chishti, Brian Freyburger, Kelsey Wirth, Andrew Beers, Huafeng Wen, Phillips Benton, Timothy Jones, and Ross Miller as the inventors. (*Id.*) It was filed on November 20, 2003 and issued November 14, 2006. (*Id.*) The Abstract of the '874 patent states:

A computer is used to create a plan for repositioning an orthodontic patient's teeth. The computer receives an initial digital data set representing the patient's teeth at their initial positions and a final digital data set representing the teeth at their final positions. The computer then uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.

(JX-006 at Abstract)

D. Products At Issue

Align accuses digital data sets made by CCUS and CCPK and customized sequential aligners made by CCUS, and the processes used to make those data sets and aligners, of infringing claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, and 39 of the '325 patent, claims 1 and 3 of the '880 patent, claims 1, 3, 5, 7, 8, and 9 of the '487 patent, claim 1 of the '511 patent, claims 1, 3, 7, and 9 of the '666 patent, claims 1, 4, 5, 6, 7, and 8 of the '863 patent, and claims 1, 2, 38, 39, 41, and 62 of the '874 patent. (*See* CIB at 4-5)

II. JURISDICTION

A. Subject Matter Jurisdiction

Align's Position: Align says that while Respondents do not dispute they import the digital data, they dispute whether the digital data is an "article" under 19 U.S.C. § 1337. Align asserts that "Article" is a Commission term of art, the precedent of which holds that "data" is an "article." Align says that when used in any context before the Commission, "articles" should include all types of "data," including the Respondents' "digital data sets." Align says that the Commission has recently confirmed, in a related investigation, that it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United

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States.” (Citing *Certain Incremental Dental Positioning Adjustment Appliances*, Inv. No. 337-TA-562, Comm’n Op. at 7 (Jan. 23, 2013))

Align contends that Congress selected the broad word “articles” to enable the Commission to serve its high purpose of protecting domestic industry from foreign infringement and other unfair trade practices. (Citing *Certain Devices for Connecting Computers*, Inv. No. 337-TA-360, USITC Pub. 2843, Comm’n Op. at 9 (Dec. 1994) (quoting Senate Committee report that predecessor to section 337 “‘is broad enough to prevent every type and form of unfair practice’ with respect to imports,” and declaring that “[n]othing since then indicates any Congressional intent to narrow this remedial authority”)) Align says that while perhaps most imported articles are tangible goods, there is nothing in the unqualified word “articles” that inherently narrows the scope of section 337. Align continues that Congress intended to vest the Commission with plenary powers to protect domestic industries from infringing articles of all kinds, irrespective of medium or shifting technologies of production or distribution.

Align says that the Commission has held that “[t]he scope of section 337 is broad enough to prevent every type and form of unfair practice, including the transmission of infringing software by electronic means, electronic transmission of software and/or data that induces an infringing use of an imported product, and the servicing of imported products that induce infringement.” (Citing *Certain Set Top Boxes*, Inv. No. 337-TA-454, USITC Pub. 3564, Final I.D. at 304-05 (Nov. 8, 2002) (citing *Certain Hardware Logic*, Inv. No. 337-TA-383, USITC Pub. 3089, Comm’n Op. at 25-29 (Mar. 1998))) Align continues that the Commission has specifically held that software and data, such as the digital data sets here, is an “article.” For example, Align says that in *Certain Hardware Logic* respondents argued “that software cannot be fairly defined as one of the ‘articles’ encompassed by section 337(a)(1)(B).” (Citing *Certain*

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Hardware, Inv. No. 337-TA-383, Final I.D. at 292 (July 31, 1997)) Align continues that Judge Luckern disagreed, in a section titled “Software Is An ‘Article’ That May Be Excluded,” and finding that “any exclusion order should cover . . . software.” (Citing *id.* at 292, 295.) Align says that Judge Luckern observed that there was:

a direct nexus between respondents importation [of software], via electronic transmission or otherwise, and infringement of the patents in issue. It is undisputed that the software necessary to operate the accused Meta systems is created in France and transmitted to the United States . . . Accordingly, the administrative law judge finds that a cease and desist order directed to Meta software is necessary to prevent respondents’ continued violation of section 337.

(Citing *Id.* at 197)

Align argues that the same situation is present here. Align says that the data created by CCPK and imported into the U.S. is essential to CCUS’s fabrication of appliances. (Citing Tr. at 320:2-9, 320:20-321:15, 443:3-6) Align says that CCUS could not make its appliances without this data, and no other customer would purchase this data, as it cannot be used for any purpose other than making customized dental appliances. (Citing Tr. at 320:2-9, 320:20-321:15, 442:24-443:10, 443:25-444:3; CX-1162C.3 at 97:1-14)

Align disagrees with Respondents’ legal arguments as to the scope of “articles” in their Prehearing Brief. First, Align says that Respondents argue that *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1372-78 (Fed. Cir. 2003), somehow limits the scope of “article” in 19 U.S.C. § 1337. Align argues that *Bayer* addressed the scope of 35 U.S.C. § 271(g) – not 19 U.S.C. § 1337. Align says that the Commission has not limited the scope of “article” in 19 U.S.C. § 1337(B) in a fashion similar to *Bayer* and has, in fact, expressly held that the word “article” may include data and that precedent controls, not *Bayer*.

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Align says that Respondents argue that the definition of “article” should be dictated by case law interpreting the meaning of “manufacture” under 35 U.S.C. § 101. Align contends that this argument is neither logically nor legally correct. Align says that 35 U.S.C. § 101 sets the scope of allowable subject matter for patenting as, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” Align continues that both cases cited by Respondents, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007), are directed toward defining, *inter alia*, the scope of the noun “manufacture” in 35 U.S.C. § 101, not “articles” as used before the Commission, and are therefore not on point.

Align says that Respondents admit that, since June of 2009, digital data from CCPK has been sent to CCUS in the U.S. for the purpose of making the physical models used to fabricate aligners for sale to U.S. providers. (Citing Tr. at 320:2-9, 320:12-15, 364:20-365:12, 442:19-23) Align says that CCPK receives payment from CCUS for that digital data. (Citing Tr. at 320:2-9, 364:20-365:12, 373:24-374:4; CX-1160C.2 at 278:2-9, 294:2-7, 296:3-7; CX-1160C.3 at 422:25-423:8) As a result, Align concludes that it is beyond dispute that CCPK sold or offered to sell the digital data in the U.S., and that these digital data sets were brought into the U.S. {
} (Citing Tr. at 316:4-22, 320:12-15, 442:19-23; CX-1160C.1 at 97:22-98:2; CX-1160C.3 at 472:3-17) Align adds that these digital data sets are then used by CCUS to fabricate the infringing aligners that it sells in the U.S. Align concludes that in sum, Respondents have jointly or individually imported into the U.S., sold for importation into the U.S., and/or sold in the U.S. after importation the accused digital data sets.

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Align says that Respondents do not address any of the precedent cited by Align and Staff, and instead cite to inapposite cases analyzing different statutes (35 U.S.C. § 271(g) and 35 U.S.C. § 101) in an attempt to graft additional restrictions onto the scope of “articles” in § 337. (Citing RIB at 5 (citing *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1375 (Fed. Cir. 2003); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980); *In re Nuijten*, 500 F.3d 1346, 1356 (Fed. Cir. 2007))) Align says that Respondents’ arguments are not proper. (Citing *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546, 568 (2005) (“[T]he authoritative statement is the statutory text, not the legislative history or any other extrinsic material. Extrinsic materials have a role in statutory interpretation only to the extent they shed a reliable light on the enacting Legislature’s understanding of otherwise ambiguous terms.”)) Align continues that even if the cases were relevant in view of the controlling precedent cited by Align and Staff (they are not), Respondents misconstrue them.

Align contends that it has introduced extensive, undisputed evidence that Respondents import, sell for importation, or sell after importation the digital data sets. Align says that the evidence shows that: (i) CCPK sold or offered to sell the relevant digital data sets to CCUS {
} (ii) these digital data sets were brought into the U.S. {
} (Citing Tr. at 316:4-22, 320:12-15, 442:19-23; CX-1160C.1 at 97:22-98:2; CX-1160C.3 at 472:3-17); (iii) this activity was designed and implemented by CCUS (Citing Tr. at 460:18-461:2, 472:9-19); and (iv) CCUS provides CCPK with process instructions on how to prepare the digital data sets CCUS uses to prepare its clear aligners (Citing Tr. at 321:21-322:8, 445:7-11, 472:9-13; *see also* CX-1151C.1 at 115:25-116:20, 117:3-118:22, 198:5-11, 199:1-9, 299:24-300:9) Align concludes, that either CCPK or CCUS, or both jointly, are importing the digital data. Align adds that CCPK also sells the digital

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data to CCUS after its importation into the U.S. or sells the digital data to CCUS for importation into the U.S., depending on the alternative acts of importation. Align says that Respondents introduced no evidence to the contrary; rather, they relied on the argument that the digital data sets cannot be “imported” because they are not “articles” under § 337. (Citing RIB at 5)

Align says that Respondents raise a brand-new argument in their *PostHearing Brief* that:

claims 7-9 of the ‘487 patent are directed to “treatment plans” contained on a “removable storage medium.” Align has offered no proof that any of the Respondents sell for importation, import, or sell after importation treatment plans contained on a computer readable storage media. Tr. at 552:20-555:9.

