

**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,  
THE APPLIANCES MADE THEREFROM,  
AND METHODS OF MAKING THE SAME**

**Investigation No. 337-TA-833**

**COMMISSION OPINION**

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| Abbreviation          | Full Name   |
|-----------------------|---|
| ID                    | Initial Determination   |
| RD                    | Recommended Determination   |
| Align Pet.            | Complainant Align Technology, Inc.'s Petition and Contingent Petition for Review of the Initial Determination   |
| Resps. Pet.           | Respondents' Petition for Review  |
| IA Pet.               | Petition of the Office of Unfair Import Investigations for Review of the Initial Determination on Violation of Section 337  |
| Align Resp. to Resps. | Complainant Align Technology, Inc.'s Response to Respondents' Petition for Review of the Initial Determination  |
| Align Resp. to IA     | Complainant Align Technology, Inc.'s Response to the Office of Unfair Import Investigations' Petition for Review of the Initial Determination   |
| Resps. Resp.          | Respondents' Response to Align's Petition for Review and Contingent Petition for Review of the Initial Determination and Response to Petition of the Office of Unfair Import Investigations for Review of the Initial Determination |
| IA Resp.              | Response of the Office of Unfair Import Investigations to the Private Parties' Petitions for Review of the Initial Determination on Violation of Section 337  |
| Align Sub.            | Complainant Align Technology, Inc.'s Written Submission on Issues Under Review and on Remedy, the Public Interest and Bonding   |
| Resps. Sub.           | Respondents' Response to the Notice of the Commission's Determination to Review the Final Initial Determination of the Administrative Law Judge   |
| IA Sub.               | Response of the Office of Unfair Import Investigations to the Commission's Request for Written Submissions on Issues Under Review   |
| Align Reply Sub.      | Complainant Align Technology, Inc.'s Reply to Respondents' and Staff's Written Submissions on Issues Under Review and on Remedy, Public Interest and Bonding  |
| Resps. Reply Sub.     | Respondents' Reply To The OUII & Align's Response To Notice Of The Commission's Determination To Review The Final Initial Determination Of The ALJ and Exhibits   |
| IA Reply Sub.         | Response of the Office of Unfair Import Investigations to Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding  |
| Align Add. Sub.       | Complainant Align Technology, Inc.'s Written Submission on the Commission's January 17, 2014 Questions  |
| Resps. Add. Sub.      | [Respondents'] Response to the Commission's January 17, 2014 Notice   |



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|------------------------|--|
| IA Add. Sub.           | OUII's Response to the Commission's Request for Additional Written Submissions   |
| MPAA Sub.              | Submission on Behalf of Motion Picture Association of America in Response to Commission's January 17, 2014 Notice  |
| Google Sub.            | Submission of Non-Party Google Inc. in Response to Commission's Request for Public Comments  |
| Katz Sub.              | Memorandum Providing Public Comment In Response To Notice Of Commission Determination To Extend The Target Date For Completion Of The Investigation; Schedule For Filing Of Additional Written Submissions From The Parties And The Public |
| Align. Reply Add. Sub. | Complainant Align Technology, Inc.'s Reply Written Submission on the Commission's January 17, 2014 Questions   |
| Resps. Reply Add. Sub. | Respondents' Non-Confidential Reply to Written Submissions in Response to the Commission's January 17, 2014 Notice   |
| IA Reply Add. Sub.     | Response of the Office of Unfair Import Investigations to the Additional Written Submissions from the Parties and the Public   |
| MPAA Reply Sub.        | Reply Comments Filed on Behalf of Motion Picture Association of America  |
| AAP Sub.               | Association of American Publishers Reply Comments  |
| Nokia Sub.             | Reply Written Submission of Non-Party Nokia Corp. to the Submissions in Response to the Commission's Request for Public Comments   |



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On May 6, 2013, the presiding administrative law judge (“ALJ”) (Judge Rogers) issued his final initial determination (“ID”) in this investigation, finding a violation of Section 337.

Having considered the ID, the submissions of the parties and the public, and the relevant portions of the record, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final ID. The Commission has determined that the Respondents have violated Section 337 in the importation, sale for importation, or sale after importation of digital models, digital data, and treatment plans for use in making incremental dental appliances. Commissioner Johanson dissents.<sup>1</sup> The Commission has determined to adopt the ALJ’s findings that are consistent with the Commission’s opinion as set forth below.

## I. BACKGROUND

### A. Procedural History

This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc. (“Align”) of San Jose, California on March 1, 2012, and a corrected complaint filed on March 22, 2012. *77 Fed. Reg.* 20648-49 (April 5, 2012). The complaint, as corrected, alleged violations of section 337 of the Tariff Act of 1930, as amended, (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental appliances by reason of infringement of U.S. Patent No. 6,217,325 (“the ‘325 patent”), U.S. Patent

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<sup>1</sup> Commissioner Johanson has filed a dissenting opinion, post.

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No. 6,722,880 (“the ‘880 patent”), U.S. Patent No. 8,070,487 (“the ‘487 patent”), U.S. Patent No. 6,471,511 (“the ‘511 patent”), U.S. Patent No. 6,626,666 (“the ‘666 patent”), U.S. Patent No. 6,705,863 (“the ‘863 patent”) and U.S. Patent No. 7,134,874 (“the ‘874 patent”). The notice of investigation named as respondents ClearCorrect Operating, LLC (“ClearCorrect USA” or “CCUS”) and ClearCorrect Pakistan (Private), Ltd (“ClearCorrect Pakistan” or “CCPK”). A Commission investigative attorney (“IA”) participated in this investigation.

On January 14, 2013, the ALJ issued Order No. 20, denying CCUS’s and CCPK’s motion for summary determination that certain asserted claims were not infringed and that claim 1 of the ‘880 patent was invalid, and finding that CCUS and CCPK waived any estoppel defense, including defenses based on implied license or patent exhaustion.

On May 6, 2013, the ALJ issued the final ID, finding a violation of Section 337 with respect to the ‘325 patent, the ‘880 patent, the ‘487 patent, the ‘511 patent, ‘863 patent, and the ‘874 patent. The ALJ found no violation as to the ‘666 patent. The ALJ recommended the issuance of cease and desist orders directed to CCUS and CCPK to prohibit the importation of digital data sets.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto.

On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

On June 7, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013, and to extend the target date to September 24, 2013.

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On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. *78 Fed. Reg.* 46611-12 (August 1, 2013). On August 8, 2013, each of the parties filed written submissions. On August 15, 2013, each filed reply submissions.

On September 24, 2013, the Commission issued notice of its determination to extend the target date to November 1, 2013. Due to the federal government shutdown and the Commission Notice tolling all deadlines by the length of the shutdown, the target date became November 18, 2013. On November 18, 2013, the Commission issued notice of its determination to extend the target date to January 17, 2014.

On December 31, 2013, the Respondents filed a notice of supplemental authority. On January 10, 2014, Align filed a reply thereto.

On January 17, 2014, the Commission issued a notice extending the target date to March 21, 2014, and soliciting further briefing from the public and the parties. *79 Fed. Reg.* 4174-74 (January 24, 2014).

On February 3, 2014, the Commission received written submissions from each of the parties and from Motion Picture Association of America (“MPAA”), Google Inc. (“Google”), and Andrew Katz (Mr. Katz).<sup>2</sup> On February 10, 2014, the Commission received reply submissions from each of the parties and from MPAA, the Association of American Publishers (“the AAP”), and Nokia Corporation (“Nokia”).

On March 21, 2014, the Commission issued notice of its determination to extend the target date to April 3, 2014.

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<sup>2</sup> Mr. Katz is an attorney of the law firm Belles Katz LLC in Horsham, Pennsylvania.



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### B. Related Cases

On February 15, 2006, the Commission instituted an original investigation captioned *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (“the 562 investigation”), based on a complaint also filed by Align. 71 *Fed. Reg.* 7995-96 (February 15, 2006). Briefly, the complaint alleged that the OrthoClear Respondents<sup>3</sup> violated Section 337 when they imported and sold aligners in the United States which had been manufactured in Pakistan. The orthodontic aligners at issue were accused of infringing the ‘880 and ‘511 patents asserted in this investigation, among numerous others. *Id.*

On October 27, 2006, the presiding ALJ issued an Initial Determination granting Align’s and OrthoClear’s joint motion to terminate the investigation based on a consent order. The Commission determined not to review the ID. Notice (November 13, 2006).

The consent order provides in relevant part:

1. The incremental dental positioning adjustment appliances manufactured by or for OrthoClear referenced in the complaint and any other articles manufactured in violation of the patents or trade secrets described therein (the “Articles”) are hereby prohibited from importation into the United States until the expiration of the last to expire of the following patents: (i) U.S. Patent No. 6,685,469 (“the ‘469 patent”); (ii) U.S. Patent No. 6,394,801 (“the ‘801 patent”); (iii) U.S. Patent No. 6,398,548 (“the ‘548 patent”); (iv) U.S. Patent No. 6,722,880 (“the ‘880 patent”); (v) U.S. Patent No. 6,629,840 (“the ‘840 patent”); (vi) U.S. Patent No. 6,699,037 (“the ‘037 patent”); (vii) U.S. Patent No. 6,318,994 (“the ‘994 patent”); (viii) U.S. Patent No. 6,729,876 (“the ‘876 patent”); (ix) U.S. Patent No. 6,602,070 (“the ‘070 patent”); (x) U.S. Patent No. 6,471,511 (“the ‘511 patent”); and (xi) U.S. Patent No. 6,227,850 (“the ‘850 patent”) (collectively “the Patents-In-Suit”), except under license of the patent owner or as provided by law.

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<sup>3</sup> The Commission’s notice of investigation named OrthoClear, Inc. of San Francisco, California; OrthoClear Holdings, Inc. of Tortola, British Virgin Islands; and OrthoClear Pakistan Pvt, Ltd. of Lahore, Pakistan (collectively, “OrthoClear”) as respondents.

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2. Upon entry of this Consent Order, OrthoClear shall not sell for importation, import into the United States, or sell in the United States after importation the Articles, or knowingly aid, abet, encourage, participate in, or induce the sale for importation into the United States or sale in the United States after importation of the Articles.

3. This Consent Order shall be applicable and binding upon OrthoClear, its officers, directors, agents, servants, employees, successors and assigns, and all persons, firms, or corporations acting or claiming to act on its behalf or under its direction or authority.

On March 1, 2012, Align filed a complaint for an enforcement proceeding under Commission Rule 210.75, 19 C.F.R. § 210.75, which was instituted on April 25, 2012 (“the 562 Enforcement Proceeding”). Align based its complaint on alleged violations of the consent order by ClearCorrect USA of Houston, Texas (“CCUS”); ClearCorrect Pakistan (Private), Ltd. (“CCPK”) of Lahore, Pakistan; and Mudassar Rathore, Waqas Wahab, Nadeem Arif, and Asim Waheed (collectively, “Enforcement Respondents”). 77 Fed. Reg. 25747 (May 1, 2012).

In the complaint for enforcement, Align alleged that the Enforcement Respondents violated the consent order when they sold for importation, imported, or sold after importation digital data sets, including digital models of a patient’s teeth, digital data and/or treatment paths transmitted (electronically) to the United States, and subsequently manufactured aligners in the United States using those imported digital data sets. According to Align, the Enforcement Respondents’ use of certain processes, systems, and techniques infringe at least claim 1 of the ‘511 patent and claims 1 and 3 of the ‘880 patent. Enforcement Complaint ¶¶ 90, 94-95.



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Align further alleged that both CCUS and CCPK are “successor[s], assign[s], or agent[s]” of the original OrthoClear respondents. *Id.* ¶ 24, 31.<sup>4</sup> The complaint also alleges that the named individuals are former employees or a director of OrthoClear. Enforcement Complaint ¶¶ 34, 38, 42, 46. ClearCorrect Pakistan admits that the individuals are former employees of OrthoClear and further admits that Mudassar Rathore is the CEO of CCPK, Waqas Wahab and Nadeem Arif are directors of orthodontics for CCPK, and that Asim Waheed is a manager of quality control at CCPK. Response of CCUS to Enforcement Complaint ¶¶ 34-35, 38-39, 42-43, 46-47.

On November 28, 2012, the ALJ issued Order No. 57, finding that the accused digital data sets are “articles manufactured” within the meaning of paragraph 1 of the consent order. On January 4, 2013, the Commission issued notice of its determination to review and reverse the ID and to terminate the proceeding with a finding of no violation of the consent order. 78 Fed. Reg. 2282-83 (January 10, 2013). In its opinion, the Commission held that, since the consent order at issue contained no express provision for electronic transmissions, the consent order did not cover electronic transmissions under Commission precedent and thus there was no violation of the consent order. *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Comm’n Op. (January 23, 2013). Align has appealed the Commission’s determination from the 562 Enforcement Proceeding to the U.S. Court of Appeals for the Federal Circuit. Case Nos. 2013-1240, -1363. That appeal is currently pending.

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<sup>4</sup> ClearCorrect USA and ClearCorrect Pakistan have denied these allegations. Response of CCUS to Enforcement Complaint ¶ 24; Response of CCPK to Enforcement Complaint ¶ 31.



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### C. The Patents

Align asserts seven U.S. patents that all claim priority to provisional application No. 60/050,342 filed on June 20, 1997. As with the specifications of all the patents in suit, each patent is directed towards a system for repositioning teeth comprising a plurality of individual appliances (aligners) which are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement to a final tooth arrangement.<sup>5</sup> *See, e.g.*, '880 Patent Abstract.<sup>6</sup> While the seven asserted patents all share a common inventive concept of using digital data sets to construct the individual appliances, a description of each asserted patent is set forth below.

#### 1. The '325 Patent

The '325 patent,<sup>7</sup> entitled "Method and System For Incrementally Moving Teeth," issued on April 17, 2001, based on Application No. 09/298,268, filed by Muhammad Chishti, Apostolos Leros, Brian Freyburger, Kelsey Wirth, and Richard Ridgley on April 23, 1999. ID at 2-3. The '325 patent is a divisional of non-asserted U.S. Patent No. 5,975,893 filed Oct. 8, 1997. The '325 patent was the subject of an *ex parte* reexamination based on a request received on July 27, 2005, that added limitations to original claims 1 and 18-21 and added new claims 27-39. *Id.* A reexamination certificate issued on January 15, 2008. *Id.*

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<sup>5</sup> The asserted patents note that "the appliances can be braces, polymeric shells, or other forms of orthodontic appliances." '511 patent Abstract.

<sup>6</sup> The asserted patents have different specifications, but are from the same family.

<sup>7</sup> JX-3.

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Align has asserted claims 1-3, 11, 13-14, 21, 30-35, and 38-39. Claims 1, 11, 21, 31, 35 and 38 are independent claims. Certain claims of the '325 patent are directed to a method for fabricating a plurality of dental incremental position adjustment appliances using digital data sets representing an initial tooth arrangement, a final tooth arrangement, and a series of intermediate digital data sets representing the tooth arrangements progressing from the initial to the final arrangement. '325 patent, col. 16, lines 19-34.

Claim 1 recites:

1. 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.

*Id.* Ex Parte Rexam Cert. at col. 1, lines 29-48.

### 2. The '880 Patent

The '880 patent,<sup>8</sup> entitled "Method and System for Incrementally Moving Teeth," issued on April 20, 2004, based on Application No. 10/047,077, filed by Muhammad Chishti and Kelsey Wirth on January 14, 2002. ID at 3. The '880 patent arises from an

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<sup>8</sup> JX-2.

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application which is a continuation-in-part of a related, non-asserted patent. Align has asserted claims 1 and 3; claim 1 is an independent claim.

Similar in manner to the '325 patent, claim 1 of the '880 patent is directed to a method for fabricating dental adjustment appliances using digital data sets. The asserted claims of the '880 patent expressly define the "dental adjustment appliances" as comprising "polymeric shells having cavities shaped to receive and resiliently reposition teeth." '880 patent, col. 22, lines 12-29. Claim 1 recites:

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

*Id.* Dependent claim 3 teaches that the digital data set is obtained by defining boundaries of the individual teeth and moving at least some of the tooth boundaries relative to other teeth in an image. *Id.* col. 22, lines 33-41. Claim 3 recites:

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

*Id.*



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### 3. The '487 Patent

The '487 patent,<sup>9</sup> entitled "System and Method for Positioning Teeth," issued on December 6, 2011, based on Application No. 11/981,680, filed by Muhammad Chishti and Andrew Beers on October 31, 2007. ID at 3. Align has asserted claims 1, 3, 5 and 7-9, of which claims 1 and 7 are independent.

The asserted claims are directed to a method of planning dental treatment by producing digital data sets. The '487 patent teaches the concept of an "orthodontic treatment plan." '487 patent, col. 11, lines 26-35. Claim 1 recites:

1. A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:
  - receiving an initial digital data set representing an initial arrangement of the patient's teeth;
  - producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;
  - producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement.

*Id.*, col. 10, line 61 to col. 11, line 6. In addition, claim 7 provides that the "treatment plan resid[es] on a computer readable media." *Id.*, col. 11, lines 28-29. Claim 7 recites:

7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

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<sup>9</sup> JX-7.

