

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN DENTAL AND
ORTHODONTIC SCANNERS AND
SOFTWARE**

Investigation No. 337-TA-1144

**NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL
INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; REQUEST
FOR WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON
REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF THE
TARGET DATE**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to review in part a final initial determination (“ID”) of the presiding administrative law judge (“ALJ”). The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below. The target date is extended to September 28, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on March 5, 2019. 84 FR 7933-34 (March 5, 2019) based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California (“Align”). The complaint alleges 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, or the sale within the United States after importation of certain dental and orthodontic scanners and software by reason of infringement of one or more claims of U.S. Patent Nos. 9,299,192 (“the ’192 patent”); 7,077,647 (“the ’647 patent”); 7,156,661 (“the ’661 patent”); 9,848,958 (“the ’958 patent”); and 8,102,538 (“the ’538 patent”). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission’s notice of investigation named as respondents 3Shape A/S of Copenhagen, Denmark; 3Shape, Inc. of Warren, New Jersey; and 3Shape Trios A/S of Copenhagen, Denmark (together, “3Shape”). *Id.* The Office of Unfair Import Investigations (“OUII”) is not participating in the investigation. *Id.*

The Commission subsequently terminated the investigation with respect to the ’958 patent based on Align’s withdrawal of those allegations. Order No. 17 (Jul. 2, 2019), *not reviewed* Notice (Jul. 23, 2019). On October 8, 2019, Align stated that it would no longer pursue a violation with respect to claims 4 and 20 of the ’647 patent, claims 1 and 19 of the ’661 patent, and claims 1, 3-5, and 22 of the ’192 patent. On October 21, 2019, Align stated that it would no longer pursue a violation with respect to claim 2 of the ’647 patent. Accordingly, at the time of the Final ID, Align asserted claims 1 and 18 of the ’647 patent, claims 2 and 20 of the ’661 patent, claims 1 and 2 of the ’538 patent, and claims 2, 28, and 29 of the ’192 patent.

On April 30, 2020, the ALJ issued the Final ID finding a violation of section 337 with respect to the ’647 and ’661 patents, and no violation with respect to the ’538 and ’192 patents. Specifically, the ALJ found that claims 1 and 18 of the ’538 patent are not infringed and that claims 2, 28, and 29 of the ’192 patent are invalid. The ALJ found that Align satisfied the remaining requirements for a violation with respect to the ’538 and ’192 patents.

On May 12, 2020, 3Shape and Align each filed a petition for review of the Final ID. On May 20, 2020, the parties responded to each other’s petitions. The Commission also received four comments on the public interest.

Having reviewed the record of the investigation, including the final ID and the parties’ petitions and responses, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review: (1) the findings regarding importation and induced infringement; (2) the construction of limitation 1.5/18.5 of the ’647 patent (“individually matching [match] each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising [including instructions to]”) in the asserted claims of the ’647 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry; (3) the findings regarding whether the asserted claims of the ’647 and ’661 patents are directed to patentable subject matter; (4) the construction of the limitation “wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and imaging means” in the asserted claims of the ’538 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry requirement; (5) the findings regarding whether Okamoto

anticipates the asserted claims of the '538 patent; (6) the findings regarding whether Paley-Kriveshko anticipates or renders obvious the asserted claims of the '192 patent; and (7) the findings regarding the satisfaction of the economic prong of the domestic industry requirement.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

- (1) Please explain whether it is proper to construe the limitation “wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and imaging means” to mean “the operation of the optical scanner and imaging means is substantially or effectively simultaneous.” Please note that this proposed construction removes the following requirement of the ALJ’s construction: “such that movement (*i.e.*, a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array.” Additionally, please explain how the above construction would impact findings on infringement, invalidity, and the domestic industry requirement.
- (2) Please explain, with citations to the record, whether there is a motivation to modify Paley-Kriveshko in a way that renders invalid as obvious the asserted claims of the '192 patent.
- (3) What information, if any, is contained in the record concerning Align’s employee headcount and salary and compensation expenditures outside the United States pertaining to Align’s DI Products? What information, if any, is contained in the record concerning the value added in the United States to Align’s DI Products?
- (4) Please explain, with citations to the record, whether Align’s investments in plant and equipment under a sales-based allocation are significant.

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties’ existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm’n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to state the dates that the Asserted Patents expire, the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on August 11, 2020. Reply submissions must be filed no later than the close of business on August 18, 2020. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Initial submissions are limited to 40 pages. Reply submissions are limited to 20 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1144) in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such

treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The target date is extended to September 28, 2020.

The Commission vote for this determination took place on July 28, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', with a date '7/28' written below it.

Lisa R. Barton
Secretary to the Commission

Issued: July 28, 2020