(Citing RIB at 5) Align says that this argument fails because it was not raised in Respondents’ Prehearing Brief (Citing RPHB at 6-7) and is therefore waived. (Citing GR 8.2)

Respondents’ Position: Respondents argue that the Commission has neither subject matter jurisdiction nor *in rem* jurisdiction because the allegedly imported digital data sets are not “articles” within the meaning of the statute and are not “imported.” Respondents continue that Respondents have not been involved in any acts that would constitute the sale for importation, importation, or sale after importation of the CCPK data sets.

Respondents say that the Federal Circuit has construed the term “article” according to its plain, common meaning as requiring tangibility. Respondents continue that the Federal Circuit defined both “manufactured” and “articles” in *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1375 (Fed. Cir. 2003). According to Respondents, the Federal Circuit rejected the argument that intangible information is “manufactured” when it held “[t]hus, the production of information is not within the scope of processes of ‘manufacture.’” (Citing *Id.* at 1372) Respondents say that the Federal Circuit ~~next~~ considered whether reading the term “manufactured” in conjunction with “articles” changed the meaning and, in so doing, drew from amendments to the ITC’s enabling legislation concerning the importation of “articles” in concluding that the terms “manufactured”

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and “articles” “failed to reach intangible information.” (Citing *id.* at 1374-75) Respondents continue that the Federal Circuit, in interpreting the Supreme Court’s decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (citation omitted), acknowledged the tangibility requirement of the term “article.” (Citing *In re Nuijen*, 500 F.3d 1346, 1356 (Fed. Cir. 2007))

Respondents conclude that their digital data sets are not “articles,” nor are they “imported” in any common usage of that term. Respondents add that claims 7-9 of the ‘487 patent are directed to “treatment plans” contained on a “computer readable storage medium.” Respondents say that Align has offered no proof that any of the Respondents sell for importation, import, or sell after importation treatment plans contained on a computer readable storage media. (Citing Tr. at 552:20-555:9) Respondents conclude that, as to those claims, Align fails to meet its burden of proof relating to the importation requirement of the statute.

Respondents’ do not agree that *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1372-78 (Fed. Cir. 2003) is irrelevant because that case addresses the scope of §271(g), not Section 337. Respondents say that while the primary issue addressed in *Bayer* was the scope of §271(g), the Federal Circuit stated its understanding of the term “articles” as used in Section 337. Respondents continue that the Federal Circuit considered how to interpret language in §271(g) referring to “a product which is made by a process patented in the United States” and “a product which is made by a patented process.” Respondents contend that the issue was whether this language encompassed the production of information.

Respondents say that the Federal Circuit, in resolving this question, considered the fact that §271(g) “was not enacted on an entirely blank slate. Rather, it was designed to provide new remedies to supplement existing remedies available from the International Trade Commission (“ITC”) under 19 U.S.C. §1337 (2000).” (Citing *id.* at 1373) Respondents continue that

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Congress recognized that the remedies available under Section 337 “were insufficient to fully protect the owners of process patents. ... Thus, the legislative history suggests that §271(g) was intended to address the same ‘articles’ as were addressed by section 1337, but to add additional rights against importers of such ‘articles.’” (Citing *id.* at 1374) Respondents note that the Federal Circuit concluded that 271(g) does not cover intangible information, only tangible products. Respondents argue that the Federal Circuit specifically noted that “nothing in §1337 suggests coverage of information, in addition to articles, under section §271(g).” (Citing *id.* at 1374 n.9) Respondents conclude, as a result, that the Federal Circuit in *Bayer* expressly held that information is not an “article” and recognized that information is not included within the scope of Section 337. Respondents say that the Commission did not have the benefit of the *Bayer* decision (decided in 2003) when it decided *Hardware Logic Emulation Systems* (decided in 1998) and the Federal Circuit’s decision in *Bayer* is controlling here.

Respondents add that Align fails to meet its burden of proving the importation requirement as claims 7-9 of the ‘487 patent, directed to treatment plans on computer readable storage media. Respondents say that this is a jurisdictional issue. Respondents say that Mr. Beers testified that “I have analyzed this element and conclude that {

} (Citing CX-

1150C, Q. 252; Tr. at 554:7-23) {

} (Citing Tr. at 554:24-555:9)

Staff’s Position: Staff asserts that the Commission has both subject ~~matter~~ jurisdiction and *in rem* jurisdiction over the digital data sets that are created in Pakistan and that are imported into the United States. Staff says that Section 337(a)(1)(B) prohibits “the importation into the

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United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent . . . ; or (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.” (Citing 19 U.S.C. §1337(a)(1)(B)) Staff continues that pursuant to this statutory authority, the Commission has issued, on multiple occasions, remedial orders covering electronically transmitted data. (Citing *Certain Systems for Detecting and Removing Computer Viruses or Worms, Components Thereof* (“*Computer Viruses*”), Inv. No. 337-TA-510, Comm’n Determination at 16 (August 2007) (holding that a cease and desist order covering electronically transmitted data is appropriate where the failure to cover such would result in the circumvention of the cease and desist order); *Certain Set Top Boxes and Components Thereof*, Inv. No. 337-TA-454, Final Initial Determination at 304-314 (November 8, 2002) (noting that Section 337 is broad enough to prevent the electronic transmission of software and/or data that induces infringing use of an imported product) *Certain Hardware Logic Emulation Systems and Components Thereof* (“*Hardware Logic*”), Inv. No. 337-TA-383, Comm’n Opinion at 25-29 (March 1998) (issuing permanent cease and desist order prohibiting importation of electronically transmitted software))

Staff avers that one important policy rationale behind these decisions was that the failure to cover electronically transmitted data would allow for an obvious method of circumvention such that cease and desist orders would be rendered meaningless. Staff says that, for example, in *Hardware Logic*, the respondents imported software via the Internet and argued that the Commission did not have the power to regulate such electronic transmission. Staff continues that the Commission disagreed, stating that:

It is well settled that the scope of section 337 is “broad enough to prevent every type and form of unfair practice.” Software is useful only if it is reduced to an

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electronic form. Consequently, in applying the cease and desist order to respondents' software when it is transferred in an electronic form . . . , we are simply preventing the transfer of the infringing software in the very form in which it is executed by the computer.

Indeed, a cease and desist order that did not prohibit electronic transmission would be meaningless as to the software since respondents would be free simply to transmit the software electronically to a U.S. customer, who would then copy it onto a diskette or other tangible medium for use with an infringing emulation system. As the ALJ noted, the Commission clearly could and should reach software if it were sought to be transferred on a CD-ROM or diskette. We agree . . . that it would be anomalous for the Commission to be able to stop the transfer of a CD-ROM or diskette containing respondents' software, but not be able to stop the same software when transmitted in machine readable form by electronic means.

(Citing *Hardware Logic*, Inv. No. 337-TA-383, Comm'n Opinion at 56-57 (March 1998)) Staff argues that recognizing the duty to prevent its remedial orders from being circumvented, the Commission issued a permanent cease and desist order covering both software in a tangible medium; and software transmitted in an electronic form. Staff says that the Commission interpreted the term articles from section 337(a)(1)(B) to encompass both tangible and intangible subject matter.

Staff says that in *Computer Viruses*, the parties disagreed about the proper scope of the cease and desist order. Staff continues that the respondent argued that electronic transmissions of its software should not be prohibited under the cease and desist order although the software continued to include infringing modules. Staff says that the Commission disagreed and noted that without a prohibition against the electronic submission of the software (including the infringing module), the respondent could simply instruct its customers to electronically download the anti-virus module from the Internet, thereby circumscribing cease and desist orders. Staff concludes that the Commission then issued a cease and desist order covering electronically transmitted software. (Citing *Computer Viruses*, Inv. No. 337-TA-510, Comm'n Determination at 16)

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Staff contends that in all of the above mentioned investigations, the term “articles” was consistently understood to include software and data whether in a tangible medium or in an electronic format. Staff asserts that any argument advanced by Respondents that the Commission does not have subject matter jurisdiction or *in rem* jurisdiction because the accused digital data sets are not “articles” within the meaning of the statute, should be rejected.

Staff argues that the evidence demonstrates that Respondents have been involved in the importation, sale for importation, or sale after importation of the accused digital data sets. Staff says that the evidence demonstrates that digital data sets are sent from CCPK in Pakistan to CCUS in the United States for purposes of manufacturing a model for fabricating an aligner for sale to a provider or a patient. (Citing Tr. at 171:4-172:19, 192:3-193:19, 206:16-208:9, 315:19-318:11, 341:2-21, and 442:5-23).

Staff contends that, with respect to digital data sets, the Commission has confirmed that “it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States.” (Citing *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing the Same*, Inv. No. 337-TA-562 (Enforcement Proceeding), Comm’n Opinion at 7 (Jan. 23, 2013))

Staff says that Respondents’ argument that the digital data sets at issue are not imported should be rejected because the evidence demonstrates that the digital data sets at issue are sent from CCPK in Pakistan to CCUS in the United States for purposes of manufacturing models for fabricating aligners. (Citing Tr. at 171:4-172:19, 192:3-193:19, 206:16-208:9, 315:19-318:11, 341:2-21, and 442:5-23) Staff says that Respondents actually admit as much in their brief when reciting their summary of {

}

A. I believe that's fair, yes.

(Citing RIB at 4)

Analysis and Conclusions: The complaint alleges that CCUS and CCPK have violated Subsection 337(a)(1)(B) by the importation and/or sale of products that infringe the asserted patents or are produced by methods that infringe the asserted patents.