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*Id.*, col. 11, lines 26-35. Although the '487 patent introduces the limitation of "orthodontic treatment plan," the underlying structure of the claim remains directed to development of digital data sets. *Id.*

### 4. The '511 Patent

The '511 patent,<sup>10</sup> entitled "Defining Tooth-Moving Appliances Computationally," issued on October 29 2002, based on Application No. 09/169,034, filed by Muhammad Chishti, Elena I. Pavlovskaja, Gregory P. Bala and Brian Freyburger on October 8, 1998. ID at 4. The '511 patent arises from an application which is a continuation-in-part of a non-asserted patent. The sole asserted claim is claim 1.

The '511 patent is directed towards methods for segmenting an orthodontic treatment plan, as referred previously in the '487 patent, into clinically appropriate sub-steps for repositioning the teeth of a patient. '511 patent, Abstract. The limitations presented in claim 1 of the '511 patent are distinguished from the claims of other asserted patents because claim 1 further provides for "calculating a segmentation of the aggregate tooth paths...so that each tooth's motion stays within threshold limits of linear and rotational translation." *Id.*, col. 11, lines 9-12. Claim 1 recites:

1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:
  - for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;
  - calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and
  - generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of

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<sup>10</sup> JX-1.



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successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

*Id.*, col. 11, lines 4-19.

### 5. The '666 Patent

The '666 patent,<sup>11</sup> entitled "Method and System for Incrementally Moving Teeth," issued on September 30, 2003, based on Application No. 09/757,044, filed by Muhammad Chishti, Apostolos Lerior, Brian Freyburger, Kelsey Wirth and Richard Ridgley on January 8, 2001. ID at 4-5. Align has asserted claims 1, 3, 7 and 9; claims 1 and 7 are independent claims.

The claims of the '666 patent are directed to a method of producing a "plurality of digital data sets." '666 patent, col. 15, lines 27-48. Similar to the manner of claims for the '880 patent, the '666 patent produces digital data sets by "moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set." *Id.* at col. 15, lines 38-40. Claim 1 recites:

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

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<sup>11</sup> JX-4.



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arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

*Id.*, col. 15, lines 27-47. Additionally, claim 7 of the '666 patent introduces the limitation of “interpolating positional differences between the teeth in the initial and final data sets.”

*Id.* at col. 16, lines 7-13. Claim 7 recites:

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

*Id.*, col. 15, line 64 to col. 16, line 13.

### 6. The '863 Patent

The '863 patent,<sup>12</sup> entitled “Attachment Devices and Methods for a Dental Appliance,” issued on March 16, 2004, based on Application No. 10/040,269, filed by Loc X. Phan, Muhammad Z. Chishti and Ross J. Miller on October 29, 2001. *Id.* at 5. The '863 patent was the subject of an ex parte reexamination based on a request received on June 23, 2005. *Id.* The '863 patent is a continuation-in-part of a non-asserted U.S. patent 6,309,215 filed Dec. 3, 1999.

Align has asserted claims 1 and 4-8; claim 1 is an independent claim. Claim 1 of the '863 patent was subject to ex parte reexamination and is directed towards a method

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<sup>12</sup> JX-5.

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for producing digital models of dental appliances. ‘863 patent, Ex Parte Reexam Cert. col. 1, lines 57-col. 2, line 4. The asserted claims disclose a method of “producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment.” *Id.* Claim 1 recites:

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

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

*Id.*

### 7. The ‘874 Patent

The ‘874 patent,<sup>13</sup> entitled “Computer Automated Development of an Orthodontic Treatment Plan and Appliance,” issued on November 14, 2006, based on Application No. 10/718,779, filed by Muhammad Chishti, Brian Freyburger, Kelsey Wirth, Andrew Beers, Huafeng Wen, Phillips Alexander Benton, Timothy N. Jones, and Ross J. Miller on November 20, 2003. ID at 5-6.

Align has asserted claims 1, 2, 38-39, 41, and 62; claim 1 is an independent claim. Claim 1 of the ‘874 patent is directed to a method for “creating a treatment plan to reposition a patient’s teeth from a set of initial tooth positions to a set of final tooth

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<sup>13</sup> JX-6.



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positions” in a manner similar to the other asserted patents. ‘874 patent, col. 32, lines 37-

56. Claim 1 recites:

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

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

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

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

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.

*Id.* In contrast to the other patents in suit, the asserted claims of the ‘874 patent have a limitation of generating a plurality of appliances “prior to patient wearing any appliance.” ‘874 patent, col. 32, lines 53-56.

### **D. The Groups of Asserted Claims**

The asserted claims across the seven patents-in-suit share characteristics and limitations. Complainant Align placed them into four groups for the purpose of analyzing the threshold issues of violation, *e.g.*, whether there is an imported “article,” and whether the territorial requirements of violation have been met. Align’s Response to Respondents’ Petition for Review (“Align Pet.”) at 4-5. Some claims are in more than one group. There was no objection raised to the use of these groupings.<sup>14</sup>

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<sup>14</sup> See Respondents’ Response to the Notice of the Commission’s Determination to Review the Final Initial Determination of the Administrative Law Judge (“Resps. Sub.”); Response of the Office of Unfair Import Investigations to the Commission’s Request for Written Submissions on Issues Under Review (“IA Sub.”);



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### 1. Group I

The Group I claims (Claims 21 and 30 of the '325 patent and claim 1 of the '880 patent) are directed to a method of forming dental appliances starting with a digital data set.

### 2. Group II

The Group II claims (Claims 31 and 32 of the '325 patent; claims 1 and 4-8 of the '863 patent; claims 1, 3, 7 and 9 of the '666 patent; and claims 1, 3 and 5 of the '487 patent) are directed to methods of producing digital data sets.

### 3. Group III

The Group III claims (Claims 7-9 of the '487 patent) are directed to a treatment plan (*i.e.*, a series of digital data sets) on a storage medium.

### 4. Group IV

The Group IV claims (Claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, 39 of the '325 patent; claims 1 and 3 of the '880 patent; claims 1 of the '511 patent; and claims 1, 2, 38, 39, 41, and 62 of the '874 patent) are directed to methods of producing dental appliances.

## E. The Accused Products and Processes

### 1. Accused Products

Align accuses digital data sets made by CCUS and CCPK and the customized sequential dental positioning appliances made therefrom for the purpose of orthodontic treatment.

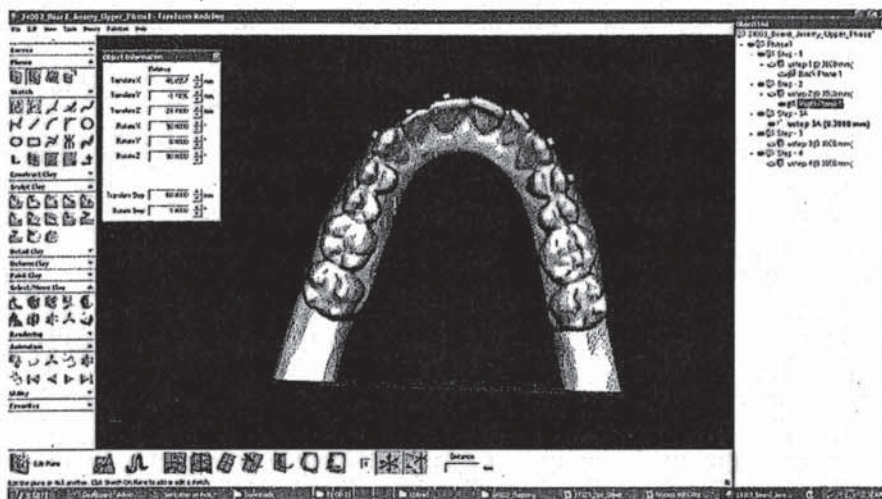
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Respondents' Reply To The OUII & Align's Response To Notice Of The Commission's Determination To Review The Final Initial Determination Of The ALJ and Exhibits ("Resps. Reply Sub."); Response of the Office of Unfair Import Investigations to Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("IA Reply Sub.").

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The ALJ found the accused products to be digital models, digital data, and treatment plans, expressed as digital data sets, which are virtual three-dimensional models of the desired position of patients' teeth at various stages of orthodontic treatment. The models are initially created based on impressions of patients' teeth. The models are manipulated in Pakistan by CCPK, as set forth below, and transmitted to CCUS. ID at 21-22. The digital models, digital data, and treatment plans are electronically transmitted by uploading them (a CCPK technician in Pakistan electronically transmits the digital data to CCUS's server for CCUS use in the United States). ID at 21-22; Tr. at 316-17; CX-1150C at Qs. 92-145; Tr. at 168:14-170:11, 170:18-173:24, and 177:2-193:6; Tr. at 312:20-322:12; Tr. at 442:5-443:10. The digital models are subsequently used to print 3-D physical models of a patient's teeth. *Id.* The aligners, *i.e.*, the incremental dental positioning adjustment appliances, are formed over the physical models of the teeth. *Id.*

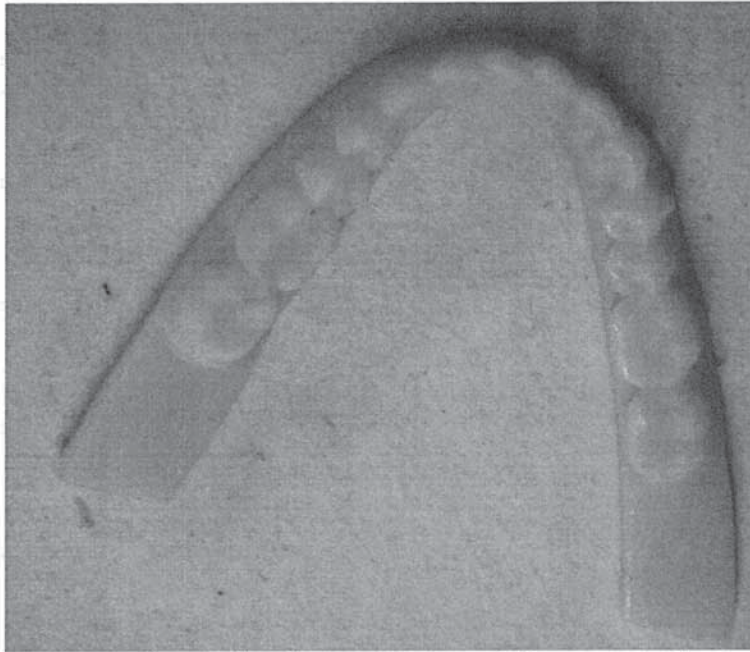
Below is an image of a computer model of the teeth.



CX-90C at 54.

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Below is a picture of a physical model of teeth.



CX-875C. CCUS forms aligners by thermoplastic molding over a physical model of the teeth. Tr. at 318:4-7.

### **2. Accused Processes**

As set forth below, the ALJ found the process implemented by CCPK and CCUS to produce the digital data sets and subsequent dental positioning adjustment appliances to constitute the “accused process.” CCUS performs certain steps in the United States and CCPK performs certain steps in Pakistan. *See* ID at 472-73.

**a. Scanning stone models into a digital model:** Employees of CCUS and CCPK testified that CCUS creates digital data sets by scanning stone models of a patient’s dental impressions, which represent the patient’s initial tooth arrangement. ID at 472 (citing Tr. at 171:8-11; 314:19-315:18).



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**b. and c. Transmission of initial digital data sets (from Texas to Pakistan) and software conversion:** CCUS uploads the 3D digital scan to a server for CCPK to access. ID at 698. CCPK imports the scan data into FreeForm, which is a 3D modeling software program, to prepare the initial digital data set. *Id.*

**d. Sectioning:** Mr. Pumphrey, an employee of CCUS, testified that CCPK sections the initial digital data sets representing the initial position of teeth for the upper and lower jaws into 16 separate teeth. Tr. at 330:11-331:5. The ALJ found that this sectioning, depicted in CX-889C, shows that the sectioning defines boundaries about the individual teeth. ID at 484 (citing Tr. at 330:13-331:5; CX-889C).

**e. [[**

**]]**

**f. [[**

**]]**

**g. Transmission of treatment setup to professional for approval:** Mr. Arif testified that a copy of the “treatment setup” is transmitted to CCUS, which then sends the “treatment setup” to the dentist for approval. ID at 689; Tr. at 172:10-172:14; 335:1-

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13; 335:19-336:2. Transmission occurs when CCPK uploads the setup to the CCUS server. Tr. at 316:4-8.

**h. Stepping process (interpolation and festooning):** If the dentist in the United States approves the planned model of the final position, CCPK proceeds to the “stepping process,” which consists of creating steps, or intermediate tooth positions, that move the teeth from their initial position to the final position. Tr. at 172:15-173:13. The ALJ found that the CCPK technicians use the “Generate Steps” function of the FreeForm software to generate a set of stepped locations for a tooth between two tooth positions. ID at 495 (citing Tr. at 336:11-337:9; *see also* CX-1150C at Q. 198). The ALJ found that the text in the FreeForm software regarding the “Generate Steps” function states that “[s]teps will be generated automatically by interpolating between the positions of the corresponding pieces in the starting and ending folders.” *Id.* (citing CX-107C at 5:33). The operator also cleans up the models of the teeth through a process known as “festooning” after the computer has performed the interpolation. Tr. at 339:23-341:5.

**i. and j. Uploading of digital data sets [[**

**]]:** CCPK electronically transmits the digital data sets to CCUS by uploading them onto the CCUS server. Tr. at 316:12-22; 341:14-17. [[

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### II. STANDARD FOR DETERMINATION ON REVIEW

Once the Commission has determined to review the decision of the ALJ, the agency has all of the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. 5 U.S.C. § 557(b); *Certain Acid-Washed Garments and Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 4-5 (Aug. 6, 1992). Commission Rule 210.45(c) implements 5 U.S.C. § 557(b). In other words, once the Commission decides to review the decision of the ALJ, the Commission may conduct a review of the findings of fact and conclusions of law presented by the record under a *de novo* standard.

### III. DISCUSSION

#### A. “Importation . . . of Articles”

There is a threshold issue that relates to all of the patent claims asserted, *i.e.*, whether Respondents’ electronic transmissions of digital data sets constitute “importation of . . . articles” within the meaning of Section 337.

In their petition for review, Respondents argue that the digital data sets representing the initial, intermediate, and final positions of patients’ teeth are not “articles” within the meaning of Section 337(a)(1)(B), and therefore cannot be the basis of any unfair act under the statute. Resp. Pet. at 66-67. Moreover, Respondents contend that because the accused data sets are brought into the United States by CCPK by uploading them to CCUS’s server in Houston, Texas, this mode of bringing the accused products into the United States is not an importation into the United States as anticipated by Section 337(a)(1)(B). *Id.* at 67. Align and the IA oppose Respondents’ position,



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arguing that the ALJ correctly found that the language of the statute and its legislative history indicate that the term “articles” includes within its meaning the accused products.

The Commission affirms the ALJ’s finding that the accused products are “articles” within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B).

### 1. The ID

The ALJ found that the accused digital data sets are “articles” within the scope of the Commission’s “jurisdiction,” although he acknowledged that the issue is not necessarily jurisdictional and that he was only treating the issue as one of jurisdiction because the parties had raised the issue in that manner. ID at 17 and n.1 (discussing *Certain Drill Bits and Products Containing Same*, Inv. No. 337-TA-844, Comm’n Notice (August 22, 2012) (not adopting statement in ID that issue was jurisdictional)). The ALJ found that *Hardware Logic* is directly on point. *Id.* at 18 (discussing *Certain Hardware Logic*, Inv. No. 337-TA-383). The ALJ noted that in *Hardware Logic*, the Commission rejected the argument that software is not an “article” and that remedial orders could not reach energy, which is intangible. *Id.* (citing *Hardware Logic*, Comm’n Op. at 18, fn. 84 (Dec. 1994)). The ALJ observed that 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.” *Id.* (citing *Hardware Logic* Comm’n Op. at 21).

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The ALJ stated that this understanding of *Hardware Logic* is confirmed by the Commission's Opinion in Investigation No. 337-TA-562 (Enforcement), where the Commission cited *Hardware Logic* to hold that "it has jurisdiction and authority to reach digital data electronically transmitted to a recipient in the United States," before finding that the consent order did not expressly prohibit electronic transmissions. *Id.* at 7.

The ALJ rejected Respondents' argument that the Federal Circuit opinion in *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003), stated that Section 337 does not cover information because the court in *Bayer AG* was addressing 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.<sup>15</sup> *Id.* at 19 (discussing *Bayer*, 340 F.3d at 1371). The ALJ concluded that any discussion in *Bayer* regarding the scope of 19 U.S.C. § 1337 was dicta and is not controlling, and that in any case, the Federal Circuit acknowledged that the scope of 19 U.S.C. § 1337 may be broader than 271(g). *Id.*

The ALJ also rejected Respondents' argument that the Federal Circuit stated in *Nuijten* that an "article" must be tangible because that case 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. *Id.* at 20 (citing *In re Nuijten*, 500 F.3d 1346, 1348 (Fed. Cir. 2007)).

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<sup>15</sup> The Federal Circuit in *Bayer* 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).

*Bayer AG*, 340 F.3d at 1374 n.9.



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### 2. Arguments<sup>16</sup>

Respondents argue that neither the plain language of Section 337 nor its legislative history provide a basis for interpreting intangible, electronic transmissions as “articles.” Resps. Submission at 2. Respondents assert that the Federal Circuit has already concluded that the legislative history and language of Section 337 limit “articles” to tangible items. Respondents assert that the Court concluded that “product” in § 271(g) is the same as “articles” described in Section 337. *Id.* at 2-3 (quoting *Bayer*, 340 F.3d at 1373).

