



7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1091]

Certain Color Intraoral Scanners and Related Hardware and Software; Notice of a Commission Determination to Review In-Part the Final Initial Determination; Request for Briefing

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination (“ID”) in-part and requests briefing from the parties.

FOR FURTHER INFORMATION CONTACT: Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, D.C. 20436, telephone (202) 205-2737. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.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 the underlying investigation on December 20, 2017, based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California (“Align”). 82 FR (Dec. 20, 2017). The complaint alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain color intraoral scanners and related hardware and software by reason of infringement of certain claims of U.S. Patent Nos. 8,363,228 (“the ’228 patent”); 8,451,456 (“the ’456 patent”); 8,675,207 (“the ’207 patent”); 9,101,433 (“the ’433 patent”); 9,48,931; and 6,685,470. *See id.* The complaint named 3Shape A/S and 3Shape Inc. as the respondents. On March 15, 2018, the ALJ granted Align’s unopposed motion to amend the complaint and notice of investigation to add 3Shape Trios A/S of Copenhagen, Denmark as an additional respondent in this investigation. *See* 83 FR 13781-82 (March 30, 2018), *unreviewed*, Notice (March 27, 2018). The Office of Unfair Import Investigations did not participate in the investigation.

On March 1, 2019, the ALJ issued his final ID finding that no violation of section 337 has occurred. On March 18, 2019, Align filed a petition for review and 3Shape filed a contingent petition for review of the ID. On March 26, 2019, all of the parties filed responses to the respective petitions for review.

Having examined the record of this investigation, including the ALJ’s final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in-part. Specifically, the Commission has determined to review the ID’s findings on (1) importation; (2) the construction of “processor”; (3) the construction of “confocal imaging techniques”; (4) all findings concerning infringement; (5) all findings concerning invalidity;

(6) all findings concerning whether Align's products practice one or more claims of the asserted patents; and (7) all findings concerning whether Align's financial investments and activities relating to Align's products meet the domestic industry requirement.

In connection with its review, the Commission is interested in responses to the following questions from the parties:

1. Discuss whether the "processor" term of the asserted claims is understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure? Is the "processor" of the asserted claims a general purpose processor? Please discuss and identify any expert testimony addressing these questions.
2. If the Commission determines that the claimed "processor" of the asserted claims is subject to means-plus-function treatment under 35 U.S.C. § 112, ¶ 6, please identify the corresponding structure(s) in the specification and the proper construction for each of the asserted patents.
3. Did Respondents show by clear and convincing evidence that a person of ordinary skill in the art would not find, from reading the specification, that the inventor had "possession" of a hand-held device having the claimed processor for the '228, '456, and '207 patents? *See Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Include citations to expert testimony in your response.
4. Does the language of claim 1 of the '228, '456, and '207 patents require that the "depth data" be the depth of the scanned three-dimensional object? *See* 3Shape Pet. at 13-14.
5. Did Align waive its argument that its domestic industry products practice the asserted patents by introducing a new theory/evidence for the first time in its petition for review? *See* Align Pet. at 43-45; 3Shape Resp. at 19-20.
6. For the '228, '456, and '207 patents, is the evidence relied on by the parties before the ALJ sufficient to establish that the domestic industry products "associate the depth data with the color image data"? Please discuss all relevant evidence.
7. Did Respondents waive their challenge to the specific percentages used to determine the significance of Align's domestic industry investments? Align Resp. at 45.
8. In analyzing domestic industry, did the ID improperly credit expenses that were incurred after the filing of the complaint in this investigation or expenses that were unrelated to the domestic industry products? *See* 3Shape Pet. at 53-54. If certain expenses were

improperly included in the analysis, please discuss whether Align's investments without the improper expenses were significant.

The parties are requested to brief only the discrete issues above, with reference to the applicable law and evidentiary record. 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 Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more 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 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders 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 or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 *Fed. Reg.* 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. Complainant is requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the date that the subject patents expire and the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the Respondents' products at issue in this investigation.

The written submissions and proposed remedial orders must be filed no later than close of business on Tuesday, July 30, 2019. Reply submissions must be filed no later than the close of business on Tuesday, August 6, 2019. Opening submissions are limited to 75 pages. Reply submissions are limited to 50 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 and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) Of the Commission's Rules of Practice and Procedure (19 CFR 2.10.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1091") in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.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. 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,¹ solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

¹ All contract personnel will sign appropriate nondisclosure agreements.

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.

Issued: July 18, 2019.

Lisa Barton,

Secretary to the Commission.

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