I find that the accused digital datasets are “articles” within the scope of the Commission’s jurisdiction.¹ *Hardware Logic* is directly on point. In that case Respondents contended, assuming *arguendo* that the Commission has authority to prohibit the importation of articles that do not literally infringe², the prohibition of importation of respondents’ software would restrict the importation of “things that are not ‘articles’ and that do not induce infringement, under 35 U.S.C. §§ 271(b).” According to respondents in that case, the legislative history of section 337 demonstrates that an article must be “tangible merchandise.” *Hardware Logic, Commission*

¹ In *Certain Drill Bits and Products Containing Same*, in reviewing an initial determination terminating the investigation on jurisdictional grounds, the Commission indicated that “[o]n review, the Commission affirms the ALJ’s grant of summary determination of no importation but does not adopt any statements in the ID to the effect that the determination is on jurisdictional grounds.” Inv. No. 337-TA-844, Comm’n Notice (August 22, 2012). As a result, I am treating this issue as one of jurisdiction solely because the parties raised this issue as one of jurisdiction.

² In *Hardware Logic* respondents also argued that an exclusion order should be limited to articles that directly infringe, and should not extend to components that indirectly infringe, including software. *Hardware Logic* at 4. Respondents raised the possibility that their software would be transmitted electronically into the United States and argued that the Commission does not have jurisdiction to exclude such transmissions. (*Id.* at 5) Respondents contended that software, either in source code or object code form, should not be covered by the Commission’s remedial orders. Respondents said that their software, when it exists in the form of source code, cannot contributorily infringe the claims at issue, because source code is not executable by the accused emulation systems. Respondents reasoned that coverage of source code is, therefore, beyond the Commission’s remedial jurisdiction. *Id.* at 8, 9.

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Opinion on Remedy The Public Interest and Bonding at 9, 10. In addition, respondents argued that the importation by electronic transmission of their infringing software should not be covered by the Commission's remedial orders, because such transmissions are "energy, which is not tangible." *Hardware Logic* at 10.

The Commission rejected the respondents' arguments, finding *inter alia*, that remedial orders must reach software whether imported in the form of source code or otherwise. In a footnote, the Commission discussed this finding in more depth, saying:

As discussed above, source code cannot be run by a computer unless and until it is transformed into object code. However, as the ALJ found and as respondents conceded, source code is typically considered the primary software medium. The substance – the intellectual property – of software is most clearly embodied in the programmer's (sic) source code. Object code is merely a form of the software that the computer can "read." Indeed, respondents ... have only alleged that there is "no legal authority which provides that something that can 'easily and automatically' be transformed to produce a component constitutes or is equivalent to that 'component'." In effect, if source code could not be considered a component of a patented invention, then no software could ever be considered such a component. Yet it is clear that software can be a "component" of a patented invention. Indeed, respondents' software falls within the realm of patentable subject matter.

Hardware Logic at 18, fn. 84 (internal citations omitted). The Commission issued a cease and desist order in *Hardware Logic* that prohibited, *inter alia*, "the importation (including via electronic transmission), sale, offer for sale, lease, loan, other transfer, duplication, or distribution (including electronic distribution) of imported software and other components that contributorily infringe the patents in issue." *Hardware Logic* at 21.

This understanding of *Hardware Logic* is confirmed by the Commission's Opinion in Investigation No. 337-TA-562, which was an enforcement action that addressed the same data sets that are at issue in this investigation. See *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562, Public Comm'n

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Op. (February 19, 2013). The Commission ultimately ~~determined~~ that the same digital data sets at issue in this investigation were not within the scope of a ~~consent~~ order in that enforcement action “because the subject consent order did not contain an ~~express~~ provision prohibiting the electronic transmission of data.” *Id.* at 1. The Commission, however, confirmed that it had jurisdiction and cited *Hardware Logic* to hold that “it has ~~jurisdiction~~ and authority to reach digital data electronically transmitted to a recipient in the United States.” *Id.* at 7.

In this investigation, the asserted claims are ~~method~~ claims that describe processes for using software to generate digital data sets for dental appliances for straightening teeth and generating dental appliances, and apparatus claims directed to the digital data sets and dental appliances. This is undisputed. {

}

Respondents aver at that point, { } and CCPK sends the computer files (i.e., the digital datasets) to CCUS. The remaining steps needed to create the aligners are completed in Houston, Texas by CCUS using the digital datasets provided by CCPK.

Respondents’ reliance on *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003) is misplaced. *Bayer AG* specifically addressed the issue of whether or not 35 U.S.C. § 271(g) applied to claims directed to methods of use rather than methods of manufacture. *Id.* at 1371. As a result, any discussion regarding the scope of 19 U.S.C. § 1337 was dicta and is not controlling. *See id.* Moreover, the Federal Circuit acknowledged that the scope of 19 U.S.C. § 1337 may be broader than 271(g):

We recognize that section 1337 covers both articles ~~that~~ were “made” and articles that were “produced, processed, or mined.” While this language in

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section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

Id. at n.9. As a result, I find that Bayer does not limit the jurisdictional scope of 19 U.S.C. § 1337.

Respondents' reliance upon *Nuijten* is also wide of the mark. In *Nuijten*, the sole subject of the claim was a "signal" that had been encoded in a particular manner. The process of embedding additional data into the "signal," called watermarking, was patented. The watermarking was accomplished by a technique by which an original signal (such as a digital audio file) was manipulated to embed within it additional data. *Nuijten*, 500 F.3d at 1353, 1354, 1356, 1357.

Nuijten is distinguishable from the facts before me. *Nuijten* addressed the specific question of whether certain claims directed to a "signal" were invalid as being directed to non-statutory subject matter under 35 U.S.C. § 101. *Nuijten* 500 F.3d at 1348. Here, the issue is not whether or not the asserted claims are valid, because validity under 35 U.S.C. § 101 has not been raised as a defense. Rather, the question is whether or not digital data sets are "articles." The Court in *Nuijten* did not find that software is not an article of manufacture. *Nuijten* is, therefore, inapposite.

I find that the digital datasets produced by CCPK {
} are clearly articles over which the Commission has jurisdiction and authority. Thus, I find that the Commission has subject matter jurisdiction over this investigation under Section 337 of the Tariff Act of 1930. *See Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

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B. Personal Jurisdiction

CCUS and CCPK each responded to the complaint and notice of investigation, participated in the investigation, made an appearance at the hearing, and submitted joint post-hearing briefs. Thus, I find that CCUS and CCPK submitted to the personal jurisdiction of the Commission. *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, Initial Determination, 1986 WL 379287 (October 15, 1986).

C. In Rem Jurisdiction

The Commission has *in rem* jurisdiction over the digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, and the appliances made therefrom, because the digital data sets have been imported into the United States. *See Sealed Air Corp. v. United States Int'l Trade Comm'n*, 645 F.2d 976, 985 (C.C.P.A. 1981). Mr. Pumphrey admitted that digital data sets prepared by CCPK are sent from CCPK in Pakistan to CCUS in the United States and are used by CCUS to manufacture clear aligners. (Tr. at 341:14-21) Moreover, in its prehearing brief, Respondents admitted that CCPK creates the digital data sets in Pakistan, sends the digital data sets to CCUS, which then uses the digital data sets to prepare aligners:

The accused 'products' are computer files that are created in Pakistan as part of the service provided by CCPPL to ClearCorrect. ClearCorrect subsequently uses the computer files to print 3-D physical models of a patient's dentition.

(RPHB at 6-7)

Respondents' arguments regarding claims 7-9 of the '487 patent are unpersuasive. First, these arguments were waived because they were not raised in Respondents' prehearing brief. (See RPHB at 5-7) Second, there is no question that the digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances are

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imported. The evidence shows that the data is imported by being transmitted electronically.³

As a result, I find that the Commission has *in rem* jurisdiction over the digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, and the appliances made therefrom, because the digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances have been imported into the United States.

III. CLAIM CONSTRUCTION

A. Applicable Law

“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996) (citation omitted). Claim construction “is a matter of law exclusively for the court.” *Id.* at 970-71. “The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims.” *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000). “[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.” *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See generally Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). The Federal Circuit in *Phillips* explained that in

³ The separate question of whether or not the imported digital data sets infringe claims 7, 8, and 9 of the ‘487 patent is addressed in Sections V.D.4-6, *infra*.

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construing terms, courts must analyze each of these components to determine the “ordinary and customary meaning of a claim term,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Id.* at 1313.

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Id.* at 1312 (citations omitted). “Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Id.* at 1314. For example, “the context in which a term is used in the asserted claim can be highly instructive,” and “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term.” *Id.*

“[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* (citation omitted). “The longstanding difficulty is the contrasting nature of the axioms that (a) a claim must be read in view of the specification and (b) a court may not read a limitation into a claim from the specification.” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004). The Federal Circuit has explained that there are certain instances when the specification may limit the meaning of the claim language:

[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs. In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.

Phillips, 415 F.3d at 1316.