Respondents argue that it is clear from the debate that led to the enactment of the Tariff Act of 1930 that members of both houses equated “articles” with tangible items, often using the term “articles” synonymously with “goods,” “merchandise,” and “commodities.” *Id.* Respondents state that Section 337 has been amended a dozen times, but none of these amendments suggest any Congressional intent to change its long-standing interpretation of “articles” from something tangible. *Id.* at 6-7. Respondents argue that, in other legislation, Congress explicitly exempted telecommunications from tariff duties and concludes that this is express evidence of Congress’s intent not to regulate the entry of digital information through telecommunications transmission. *Id.*

Respondents argue that the Commission’s order in *Hardware Logic* does not hold that electronic transmission is an “importation” or that digital data is an “article.” *Id.* at 10. Respondents assert that the “software” component described in the Recommended Determination (“RD”) was stored on a cartridge tape and was imported only one time, on

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<sup>16</sup> The Commission fully considered the submissions of the parties and of the public third-party submitters. The full submissions are available on the Commission website at <https://edis.usitc.gov>.



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August 2, 1996. *Id.* (citing RD at 6, 202). Respondents assert that “nowhere in the RD or cease and desist order did the Commission hold that the possible electronic transmission of that software was an importation of an article under the statute. Nor did it hold that the electronic data itself was an ‘article.’” *Id.*

Respondents argue that the Commission’s ability to protect domestic patents and copyrights would not be “eviscerated” if “articles” doesn’t include electronic transmissions because patent and copyright holders will have remedies elsewhere, and the Federal Circuit rejected a similar argument in *Bayer* when it construed the scope of § 271(g). *Id.* at 2

Respondents note Align’s proposed definition of “articles” as “units of commerce,” and argue that there is no evidence that the electronic transmissions are sold as “units of commerce.” Resps. Add. Sub. at 6. Respondents state that “[i]t is clear that CCUS paid CCPK for its services rendered in total and was not paid for “units.” *Id.*

Respondents contest Align’s reliance on two district court decisions, *CNET* and *Ormco*. *Id.* at 3. Respondents assert that *CNET* is simply the denial of defendant’s motion for summary judgment, involved § 271(g), and is distinguishable on its facts because in *CNET* the electronic catalog is bought and sold while in the instant case there is no record evidence that the computer files are bought and sold. *Id.* at 3-4.

Respondents assert that *Ormco*’s holding that no product was required to be sold under § 271(g) is undercut by the Federal Circuit’s holding that such a sold product is required under § 271(c) in *PharmaStem Therapeutics, Inc. v. ViaCell*, 491 F.3d 1342, 1357-58 (Fed. Cir. 2007)).

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Align argues that electronic transmission of data constitutes “importation” of “articles” under Section 337. Align Sub. at 1. Align suggests that the text, legislative history, and overall purpose of Section 337 support the conclusion that the term “articles” encompasses any identifiable unit of commercial value, including electronically transmitted data. *Id.* at 1-2. Align asserts that the Commission has interpreted “importation” of “articles” accordingly in *Hardware Logic* and in *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562. *Id.* at 2. Align quotes the Commission Opinion in the latter case that “it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States,” and states that this is a conclusion equally applicable to determinations of violation and subsequent remedy. *Id.*

Align cites dictionary definitions to support its position. *Id.* at 3. Align further contends that the broad meaning of the term “articles” is set by Section 337 itself, and that its title (“Unfair practices in import trade”) and its terms reflect a concern regarding commercial practices. *Id.* Complainant argues that the accompanying terms “sale for importation,” “importation,” and “sale after importation,” indicate that Congress meant all units of commercial value - - items that can be bought, sold, or otherwise transferred. Align concludes that this is consistent with other courts’ findings that digital data is an “article of commerce.” *Id.* at 4. Align argues that Congress intended “article” to encompass anything that infringes, and that limiting “articles” to physical objects would arbitrarily exclude a broad range of infringing products and severely limit the ability of this agency to perform its intended function. *Id.* at 4-5. Align states that a remedial



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statute should be “construed broadly to effectuate its purposes,” and suggests that Section 337 is such a remedial statute. *Id.* at 7.

Align asserts that “[e]xempting electronically transmitted data from Section 337(a)(1)(B) would eviscerate the Commission’s ability to protect the domestic recording, entertainment, publishing, and software industries from copyright infringement by downloadable books, movies, television programs, software, and music.” *Id.* at 7. Align also suggests that new three-dimensional printers could allow importers to switch from the importation of physical products to the electronic transmission of designs for these products. *Id.*

Align notes that, in issuing a cease and desist order in *Hardware Logic*, the Commission relied on the legislative history of Section 337 and the statutory mandate to ensure adequate protection of U.S. intellectual property rights, and found that coverage of electronic transmissions was necessary in order to make the order fully effective. *Id.* at 10.

Align argues that its view is supported by the conclusions of other courts and agencies. *Id.* at 11. Align points to a statement by the Supreme Court that “[i]f there be actual bringing in [to the United States] it is importation ***regardless of the mode in which it is effected.***” *Id.* at 8 (quoting *Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923) (emphasis in brief)). Align points to a Customs ruling that “the transmission of software modules and products to the United States from a foreign country via the Internet is an importation of merchandise into the customs territory of the United States in that the software modules and products are brought into the United States from a foreign country.” *Id.* at 11-12 (quoting Customs Ruling HQ 114459 (Sept. 17, 1998)). Align



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similarly points to a series of Court of International Trade (“CIT”) decisions interpreting Section 222 of the Trade Act of 1974, 19 U.S.C. § 2272, in which the CIT refused to read a tangibility requirement into the statute. *Id.* at 12 (citing, *inter alia*, *Computer Scis. Corp v. Sec’y of Labor.*, 414 F. Supp.2d at 1340-41 (CIT 2006)). Align argues that the Trade Act of 1974 was an outgrowth of the Tariff Act of 1930 and that when Congress uses the same language in two statutes having the same purposes, it is appropriate to presume that Congress intended the text to have the same meaning in both statutes. *Id.* at 12-13 (citing *Smith v. City of Jackson*, 544 U.S. 228, 233 (2005)).

Align distinguishes *Bayer*, stating that the product in *Bayer* was “information in the abstract,” specifically, “the knowledge that a substance possesses a particular quality,” which is not the result of practicing a patented process. *Id.* at 3. Align states that in *CNET*, the court found that an electronic catalogue, maintained as a data file and downloaded, is a product under section 271(g). *Id.*

The IA also argues that “articles” includes electronic transmissions. The IA highlights a statement from the Commission Opinion on Remedy in *Hardware Logic*, and argues that this statement would be accorded deference by the Federal Circuit under *Chevron*: “We do not think the legislative history of Section 337 precludes coverage of electronically transmitted software; in fact, we believe that it supports the conclusion that such coverage is proper.” IA Reply Sub. at 4 (quoting *Hardware Logic*, Commission Opinion on Remedy, the Public Interest, and Bonding at 28 (April 1, 1998); citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984)). The IA argues that *Hardware Logic* necessarily supports the conclusion that electronic transmission of data is importation for purposes of violation, and that this was confirmed

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recently by *Dental Appliances*, Inv. No. 337-TA-562 (Enforcement). *Id.*; IA Add. Reply Sub. at 4.

The IA further agrees with the MPAA that the Commission's practice of exercising jurisdiction over electronically imported articles is mandated by Supreme Court precedent, specifically *Cunard* and *Canton Railroad*, because importation occurs regardless of the mode an article is brought into the country. IA Add. Reply Sub. at 2-3. The IA counters Google and Katz's reliance on *Nuitjen*, *Bayer*, *NTP*, *Microsoft*, and *Suprema*, arguing that *Nuitjen* is directed to an issue of patentability under § 101, *Bayer* and *NTP* were directed to the scope of § 271(g), *Microsoft* was directed to the scope of § 271(f), and *Suprema* was directed to the scope of § 271(b) not § 271(c). *Id.* (discussing *Suprema, Inc. v. ITC*, 742 F.3d 1350 (Fed. Cir. 2013); *In re Nuitjen*, 500 F.3d 1346, 1353 (Fed. Cir. 2007); *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 (Fed. Cir. 2003); *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007)).

Third-Party Submitter Motion Picture Association of America, Inc. ("MPAA") states that physical media are being replaced by electronic, downloadable formats. MPAA Sub. at 2. The MPAA asserts that infringement is also shifting to downloadable formats, leading to a loss of \$58 billion annually, including 373,000 jobs, \$16 billion in lost employee earnings, and \$3 billion in tax revenue. *Id.*

The MPAA states that the legislative history of Section 337 demonstrates that Congress intended for the Commission to have very broad jurisdiction over unfair acts in international trade. *Id.* at 11. The MPAA argues that the Commission has a longstanding



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practice, affirmed by the Federal Circuit, of taking a flexible approach to its jurisdiction and authority, reflecting the “realities of the marketplace.” *Id.* at 11-12.

The MPAA argues that the Federal Circuit’s decisions in *Suprema* and *Bayer* were related to narrow patent issues and do not bear on whether imported electronic transmissions can constitute “articles” for purposes of Section 337. *Id.* at 13.

The MPAA asserts that the remedy provisions of Section 337 do not dictate that “articles” be limited to physical objects because Section 337 also gives the Commission authority to issue cease and desist orders, and that cease and desist orders need not be limited to the situation where they aid enforcement of exclusion orders or are issued in lieu of exclusion orders. *Id.* at 3-4.

The MPAA draws a different conclusion than Google about the absence of a specific discussion of electronic transmissions in the legislative history, stating that “the technological state of affairs at the time the statute was drafted does not lock in historical amber the meaning of a general term such as the word ‘articles.’” *Id.* The MPAA instead cites *Diamond v. Chakrabarty* for the proposition that a statute is not to be confined to the particular applications contemplated by the legislators, and argues that statutory silence cannot be interpreted as lack of coverage. *Id.* at 5-6 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980)).

The MPAA argues that the Commission’s established practice regarding its authority over electronic articles is consistent with U.S. government policy. *Id.* at 8.

Third-Party Submitter Andrew Katz asserts that Federal Circuit case law strongly suggests that electronic transmissions are not articles under either Section 337(a)(1)(B)(i) or (ii) because they are intangible. Katz Sub. at 2.



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Mr. Katz states that the article in § 271(a) is the “patented invention” and that a patented invention is one within the statutory classes of patentable subject matter in 35 U.S.C. § 101. *Id.* at 3. Mr. Katz reasons that electronic transmissions cannot be patentable inventions under *In re Nuijten*, 500 F.3d 1346, 1353 (Fed. Cir. 2007), and therefore cannot be directly infringing articles under Section 337(a)(1)(B)(i). *Id.* at 2, 11. Mr. Katz further asserts that the case law, including *Microsoft*, suggests that an article for purposes of § 271(c) must also be a tangible product. *Id.* at 4.

Mr. Katz submits that the Commission should be guided by § 271 in deciding the meaning of “article” for purposes of Section 337 because the Federal Circuit in *Suprema* indicated that the infringement provisions of Section 337 must be interpreted to be consistent with, and limited by, the court’s jurisprudence under 35 U.S.C. § 271. *Id.*

Mr. Katz argues that the Commission’s opinion in *Hardware Logic* has been displaced by the Federal Circuit’s decisions in *Suprema* and *Bayer* and the Supreme Court’s decision in *Microsoft*. *Id.* at 12-13.

Third-Party Submitter Google submits that, as a matter of law and policy, the Commission is not an appropriate forum for software patent litigation if the accused products are non-tangible electronic transmissions into the United States. Google Sub. at 2.

Google submits that the Commission has recognized the limits of its jurisdiction and remedial powers when it observed that it is a creature of statute and that its authority must be found in its enabling statute. *Id.* at 2. Google argues that the *Electronic Devices* investigation stands for the proposition that Section 337 does not apply to all instances of infringement of a U.S. patent, even with a nexus to importation, because infringement

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must apply to the “articles as imported.” *Id.* at 2-3 (citing *Electronic Devices*, Comm’n Op. at 14, 19).

Google points out that the Commission recently reinforced the “finding of actual ‘articles protected’ even with respect to licensing-based domestic industries.” *Id.* at 6 (citing *Certain Computers and Computer Peripheral Devices, and Components Thereof, and Products Containing Same*, Inv. No. 337-TA-841, Comm’n Op. at 32 (Jan. 9, 2014) (“There is an ‘articles’ requirement for subparagraph (C), in addition to (A) and (B).”) Google further argues that exclusion orders under Section 337(d)(1) and seizure and forfeiture orders, under Section 337(i), cannot apply to electronic transmissions. *Id.* at 6.

Google argues that *Hardware Logic* did not consider the full legislative history and was incorrectly decided. *Id.* at 7.

Google further argues that “it would fly in the face of Section 337” to issue cease and desist orders directed at electronic transmissions when cease and desist orders were intended to aid the enforcement of exclusion orders. *Id.* at 14. Google states that regulation of electronic transmissions by the Commission should be left for Congress to decide. *Id.*

Third-Party Submitter Association of American Publishers (“AAP”) submitted a reply submission, endorsing the comments submitted by the MPAA and taking the position that “electronic transmissions” are “articles” within the meaning of Section 337. AAP Reply Sub. at 1. The AAP submits that this topic is of critical concern to the U.S. publishing industry, which produces and trades millions of eBooks around the world annually. *Id.* The AAP states that today, software, books, movies, music, and games are increasingly transmitted to consumers in machine-readable form by electronic means



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such as eBooks, mp3s, etc. *Id.* The AAP argues that the need for the Commission to provide a remedy for eBooks is greater than the need to provide a remedy for physical books. *Id.*

The AAP argues that Congress has consistently intended “the primary purpose of section 337 . . . to be a trade statute to prevent unfair practice through importation of goods.” *Id.* at 2 (quoting Google Sub. at 4). The AAP suggests that Congress has left the term “articles” undefined in order to ensure that the language of Section 337 remains broad enough to prevent all types of unfair practice. *Id.* at 2-3.

The AAP argues that trade includes digital trade, which includes products and services delivered via the internet. *Id.* at 3. In reaching this understanding, the AAP relies on the Commission’s definition of digital trade in its report “Digital Trade in the U.S. and Global Economies, Part 1.” *Id.* at 3.

Third-Party Submitter Nokia argues that *Bayer* does not establish that electronic transmissions are not articles under Section 337. Nokia argues that the court’s discussion of Section 337 was dicta, that it relates to Section 337(a)(1)(B)(ii) rather than Section 337(a)(1)(B)(i), and that electronic transmission of software that can be read and combined by a device is much more than intangible information. Nokia Sub. at 8.

Nokia argues that electronic transmissions are within the Commission’s remedial authority, and that the Commission has broad discretion in selecting the form, scope, and extent of the remedy. *Id.* at 8-9. Nokia argues that if a violator attempts to circumvent an exclusion order, then Section 337(f) authorizes the Commission to order the violator to cease and desist. *Id.* at 9.

### 3. Analysis



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In this investigation, Align’s infringement claims concern respondents’ digital datasets and treatment plans representing the initial, intermediate, and final positions of patients’ teeth for use in fabricating dental appliances for orthodontic treatment of individual patients.<sup>17</sup> The Commission therefore must determine whether the phrase “importation ... of articles” as used in Section 337(a)(1)(B) encompasses these digital data sets that are electronically transmitted into the United States.

The Commission affirms the ALJ’s conclusion that the accused products are “articles” within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B).

The parties’ arguments revolve around the specific authority conferred upon the Commission to investigate and determine whether a violation of Section 337 has occurred by the importation or sale of infringing articles in the United States pursuant to Section 337(a)(1)(B). The language of Section 337(a)(1)(B)(i) and (ii) at issue here provides:

*(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--

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under Title 17; or

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<sup>17</sup> Align disputes that the accused products are intangible, noting that the digital data sets at issue here are physical articles whether they are stored on a physical medium, *i.e.*, a physical server or hard drive, or transmitted in between storage media. Align Sub. at 1 n.2. Further, Align argues that the act of importation into the United States from Pakistan is not complete until the entire treatment plan is saved on a U.S.-based server. Align Sub. on Issues Under Review at 7 n.9.

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(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.

The phrase “importation . . . of articles” appears in the introductory text of Section 337(a)(1)(B) and applies to both Section 337(a)(1)(B)(i) and (ii), which define a violation by reason of articles that infringe a valid and enforceable U.S. patent or that are “made, produced, processed or mined under, or by means of” a valid and enforceable process patent. The same language is used in defining a violation of Section 337 by reference to infringement of a valid and enforceable registered U.S. copyright, a valid and enforceable registered U.S. trademark, and a vessel design protected by chapter 13 of Title 17. *See* 19 U.S.C. § 1337(a)(1)(B), (C), and (E).<sup>18</sup> The Commission sought briefing from the parties and the public in order to address respondents’ arguments concerning whether the statutory term “importation . . . of articles” may encompass the respondents’ digital data sets that are electronically transmitted into the United States.<sup>19</sup>

78 *Fed. Reg.* 46611 (Aug. 1, 2013); 79 *Fed. Reg.* 4174 (Jan. 24, 2014).

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<sup>18</sup> Section 337(a)(1)(D), which relates to a registered semiconductor mask work, does not use the term “article.” 19 U.S.C. § 1337(a)(1)(D).