In addition to the claims and the specification, the prosecution history should be

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examined if in evidence. “The prosecution history...consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.” *Id.* at 1317 (citation omitted). “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony and learned treatises. *Id.* at 1317. Extrinsic evidence is generally viewed “as less reliable than the patent and its prosecution history in determining how to read claim terms[.]” *Id.* at 1318. “The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence.” *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

“Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one. However, such a result can ensue when the method steps implicitly require that they be performed in the order written.” *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) (citing *Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed. Cir. 1999)) (internal citations omitted). This determination requires a two-part test to decide whether or not the steps of a method claim that do not otherwise recite an order must be performed in the order in which they are written. *Altiris, Inc. v. Symantec Corp.*, 318

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F.3d 1363, 1369-1370 (Fed. Cir. 2003) (citing *Interactive Gift* 256 F.3d at 1342-43).

First, I must look to the claim language to determine if logic or grammar requires they be performed in the order written. *Id.* (citing *Interactive Gift* 256 F.3d at 1343). In *Loral Fairchild Corp. v. Sony Electronics Corp.*, the Federal Circuit held that the claim language required the steps be performed in their written order because the second step required the alignment of a second structure with a first structure that was formed by the first step. 181 F.3d 1313, 1321 (Fed.Cir.1999); see also *Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370. If the first part of the test is not met, I must look to the rest of the specification to determine whether or not it directly or implicitly requires the steps be performed in the order written. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370 (citing *Interactive Gift* 256 F.3d at 1343). If the second part of the test also is not met, the sequence in which such steps are written is not a requirement. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370.

B. The '325 Patent

1. Level of Ordinary Skill in the Art

Align's position: Align asserts that one of ordinary skill in the art at the time of the invention of the asserted claims of all of the patents-in-suit was a practicing orthodontist, or an individual with expertise in digital modeling and analysis and a substantive knowledge of orthodontics. (Citing CX-1247C, Qs. 120-121; CX-1254C at 14-15) Align says that this is confirmed by: (i) the "well-settled understanding that inventors are typically persons skilled in the field of the invention" (Citing *Phillips*, 415 F.3d at 1313) because the inventors of the asserted patents fall within the latter category (Citing Tr. at 598:20-608:19); and (ii) the systems discussed in the specification of the asserted patents. (Citing JX-0001 at 1:24-30, 2:40-58; JX-0002 at 1:19-2:22, 5:31-7:46, 11:8-20:3, Figs. 2-3, 8A, 8D; JX-0003 at 1:12-2:23; 5:28-51; JX-

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0004 at 1:17-2:63, 5:31-54; JX-0005 at 1:31-36, 6:54-7:5; JX-0006 at 1:29-2:26, 3:7-4:42; JX-0007 at 1:22-24, 3:3-9)

Align says that because Respondents advance only attorney argument in support of their definition and do not cite to a single fact or opinion supporting their attorney argument, their definition should be rejected.

Respondents' Position: Respondents assert that the applicable level of ordinary skill in the art is that of an experienced orthodontist who has access to an individual, such as an engineer, who has training in developing computer-aided design and computer-aided manufacturing programs (CAD/CAM). Respondents say that the '325 Patent and other patents at issue are directed to orthodontic appliances and methods for making those appliances. Respondents continue that orthodontists prescribe the type of appliance to be used and are involved in the design of those orthodontic appliances. Respondents say that the patents attest, that typically, orthodontists prescribe the type of appliance to be used and are involved in the design of those orthodontic appliances. Respondents say that a person of ordinary skill is presumed to have complete knowledge of all pertinent prior art.

Respondents agree that a practicing orthodontist is one of ordinary skill in the art to the extent that "practicing" means experienced. Respondents disagree with Align's alternative definition "individual with expertise in digital modeling and analysis and a substantive knowledge of orthodontics." Respondents say that this definition does not delineate what constitutes "substantive knowledge of orthodontics" or how that knowledge is to be measured. Respondents continue that under Align's measure it is clear that Mr. Beers does not qualify as one of ordinary skill. Respondents allege that Mr. Beers has provided no showing of "substantive knowledge of orthodontics" and testified that his only source of knowledge of

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orthodontics was on the job training with Align during the time that he worked there approximately ten years ago. (Citing Tr. at. 510:12-511-10; Tr. at 511:25-512:11)

Staff's Position: Staff says that Complainant's technical expert Dr. Maureen Valley testified that a person of ordinary skill is "a practicing orthodontist, or an individual with expertise in digital modeling and analysis and substantive knowledge of orthodontics." (Citing CX-1247C (Valley) at Q. 121) Staff continues that Respondents' technical expert Dr. James Mah testified that a person of ordinary skill is "an experienced orthodontist who has access to an individual, such as an engineer, who has training in developing computer-aided design and computer-aided manufacturing programs (CAD/CAM)." (Citing RX-0129C (Mah) at Q. 23)

Staff contends that the difference in the proposed levels of ordinary skill does not impact the opinions of these technical experts or the positions of the private parties or Staff. Staff says that none of the private parties has identified differences between the two hypothetical persons of ordinary skill in the art that would affect claim construction (or infringement/invalidity). Staff continues that the technical experts testified that their opinions would not change if the other's proposed level of ordinary skill was determined to be proper. (Citing CX-1247C (Valley) at Q. 125-127; RX-0129C (Mah) at Q. 24; Tr. at 597:4-18; CX-1198C at 3) Staff says that the parties and the technical experts agree that the same level of ordinary skill in the art applies to all of the patents at issue herein.

Staff reasons that based on the educational background and professional experience of the inventors of the patents at issue, and the opinions provided by Complainant's technical experts, whose opinions appear to the Staff to be more consistent with the disclosures of the subject matter at issue, Staff submits that the more appropriate level of ordinary skill in the art is that proposed by Complainant and Complainant's technical experts. Staff continues that Mr. Beers,

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who is one of the named inventors of the '487 patent and '874 patent, testified that the majority of the inventors of the patents at issue are not orthodontists; rather, they are computer scientists who had access to orthodontists while working at Align (which is a qualification generally reflected in Complainant's proposed level of ordinary skill in the art). (Citing Tr. at 598:17-607:22)

Analysis and Conclusions: I find that one of ordinary skill in the art at the time of the invention of the asserted claims of all of the patents at issue in this investigation was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles.

Focusing on the '325 patent, I note that it is directed to a method and system for incrementally moving teeth. (JX-0003 at Title) Although the '325 patent discusses orthodontic principles (*see, e.g.*, JX-0003 at 1:13-2:5) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions (JX-0003 at 6:4-14), the '325 patent does not delve into the intricacies of the practice of orthodontics. (*See* JX-0003 at 6:4-14) Rather, the focus of the '325 patent is the methods used to generate the digital data sets for treatment, including the intermediate digital data sets representing tooth positions between the initial position and the final position. (*See, e.g.*, JX-0003 at 6:15-40) The '325 patent discusses, in detail, the manipulation of digital data to prepare the initial data set (JX-0003 at 11:1-12:22), generate the final tooth arrangement, and generate the intermediate digital data sets. (JX-0003 at 12:30-65; *see also* JX-0003 at 13:59-14:25) Because of the level of complexity and detail including regarding the manipulation of digital data, I find that one of ordinary skill in the art would have expertise in digital modeling and analysis.

Although a person of ordinary skill in the art would not need to be an orthodontist, the

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'325 patent notes that software that operates in accordance with the invention is designed to operate at a sophistication commensurate with the operator's training level, including "providing feedback regarding permissible and forbidden manipulations of the teeth." (JX-0003 at 14:26-36) As a result, I find that a person of ordinary skill in the art would need to have a working knowledge of orthodontic principles to implement software that provides such feedback.

As explained in Sections III.C.1, III.D.1, III.E.1, IV.F.1, IV.F.1, and III.G.1 *infra*, all of the patents at issue have very similar focus and details, and the parties have agreed that the person of ordinary skill in the art is the same for each of the patents at issue. Based upon the similarities between the patents and the agreement of the parties, I find that a person of ordinary skill in the art is the same for each of the patents at issue.

2. "Fabricating a plurality of successive tooth repositioning appliances"

The term "fabricating a plurality of successive tooth repositioning appliances" appears in asserted claims 1 and 33.

Align's position: Align says that this term should be given its plain and ordinary meaning. Align continues that to the extent construction is required, this term should be construed to mean "fabricating more than one of a series of appliances to be worn for incrementally positioning teeth."

Align asserts that if this term is construed, it should be construed simply to have its plain and ordinary meaning. Align contends that because the words in the phrase are easily understandable and there is no explicit definition or disclaimer of the scope of the disputed phrase in the '325 patent, construction is not needed. (Citing *CCS Fitness*, 288 F.3d at 1366-67)

Align disagrees with Respondents' "all aligners" argument, because it seeks to add an improper "temporal requirement" that the appliances must be "fabricated prior to the outset of

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treatment.” Align says that Respondents cite to no evidence that supports their construction. Align continues that Respondents cite to a portion of the ‘325 patent specification says that aligners must be designed before they can be fabricated. Align asserts that the cited portion does not mention treatment and Respondents’ position is therefore logically incoherent. Align says that no portion of the ‘325 patent requires that appliances be fabricated prior to the outset of treatment.