<sup>19</sup> Commenters dispute whether the Commission decided this issue in *Hardware Logic* and whether it held that electronic transmissions are “articles” within the meaning of Section 337 for purposes of violation in *Hardware Logic* and subsequent determinations. In *Hardware Logic*, the products at issue were hardware logic emulation systems consisting of reconfigurable logic devices and interconnect resources that were programmed primarily via software to emulate an integrated circuit design. *Certain Hardware Logic Systems and Components Thereof (“Hardware Logic”)*, Inv. No. 337-TA-383, Initial Determination, 1997 WL 665006 at \*8 (July 31, 1997). The ALJ found that software contributorily infringed certain asserted claims, including method claims. *Id.* at \*92-\*98. *See also* Comm’n Op. at 27. In so ruling, the ALJ found that the software components were electronically transmitted to the United States in some instances. *Id.* at \* 95. With regard to importation, the ALJ found that the importation requirement was met by undisputed evidence of respondents’ importation of logic boards and components such as software, and that even if he were to accept respondents’ argument regarding electronic transmission of software, respondents had also imported software on a cartridge tape on at least one occasion. *Id.* at 6. In the RD, the ALJ, referring to the Commission’s broad remedial authority to fashion a remedy once it finds a violation, found that “there is a direct nexus between respondents’ importation, via electronic transmission or otherwise, and infringement of the patents in issue,” and recommended an exclusion order and cease and desist order prohibiting infringing imports, including electronic transmissions. RD at 197. Noting that “the Commission has the



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We acknowledge that the construction of the term “articles” is a difficult question in part because the term “articles” is not expressly defined in the statute. The term “articles” in connection with unfairly traded imports originated in the 1922 Tariff Act and was re-enacted in the Tariff Act of 1930 at a time when internet downloads were not in existence. We have carefully examined the arguments of the parties and the third-party submitters on this issue. On balance, the Commission concludes that the statutory construction of “articles” that hews most closely to the language of the statute and implements the avowed Congressional purpose of Section 337 encompasses within its scope the electronic transmission of the digital data sets at issue in this investigation.

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legal authority to cover electronic importations,” the Commission issued a cease and desist order including electronically transmitted software within its scope. *Hardware Logic*, Comm’n Op. on Remedy, the Public Interest, and Bonding, 1998 WL 307240 at \*1 (March 1998). The Commission also issued an exclusion order, but declined to extend the scope to cover electronic transmissions deferring to Customs’ enforcement position. *Id.* at \*11, \*15.

In *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, respondent Fortinet’s accused products were an encased combination of hardware and software. Final ID at 57 (May 9, 2005). The parties stipulated that at least certain hardware components were imported and either included the software or had the software installed in the United States after electronic transmission of the software to Fortinet’s U.S. facility. The Commission determined not to review the ALJ’s finding of violation. Notice, 70 *Fed. Reg.* 40731 (July 14, 2005). Consistent with *Hardware Logic*, the Commission included electronic transmissions in the cease and desist order but not the exclusion order. Comm’n Op. at 4-5 (August 23, 2005).

In *Certain Set Top Boxes and Components Thereof*, Inv. No. 337-TA-454, the accused products were hardware devices with software. The ALJ recommended an exclusion order covering software, RD at 306 (June 21, 2002), but the Commission determined not to review the ALJ’s finding of no violation and therefore did not reach the issue of remedy. Notice, 67 *Fed. Reg.* 56856 (Sept. 5, 2002). The RD is a recommendation and has no legal effect itself. See *Key v. Sullivan*, 925 F.2d 1056 (7<sup>th</sup> Cir. 1991).

In *Certain Machine Vision Software, Mach. Vision Systems*, Inv. No. 337-TA-680, the ALJ found importation based on electronic transmission of software. Both the final ID and the Commission found no violation of Section 337. See ID at 96; Commission Notice, 75 *Fed. Reg.* 71146 (Nov. 22, 2010) (modifying the ID and finding no violation of Section 337 based on invalidity under 35 U.S.C. § 101). The ALJ noted in the ID that it was not disputed that the importation requirement may be satisfied by electronic transmission based on *Hardware Logic*, ID at 8 and n.2. The only importation issue in the final ID was with regard to Resolution Technology and Visics. They argued that they obtained their products from MVTec in the United States. But MVTec had been found to import in Order No. 60, so Resolution Technology and Visics were found to “sell after importation.” It is unclear from Order No. 60 (and thus unclear from the ID) whether the ALJ relied on electronic transmission for importation.

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 held that the scope of its cease and desist orders and consent orders can cover electronic transmissions when explicitly recited in those orders. That proceeding did not address whether electronic transmissions of digital data are articles in the context of violation.



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The statute was drafted with broad language that encompasses imports that infringe the major forms of intellectual property rights – patent, trademark, and copyright – as well as other forms of unfair acts and methods of competition. Moreover, each time the statute has been amended, the legislative history has stated that the legislative purpose is to prevent every type of unfair act in connection with imported articles (assuming, starting with the Trade Act of 1974, consistency with the public interest) and to strengthen protection of intellectual property rights. To faithfully carry out the clear purpose of the statute in accordance with Congress’s intent, the Commission concludes that “articles” cannot be limited in the manner argued by the respondents.

Our analysis begins with the language of the statute. *Perrin v. United States*, 444 U.S. 37, 42 (1979). The term “articles” in connection with unfair acts relating to imports first appeared in Section 316 of the 1922 Tariff Act, which was the predecessor to Section 337 of the Tariff Act of 1930. The 1922 Act provided remedies against unfair methods of competition and unfair acts in connection with articles imported or sold in the United States. This provision was re-enacted with some modifications in 1930. With each subsequent amendment, the term “articles” was retained in the statutory provisions circumscribing unfair acts in connection with importation.

“Articles” is not explicitly defined within Section 337. Notably, there are no statutory words of limitation used in conjunction with “articles” in Section 337 that would restrict the category, type, or form of imports that are covered by the scope of “articles” subject to Section 337. The fact that Congress did not place express restrictions limiting the scope of “articles” to any particular type or form is instructive as to the meaning of this term. *See generally* 2A Singer, Sutherland Statutory Construction

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§ 47.38 (7<sup>th</sup> ed. 2007) (“In construing a statute, it is always safer not to add or to subtract from the language of the statute unless imperatively required to make it a rational statute.”); *62 Cases of Jam v. United States*, 340 U.S. 593, 596 (1951) (in statutory construction, the court’s role “is ... to ascertain – neither to add nor to subtract, neither to delete nor to distort”). Likewise, the statutory language at issue here does not encompass some infringing importations while excluding others. *See United States v. Simpson*, 252 U.S. 465, 466-67 (1920) (refusing to confine the meaning of “transported” to be limited to transportation for hire or by public carriers and thereby exclude transportation by automobile).

Consistent with these authorities, the Commission, having examined the identical statutory language at issue here, has previously refused to impose limitations upon the term “articles” that were not mandated by this statutory language. *See Certain Sputtered Carbon Coated Computer Disks and Products Containing Same, Including Disk Drives*, Inv. No. 337-TA-350, USITC Pub. 2701, Comm’n Op. at 4-10 (Nov. 1993) (rejecting respondents’ proposed construction of “articles” as restricted to “articles of foreign manufacture” because the statutory term “articles” contained no such restriction). In so doing, the Commission stated that “it is not appropriate for the Commission to insert into the statute jurisdictional limitations not placed there by Congress.” *Id.* at 5. Thus, the Commission finds that the statutory language does not circumscribe the category of items that fall within the scope of articles. It appears to broadly cover infringing imports, without express limitation as to form or type of said articles.

To further ascertain the Congressionally intended scope of “articles,” it is helpful to look to contemporaneous dictionaries to understand the plain and ordinary meaning of



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“article” at the time of enactment. *See FDIC v. Meyer*, 510 U.S. 471, 476 (1994) (looking to dictionary definition); *Hibbs v. Winn*, 542 U.S. 88, 117 (2004) (contemporaneous dictionary is the relevant dictionary).

Contemporaneous definitions of “article” embrace a generic meaning that is synonymous with a particular item or thing, such as a unit of merchandise.<sup>20</sup> A 1924 edition of Webster’s, which uses the 1909 edition’s typesetting, defines “article,” in pertinent part, as “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).<sup>21</sup> Thus, the term “article” was understood at the time of the enactment of the Tariff Act to carry the meaning of an identifiable unit, item, or thing, with examples indicating that such articles may be traded in commerce or used by consumers.

Another common definition of the term “article” is a piece of writing included with others in a newspaper, magazine, or other publication. *See, e.g.*, Funk, NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE, Funk & Wagnalls Co. at 162 (1929)

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<sup>20</sup> Some definitions of “article,” in addition to stating a broader generic meaning, also set forth a more granular meaning of a material thing. For example, a 1929 edition of Funk and Wagnalls defines “article,” in pertinent part, as: “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). The Federal Circuit, interpreting 35 U.S.C. § 271(g), noted one definition of “article” in Webster’s Third New International Dictionary (a more recent edition of Webster’s). “Article” is there defined as “one of a class of material things . . . pieces of goods; COMMODITY.” *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 n.4 (Fed. Cir. 2003). Thus, while an “article” was understood to include something material, as shown in the text above, the term was also understood to embrace a broader meaning that describes something that is traded in commerce.

<sup>21</sup> More recent context relevant definitions of “articles” are in accord. *See, e.g.*, WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY (2002) (“5: a material thing”; . . . “6a: a thing of a particular class or kind as distinct from a thing of another class of kind”); RANDOM HOUSE WEBSTER’S UNABRIDGED DICTIONARY (2nd Edition 2001) (“2. An individual object, member, or portion of a class; an item or particular; an article of food; articles of clothing; . . . 4. An item for sale; commodity”).

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(providing an alternate definition of “article” as “A brief composition, as in a serial publication; an essay; a paper; as, an *article* in the morning daily.”); Harris, WEBSTER’S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE at 131, G. & C. Merriam Co. (1924) (also defining “article” as “A literary composition forming an independent portion of a magazine, newspaper, or cyclopedia, etc.”). Courts have long recognized various unfair competition causes of action for misappropriation when such literary works (articles) are electronically transmitted, including when the gravamen of the cause of action is the mere data contained within a broader arrangement of literary work.. *See, e.g., International News Service v Associated Press*, 248 US 215, 234 (1918) (misappropriation of “fresh” news within “news articles”) (citing *Board of Trade v. Christie Grain & Stock*, 198 US 236 (1905) (wrongful appropriation of price quotes), and *National Tel. News Co. v. Western Union Tel. Co.*, 119 F. 294 (7<sup>th</sup> Cir. 1902) (injurious appropriation of news sent by telegraph before printing on ticker tape)).

The meaning of “articles” must also be interpreted in the context in which it appears in the statute. *Dolan v. United States Postal Service*, 546 U.S. 481, 486 (2006). In the statutory provisions defining a violation of Section 337, 19 U.S.C. §§ 1337(a)(1)(A), (B), (C), and (E), “articles” appears in conjunction with the terms “importation” and “sale,” indicating that articles subject to the statute are imported items that are bought and sold in commerce. Pertinent to the present inquiry, both the Supreme Court and appellate courts have held that digital files are “articles of commerce.” *Reno v. Condon* 528 U.S. 141, 148 (2000) (“Because drivers’ information is, in this context, an article of commerce, its sale or release into the interstate stream of business is sufficient to support congressional regulation.”); *Senne v. Vill. Of Palatine*, 695 F.3d 617, 620 (7<sup>th</sup>



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Cir. 2012) (“Notably, *Reno* does not appear to rely on the *sale* of any information. Instead, it identifies the information that the state possesses and ‘release[s]’ into interstate commerce as ‘an article of commerce.’”) (emphasis in original). Further, with respect to importation, the Supreme Court explained in *Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923) that importation “consists in bringing an article into a country from the outside. If there be an actual bringing in it is importation regardless of the mode by which it is effected.” *See also Canton Railroad Co. v. Rogan*, 340 U.S. 511, 515 (1951) (“to import means to bring into the country”). Accordingly, based on the juxtaposition of the term “articles” in relation to “importation” and “sale” in the violation provisions of Section 337, 19 U.S.C. §§ 1337(a)(1)(A), (B), (C), and (E), the Commission finds that the intended meaning of “articles” encompasses such items as are bought and sold in commerce and that are imported into the United States, regardless of the mode of importation. This meaning is consistent with the title of Section 337, “Unfair Practices in Import Trade,” which further indicates that “articles” are involved in “import trade.” *See Federal Trade Commission v. Mandel Bros. Inc.*, 359 U.S. 385, 388-89 (1959) (title of a statute is “a useful aid in resolving an ambiguity”).

Moreover, in defining a Section 337 violation in connection with statutory intellectual property rights (as in the present investigation), the term “articles” appears in the phrase “articles that infringe” a patent, a registered trademark, and a registered copyright. 19 U.S.C. §§ 1337(a)(1)(B) and (C). Similarly, with respect to protected vessel hull designs, a violation is defined by an “article,” the importation or sale of which “constitutes infringement of the exclusive rights in a design protected under chapter 13 of Title 17.” 19 U.S.C. § 1337(a)(1)(E). The Supreme Court has found that digital

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distribution of copyrighted songs and movies can infringe a U.S. copyright. *See, e.g., MGM Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005). Similarly, the use of trademarks on websites, or in internet domain names, can infringe a U.S. trademark under the Lanham Act or the Anticybersquatting Consumer Protection Act. *E.g., Voice of the Arab World, Inc. v. MDTV Medical News Now, Inc.*, 645 F.3d 26, 36 (1<sup>st</sup> Cir. 2011); *Coca-Cola Co. v. Purdy*, 382 F.3d 774, 778 (8th Cir. 2004). Thus, based on the statutory phrase “articles that infringe” with respect to statutory intellectual property rights in 19 U.S.C. §§ 1337(a)(1)(B), (C), and (E), the Commission finds that the meaning of “articles” is intended to encompass imported items of commerce as to which a finding of infringement of a patent, trademark, copyright or protected hull design may be sustained (provided that all other requirements of the statute are met).

Similarly, in defining a violation under Section 337(a)(1)(A) in connection with other “unfair methods of competition and unfair acts,” the phrase “importation of articles” appears with the description that the “articles” at issue in the subparagraph are “other than articles provided for in subparagraphs (B), (C), (D), and (E).” 19 U.S.C. § 1337(a)(1)(A). *See TianRui Group Co. Ltd. v. ITC*, 661 F.3d 1322, 1331 (Fed. Cir. 2011) (citing S.Rep. No. 67–595, pt. 1, at 3 (1922) (“The provision relating to unfair methods of competition is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any antidumping statute the country ever had.”)). As an example, the Commission has held that trade secret misappropriation in the context of the importation of articles can constitute an unfair act under Section 337(a)(1)(A). *See, e.g., Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, Comm’n Op. (Jan. 15, 2014). Based on the use of the broad



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phrase “unfair methods of competition and unfair acts” in connection with “articles” in defining a violation of Section 337(a)(1)(A), the Commission finds that this subparagraph of the statute further suggests a broad meaning of “articles” that embraces imported items without limitations as to form or type of the articles.

Additional guidance as to the intended meaning of “articles” may be gleaned from the understanding of legislators considering the bill at the time of enactment. *See, e.g., Mastro Plastics Corp. v. National Labor Relations Bd.* 350 U.S. 270, 287-88 (1956) (discussing legislative reports and debates). The House and Senate Reports of the 1922 and 1930 Acts and Congressional debate refer to articles as synonymous with goods, commodities, and merchandise. *See* S. Rep. 67-595 at 3 (1922); H. R. Rep. 71-7 at 3 (1929); 71 Cong. Rec. S. 3872, 4640 (1929). The meanings of these terms, according to BLACK’S LAW DICTIONARY (2<sup>nd</sup> ed. 1910) in use at that time, indicate that the term “articles” broadly covers items that are bought and sold in commerce. *Id.* (“1. an item acquired through contract or purchase.”). These definitions do not provide any particular limitations as to specific categories of articles, or specific forms or types of articles that would fall outside the ambit of Section 337’s proscriptions. Indeed, these definitions of goods, merchandise, and commodities would encompass within their meaning various types and forms of products that are bought and sold in commerce.<sup>22</sup> These commercial terms have retained their expansive meanings even as the fundamental nature of international commerce has evolved over the many decades since Section 337 was

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<sup>22</sup> Even if, as respondents contend, legislators in 1930 had contemplated goods, merchandise, and commodities to be the types of products traded at that time, the Supreme Court “frequently has observed that “a statute is not to be confined to the ‘particular application[s] . . . contemplated by the legislators.’” *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980) (quoting *United States v. Barr*, 324 U.S. 83, 90 (1945). *Accord Browder v. United States*, 312 U.S. 335, 339 (1941); *Puerto Rico v. Shell Co.*, 302 U.S. 253, 257 (1937)).

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originally enacted. We note recent developments that show the acceptance of digital goods traded in commerce as falling within international trade. Senators Baucus and Hatch and Congressman Camp have introduced Trade Promotion Authority bills that instruct the Administration to seek increased protections for digital trade in future trade agreements. S.1900, 113th Congress, introduced January 9, 2014; H.R.3830, 113th Congress, introduced January 9, 2014. Moreover, Congress has requested that the Commission study the impact of digital trade under Section 332, another part of Title 19.<sup>23</sup> *See Digital Trade In the U.S. and Global Economies, Part I, Inv. No. 332-531, USITC Pub. 4415 (July 2013) (recognizing trade in digital products as U.S. and global commercial activity).*<sup>24</sup> Commenters have cited a number of industry and academic papers that have treated digital goods as articles of commerce.<sup>25</sup> Accordingly, the commercial terms that were used in the legislative history synonymously with “articles” suggest that Congress intended the statute expansively to embrace “articles” that may be traded in commerce, regardless of form or type.

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<sup>23</sup> Following receipt of a request dated December 13, 2012 from the Senate Committee on Finance under section 332(g) of the Tariff Act of 1930 (19 U.S.C. §1332(g)), the U.S. International Trade Commission instituted investigation Nos. 332-531 and 332-540, *Digital Trade in the U.S. and Global Economies, Parts I and II*.

<sup>24</sup> In its *Digital Trade Report*, the Commission requested public comments on how to describe digital trade in the context of the broader economy. The Commission adopted the following definition of digital trade: “Defined in this report as the delivery of products and services over either fixed line or wireless digital networks. This definition includes U.S. domestic commercial activity as well as international trade. It excludes commerce in most physical goods, such as goods ordered online and physical goods that have a digital counterpart such as books and software, music, and movies sold on CDs or DVDs.” *Digital Trade In the U.S. and Global Economies, Part I, Inv. No. 332-531, USITC Pub. 4415, at xii (July 2013)*.

<sup>25</sup> *See, e.g.*, MPAA Reply Sub. at 10 (citing recent publications including: Joshua Meltzer, “Supporting the Internet as a Platform for International Trade,” Brookings Institution, *Global Economy & Development Working Paper 69* (Feb 2014); *Powering the Digital Economy: A Trade Agenda to Drive Growth*,” Business Software Alliance (2014); Edward Gesser, *The Internet and the Next Generation’s Global Economy*,” *Progressive Economy* (Jan. 30, 2014); Drs. William Kerr and Chad Moutray, “Economic Impact of Global Software Theft on U.S. Manufacturing Competitiveness and Innovation,” *National Association of Manufacturers and National Alliance for Jobs and Innovation* (2014).



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Importantly, the Commission must construe the term “articles” in such a manner as to faithfully implement the express purpose for which Congress enacted the statute. The central purpose of Section 337, since the enactment of the original statute in 1922, has been to prevent every type of unfair act or practice in import trade that harms U.S. industries. *See, e.g.*, S. Rep. 67-595, at 3 (1922) (“The provision relating to unfair methods of competition is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any antidumping statute the country ever had.”); *see also* H. R. Rep. 100-40 at 155 (1987).

The Commission’s reviewing courts have instructed that the terms of the statute must be construed to effectuate this central purpose of Section 337. The Court of Customs and Patent Appeals explained that Congress intended for a broad interpretation of the statutory terms of Section 337:

The statute here under consideration provides broadly for action by the Tariff Commission in cases involving ‘unfair methods of competition and unfair acts in the importation of articles’, but does not define those terms nor set up a definite standard. As was noted in our decision in *In re Northern Pigment Co.*, 71 F.2d 447, 22 C.C.P.A., Customs, 166, T.D. 47124, the quoted language is broad and inclusive and should not be held to be limited to acts coming within the technical definition of unfair methods of competition as applied in some decisions. The importation of articles may involve questions which differ materially from any arising in purely domestic competition, and it is evident from the language used that Congress intended to allow wide discretion in determining what practices are to be regarded as unfair.

*In re von Clemm*, 229 F.2d 441 (CCPA 1955). Similar guidance was provided by the Federal Circuit in *TianRui* in which the Court stated that “Congress intended a similarly broad and flexible meaning when it used the same language [as the Federal Trade Commission Act] to prohibit ‘unfair methods of competition’ in importation.” *TianRui*

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*Group Co. Ltd. v. ITC*, 661 F.3d 1322, 1331 (Fed. Cir. 2011). Pertinent to the issue of “articles,” the *Tian Rui* Court noted that “Congress contemplated that, in exercising its new authority over unfair competition, the Commission would consider conduct abroad in determining whether *imports that were the products of, or otherwise related to, that conduct* were unfairly competing in the domestic market.” *Id.* at 1332. In accordance with our reviewing Court’s instructions and to ensure that we properly implement Congressional intent, the Commission reviews the pertinent legislative history of Section 337 below.

The legislative history emphasizes the central purpose of preventing every type of unfair act or practice in connection with imported articles (assuming, starting with the Trade Act of 1974, consistency with the public interest), and endeavors to strengthen the reach of Section 337 to provide effective relief to U.S. industries that are harmed by imported articles. As the Court of Customs and Patent Appeals noted in *Frischer & Co. v. Bakelite Corp.*, “the purpose of the law is to give to industries in the United States, not only the benefit of favorable laws and conditions to be found in this country, but also to protect such industries from being unfairly deprived of the advantage of the same and permit them to grow and develop.” 39 F.2d 247, 259 (C.C.P.A. 1930). *See also In re Orion Co.*, 71 F.2d 458 (CCPA 1934) (“these various provisions were intended to shelter, protect, and conserve the industries of the United States, as well as to provide revenues.”).

The legislative history of the 1930 Act demonstrates Congress’s continuing concern with protection of U.S. industries from unfairly traded imported articles. *See, e.g.*, H.R. Rep. 71-7 at 166 (1929); S. Rep. 71-37, at 68 (1929). This legislative history



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also evinces Congress's recognition that innovation would yield many new types and forms of articles that would be traded in commerce in the future. For example, a Congressional Report accompanying the Tariff Act of 1930 recognizes that many new goods and manufacturing processes had been invented and brought to the U.S. market since the 1922 Act, and anticipates that many new goods and processes would come in the future. H. R. Rep. 71-7 at 3-4. It was also noted that U.S. industries needed protection from competition, particularly unfair competition, so that they could come forward with these new goods and processes. *See id.* at 4, 166. This forward-looking recognition in the legislative history that innovation would bring new goods to the U.S. market, and that U.S. industries needed protection against unfairly traded goods to foster such innovation, indicates that the term "articles" should be construed flexibly to fit new technologies. *See Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980) ("Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable."); *WGN Continental Broadcasting Co. v. United Video, Inc.*, 693 F.2d 622, 627 (7<sup>th</sup> Cir. 1982) (Congress intended definitions to be interpreted flexibly so that as new technologies appeared, Congress wouldn't have to update the statute periodically).

Likewise, the Trade Act of 1974 strengthened the statute to protect against unfairly traded imports by providing additional remedies for a violation, namely cease and desist orders, and by providing authority to the Commission itself to administer the statute and issue remedies. In so doing, the legislative history echoes the concerns of previous Congresses that Section 337 should provide strong protections against unfair

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acts in connection with imported articles. *See, e.g.*, H.R. Rep. 93-571 at 77-79 (1973); S. Rep. 93-1298 at 193-200 (1974).

By the mid-1980s, Congress recognized the growing problems that infringing imports posed for U.S. intellectual property rights owners. The Omnibus Trade and Competitiveness Act of 1988 further strengthened Section 337 with respect to the protection of intellectual property rights and expressed the will of Congress to encompass within its scope infringing imports:

Any sale in the United States of a product covered by an intellectual property right is a sale that rightfully belongs to the holder or licensees of that property. The importation of *any infringing merchandise* derogates from the statutory right, diminishes the value of the intellectual property, and thus indirectly harms the public interest.

S. Rep. 100-71 at 128-29 (1987) (emphasis added); H.R. Rep. 100-40 at 156 (1987) (same).

In further amending Section 337 in the Uruguay Round Agreements Act of 1994, Congress continued to emphasize the focus of Section 337 as authorizing the Commission “to exclude goods from the United States and enjoin activities with respect to imports that are found to infringe U.S. intellectual property right or are otherwise found to violate that statute.” H.R. Rep. 100-826 at 140. The 1994 Act made certain procedural changes to remove the time limits on Commission proceedings and to stay simultaneously filed parallel district court litigation. H.R. Rep. 100-826 at 140 (1994); S. Rep. 103-412 at 118 (1994). The 1994 amendments made no change in the substance of the unfair acts or scope of the articles that are subject to a finding of a statutory violation.

Respondents urge the Commission to find that the term “articles” cannot be construed to include within its meaning the subject digital data sets that are electronically



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transmitted into the United States, relying principally upon the Federal Circuit's decision in *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 (Fed. Cir. 2003). Resp. Sub, at 2-4. *Bayer*, however, is of limited relevance to the proper construction of the statutory term "articles," and does not mandate a different conclusion. At issue in *Bayer* was a patented method for screening substances to ascertain whether the substance inhibits or activates a particular protein. *Id.* at 1369. The practice of the patent there resulted in "information in the abstract," specifically, "the knowledge that a substance possesses a particular quality." *Id.* at 1371-72, 1376. Housey alleged that Bayer was liable as an infringer under 35 U.S.C. § 271(g), *not* 19 U.S.C. § 1337 (a)(1)(B), when it imported this "knowledge" or "information" obtained from performing the Housey patented methods. In finding that § 271(g) did not cover this type of abstract research data or information, the Federal Circuit held that the statutory term "made" in § 271(g) means "manufactured." According to the Court, the production of the information at issue was not within the scope of "manufacture."

In its analysis, the Federal Circuit examined the 1988 legislative history of 35 U.S.C. § 271(g) and Section 337(a)(1)(B)(ii). In so doing, the Court did not purport to ascertain the parameters of the Commission's Section 337 jurisdiction, but rather was construing 35 U.S.C. § 271(g). Indeed, the Court noted in a footnote that Section 337 may have a broader scope than 35 U.S.C. § 271(g), although it observed, without analysis, that Section 337 does not indicate that § 271(g) covers the type of "information" about the inhibitive or activating characteristics of a substance obtained through the practice of the process patent that was at issue in that case. *Id.* at 1374 n.9 ("We recognize that section 1337 covers both articles that were 'made' and articles that were

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‘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).”). As is clear from the Court’s recitation of the specific “information” pertaining to the patent at issue in that case, that “information” obtained through the practice of the patent at issue in *Bayer* was whether a substance was an inhibitor or an activator of a protein. Thus, *Bayer* provides little, if any, guidance concerning the articles at issue here. In contrast to *Bayer*, the articles at issue here comprise infringing digital data sets that are models of an individual patient’s teeth, as well as the aligners made therefrom, that result in incremental movements of those teeth through successive orthodontic treatments.

Comments of third party submitters present practical considerations that echo the concern of legislators in enacting Section 337 in order to protect U.S. industries against unfairly traded imports. The Motion Picture Association of America (“MPAA”) and the Association of American Publishers (“AAP”) describe the transition by IP-based industries to digital distribution (including industries producing motion pictures, software, books, music and games). MPAA Sub. at 2; AAP Sub. at 2. Both groups describe the problems of infringement by illegal download and streaming, and the importance of Section 337 to IP-based industries.<sup>26</sup> They point out that protecting the copyrights of U.S. companies from the importation of these infringing articles that are electronically transmitted by foreign sources is consistent with the intent of Congress and the longstanding purpose of Section 337. MPAA Sub. at 10-13; AAP Sub. at 3.

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<sup>26</sup> MPAA estimates the cost of such infringement to the U.S. economy at \$58 billion annually, including more than 373,000 jobs, \$16 billion in lost employee earnings, and \$3 billion in federal, state, and local tax revenue. MPAA Sub. at 2-3. MPAA cites numerous Congressional and industry studies that have estimated losses to the U.S. economy due to such IP infringement. *Id.* at 2-4.



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MPAA also points out that construing “articles” in Section 337 to cover electronic transmissions is consistent with established practices of U.S. Customs and Border Protection (“CBP”) and the Department of Labor (“DOL”). MPAA notes that CBP, which is charged with interpreting and administering the Harmonized Tariff Schedule of the United States (“HTSUS”), has ruled that the transmission of software modules and products into the United States via the internet constitutes an importation of foreign merchandise into the United States. MPAA Sub. at 8 (citing HQ 114459, 1998 US CUSTOM HQ LEXIS 640 (Sept. 17, 1988)). Similarly, MPAA notes that DOL, which administers trade adjustment assistance to U.S. workers displaced by imported products under the Trade Adjustment Assistance Act,<sup>27</sup> has ruled as a matter of policy that “[s]oftware and similar intangible goods that would have been considered articles ... if embodied in a physical medium will now be considered to be articles regardless of their method of transfer. *Id.* (citing 71 Fed. Reg. 18355, 18357 (Apr. 11, 2006)).<sup>28</sup> We more broadly observe that MPAA’s submission shows that U.S. federal agencies charged with responsibilities over international trade agree that digital merchandise are articles of international commerce.

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<sup>27</sup> The Trade Adjustment Assistance Act (“TAA”) was part of the Trade Expansion Act of 1962, Pub. L. 87-794, 76 Stat. 883.

<sup>28</sup> MPAA also cites a 2006 CIT decision finding that electronic transmissions of software were “articles produced” within the meaning of the TAA. MPAA Sub. at 8-9 (citing *Former Emps. of Computer Scis. Corp. v. Secretary of Labor*, 414 F. Supp.2d 1334 (Ct. Int’l Trade 2006); *Former Emps. Of Merrill Corp. v. United States*, 483 F. Supp. 2d 1256, 1257-68 (Ct. Int’l Trade 2007)). We note, for completeness, a Federal Circuit decision in *Woodrum v. United States*, 737 F.2d 1575 (Fed. Cir. 1984), “affirm[ing] on the basis of [the CIT] opinion,” 564 F.Supp. 826, 829 (CIT 1983). In the CIT opinion, the CIT construed the TAA language “articles produced” such that “production under section 222(3) requires the manufacture or creation of something tangible” and therefore affirmed the Labor Secretary’s denial of TAA benefits to mechanics employed by an independent automobile dealership who service and prepare vehicles for retail sale because they “have not transformed articles into new and different articles.” 564 F.Supp. 2d at 829. Similarly, in *Nagy v. Donovan*, 571 F. Supp. 1261, 1264 (Ct. Int’l Trade 1983), the CIT held that employees who provide automotive services do not engage in production of a new and different article.

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Third party Google notes that Commission exclusion orders (and seizure and forfeiture orders) enforced by U.S. Customs and Border Protection relate only to physical goods passing through U.S. ports of entry, and thus would not remediate violations involving electronically transmitted articles. *See* Google Sub. at 6-7. Exclusion orders, however, are not the exclusive remedy for violations of Section 337.<sup>29</sup> The statute provides for highly effective remedies in the form of cease and desist orders under Section 337(f), to prevent further electronic shipments of infringing goods. 19 U.S.C. § 1337(f)(1). Under Section 337(f), cease and desist orders may be issued “[i]n addition to, or in lieu of” an exclusion order. The Commission vigorously enforces violations of cease and desist orders, and under the statute, may impose civil penalties for violations of up to \$100,000 per day. 19 U.S.C. § 1337(f)(2). Moreover, the Commission’s cease and desist orders typically require the posting of a bond with the Office of the Secretary to cover continued prohibited conduct during the Presidential review period “in an amount determined by the Commission to be sufficient to protect the complainant from any injury.” 19 U.S.C. § 1337(j)(3). Thus, the fact that Customs enforces exclusion orders issued by the Commission by excluding from entry physical goods passing through U.S. ports does not limit our understanding of the scope of “articles.” It should be noted that

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<sup>29</sup> It is a feature, not a flaw, for a set of remedy provisions to include some subsections that apply only in some settings; and agencies are given deference on their choices about which statutory remedy to apply so they can appropriately address the particular facts of each case. *See Butz v. Glover Livestock Commission Company, Inc.*, 411 US 182, 188 (1973) (agencies must carefully weigh their selection of authorized remedy based on the evidence and the statutory scheme); *Mourning v. Family Publications Service, Inc.*, 411 US 356, 371-72 (“We have consistently held that where reasonable minds may differ as to which of several remedial measures should be chosen, courts should defer to the informed experience and judgment of the agency to whom Congress delegated appropriate authority.”) This helps to ensure that at least some remedy is available for a violation. *See* S. Rep. 93-1298 at 198 (1974) (explaining the provision for cease and desist orders in the new amendment to Section 337) (“It is clear to your committee that the existing statute, which provides no remedy other than exclusion from entry, is so extreme or inappropriate in some cases that it is likely to result in the Commission not finding a violation of this section, thus reducing the effectiveness of section 337 for the purposes intended.”).



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in this investigation, complainant Align requests only cease and desist orders, as discussed more fully in Part IV below.

Third parties Nokia, the AAP, and the MPAA caution that “articles” should not be construed in such a way that infringers could avoid liability under Section 337, thereby denying an avenue of relief to IP-based industries in the United States. AAP Sub. at 2; MPAA Sub. at 6; Nokia Reply Sub. at 9. For example, an infringer could shift from importing its infringing software on a disk to importing the very same software by electronic transmission. They note that “it would be anomalous for the Commission to be able to stop the transfer of a CD-ROM or diskette containing the respondents’ software but not be able to stop the transfer of the very same software when transmitted in machine readable form by electronic means.” MPAA Sub. at 6; AAP Sub. at 2. The Commission concurs. “It has been called a golden rule of statutory interpretation that, when one of several possible interpretations produces an unreasonable result, that is a reason for rejecting that interpretation in favor of another which would produce a reasonable result.” 2A Singer, Sutherland Statutory Construction § 45.12 (7<sup>th</sup> ed. 2007). The Commission concludes, in the context of this case, that an interpretation of “articles” that allows the Commission to reach the imported physical aligners at issue in Investigation No. 337-TA-562, but does not include the infringing digital data sets from which the aligners are produced, simply because they are in digital form, is unreasonable and inconsistent with the purpose of the statute.