Align says that the intrinsic record does not require that any part of the claimed process occur prior to the outset of treatment. (Citing JX-0003 at 1:29-48, 2:2:54-57) Align contends that Claim 1 simply requires that “a plurality of successive tooth repositioning appliances” be fabricated, and that they be related to at least some of the previously produced digital data sets. (Citing JX-0003 at 1:29-48) Align adds that the specification requires only that the appliances be “fabricated based on at least some of the digital data sets.” (Citing JX-0003 at 6:53-61) Align reasons that as long as at least two appliances are fabricated, which relate to at least two of the previously produced digital data sets, the claim is satisfied. Align says that the only “temporal” requirement of the claim is that the digital data sets be determined prior to fabricating appliances.

Align also disagrees with Respondents’ argument that Align is estopped from seeking a construction that covers sets of appliances “fabricated after the outset of treatment” citing the prosecution history of the ‘874 patent for support. Align contends that Respondents confuse the concept of (i) a single “set” of appliances (one upper and one lower) used in one treatment stage with (ii) a series of appliances for use in successive treatment stages. Align continues that during the prosecution of the ‘874 patent, it distinguished prior art that “teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance)”

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(Citing JX-0016 at 274) ~~Align~~ says that its statement that the prior art “teaches making one set of appliances at a ~~time~~” ~~in the~~ prosecution history refers to one upper appliance and one lower appliance corresponding to a single treatment stage. ~~Align~~ adds that Respondents have also failed to explain how the prosecution of the ‘874 patent can affect the asserted claims of the other patents at issue ~~herein~~. ~~Align~~ argues that Respondents’ argument is incorrect because the statements were made *after* the ‘325 patent issued in a different application chain.

~~Align~~ says that “[i]n the absence of an incorporation into the intrinsic evidence, [the Federal Circuit’s] precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue[.]” (Citing *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004); *see also Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1333 (Fed. Cir. 1999) (For a patentee “to be bound by the statement made to the PTO in connection with a later prosecution of a different patent, the statement would have to be one that the examiner relied upon in allowing the claims in the patent at issue.”); and *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1284-85 (Fed. Cir. 1986) (“In cases where a patentee’s amendments were not required in response to an examiner’s rejection or critical to the allowance of the claims, no estoppel has been found.”)) ~~Align~~ continues that Respondents have not shown how these narrow exceptions would apply. ~~Align~~ contends that the fact that ~~Align~~’s other asserted claims do not recite “generating a plurality of sets of appliances at the outset of treatment” (the limitation advocated by Respondents) confirms that prosecution history estoppel cannot apply to the other claims. (Citing *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1322-23 (Fed. Cir. 1999))

~~Align~~ contends that Respondents’ characterization of ~~Align~~’s argument is wrong, because during prosecution of the ‘874 patent, ~~Align~~ distinguished a pending claim that recited

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“generating a plurality of sets of appliances at the outset of treatment” from the prior art by arguing that the prior art “simply teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance) using a manually manipulated wax setup.” (Citing JX-0016 at 274) Align asserts that Respondents seek to muddy the waters by arguing that “one set” (*i.e.*, one lower and one upper) actually means “one series” (*i.e.* two or more successive treatment stages). Align argues that there is no support for such an interpretation other than argument by Respondents’ attorney, and Align did not limit its claims in the manner suggested by Respondents.

Respondents’ Position: Respondents assert that this term should be construed to mean “the appliances are fabricated prior to the outset of treatment.”

Respondents say that the specification of the ‘325 Patent provides:

In still another aspect, methods according to the present invention provide for fabricating a plurality of dental incremental position adjustment appliances. Said methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements, generally as just described. The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements.

(Citing JX-3 at 6:53-61) Respondents contend that this has a temporal requirement, “the dental appliances are then fabricated,” and requires that the “digital data sets,” including an “initial,” “final,” and a “plurality of successive,” be “provided” prior to fabrication. Respondents reason that this requires “a plurality of successive tooth repositioning appliances” to be fabricated prior to the outset of treatment, otherwise the treatment could not begin. Respondents say that there is no teaching in the patent of multiple pluralities of successive tooth repositioning appliances. Accordingly, the Respondents contend that this phrase should be construed to mean that the appliances are fabricated prior to the outset of treatment.

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Respondents assert that Align is estopped from seeking a claim construction that covers sets of appliances that are fabricated after the outset of treatment. Respondents say that during the prosecution of the '874 patent Align overcame rejection by distinguishing prior art and disavowing the scope of its claims. (Citing JX-0016 at 274) Respondents continue that Align argued that its modified claim of “generating a plurality of sets of appliances at the outset of treatment” was not disclosed in the prior art. (Citing JX-0016 at 299-300) Respondents conclude that Align is therefore estopped from arguing a different interpretation for the '874 patents, as well as the other patents asserted here. (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (citing *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) (holding that statements made in prosecution of one patent are relevant to the scope of all sibling patents) & *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1460 & n. 2 (Fed. Cir. 1998) (noting that it was proper to consider the prosecution histories of two related re-examination patents originating from the same patent, to determine the meaning of a term used in both patents))) Respondents contend that it is well settled that a patentee’s disavowal of scope of claimed subject matter applies to related patents.

Staff’s Position: Staff contends that this term should be construed to mean “producing more than one of a series of dental appliances for repositioning teeth that are made according to data sets.”

Staff contends that the parties’ claim construction dispute encompasses two issues. Staff says that the parties disagree over whether there is a temporal requirement, *i.e.*, whether the appliances (i) must be fabricated prior to the outset of treatment, as proposed by Respondents, or (ii) need not be fabricated prior to the outset of treatment, as proposed by Complainant. Staff contends that there is no temporal requirement requiring the appliances to be fabricated prior to

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the outset of treatment. Staff says that Respondents improperly seek to rewrite the claims by inserting the phrase “prior to the outset of treatment” into the claims.

Staff continues that in addition to rewriting the claims, Respondents seek to limit the claims to a disclosure in the specification that states, *inter alia*, that “[s]aid methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets....The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements.” (Citing JX-0003 at 6:53-61) Staff disagrees with Respondents’ proposed reading of this disclosure, noting that the specification discloses, *inter alia*, “[t]he system of appliances is *usually* configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.” (Citing JX-0003 at Abstract (emphasis added by Staff)) Staff continues that the specification also discloses that “the systems *may* be planned and all individual appliances fabricated at the outset of treatment.” (Citing JX-0003 at 3:53-56)

Staff says that the parties also disagree about whether or not the plurality of tooth repositioning appliances (i) must include all the appliances in the patient’s treatment, as proposed by Respondents, or (ii) need not include all the appliances in the patient’s treatment, as proposed by Complainants. Staff notes that Respondents are precluded from presenting any arguments in this regard because Dr. Mah was precluded from offering testimony that “fabricating a plurality of successive tooth repositioning appliances” requires all the appliances in the patient’s treatment. (Citing RX-0129C, Q. 51)

Staff contends that the plurality of tooth repositioning appliances need not include all the appliances in the patient’s treatment. Staff says that Respondents rely on the same disclosure of

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the specification to support their argument. Staff continues that for at least the reasons stated above, the specification does not support construing “fabricating a plurality of successive tooth repositioning appliances” restrictively as proposed by Respondents.

Staff disagrees with Respondents’ contention that Complainant is estopped based on statements made during prosecution of the related ‘874 patent. Staff says that under the circumstances here, arguments made with respect to the “outset of treatment” limitation do not affect the proper construction of a different term. (Citing *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1322-23 (Fed. Cir. 1999))

Construction to be applied: “fabricating two or more dental appliances to be used successively to adjust the position of teeth”

The plain language of claim 1 teaches:

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

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

presenting a visual image based on the initial data set;

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

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

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

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

(JX-0003-027 at 1:29-48 (emphasis added)) Similarly, claim 33 requires:

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

(JX-0003-027 at 2:54-57 (emphasis added)) At its essence, the dispute between the parties is whether or not “fabricating a plurality of successive tooth repositioning appliances” requires that all appliances to be used in treatment be fabricated before any treatment is begun. I find nothing in the intrinsic record to support Respondents’ restrictive construction.

The plain language of the asserted claims does not require that all appliances to be used in treatment be fabricated before treatment begins. Element five of claim 1 requires, *inter alia*, producing a plurality of intermediate digital data sets that represent tooth arrangements that progress “from the original tooth arrangement to the final tooth arrangement.” Element six requires fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least “some” of the produced digital data sets. Thus, the plain language of element six only requires fabricating appliances that are related to “some” of the digital data sets, but not necessarily *all* intermediate data sets. Requiring that all appliances to be used in treatment be fabricated before any treatment begins would directly conflict with the language of the claim. Claim 33 includes similar language, requiring only that appliances be fabricated “based on *at least a plurality* of said produced digital data sets provided to the fabrication operation.” It does not provide a limitation that the appliances be fabricated based upon *all* produced digital data sets.

In my view the specification does not assign a special meaning to this phrase that deviates from the plain and ordinary meaning reflected in the claim. There is a “heavy presumption in favor of the ordinary meaning of claim language.” *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed.Cir.1999); cf. *Markman*, 52 F.3d at 980 (“[A]ny special

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definition given to a word must be clearly defined in the specification.”). Although the written description may aid in the proper construction of a claim term, limitations, examples, or embodiments appearing only there may not be read into the claim. *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-1187 (Fed. Cir. 1998). The Federal Circuit has explained that:

We do not import limitations into claims from examples or embodiments appearing only in a patent’s written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that “the patentee ... intends for the claims and the embodiments in the specification to be strictly coextensive.”