Finally, a few commentators argue that principles of patent law preclude a finding that electronic data transmissions constitute “articles” under Section 337. Google Sub. at 10-13; Katz Sub. at 3, 8 (citing *In re Nuijten*, 500 F.3d 1346, 1353 (Fed. Cir. 2007)).

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They argue that because an electronic transmission is not patent eligible subject matter under 35 U.S.C. § 101, section 337 should not be construed to include electronic transmissions. The Commission disagrees with this view. First, the question we are deciding – whether the “importation . . . of articles” includes digital data sets that are electronically transmitted into the United States – goes to the importation requirement, not patent eligibility *per se*.<sup>30</sup> Second, the argument overlooks the fact that in defining a Section 337 violation in connection with statutory intellectual property rights the term “articles” appears in the phrase “articles that infringe” a patent, a registered trademark, and a registered copyright. Thus, the commenters fail to take into account that the phrase “articles that infringe” is not simply limited to patents, but also applies to trademarks and copyrights, as well as other unfair acts and methods of competition in connection with importation and sale of articles.<sup>31</sup> Third, section 337 is a trade statute that is part of Title 19. As we observe above, there is a consensus among government agencies charged with responsibilities over international trade that digital merchandise are articles of

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<sup>30</sup> In this investigation, respondents did not raise any § 101 arguments concerning the asserted patents. Furthermore, any such arguments are more properly addressed regarding validity, not importation, and the Commission may not invalidate a patent claim *sua sponte*, *i.e.*, where invalidity has not been asserted by the respondent as a defense to infringement of a properly asserted claim. *See generally, Lannom Mfg. Co. v. United States Int'l Trade Comm'n*, 799 F.2d 1572, (Fed.Cir.1986). We also note that the commenters may not be correct in their suggestion that the patent claims at issue would be invalid under § 101. In cases such as this one, where the digital data sets cause a physical arrangement (here, where to place the mechanical braces used to align human teeth), the Federal Circuit has determined that §101 would be satisfied, *see In re Alappat*, 33 F.3d 1540 (Fed. Cir. 1994 ) (*en banc*) (digital data produced a “useful, concrete, and tangible result” in the form of a smooth curve displayed on the screen). Similarly, in cases such as this one where the digital data sets correspond to a “useful, concrete, and tangible” thing (here, the relative locations of the human teeth), the Federal Circuit has determined that § 101 is satisfied, *see also Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed.Cir.1992) (digital data set corresponded to electrical signals in a human heart).

<sup>31</sup> We note, in the sections that follow, that we find that the subject imports are processed by means of patented processes and are materials for use in practicing patented processes. Here, we are solely construing the statutory term “importation . . . of articles” in the violation provisions of Section 337.



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international commerce. Accordingly, we reject these arguments presented by Google and Katz.

In sum, our 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. Having carefully reviewed the plain language of the statute, its legislative history and purpose, pertinent case law, and the arguments of the parties and public commenters, we conclude that the statutory phrase “importation ... of articles” should be construed to include electronic transmission of digital data because the digital data sets at issue in this investigation are true articles of international commerce that are imported into the United States and their inclusion within the purview of section 337 would effectuate the central purpose of the statute.

### **B. Claim Construction**

#### **1. One of Ordinary Skill in the Art**

The ALJ found that one of ordinary skill in the art at the time of the invention of the asserted claims of each 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. ID at 28.

Align argues that it showed that one of ordinary skill in the art at the time of the inventions for each of the asserted patents would include a practicing orthodontist. Align Pet. at 33.

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The issue does not affect the outcome of the investigation. However, the issue is undisputed and the Commission agrees with Align that practicing orthodontists are also persons of ordinary skill in the art.

**2. “a predetermined series of dental incremental position adjustment appliances”/“predetermined series of dental incremental position adjustment appliances” (the ‘880 patent)**

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

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. ID at 52. The ALJ found that the claims and the specification do not support Respondents’ argument that the “repositioned tooth arrangement” would have to be further limited to mean the final tooth arrangement at the *end of treatment*. ID at 54. The ALJ explained that 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. *Id.* (citing JX-0002 at 6:56-67).

The ALJ found that claim 1 requires a method that comprises four steps that are performed in order. *Id.* at 52. The ALJ reasoned that, 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. *Id.* (discussing *Interactive Gift Exp., Inc. v. Compuserve*



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*Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001)). The ALJ explained that each subsequent step in claim 1 necessarily requires the previous step to have been executed.

Align argues that the ALJ should not have construed claim 1 of the '880 patent to require that the steps be performed in an ordered process. Align Pet. at 25. Align argues that one need not obtain a “repositioned tooth arrangement” before obtaining the “series of successive digital data sets.” *Id.* Align argues that the Respondents waived any such construction, and that the ALJ further erred in finding that the fourth claim element builds on the third claim element. *Id.* (citing JX-0002 at 22:26–28).

The Respondents did not comment on this claim construction in their petition or response, or in their briefing on review.

We agree with the ALJ that each step of claim 1 of the '880 patent assumes the prior completion of the previous step.<sup>32</sup> For example, step b is “based on the initial tooth arrangement” of step a. The digital data sets of step c are based on the tooth arrangements of step b. The dental appliances of step d are based on the digital data sets of step c. We therefore affirm the ALJ’s claim construction of these terms, and adopt the ALJ’s reasoning, as set forth in the ID at 51-58, including his construction that the predetermined series can be constructed prior to an intermediate aligner and need not be prior to the fabrication of all aligners. See ID at 54-55 (discussing how repositioned tooth arrangements include intermediate tooth arrangements and not just final tooth arrangements).

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<sup>32</sup> The ALJ was not precluded from deciding that the correct claim construction is one that was not argued. See *Exxon Chemical Patents Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1558 (Fed. Cir. 1995) (Court did not adopt the construction proposed by either party).

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### 3. “treatment plan” (the ‘487 patent and the ‘874 patent)

The term “treatment plan” appears in asserted claims 7, 8 and 9 of the ‘487 patent and claim 1 of the ‘874 patent.

The ALJ found that Respondents waived the right to offer a construction for the term “treatment plan.” ID at 68 (citing Second Revised Joint Claim Construction Chart (“SRJCCC”) at 8 (“No construction proposed.”)). The ALJ found that the plain language of claim 7 of the ‘487 patent defines a “treatment plan” as “two or more successive digital data sets representing arrangements of a patient’s teeth progressing from an initial tooth arrangement toward a final tooth arrangement.” ID at 68-69. The ALJ found that claim 7 is not limited to final arrangements that are prescribed. *Id.* at 70. The ALJ relied on the plain language of claim 7, which provides that the “treatment plan” comprises “a plurality of intermediate digital data sets.” *Id.* at 68-69 (citing ‘487 patent, col. 11, lines 26-35.) The ALJ explained that claim 7 continues to explain that the intermediate digital data sets “represent[] intermediate arrangements of the patient’s teeth,” and the final data set “represent[s] the patient’s teeth in a desired or prescribed arrangement.” *Id.* at 69 (citing ‘487 patent, col. 11, lines 26-35). The ALJ continued that the specification supports this understanding of beginning, middle, and final tooth arrangements. *Id.* at 69-70 (citing ‘487 patent, col. 8, lines 38-47).

The Respondents argue that the plain and ordinary meaning of “treatment plan” is the course of treatment devised by the treating dentist or orthodontist, not by a dental lab like CCUS. *Resp. Pet.* at 63. The Respondents highlight that Align’s expert, Dr. Valley, relied on the provisional application for priority, which states: “[u]sing treatment planner software, the orthodontist then creates a series of intermediate treatment states.” *Id.*



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(referring to CX-1247C at Q. 115; CX-1252-007). The Respondents further point to the testimony of Mr. Jarrett Pumphrey, a witness for CCUS, and Dr. Willis Pumphrey, an orthodontist, who stated that dental labs like ClearCorrect do not prepare treatment plans. *Id.* (citing Tr. 415:4-11; Tr. 350:15-351:13). Respondents also note that Dr. Pumphrey stated that treatment by the physician is a matter of law and industry standard. Tr. 415:12-14.

Align argues that the ALJ misconstrued the claim term “treatment plan” in claim 1 of the ‘874 patent and claim 7 of the ‘487 patent. Align Pet. at 23. Specifically, Align states that the ALJ improperly imposed a requirement that the “treatment plan” include “successive digital data sets.” Align argues that there is no requirement that an “initial tooth arrangement” be present in the “treatment plan,” but that the ALJ’s construction is ambiguous in that regard. *Id.* Align also argues that Respondents’ proposed construction is based on a single embodiment described in a provisional application to which the ‘487 Patent claims priority, and that this limitation cannot be imported into the claim. Align Resp. to Resps. at 47 (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996)). Align further argues that Respondents ignore the *other* embodiments described in the specification - - that either an “orthodontist or other operator” may perform the steps of treatment planning. *Id.* (quoting CX-1252 at 13).

The Commission has determined to affirm the ALJ’s construction of “treatment plan,” and adopt the ALJ’s reasoning, as set forth in the ID at 68-74 and 102-104. By the terms of claim 7, it is the “final arrangement representing the patient’s teeth” which is “desired or prescribed.” ‘487 patent, col. 11, line 34; see also col. 1, lines 37-41

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(Background of the Invention); col. 11, lines 26-35. There is no requirement that the “intermediate digital data sets” are themselves prescribed by the dentist. Rather, the purpose of the invention is to allow a computer to calculate these intermediate positions based on the patient’s initial and the prescribed final position. *See* Figure 3 (flow chart); col. 5, lines 56-61.

#### 4. “computer-implemented method” (the ‘511 patent and the ‘874 patent)

The term “computer-implemented method” appears in the preamble to asserted claim 1 of the ‘511 patent and claim 1 of the ‘874 patent.

The ALJ found that “computer-implemented method” means “a method accomplished using a computer.” The ALJ found the preamble to be limiting.

Align argues that the ALJ erred in finding that the claim term “computer-implemented” should be read into each element of claim 1 of the ‘511 patent and claim 1 of the ‘874 patent, *i.e.*, Align argues that the preamble does not place a restriction on each claim element to be computer-implemented. Align Pet. at 26. Align argues that Respondents waived such an argument, and that even where a court finds a preamble limiting, the limitation is not necessarily read into each element of the claim. *Id.* at 26 (citing *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323 (Fed. Cir. 2005), *vacated on other grounds sub. nom. eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006)). Align points, *inter alia*, to the specification of the ‘511 patent, which teaches that generating the appliances may be done manually. *Id.* at 26-27 (citing ‘511 patent at 5:1-6).

The Respondents did not comment on this claim construction in their petition, response, or briefing on review.



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The Commission has determined to affirm the ALJ's construction of "computer-implemented method" in claim 1 of the '511 patent and claim 1 of the '874 patent, and adopt the ALJ's reasoning, as set forth in the ID at 77-81 and 93-97. The ALJ is correct that the preamble is limiting in this case because it provides structure, *i.e.*, it explains that the computer will be performing the calculations. *See, e.g., Catalina Mktg. Int'l v. Coolsavings.com*, 289 F.3d 801, 808 (Fed. Cir. 2002) (one of the types of preamble that is limiting is a preamble that provides necessary structure). While we agree with the ALJ that the claims do not preclude human supervision or intervention as a supplement to computer computation, the both patents teach that the interpolations are performed by a computer. *See, e.g., '874 patent (Abstract) (A computer is used to create a plan . . . "');* '511 patent, col. 1, line 23-24 (Background of the Invention) ("The present invention relates to computational orthodontics"). Further, a computer may be used to provide the original digital data set for interpolation, *see '511 patent, col. 5, line 44 – col. 6, line 5,* and to manufacture ("generate") the appliance from the digital data sets through an automated process. *See '511 patent, col. 5, lines 1-5; '874 patent, col. 30, lines 9-13.* The patent's specification and claims plainly contemplate the use of a computer for each step. *See also '511 patent, col. 3, line 64 - col. 4, line 4 (discussing digital models of initial and final data sets); '874 patent, col. 11, lines 49-61.* Similarly, the aligners are fabricated using models of the teeth based on the computer program. *See, e.g., '511 patent, col. 5, line 1-5 (discussing using automated processes and electronic information for manufacturing); '874 patent, col. 19, line 30-59 (discussing using data sets and application software for manufacturing).*

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### 5. “distinct successive incremental dental positioning appliance”/“successive incremental dental positioning appliance” (the ‘863 patent)

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

The ALJ found that “distinct successive incremental dental positioning appliance”/“successive incremental dental positioning appliance” means “a single, separate appliance to be used during a particular interval for repositioning teeth.”

The ALJ found that the claim language only requires that two or more digital models be produced. ID at 87-88 (citing *Apple Inc. v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1379 (Fed. Cir. 2012); *August Technology Corp. v. Camtek, Ltd.*, 655 F.3d 1278 (Fed. Cir. 2011)). The ALJ found that use of the term “successive” in conjunction with the terms “distinct” and “incremental” does not require fabrication of “a series.” The ALJ further found that the specification and prosecution history of the ‘863 patent describe replacing attachment devices mid-treatment or placing new attachment devices throughout treatment, JX-005 at 7:61-64; CX-1251 at 212, and teaches away from fabricating all of the dental appliances prior to the outset of treatment. ID at 88-89.<sup>33</sup>

There are two issues on review: whether there is more than one dental appliance and whether dental appliances are all fabricated before the beginning of treatment. Align argues that the ALJ misconstrued the claim term “distinct successive incremental dental positioning appliance” in claim 1 of the ‘863 patent. Align further argues that the ALJ was correct to reject late-proposed limiting constructions by the Respondents but

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<sup>33</sup> ID at 89 (citing ‘863 patent, col. 7, lines 61-64; CX-1251 at 212). The ALJ found that Respondents had waived any proposed claim construction of this term because they relied on plain meaning in the SRJCCC. The ALJ further granted Align’s first motion in limine and excluded that portion of Question 120 of Dr. Mah’s testimony upon which Respondents rely to support their waived argument on construction.



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disagrees with the ALJ's construction to the extent it disassociates the appliance from the series of which it is a part.

The Respondents do not discuss Align's contingent petition for review in their response or briefing on review. Resps. Resp. at 9.

The IA argues that the ALJ correctly construed the disputed claim terms and suggests that Align's disagreement with the ALJ's claim constructions has no bearing on the current dispute.

Although the claim construction has no bearing on the resolution of the current dispute, the Commission reverses the ALJ's construction and concludes that claim 1 requires a series of dental appliances. Although the specification mentions "one or more attachment devices," the '863 patent, col. 3, lines 14-15, the claims recite a "plurality" of modified digital models in the claims, each to be used to fabricate "successive" appliances. '863 patent, Ex Parte Reexam. Certificate, col. 1, line 60, 64-65. We note, however, that nothing requires the entire series to be manufactured before treatment begins. *See* '863 patent, col. 7, lines 61-64.

### **6. "providing" (the '325 patent)**

The term "providing" appears in all of the asserted claims of the '325 patent. This claim construction issue arises from the ALJ's infringement analysis. The Respondents argue that the ALJ's infringement analysis indicates an inconsistent use of the term "providing" by the ALJ. The Respondents argue that while, for most asserted claims in this investigation, the ALJ found that CCPK provided information to CCUS or that CCUS provided information to CCPK, with respect to claim 31 of the '325 patent the ALJ found that CCPK "provides" the initial digital data set internally to itself. Resps.

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Pet. at 61-62 (citing ID at 475, 512).<sup>34</sup> The Respondents argue that the ALJ apparently realized that his application of the term “providing” is tortured because he stated in the ID that “Mr. Beers [the witness] clearly did not intend to say that CCUS provided digital models to itself, and such a statement was clearly in error,” ID at 435, in explaining that the witness meant to say CCPK instead of CCUS. *Id.*

Align argues that the ALJ applied a consistent interpretation of the term “providing” across the claims. Align Resp. to Resps. at 44. Align argues that in the context of the asserted claims and intrinsic evidence, the ALJ interpreted the term “providing” to broadly cover both transmitting to an external entity or uploading into a computer or machine. *Id.* (discussing ID at 475). Align argues that the ALJ found CCPK provides the digital data set to the FreeForm software, not to itself. *Id.* (discussing ID at 475, 512). Align further argues that Respondents’ argument regarding the meaning of “providing” is waived because they failed to identify the term “providing,” and their newly-advanced limiting construction in any of the *Joint Claim Construction Charts* (“JCCC”). *Id.*

The IA argues that the Respondents’ arguments with respect to the claim term “providing” should be rejected because, as admitted by ClearCorrect, the parties did not ask that the term be construed beyond its plain and ordinary meaning. IA Resp. at 22. The IA further argues that the Respondents cite no support for their proposed limitation and the claim language does not recite any restriction as to whom or to what the “providing” is directed. *Id.*

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<sup>34</sup> The Respondents argue that the ALJ made the same inconsistent use when he held that CCUS “provides” the modified digital data sets it actually receives from CCPK. *Id.* (citing ID at 502). The Commission does not view this usage of providing as inconsistent.



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While Respondents challenge the ALJ's use of "providing" in his infringement analysis, the issue is really one of claim construction. Even where the term "providing" is used only once in a patent claim (as in claim 1 of the '325 patent), the ALJ found that both CCUS and CCPK both provide data. ID at 475. The required "providing" of data may occur by the transmission of data from CCUS to CCPK, from CCUS to CCPK, from CCUS to a computer, or from CCPK to a computer. In claim 1, with respect to one occurrence of the term "providing," the ALJ found that both CCUS and CCPK satisfied the same claim term. The ALJ found that CCUS provides the initial data set to CCPK and also that CCPK provides the initial data set to a computer (by uploading the data). ID at 436, 475. Regarding the first element of claim 11, the ALJ found that CCUS provides an initial data set to CCPK and CCPK provides an initial data set to a computer; regarding the second element of claim 11, the ALJ found that CCPK provides the final data set to CCUS and CCUS provides the data set to a treatment professional. ID at 490. Regarding claim 21, the ALJ found that CCUS provides a digital data set to a computer and also that CCPK provides a data set to CCUS. ID at 502-03. The ALJ found the first through sixth elements of claim 31 to be identical to claim 1, and found that CCPK transmits the intermediate data sets to CCUS (and found an admission that CCUS imports them into a computer). ID at 512-13. The ALJ found that CCUS and CCPK both practice the first and second elements of claim 35 and claim 38. See ID at 522, 527-28.

In our view, the ALJ used the term "providing" in accordance with its plain and ordinary meaning of conveying or giving, including by "electronically transmitting." This is consistent with the meaning of "providing" within the specification. *See, e.g.,* '325 patent, col. 5, lines 36-41 ("Conveniently, the initial digital data set may be *provided*

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by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the 40 like.”)(emphasis added). It does not matter if the electronic transmission was to a computer owned by another individual or to a computer owned by the same individual. The patent claims do not make a distinction as to who receives the transmission. The plain language of the claims simply requires “providing.” The Commission therefore affirms the ALJ’s construction of “providing” with this clarification.

### **7. The Standard for Claim Construction As to Claims 1 and 33 of the ‘325 patent, Claim 2 of the ‘511 patent, and Claim 2 of the ‘874 patent**

The ALJ provided the “broadest, reasonable” construction with respect to claims 1 and 33 of the ‘325 patent, claim 2 of the ‘511 patent, and claim 1 of the ‘874 patent. The ALJ relied on *Genentech, Inc. v. Chiron Corporation*, 112 F.3d 495, 499 (Fed. Cir. 1997), for the “broadest reasonable construction” standard. *See* ID at 81 n.9; 97 n.12 and 9. This is, however, the standard for an interference (or reexamination) at the PTO, *see Genentech*, 112 F.3d at 496-96, and is not the appropriate standard for claim construction in the context of an infringement analysis in district court or at the Commission, *i.e.*, claim terms are interpreted as they would be understood by a person of ordinary skill in the art in light of their ordinary meaning, the intrinsic evidence of the specification and the prosecution history, and certain extrinsic evidence. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (*en banc*). Nevertheless, the Commission agrees with the ALJ’s ultimate claim construction of these four claims. As set forth below, the ALJ correctly interpreted the claims in light of the specification and other



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intrinsic evidence. Thus, we have concluded that the ALJ's incorrect statement of the standard is harmless error, as his claim construction is consistent with an application of the correct standard for claim construction.

With respect to claims 1 and 33 of the '325 patent, the ALJ's claim construction of "at the outset of treatment" was correct because the ALJ properly rejected a prosecution history disclaimer argument which was based on claim language that is not present in claims 1 and 33 of the '325 patent. ID at 39.

With respect to claim 2 of the '511 patent, the ALJ correctly construed "a method accomplished using a computer," finding that the specification contemplates direct interaction with the computer by a clinician who may reset the final position(s) of teeth and specify constraints to be applied to segmented paths. ID at 80 (citing JX-001, 4:36-50).

With respect to claim 1 of the '874 patent, the ALJ correctly construed "a method accomplished using a computer," finding that the specification allows user modification: "some embodiments allow the user to modify the underlying digital data set by repositioning a tooth in the 3D graphical representation"; "[d]eveloping an orthodontic treatment plan for a patient involves manipulating the IDDS [Initial Digital Data Set] at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images"; and Figure 3 of the '874 patent illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS [final digital data set] on the computer. ID at 95-96 (citing JX-006, 3:51-53, 10:12-15, 12:4-6, 12:11-44, 12:53-62).

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### 8. Waiver of Other Arguments

With the exception of the claim terms “providing” and “treatment plan,” the Respondents do not make specific arguments in their petition for review regarding claim construction or infringement, but rather attempt to stand on and incorporate by reference their contentions about claim construction and infringement from their post-hearing brief and post-hearing reply brief before the ALJ, and as summarized by the ALJ in his ID. Resp. Pet. at 64-65. We find these arguments to be waived under Commission rule and practice. *See* 19 C.F.R. § 210.43(b)<sup>35</sup>; *see also Finnigan Corp. v. ITC*, 180 F.3d 1354, 1362 (Fed. Cir. 1999) (“A party seeking review in this court of a determination by the Commission must ‘specifically assert’ the error made by the ALJ in its petition for review to the Commission.”).

The Respondents argue that incorporation by reference is reasonable because the ALJ’s ID is 814 pages long and his analysis of claim construction and infringement spans approximately 421 pages. Nevertheless, the Respondents did not make any motion for an extension of the 100 page limit to the petition for review. Instead, the Respondents submitted a petition for review of 72 pages, with the argument for incorporation by reference. Moreover, to the extent that most of the claim terms and elements of the claimed processes are common to multiple claims and multiple patents, the Respondents could have made arguments directed to most of the elements of the claimed processes without the repetition found in the ALJ’s ID.

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<sup>35</sup> The Commission stated in its recent rulemaking that it “believe[d] . . . incorporation by reference to be inconsistent with the existing rule [*i.e.*, the former version of the rule].” 76 *Fed. Reg.* 23474, 23479 (April 19, 2013). Thus, the Commission considered the recent rule to be a clarification, and a prohibition on any attempt at an end-run around the existing rule, rather than a new rule.



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### C. Infringement

As set forth herein, the Commission has adopted the ALJ's finding that the CCUS and CCPK accused products satisfy the claim limitations as construed. The Commission herein analyzes whether infringement has been demonstrated in light of the requirements of Section 337 for each of the four asserted groups of claims. There is also an issue with respect to the Group I claims as to whether the elements of 35 U.S.C. § 271(c) are satisfied.

#### 1. Group I Claims (Claims 21 and 30 of the '325 patent; Claim 1 of the '880 patent)<sup>36</sup>

##### a. Direct Infringement

The Group I claims are directed to methods of manufacturing dental appliances starting with a digital data set. Prior to the accused manufacturing activity related to these claims, CCPK manipulates the digital models, thereby generating intermediate and final digital data sets in Pakistan, and electronically transmits them to CCUS in the United States. ID at 472-73. Then, as relevant to these claims, CCUS uses the generated data sets to prepare molds of the patient's teeth which are in turn used to make the physical dental appliances in the United States. ID at 473 (citing Tr. at 172:15-173:8; 316:12-318:11; CX-1150C at 200-11).

As to the '325 patent, the ALJ found that CCUS independently practices each and every limitation of asserted claim 21 in the United States, and that CCPK and CCUS act

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<sup>36</sup> Align includes these claims in both Group I and Group IV. Align includes the claims in Group I because the ALJ found that CCUS practices the claims entirely in the United States when it "provides" the data to the fabrication machine. The ALJ also found that CCPK acts in concert with CCUS, which would place the claims in Group IV, because CCPK "provides" the data to CCUS. As noted in our claim construction section, we understand "provide" to include conveying by an 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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in concert to practice claim 21 of the '325 patent when the digital data sets created by CCPK are used by CCUS to fabricate aligners (“dental appliances”). ID at 502-503. Similarly, the ALJ found that CCUS independently, and CCUS and CCPK acting in concert, practice dependent claim 30 of the '325 patent. ID at 505.

As to the '880 patent, the ALJ found that CCUS independently practices each and every limitation of claim 1 and that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners. ID at 571-72.

The only claim construction issue which was the subject of a petition for review is construction of “predetermined digital data sets” for claim 1 of the '880 patent. The Commission has determined to affirm the ALJ’s claim construction, and therefore agrees with the ALJ that the claim elements are met. There is no dispute that, under this claim construction, there is direct infringement of the Group I claims entirely in the United States by CCUS.<sup>37</sup> However, since the direct infringement of the method claims occurs entirely within the United States, it does not itself constitute a violation of Section 337. *See* 19 U.S.C. § 1337(a)(1)(B); *Certain Electronic Devices*, Inv. No. 337-TA-724, 2012 WL 3246515, Comm’n Op. at \*8–9 (Dec. 2011). We therefore examine in the next section whether there is indirect infringement by the digital data sets.

### **b. Indirect Infringement**

#### **i. The ID**

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<sup>37</sup> Joint infringement with CCPK is addressed in the section on Group IV claims, *infra*. (The ALJ found that the Group I claims are satisfied in two ways. The ALJ found that CCUS independently satisfies the Group I claims and that CCPK acts in concert with CCUS to satisfy the claims). ID at 571-72.



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The ALJ found that CCPK contributorily infringes claims 21 and 30 of the '325 patent by sending the digital data sets into the United States to CCUS. ID at 549.

Similarly, the ALJ found that CCPK contributorily infringes claim 1 of the '880 patent, but did not find induced infringement of claim 1 of the '880 patent because Align did not prove specific intent. ID at 589-90.

### ii. Parties' Arguments

The Respondents first argue that the ALJ applied the wrong intent standard for contributory infringement. Resp. Pet. at 55. Respondents rely on *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*), and *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060, 2068 (2011) for the proposition that inducement requires knowledge that the induced acts constitute patent infringement. *Id.* The Respondents further note that the Supreme Court in *Global-Tech* adopted a willful blindness test for inducement. Resp. Pet. at 55-56 (citing *Global-Tech*, 131 S. Ct. at 2070). The Respondents argue that the intent required to show contributory infringement is at least as high, if not higher, than the standard for induced infringement. Resp. Pet. at 56 (citing *Global-Tech*, 131 S. Ct. at 2067-68; *Aguirre v. Powerchute Sports, LLC*, 2011 WL 3359554 (W.D. Texas 2011); *Bose Corp. v. SDI Technologies Imation Corp.*, 2012 WL 2862057 (D. Mass. 2012)).

The Respondents argue that with respect to the '325 and the '880 patents, the ALJ found only that the Respondents were aware of the patents, but did not satisfy the willful blindness standard for liability. Resp. Pet. at 57. Respondents argue that the ALJ's

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finding that there was no intent to induce direct infringement should apply equally to Align's claims of contributory infringement. *Id.*

Respondents also argue that the ALJ improperly excluded evidence disproving any intent to infringe. *Id.* at 58. Respondents argue that, whether or not Align's covenant not to sue resulted in exhaustion of the patents-in-suit and liberated any acts from the possibility of infringement, Respondents' good faith belief in this defense bars a finding of culpable mens rea required for indirect infringement. *Id.*

In addition, Respondents argue that the files need only be "suitable" for a non-infringing use to avoid liability, meaning the ALJ erred in finding the files must *actually* be used for the non-infringing purpose. *Id.* (citing Robert L. Harmon, HARMON ON PATENTS: BLACK LETTER LAW AND COMMENTARY pp. 193-95 (2007)(citing *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984); *Metro-Goldwyn-Mayer Studios Inc. v. Grokster Ltd.*, 545 U.S. 913 (2005))). Respondents state that the record provides examples of non-infringing uses for the digital data sets in medical research, patient evaluation, and treatment planning. *Id.* at 11-12.

Further, the Respondents argue that digital data is not "a material" or "apparatus" used in a patented process within the meaning of the statute for contributory infringement, 35 U.S.C. § 271(c). *Id.* at 60; Resps. Add. Sub. Reply at 14. The Respondents point to the text of the statute, which requires that a person supply "a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process." 35 U.S.C. 271(c). The Respondents argue that the imported digital data is neither an "apparatus" nor "a material" used in a patented process, but is rather intangible information, which,



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according to Respondents, does not meet the requirements of the statute. Resps. Post-Hrg. Reply Br. at 26; Resps. Pet. at 60.

Respondents cite Black's Law Dictionary (9<sup>th</sup> ed. 2009) which defines "material" as "[o]f or relating to matter; physical . . ." Resps. Add. Sub. at 8. Respondents further argue that *Bayer's* analysis [of § 271(g)] uses the term "material" in discussing the meaning of manufacturing. *Id.* at 9 (citing 340 F.3d at 1372). Respondents note that the Supreme Court in *Microsoft* did not consider software to be a "component" under § 271(f). *Id.* at 10 (citing 550 U.S. at 451). Respondents also rely on *Veritas Operating Corp. v. Microsoft Corp.*, 562 F. Supp.2d 1141, 1275 (W.D. Wash. 2008), which held that electronically published software could not be "a material or apparatus." *Id.* at 13-14. Respondents argue that Align's citation to *Lucent Tech.*, where the Federal Circuit rejected Microsoft's argument as being without sufficient analysis, is also without sufficient analysis. Resps. Add. Reply Sub. at 14-15 (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.Supp.2d 1016, 1039 (S.D. Cal. 2008)). Respondents note that the three district court cases Align relies on, Align Add. Sub. at 32, were about the use of software rather than electronic transmissions of data. *Id.* at 15. Respondents assert that the alleged "products" are not software. *Id.* at 13 (citing *Eolas Techs. Inc. v. Microsoft Corp.* 399 F.3d 1325 (Fed. Cir. 2005)), but rather that the data here identifies teeth locations. *Id.* (citing ID at 19).

Align argues that the ALJ correctly found contributory infringement by CCPK. Align Resp. to Resps. at 36. Align argues that the ALJ properly applied the "*Spansion*" test for contributory infringement with respect to the asserted claims of the '325 patent, the '880 patent, the '511 patent, and the '874 patent. *Id.* at 36 and n.22 (citing ID at 546-

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551, 588-89, 638-39, 758-59; *Certain Elec. Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011) at n.9 (citing *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010)).

Align further asserts that the ALJ “correctly applied the correct” knowledge standard for contributory infringement. *Id.* at 37. Align notes Respondents’ reliance on *DSU Med. Corp.* and *Global-Tech* for their argument that contributory infringement has a greater intent requirement than that applied by the ALJ. *Id.* Align counters that *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006), held that contributory infringement has only a “minimal intent requirement,” and that *Global-Tech Appliances, Inc. v. SEB S.A.*, only addressed the intent requirement for § 271(c) in the context of explaining that knowledge of the *existence of the patent* is required for indirect infringement under both §§ 271(c) and (b). *Id.* (citing 131 S. Ct. 2060, 2067–68 (2011)). Align concludes that the “willful blindness” test for inducement does not apply to contributory infringement. Align contests Respondents’ further reliance on two district court cases, *Aguirre* and *Bose*, for the proposition that contributory infringement requires “knowledge of the infringement” because the Federal Circuit in *Spansion*, rejected this standard and found the intent requirement for contributory infringement satisfied by presumption where there are no substantial noninfringing uses. *Id.* and n.23 (citing *Spansion*, 629 F.3d at 1355; *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) (“[o]ne who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of



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his acts; he will be presumed to intend that they shall be used in the combination of the patent’’)).

Align disagrees with Respondents’ contention that the imported digital data sets have substantial noninfringing uses, actually or hypothetically. *Id.* Align asserts that Respondents’ “testimony” is directed to the vague category of “three-dimensional files”—not the specific digital data sets at issue here. Align further asserts that Respondents misconstrue the standard for showing non-infringing uses. Align argues that under Federal Circuit case law, “non-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *Id.* (citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009)). Align further notes that when assessing whether a use is substantial, the fact-finder may consider “the use’s frequency, ... the use’s practicality, the invention’s intended purpose, and the intended market.” *Id.* (citing *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010)). Align argues that the ALJ was justified in rejecting the argument that a hypothetical use was substantial. *Id.* at 40-41 and n.27 (citing *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1379–80 (Fed. Cir. 2001) (finding sufficient evidence of contributory infringement and agreeing that the jury was free to disregard the defendant’s allegation that its device had a wide range of applications to surgical procedures other than liposuction where the record did not contain any evidence of any “actual uses of the device other than ultrasonic liposuction’’)). Align argues that Respondents have provided no particular evidence of any particular non-infringing use of the digital data sets, other than conclusory and speculative testimony, let alone evidence of a substantial non-infringing use. Align finally argues that not only is it conjecture that

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there are noninfringing uses, but the evidence confirms the opposite—neither CCUS nor CCPK uses the digital files for any purpose besides making aligners (Tr. at 320:24–321:2, 442:24–443:10; CX-1160C.4 at 645:15–646:4), and the digital data sets themselves are useful only to one particular patient (Tr. at 320:20–23, 443:3–6; CX-1160C.4 at 646:1–4). *Id.* at 42.

Align argues that the ALJ correctly found that digital data can contributorily infringe, *i.e.*, constitute an “apparatus” or “material” used in a patented process within the meaning of the patent statute, 35 U.S.C. §271(c). *Id.* at 42. Align argues Respondents have waived any challenge to the ALJ’s conclusion as to contributory infringement by failing to raise it in a timely fashion.<sup>38 39</sup> Align further argues that Respondents are mistaken on the merits because various district courts have found that digital data can contribute to infringement (within the meaning of the patent statute). *Id.* at 42-43 (citing *T5 Labs (Del.) LLC v. Gaikai Inc.*, 2013 U.S. Dist. LEXIS 49710 (D. Del. Apr. 5, 2013) (finding sufficient pleadings that allege a ‘cloud’-based gaming application and service contributorily infringes); *Walker Digital, LLC v. Facebook, Inc.*, 852 F.Supp.2d 559, 566 (D. Del. 2012) (finding that pleadings of “software” that contributorily infringe were facially plausible); *Oracle Corp. v. Parallel Networks, LLC*, 778 F.Supp.2d 527, 544 (D. Del. 2011) (finding that specialized computer software could plausibly contributorily infringe); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F. Supp. 2d 1016, 1039 (S.D. Cal.