JWW Enters., Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005) (quoting *Phillips*, 415 F.3d at 1323). To put it another way, the Federal Circuit has stated that “[g]enerally, a claim is not limited to the embodiments described in the specification unless the patentee has demonstrated a ‘clear intention’ to limit the claim’s scope with ‘words or expressions of manifest exclusion or restriction.’” *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 843 (Fed. Cir. 2010) (quoting *Liebel-Flarshiem Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

Here, the specification indicates that the production of all tooth repositioning appliances before treatment begins is one embodiment. The Abstract of the ‘325 patent explains that “[t]he system of appliances is *usually* configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.” (JX-003 at Abstract (emphasis added)) Elsewhere, the ‘325 patent explains that “[a]s will be described in more detail below in connection with the methods of the present invention, the systems *may* be planned and all individual appliances fabricated at the outset of treatment, and the appliances may thus be provided to the patient as a single

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package or system.” (JX-003 at 3:49-53 (emphasis added)) The ‘325 patent also states that “[a]fter production, the plurality of appliances which comprise the system of the present invention are *preferably* supplied to the treating professional all at one time.” (JX-003 at 15:1-3 (emphasis added)) These portions of the specification describe a single embodiment, and they do not demonstrate the inventor’s clear intent to provide a limitation beyond the clear meaning of the term “fabricating a plurality of successive tooth repositioning appliances.”

Not only does the specification indicate that production of all tooth repositioning appliances before treatment begins is but one embodiment, it actually describes changes being made to the treatment plan after treatment is underway. The specification explains that one of the benefits of the treatment system taught by the ‘325 patent is that “[u]nlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made.” (JX-003 at 3:57-59) The specification continues, “[w]hile patients will usually want to visit their treating professionals periodically to assure that treatment is going according to the *original* plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller, successive steps while still reducing the time spent by the treating professional with the individual patient.” (JX-003 at 3:59-66 (emphasis added)) Thus, the specification acknowledges that treatment might not actually progress according to the “original” plan, and in so doing tacitly acknowledges that the treatment plan may need to be modified after treatment has begun. This acknowledgement is further evidence that the inventors did not clearly intend to provide a limitation beyond the clear meaning of the term “fabricating a plurality of successive tooth repositioning appliances.”

Respondents’ prosecution history estoppel arguments miss the mark. Respondents rely on arguments Align made during prosecution of the ‘874 patent to assert that the claims of the

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'325 patent should be interpreted to require that all appliances to be used in treatment be fabricated before any treatment begins. The arguments on which Respondents rely, however, were based on claim language that is not present in claims 1 and 33 of the '325 patent.

During prosecution of the '874 patent, Align argued that certain prior art references did not disclose "generating, at the outset of treatment, a plurality of sets of appliances." (JX-0016 at 258, 273 (emphasis in original)) Specifically, Align said that "Martz simply teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance) using a manually manipulated wax setup. If additional sets of appliances were made using the Martz method, they would be made after treatment had commenced ('as time goes on') and would be made one set at a time from separate wax setup models." (JX-0016 at 274) The claims at issue in the prosecution of the '874 patent explicitly included the language "at the outset of treatment." (JX-0016 at 258) In contrast, claims 1 and 33 of the '325 patent do not include the phrase "at the outset of treatment." (JX-0003-027 at 1:29-48, 2:54-57) Because claims 1 and 33 do not include the phrase "at the outset of treatment," arguments made during prosecution of the '874 patent regarding the phrase "at the outset of treatment" are not relevant to determining the scope of the claims of the '325 patent.

In a case with similar facts, the Federal Circuit rejected an argument that the scope of a claim term should be limited by statements made during later prosecution of a related patent. In reaching this conclusion, the Federal Circuit noted that for the patentee "to be bound by the statement made to the PTO in connection with a later prosecution of a different patent, the statement would have to be one that the examiner relied upon in allowing the claims in the patent at issue." *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1332-1333 (Fed. Cir. 1999) Similarly, the Federal Circuit has rejected arguments that infringement under the doctrine

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of equivalents was foreclosed based on prosecution history estoppel where the arguments at issue were made in a related patent that included different claim language. *Al-Site Corp. v. VSI Intern., Inc.*, 174 F.3d 1308, 1322-1323 (Fed. Cir. 1999). In rejecting the defendant's argument, the Federal Circuit explained that "[t]he specific limitations added to gain allowance of the '532 patent are not included in and are therefore not relevant to determining the scope of the claims of the later issued patents." Here, as noted *supra*, claims 1 and 33 do not include the language at issue during prosecution of the '874 patent. As a result, I find Respondents' arguments unpersuasive.

In order to give the asserted claims their broadest, reasonable interpretation, I conclude that, while the process clearly requires fabricating two or more dental appliances to be used successively to adjust the position of teeth, it does not require that all of the dental appliances used in treatment be fabricated prior to the outset of treatment. I, therefore, reject the narrower interpretation offered by Respondents.

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

Based upon all of the foregoing, I find that the proper construction for the term "fabricating a plurality of successive tooth repositioning appliances," as used in asserted claims 1 and 33, is "fabricating two or more dental appliances to be used successively to adjust the position of teeth."

C. The '880 Patent

1. Level of Ordinary Skill in the Art

Analysis and Conclusions: In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all asserted patents. Based upon the similarities between the teachings of the '325 patent and the '880 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '880 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '880 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Similar to the '325 patent, the '880 patent is directed to a method and system for incrementally moving teeth. (JX-0002 at Abstract) The '880 patent discusses orthodontic principles (*see, e.g.*, JX-0002 at 1:19-2:4) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions (JX-0002 at 6:15-17); but the '880 patent does not delve into the intricacies of the practice of orthodontics. (*See* JX-0002 at 6:15-17) Like the '325 patent, the focus of the '880 patent is the methods used to generate the digital data sets for treatment, including the intermediate digital data sets representing tooth positions between the initial position and the final position. (*See, e.g.*, JX-0002 at 6:27-55) The '880 patent discusses, in detail, the manipulation of digital data to prepare the initial data set (JX-0002 at 11:1-14:59), generate the final tooth arrangement, and generate the intermediate digital data sets. (JX-0002 at 14:60-15:55; *see also* JX-0002 at 16:19-44) The '880 patent also notes that software that operates in accordance with the invention is designed to

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operate at a level of sophistication commensurate with the operator's training level, including "providing feedback regarding permissible and forbidden manipulations of the teeth." (JX-0003 at 19:60-20:3)

2. "a predetermined series of dental incremental position adjustment appliances"/"predetermined series of dental incremental position adjustment appliances"

The term "a predetermined series of dental incremental position adjustment appliances"/"predetermined series of dental incremental position adjustment appliances" appears in asserted claim 1.

Align's position: Align contends that this term should be assigned its plain and ordinary meaning, and to the extent a construction is required, Align submits that the term should be construed to mean "a plurality of consecutively worn appliances for incrementally positioning teeth, wherein the geometries of each of the plurality of appliances are determined prior to the fabrication of any of the plurality of appliances."

Align contends that this phrase should be construed under its plain and ordinary meaning. Align says that no other definition is necessary, as the words in the phrase (*e.g.*, "predetermined" and "series") are easily understandable, and there is no explicit definition of "predetermined series ..." or disclaimer of the scope of this phrase in the '880 patent. (Citing *CCS Fitness*, 288 F.3d at 1366-67)

Align asserts that the claim construction advanced in Respondents' Prehearing Brief is markedly different from the construction proposed by Respondents in the SRJCCC. Align says that Respondents now assert that the construction must be that "all of the appliances in the series or system of appliances are fabricated prior to the outset of treatment." Align continues that Dr. Mah takes a similar position. (Citing RX-0129C, Qs. 136-137, 139) Align contends that the

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belated introduction of this new construction is improper because it was not disclosed in the SRJCCC. (Citing Tr. at 8:4-9:4)

Align contends that nothing in the intrinsic record requires, or even suggests, that a “series” must be every single aligner used in a patient’s treatment. Align says that “series” is used, *inter alia*, to describe a batch of successive aligners. (Citing JX-0002, 3:1-8) Align continues that this batch of successive aligners could be any subseries of the entire series of aligners (e.g., the first four, middle six, last three). (Citing CX-1150C, Q. 262) Align says that claim 1 specifies the opposite of Respondents’ construction, as it states that the “predetermined series” corresponds to a series “progressing from the initial to the repositioned tooth arrangement.” Align continues that a repositioned tooth arrangement does not have to be the final tooth arrangement, and no part of the specification leads to a different conclusion.

Align contends that no portion of the intrinsic record requires that the appliances be “fabricated prior to the outset of treatment.” Align says that a review of claim 1 shows that the word “predetermined” refers only to the dental appliances themselves, not to when any treatment begins. Align continues that treatment is not mentioned at all in claim 1. Align concludes, as a result, that the tooth arrangements of the particular appliances need only be determined before their fabrication, and no portion of the specification states otherwise.

Align asserts that respondents’ argument that Align cannot seek a construction that covers sets of appliances “fabricated after the outset of treatment” and cites its earlier discussion of the issue.⁴ Align says that this argument is improper here because the statements were made after the ‘880 patent issued and were made in a different application chain.

⁴ Align’s arguments are fully discussed in section III.B.2, *supra*.