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<sup>38</sup> Align overlooks the fact that this issue was raised by Respondents in their Post-Hearing Reply Brief. *See infra.*

<sup>39</sup> We note that this is different from the issue of whether the electronic transmission of digital data constitutes importation of an “article” within the meaning of the Commission’s statute, 19 U.S.C. §1337(a)(1)(B).



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2008) (declining to limit 271(c) to exclude software), *aff'd in part, vacated in part & remanded*, 580 F.3d 1301 (Fed. Cir. 2009)).

Align counters Respondents' argument that "digital data itself does not infringe the patents at issue" because it is not "a material or component of the aligner," and states that Respondents appear to be taking the position that a contributorily infringing article must be able to be identified in the end infringing product. Align argues that Respondents cite no precedent for such a position, that it is wrong, and that the ALJ correctly found that "the digital data sets created by CCPK are a material part of the process of creating the aligners" because the asserted claims make clear that once the digital data set(s) is (are) created, the only step remaining is to manufacture the aligners based on the digital data set(s). *Id.* at 43 (quoting ID at 547).

Align argues that the term "a material" in the phrase "a material or apparatus for use in practicing a patented process" in 35 U.S.C. § 271(c) may include electronic transmissions. Align Add. Sub. at 31. Align states that files placed by CCPK on CCUS's server do not differ in any meaningful way from digital files resident on CD-ROM and shipped by conventional means into the United States. *Id.* (citing *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp.2d 985, 994 (N.D. Cal. 2007)).

Align argues that the Federal Circuit held in *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321 (Fed. Cir. 2009), that forms of data can be a "a material or apparatus," and rejected Microsoft's reliance on *Microsoft v. AT&T* for the contrary position. *Id.* at 32. Align asserts that other courts have regularly found that digital data can contributorily infringe. *Id.* (citing *T5 Labs. (Del.) LLC v. Gaikai Inc.*, 2013 U.S. Dist. LEXIS 49710 (D. Del. Apr. 5, 2013); *Walker Digital, LLC v. Facebook*,

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Inc., 852 F. Supp.2d 559, 566 (D. Del. 2012); *Oracle Corp. v. Parallel Networks, LLC*, 778 F. Supp.2d 527, 544 (D. Del. 2011)).

The IA argues that the digital data sets have no substantial non-infringing uses. IA Resp. at 15 (citing CX-1160C (J. Pumphrey) at 174:20–175:4, 645:15–646:4; CX-1162C (Rathore) at 97:1–14). The IA counters the Respondents’ argument that the data sets have uses for “treatment planning and record keeping,” on the theory that record keeping is not a “use,” but something done in the ordinary course of medical and dental treatment. IA Resp. at 16.

The IA submits that the term “a material” in the phrase “a material or apparatus for use in practicing a patented process” in 35 U.S.C. § 271(c) includes electronic transmissions. The IA argues that the plain and ordinary meaning of the term “material” does not limit “material” to any specific type. *Id.* at 11. Further, the IA is not aware of any Federal Circuit opinion or Commission determination excluding electronic transmissions from being a material for use in practicing a patented process. The IA states that the Federal Circuit has affirmed district court determinations regarding contributory infringement based on the selling or offering for sale of software. *Id.* at 11-12 (citing *i4i Ltd. v. Microsoft Corp.*, 598 F.3d 831, 850-51 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320-21 (Fed. Cir. 2009)). The IA notes that there is a district court decision in which “electronically published” software was determined not to be “material” for use in a patented process, *Veritas Operating Corp. v. Microsoft*, 562 F. Supp.2d 1141, 1275 (W.D. Wash. 2008), but argues that the rationale of this case concerned the application of § 271(f) and *Microsoft v. AT&T*, and not § 271(c). *Id.* at 11 n.4.



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The IA agrees with Complainant that the term “material” in § 271(c) includes electronic transmissions. IA Add. Sub. Reply at 9 (citing *Lucent Techs., Inc.*, 580 F.3d at 1321). The IA argues that Respondents and Katz’ reliance on dictionary definitions to the contrary is misplaced because the term “material” is not properly limited to a physical article, and even if it is, the digital data sets are representative of physical articles. *Id.* at 9-10 (also citing *Lucent*).

Third-Party Submitter Andrew Katz argues that the term “material” in the phrase “a material or apparatus for use in practicing a patented process” in 35 U.S.C. § 271(c) does not include electronic transmission, Katz Sub. at 16, relying primarily on dictionary definitions of “material.” *Id.* at 16-17. Mr. Katz further asserts that the analysis of components in *Microsoft*, a case decided under § 271(f), is analogous to the analysis of components under § 271(c), and that *Microsoft* held that electronically transmitted software was not a component under § 271(f). *Id.* at 17-18.

Third-Party Submitter Nokia argues that both Supreme Court and Federal Circuit precedent establish that electronic transmissions can qualify as infringing “components” or “materials or apparatus” under 35 U.S.C. § 271(c), as well as be the subject of certain induced infringement claims under 35 U.S.C. § 271(b), and thus also constitute articles within the meaning of Section 337. Nokia Reply Sub. at 1. Nokia asserts that the third party arguments with respect to *Suprema* are beyond the scope of the questions posed by the Commission, and in any event mischaracterize *Suprema* because *Suprema* reaffirmed that contributory infringement is a valid basis for a violation of Section 337. *Id.* at 2.

Nokia further argues that electronic transmission of software can be a “component” or a “material or apparatus” under § 271(c). Nokia Reply Sub. at 3. Nokia

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argues that the Federal Circuit has never squarely held that electronically transmitted software is a “material or apparatus” but its rulings strongly support that notion in holding that software may be a “material or apparatus.” *Id.* at 3-4 (citing *i4i*, 598 F.3d at 850-51 and *Lucent*, 580 F.3d at 1320). Nokia further argues that *Microsoft v. AT&T* supports the notion that electronically transmitted software is a “material or apparatus” because the Court differentiated between “software in the abstract” and a “tangible” copy of software, as on a CD-ROM. *Id.* at 5 (citing 550 U.S. at 448). Nokia quotes the Supreme Court’s statement that “[u]ntil it is expressed as a computer-readable ‘copy,’ e.g., on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable.” *Id.* at 5-6 (citing 550 U.S. at 449). Nokia concludes that the “key inquiry in *Microsoft*” is whether software was available in a form in which it was combinable to form the patented invention. *Id.* at 6.

### iii. Analysis

Contributory infringement is set forth at 35 U.S.C. § 271(c), which provides as follows:

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

*See* 35 U.S.C. § 271(c).

Specifically with respect to Section 337 investigations, the Federal Circuit has held that “to prevail on contributory infringement in a Section 337 case, the complainant



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must show inter alia: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement.”

*Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

With respect to the intent element of Section 271(c), the contributory infringement statute requires that the infringer knows that the patented component is specially adapted for infringement and that there are no substantial noninfringing uses. *See* 35 U.S.C. § 271(c). Recent cases have explained that the intent requirement for contributory infringement is knowledge of the patent. *Spansion*, 629 F.3d at 1353. The Court has explained that this is based on a presumption that the intent requirement is satisfied where there are no substantial noninfringing uses for the component. *Id.*

The ALJ found that Respondents had knowledge of the '325 and '880 patents. ID at 549, 589. We affirm this finding. The ALJ also noted Respondents' admission that “digital data sets and treatment plans are not bought and sold. ***They are essentially instructions for making physical aligners. They have no separate commercial value.***” ID at 548 (emphasis in ID). This statement is evidence of no substantial non-infringing uses and may also be evidence that Respondents acted “knowing the same to be specially adapted for their infringing use.” *See* 35 U.S.C. § 271(c).<sup>40</sup> We affirm the ALJ's finding of no substantial non-infringing use. ID at 548. Therefore, we find that CCPK possessed the requisite intent for contributory infringement.

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<sup>40</sup> The Respondents argue, as a defense, that they believed in good faith that they had an implied license to practice the patents in suit. However, this defense rises and falls with the implied license defense, which we determined is waived. We therefore conclude that Respondents possessed the requisite intent for contributory infringement.

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Next we address whether the digital data sets are “a material or apparatus” within the meaning of § 271(c). To begin we determine that Respondents’ argument that digital data is not an “apparatus” or “a material” was not waived because there was no requirement for Respondents to assert a defense before their brief in reply to Align’s opening post-hearing brief. *Cf.* Ground Rules 8.2 and 11.1. The burden is on Align to establish all elements of its allegation of contributory infringement, and the defense here is not an affirmative defense, but rather a statement that complainant has failed to make out the elements of its case.

Align does not argue that an electronically transmitted data set can be an “apparatus.” Rather, Align contends that the accused digital data sets are either a material or component within the meaning of Section 271(c).

We consider whether the term “a material” connotes something tangible which might pertain to whether the digital data at issue here are encompassed within the meaning of this statutory term. In assessing the meaning of this term, we first look to contemporaneous dictionary definitions. The word “material” has long had a widely accepted definition as an input into a more finished work. For example, Webster’s defines material to include “[d]ata of any sort, such as notes, documents, sketches, etc., which may be worked up into a more finished form; as *materials* for a biography; hence, facts, perceptions; ideas, etc., viewed as data for a further operation; as the raw *material* of experience.” *Id.*<sup>41</sup> This common meaning of the term “material” is reflected in a plurality of dictionary definitions. *See, e.g.,* FUNK & WAGNALLS NEW STANDARD

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<sup>41</sup> *Accord* Webster’s New Collegiate Dictionary (1979) (defining “material” as “data that can be worked into a more finished form.”).



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DICTIONARY OF THE ENGLISH LANGUAGE (1940) (“Collected facts, impressions, or ideas or notes containing them, and sketches, etc., that may be used in completing a literary or an artistic production; as *material*, for a sermon”); THE WINSTON DICTIONARY: COLLEGE ED. (1942) (“data, as notes and sketches, for further elaboration; as material for a speech; that which may be worked up into other forms or for other purposes”);<sup>42</sup> THE NEW CENTURY DICTIONARY OF THE ENGLISH LANGUAGE. (1952) (“Material (n): the substance or substances of which a thing is made or composed; any constituent element of a thing; often, anything serving as crude or raw matter for working upon or developing (as, “the materials of seditions,” Bacon’s “Essays,” Of Seditions and Troubles; the materials of a history or drama); also, a textile fabric; also, pl., articles of any kind requisite for making or doing something (as, writing-materials)).<sup>43</sup>

Furthermore, in law, as well as in many of the humanities and social sciences, it has long been very common for the content of some text or statement to be referred to as the “material” that was being conveyed. For example, it would be well within ordinary usage for a speech writer looking for famous quotes to refer to them as source “material;” and it likewise would be well within ordinary usage for someone who attends a lecture to use the word “material” when referring to the content of the lecture rather than to any physical props, visual aids, instruments, or costumes. Indeed, the Supreme Court in *International News Service v Associated Press*, 248 US 215 (1918), used the word “material” several times in its opinion referring to the misappropriation of the content

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<sup>42</sup> Accord NEW OXFORD AMERICAN DICTIONARY (3rd ed. 2010) (defining “material” as “facts, information, or ideas for use in creating a book or other work . . .”).

<sup>43</sup> Accord WEBSTER’S NEW COLLEGIATE DICTIONARY (1979) (defining “material” to be “the elements, constituents, or substances of which something is composed.”).

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contained in fresh news transmitted electronically. 248 US 239 (“defendant...admits that it is taking material that has been acquired by complainant...”). Such intangible materials have also been the linchpin of well know contributory infringement cases for well over 100 years. *See, e.g., Kalem Co. v. Harper Brothers*, 222 U.S. 55 (1911) (contributory infringement of copyright in the book *Ben Hur*) (Holmes, J.); *Gershwin Pub. Corp. v. Columbia Artists Management*, 443 F.2d 1159 (2<sup>nd</sup> Cir. 1971) (contributory infringement of copyrights in music); *Screen Gems-Columbia Music v. Mark-Fi Records*, 327 F.Supp. 788 (SDNY 1971) (same).

Other definitions of “a material” do relate to physical matter. *See, e.g., BLACK’S LAW DICTIONARY* (4<sup>th</sup> ed. 1951) (defining “materials” as “the substance or matter of which anything is made”).<sup>44</sup> *See also WEBSTER’S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE* (2d. ed. 1948) (defining “material” as “the substance, or substances, or the parts, goods, stock, or the like, of which anything is composed or may be made . . . material things.”)<sup>45</sup> *See also THE NEW CENTURY DICTIONARY OF THE ENGLISH LANGUAGE*. (1952) (“Material (n): the substance or substances of which a thing is made or composed; any constituent element of a thing; often, anything serving as crude or raw matter for working upon or developing (as, "the materials of seditions," Bacon's "Essays," Of Seditions and Troubles; the materials of a history or drama); also, a textile fabric; also, pl., articles of any kind requisite for making or doing something (as, writing-materials)). But none of these definitions that relate to physical matter suggest they

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<sup>44</sup> Contemporary editions are in accord. *See, e.g., BLACK’S LAW DICTIONARY* (9<sup>th</sup> ed. 2009), (defining “material” as “[o]f or relating to matter; physical . . .”).

<sup>45</sup> *Accord Webster’s New Collegiate Dictionary* (1979) (defining “material” to be “the elements, constituents, or substances of which something is composed.”).



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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.<sup>46</sup>

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

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<sup>46</sup> 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).<sup>47</sup>

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<sup>47</sup> 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 patent<sup>48</sup>; 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,

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<sup>48</sup> 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)).<sup>49</sup> 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

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<sup>49</sup> 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.”<sup>50</sup> 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.*<sup>5152</sup> These definitions support the conclusion that

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

<sup>51</sup> 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”).

<sup>52</sup> 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.<sup>53</sup> 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,

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<sup>53</sup> 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.<sup>54</sup>

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.

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<sup>54</sup> 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).<sup>55</sup>

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.<sup>56</sup> As noted above, the ALJ found that CCUS also independently practices

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<sup>55</sup> 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.

<sup>56</sup> 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.<sup>57</sup>

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

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<sup>57</sup> 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.<sup>58</sup> The Respondents

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<sup>58</sup> 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).

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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).<sup>59</sup> *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

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<sup>59</sup> 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).<sup>60</sup>

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).

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<sup>60</sup> 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.<sup>61</sup> 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.”).<sup>62</sup> 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.<sup>63</sup>

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<sup>61</sup> 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).

<sup>62</sup> Claim 37 of the '325 patent was not asserted in this investigation.

<sup>63</sup> 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 maloccluded<sup>64</sup> 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.

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<sup>64</sup> 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.<sup>65</sup> 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

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<sup>65</sup> 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).<sup>66</sup>

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

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<sup>66</sup> 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.<sup>67</sup> 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

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<sup>67</sup> 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).<sup>68</sup> 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

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<sup>68</sup> 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.<sup>69</sup> 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

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<sup>69</sup> 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.<sup>70</sup> 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

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<sup>70</sup> 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.<sup>71</sup> *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

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<sup>71</sup> 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.<sup>72</sup>

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.*

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<sup>72</sup> 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.<sup>73</sup> 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

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<sup>73</sup> 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.<sup>74</sup>

### 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

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<sup>74</sup> 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 (4<sup>th</sup> 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.

#### 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.<sup>75</sup> 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

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<sup>75</sup> 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.<sup>76</sup> *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,

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<sup>76</sup> 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.<sup>77</sup> 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

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<sup>77</sup> 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.<sup>1</sup>

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.<sup>2</sup> Thus, Section 337 is not the international extension of our patent, copyright, and

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<sup>1</sup> 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.

<sup>2</sup>As 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.<sup>3</sup>

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

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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 (1<sup>st</sup> 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 (7<sup>th</sup> 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.

<sup>3</sup> 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).<sup>4</sup>

Under the HTSUS, tangible items are subject to tariff<sup>5</sup> 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.<sup>6</sup> *See Dolan v. United States*

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

<sup>5</sup> 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).

<sup>6</sup> 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.

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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”<sup>7</sup> are

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<sup>7</sup> 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)).<sup>8</sup> 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

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

<sup>8</sup> 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 data<sup>9</sup> 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

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<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> 340 F.3d at 1374. In *Bayer*, the question before the Federal Circuit

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<sup>10</sup> 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.”

<sup>11</sup> 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).”<sup>12</sup> *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.

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

<sup>12</sup> 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).<sup>13</sup> 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.*

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<sup>13</sup> 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.”<sup>14</sup> For example, in *Hardware Logic*,<sup>15,16</sup> 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

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<sup>14</sup> 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.

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

<sup>16</sup> 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).<sup>17</sup> 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.<sup>18</sup>

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

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

<sup>18</sup> 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.<sup>19</sup> In this instance, extending the term “article” in Section 337 to cover electronic

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<sup>19</sup> 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.<sup>20</sup> 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.

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<sup>20</sup> *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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