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Align says ~~that~~ Respondents' arguments ignore the language of the claims and cite to exemplary ~~embodiments~~ in the specification; but do not point out where the specification expressly limits "series." Align continues that there is no such limiting language, and it is improper to ~~limit the claims~~ to exemplary embodiments; rather, the instance of "series" Respondents cite is ~~merely~~ an exemplary discussion that a "system" uses a "series" of aligners – not a requirement ~~that~~ a "series" be any particular length, or that a "series" be all aligners from a to z.

Respondents' Position: In the Second Joint Claim Construction Chart, Respondents asserted that this term should be construed to mean "the appliances are fabricated prior to the outset of treatment." In their post-hearing brief, Respondents contend that this term means that all of the appliances ~~in~~ the series or system of appliances are fabricated prior to the outset of treatment. Respondents say that the limitation of a "predetermined series of dental incremental position adjustment appliances" appears in the preamble and in element "d." Respondents continue that the intrinsic evidence demonstrates that the combination of words used to create this phrase refers to ~~all~~ of the appliances designed to reposition teeth from the initial to the final tooth arrangement ~~collectively~~ and demonstrates that the appliances are fabricated prior to the outset of treatment. Respondents contend that the word "series" is key.

Respondents contend that the intrinsic evidence conclusively demonstrates that the claimed "series" ~~makes~~ up the "system" of all appliances. Respondents say that the '880 Patent specification states:

The ~~present~~ invention provides improved methods and systems for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of ~~appliances~~ configured to receive the teeth in a cavity and incrementally ~~reposition~~ individual teeth

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(Citing JX-0002 at 2:66-3:4) Based on ~~this statement~~, Respondents conclude that each “system” comprises “a series.” Respondents reason ~~that a single~~ “series of appliances” makes up the “system” that repositions teeth from the ~~initial tooth~~ arrangement to the final tooth arrangement. Respondents say that this definition is ~~consistently~~ repeated throughout the specification. (Citing JX-0002 at 3:37-48) Respondents say ~~that while~~ a series could have as few as three steps, or in excess of forty steps, each series must ~~reposition~~ teeth from the initial to the final arrangement. Respondents continue that the specification ~~teaches~~ that each “system,” which comprises the claimed “series,” includes all appliances necessary to complete the treatment. Citing JX-0002 at 4:21-25)

Respondents contend that the intrinsic evidence also demonstrates that “predetermined” means determined “at the outset” of treatment. Respondents say that the term “predetermined” is only used once in the specification in connection with the appliances, which confirms that “predetermined” means “determined at the outset.” (Citing JX-0002 at 4:63-5:1) Respondents say that the specification demonstrates that the appliances are fabricated prior to the outset of treatment. (Citing JX-0002 at 20:35-37) Respondents contend that under the “system” described in the specification, all appliances are ~~fabricated~~ fabricated prior to the outset of treatment. Respondents reason that, otherwise, it would be ~~impossible~~ impossible to use the preferred method of delivery, which is supplying the appliances “all at one time” to the treating professional. Respondents say that the specification ~~consistently~~ uses the phrase “outset of treatment” in connection with fabrication. (Citing JX-0002 at 3:53-56)

Respondents contend that Align is ~~estopped~~ estopped from seeking a claim construction that covers sets of appliances that are fabricated after the ~~outset~~ outset of treatment. Respondents say that during the prosecution of a related patent, Align ~~distinguish~~ distinguished prior art by disclaiming “making one set

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of appliances at a time” during the course of treatment. Respondents continue that Align claims that the ‘880 Patent and the ‘874 Patent arise from the same application and share many common terms. Respondents say that the Federal Circuit has held that courts must interpret the claims consistently across all asserted patents. (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (citing *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004); *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1460 & n. 2 (Fed. Cir. 1998))) Respondents continue that Align successfully argued “that a patentee can make a disavowal of scope as to the general nature of an invention that in turn limits all claims even though specific claim language is not being interpreted.” (Citing *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1312 (Fed. Cir. 2007)(“*Ormco IP*”)) Respondents aver that the Federal Circuit agreed with Align and held that “[w]hen the application of prosecution disclaimer involves statements from prosecution of a familial patent relating to the same subject matter as the claim language at issue in the patent being construed, those statements in the familial application are relevant in construing the claims at issue. (Citing *id.* at 1314)

Respondents say that during the prosecution of what became the ‘874 Patent, the examiner rejected Align’s proposed claims directed to a method for making a series of appliances. Respondents continue that the examiner noted that U.S. Patent No. 4,793,803 taught methods for generating a plurality of appliances having geometries to reposition teeth and U.S. Patent No. 5,454,717 taught using a computer to receive initial scanned data and calculating desired tooth positions to design and manufacture appliances and concluded that Align’s claimed invention was obvious in light of the described prior art because “[w]hile *Martz* does not show forming the appliances at the outset of treatment, it is held obvious as indicated above.” Respondents say that in response, Align argued that the prior art “simply teaches making one set

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of appliances at a time” and its modified claim of “generating a plurality of sets of appliances at the outset of treatment” was not disclosed in the prior art. Respondents say that Align ultimately prevailed and the claims issued in the ‘874 Patent. Respondents continue that the issued claim required:

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

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

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

Respondents reason that because Align successfully argued this language overcame the prior art that disclosed “making one set of appliances at a time,” Align disavowed claims to “making one set of appliances at a time” during the prosecution of the ‘874 Patent and is therefore estopped from seeking to claim a scope in the ‘880 Patent that was surrendered to obtain the ‘874 Patent.

Respondents assert that extrinsic evidence confirms that “a predetermined series of dental incremental position adjustment appliances” means that all of the appliances that comprise a system are fabricated prior to the outset of treatment. Respondents say that expert testimony confirms that the phrase at issue refers to all appliances and requires that the appliances are fabricated at the outset of treatment. Respondents say that Align relies upon its former longtime employee with a computer science background to opine as to whether orthodontists or dentists

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would understand that this limitation has been met. Respondents contend that he is not qualified as an expert. Respondents continue that even if he were qualified, Align's expert cannot now provide any opinion as to the construction of this phrase because he failed to disclose any such opinion in his expert report. Respondents assert that Dr. Mah, their expert who is an orthodontist, has provided his expert opinion that CCUS's products do not meet the claimed limitation.

Respondents assert that Align alleges that its products practice claim 1 of the '880 patent. Respondents say that Align's exclusive method is to design, fabricate, and deliver all of the aligners that comprise its system prior to the outset of treatment. Respondents say that Align's contentions corroborate Respondents' proposed construction that "a predetermined series of dental incremental position adjustment appliances" means that all of the appliances that comprise a system are fabricated prior to the outset of treatment.

Staff's Position: Staff contends that this term should be construed to mean "Dental appliances that are fabricated according to data sets which are determined at the outset."

Staff contends that the dispute over the proper meaning of "predetermined series of dental incremental position adjustment appliances" encompasses two issues. Staff says that the parties disagree over whether or not a "series" must include all the appliances used in the patient's treatment, as proposed by Respondents, or (ii) need not include all the appliances and may simply include a plurality of consecutively worn appliances, as proposed by Complainant.

Staff contends that because I excluded Dr. Mah's opinion that a "predetermined series of dental incremental position adjustment appliances" would refer to a *system* of appliances, *i.e.*, all of the appliances in the patient's treatment (Citing RX-019C at Q. 136), Respondents are precluded from presenting any arguments in this regard. Staff says because it is not clear that

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Respondents will abandon their argument of non-infringement based on their proposed claim construction requiring a system of appliances, it addresses whether the claimed “series” must include all of the appliances in the patient’s treatment.

Staff contends that that the term “series” does not necessarily require that the “series” constitute all the appliances used for a patient’s treatment. Staff says that claim 1, element (d), recites a “series of dental incremental position adjustment appliances” for tooth arrangements “progressing from the initial to the *repositioned*” arrangement,” indicating that the “series” can constitute a subset of the entire treatment series, *i.e.*, the subset between the initial and any repositioned tooth arrangement. (Citing JX-0002 at 22:12-29) Staff continues that the specification also includes language indicating that the entire treatment set of appliances is not necessarily designed or fabricated before treatment begins. (Citing JX-0002 at Abstract (“The system of appliances is *usually* configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure”); 3:53-56 (“the systems *may* be planned and all individual appliances fabricated at the outset of treatment”)) Staff says that in view of the intrinsic evidence that does not require that the “series” constitute all appliances used for a patient’s treatment, Staff agrees with Complainant that the claimed “series” may simply constitute a “plurality of consecutively worn” appliances that does not necessarily comprise an entire treatment series. Staff explains that the constructions proposed by the Staff and Complainant do not differ substantively and Staff does not object to Complainant’s proposed construction in this respect. Staff says that if Respondents rely on any testimony from their experts, that testimony is extrinsic evidence, and any testimony that is merely conclusory or that contradicts the intrinsic

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evidence should be disregarded. (Citing *Phillips*, 415 F.3d at 1318; *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1361 (Fed. Cir. 2005))

Staff says that the parties also disagree over the meaning of the word “predetermined,” including what needs to be “predetermined” and when it needs to be predetermined. Staff contends that the word “predetermined,” as used in Claim 1 of the ‘880 patent, refers to appliances fabricated based on *digital data sets*, where the series of digital data sets is *determined* “at the outset” (*i.e.*, before fabrication). Staff says that the constructions proposed the Staff and Complainant are also similar; but the Staff’s proposed construction further clarifies that the series of appliances must be based on predetermined digital data sets. Staff continues that the proposed construction of “predetermined” as referring to digital data sets finds support in the plain language of claim 1 of the ‘880 patent, which refers to appliances “based on the series of successive digital data sets.” Staff says that the plain language of claim 1 of the ‘880 patent also supports construing “predetermined” as requiring the digital data sets to be determined before the *fabrication* of the appliances. (Citing JX-0002 at 22:12-29)

Staff disagrees with Respondents argument that the entire predetermined series must be fabricated before the treatment begins. Staff says that although the specification states that it is preferable to supply all appliances at the outset of treatment, it is not required. (Citing JX-0002 at 20:35-37 (“the plurality of appliances which comprise the system of the present invention are *preferably supplied* to the treating professional all at one time”) (emphasis added); 3:53-56 (“the systems *may* be planned and all individual appliances fabricated at the outset of treatment”) (emphasis added)) Staff continues that nothing in the claim language itself refers to “treatment” (as opposed to fabrication) as the critical time marker.

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Staff also disagrees with Respondents' contention that Complainant is estopped "from seeking to claim a scope in the '880 Patent that was surrendered to obtain the '874 Patent" based on statements made during prosecution of the related '874 patent. Staff says that the statements at issue were made after the '880 patent issued and, moreover concern a limitation in the '874 patent -- "outset of treatment" -- not present in the '880 patent (among other differences in language between the patent claims). Staff submits that arguments made with respect to the "outset of treatment" limitation do not affect the proper construction of a different term -- "predetermined series" -- at issue in the '880 patent. (Citing *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1322-23 (Fed. Cir. 1999) ("the specific limitations added to gain allowance of the '532 patent are not included and are therefore not relevant to determining the scope of the claims of the later issued patents"))

Staff says that unlike Respondents' proposed construction, Staff's proposed construction (similar to Complainant's proposed construction) adheres to the claim language and does not seek to improperly import limitations from the specification.

Construction to be Applied: "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 "

The plain language of claim 1 requires a method for making a predetermined series of dental appliances. Specifically, claim 1 requires:

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;

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- 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 (emphasis added)) The parties dispute the meaning of “predetermined series” and whether or not the phrase “predetermined series” includes all appliances to be used in treatment (not just a subset) and whether or not all of those appliances must be fabricated before any treatment begins.

I note that the construction proposed by Respondents in their post-hearing briefing, requiring that all of the appliances in the series or system of appliances are fabricated prior to the outset of treatment, differs substantively from the construction Respondents identified in the Second Revised Joint Claim Construction Chart (“the appliances are fabricated prior to the outset of treatment”). One important difference between Respondents’ two proposed constructions is the addition of the argument that “all” of the appliances in the series are fabricated, not just that “the appliances” are fabricated. Because Respondents failed to disclose this construction in the Second Revised Joint Claim Construction Chart, Respondents have waived the right to argue this construction should be adopted. Assuming *arguendo* that Respondents had not waived this argument, I find nothing in the intrinsic record to support their proposed construction.

Claim 1 requires a method that comprises four steps that are performed in order. Although method claims are not ordinarily construed to require a particular order of steps, here the claims require they be performed in the order written. *Interactive Gift Exp., Inc.* 256 F.3d at

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1342. Like the claims in *Loral Fairchild Corp.*, each subsequent step in the asserted claim is directed to further processing on what was produced in the previous step. 181 F.3d at 1321. The first step of claim 1 requires “obtaining a digital data set representing an initial tooth arrangement.” (JX-0002 at 22:15-16.) The second element of claim 1 refers back to the “initial tooth arrangement” and requires “obtaining a repositioned tooth arrangement based on ~~the~~ **initial tooth arrangement.**” (*Id.* at 22:17-18 (emphasis added)) The third element of claim 1 requires “obtaining a series of successive digital data sets representing a series of successive tooth arrangements.” (*Id.* at 19-20) Although the third element does not itself refer to the repositioned tooth arrangement “obtained” in the second element, the fourth element explains that the “series of successive tooth arrangements” disclosed in element three “progress[] from the **initial to the repositioned tooth arrangement.**” (*Id.* at 22:26-28 (emphasis added)) The fourth element requires “fabricating a predetermined series of dental incremental position adjustment appliances based on the series of **successive digital data sets.**” (*Id.* at 22:21-23 (emphasis added)) Because each subsequent step in claim 1 necessarily requires the previous step to have been executed, I find that the claim 1 requires the steps be performed in the order written.

With the foregoing in mind, the plain language of claim 1 provides substantial guidance for the meaning of “a predetermined series of dental incremental position adjustment appliances.” Step number four explains that the “predetermined series of dental incremental position adjustment appliances [plural]” are “based on the series of successive digital data sets,” which step number three says represent “a series of successive tooth arrangements.” Step number four continues to explain that the predetermined series “correspond[s] to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.” The necessary implication of the plain language of the claim is that the

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“repositioned tooth arrangement” is not merely any “successive tooth arrangement”; rather, the “repositioned tooth arrangement” is the tooth arrangement at the end of a defined *series* of successive tooth arrangements. For Respondents’ construction to be correct, however, the “repositioned tooth arrangement” would have to be further limited to mean the final tooth arrangement at the end of *treatment*. The claims and the specification do not support this interpretation.

First, claim 1 uses the term “repositioned tooth arrangement,” and claim 7, which depends from claim 1, uses the term “final tooth arrangement.”⁵ (JX-0002 at 22:50-53) This differing language raises the issue of the doctrine of claim differentiation, which originates in “the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope.” *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed.Cir.1999). Claim differentiation “create[s] a presumption that each claim in a patent has a different scope.” *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998). “In the most specific sense, ‘claim differentiation’ refers to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim.” *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

The Federal Circuit has stated that the “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir.

⁵ Claim 7 is directed to an embodiment in which intermediate target tooth arrangements between the initial position and the final position are identified and a series of appliances is produced between those intermediate target tooth arrangements.

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2003); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)

(“[W]here the limitation that is sought to be ‘read into’ an independent claim already appears in a dependent claim, the doctrine of claim differentiation is at its strongest.”) Here, claim 7 uses the term “final tooth arrangement” while claim 1, from which claim 7 depends, uses the term “repositioned tooth arrangement.” Respondents have offered no evidence to rebut the presumption that the term “repositioned tooth arrangement” has a different meaning from the term “final tooth arrangement.” In fact, Respondents failed to address the issue of claim differentiation at all. (*See* RIB at 76-82.)

The specification does not support Respondents’ restrictive construction. In fact, one embodiment taught in the specification contemplates multiple series of repositioning appliances between the initial and final tooth arrangements. More specifically, the specification teaches that target intermediate tooth arrangements (“key frames”) are defined and intermediate digital data sets are generated between the target intermediate tooth arrangements, rather than just between the initial and final tooth arrangements. (JX-0002 at 6:56-67) Thus, the specification contemplates multiple series of appliances being generated, each series repositioning teeth between two target intermediate tooth arrangements, which are combined to progress from the initial tooth arrangement to the final tooth arrangement. (*See id.*) Under Respondents’ construction, the target intermediate tooth arrangement would not qualify as a “repositioned tooth arrangement.” Each of the independent claims requires a “repositioned tooth arrangement.” (JX-0002 at 22:17-18, 23:15-16) Therefore, Respondents’ construction would exclude this embodiment from all of the claims of the ‘880 patent, which the Federal Circuit has described as being rarely correct. *Verizon Servs., Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333

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(Fed. Cir. 2007). Based upon all of the foregoing, I find that the “predetermined series of dental incremental position adjustment appliances” need not necessarily include all appliances between the initial arrangement and the final arrangement as Respondents contend.

Respondents’ prosecution history estoppel argument again misses the mark. Respondents rely on arguments that Align made during prosecution of the ‘874 patent to assert that the claims of the ‘880 patent should be interpreted to require that all appliances to be used in treatment be fabricated before treatment begins. The arguments upon which Respondents rely, however, were based on claim language that is not present in claim 1 of the ‘880 patent. Like the claims of the ‘325 patent discussed in Section III.B.2, *supra*, claim 1 of the ‘880 patent does not include the phrase “at the outset of treatment.” (See JX-0002 at 22:22-29) For the reasons explained in in Section III.B.2, *supra*, which I reaffirm here, because claim 1 does not include the limiting phrase “at the outset of treatment,” arguments made during prosecution of the ‘874 patent regarding that limiting phrase are not relevant to determining the scope of the claims of the ‘880 patent.

The facts here can be distinguished from *Ormco II*, cited by Respondents to argue that statements made during prosecution of the ‘874 patent can limit the scope of the claims of the ‘880 patent. (RIB at 80-82) In *Ormco II*, the district court had interpreted certain claims of *Ormco’s* patents (not Align’s patents) to require automatic determination of “finish tooth positions.” On appeal, the Federal Circuit noted that the Ormco patents’ common specification made clear that the inventors’ primary basis for distinguishing their invention from the prior art was its high level of automation. The Federal Circuit specifically noted a statement that “[i]n reality, the treatment of patients is in many cases more of an art than a science, with results ranging from poor to excellent, and generally variable” and a statement that that the prior art had