

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

**In the Matter of**

**CERTAIN COLOR INTRAORAL  
SCANNERS AND RELATED  
HARDWARE AND SOFTWARE**

**Inv. No. 337-TA-1091**

**NOTICE OF INSTITUTION OF INVESTIGATION**

Institution of Investigation pursuant to 19 U.S.C.1337

**AGENCY:** U.S. International Trade Commission

**ACTION:** Notice

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 14, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of Align Technology, Inc. of San Jose, California. An amended complaint and supplement were filed on December 4, 2017. The amended complaint alleges 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 one or more of U.S. Patent No. 8,363,228 (“the ’228 patent”); U.S. Patent No. 8,451,456 (“the ’456 patent”); U.S. Patent No. 8,675,207 (“the ’207 patent”); U.S. Patent No. 9,101,433 (“the ’433 patent”); U.S. Patent No. 6,948,931 (“the ’931 patent”); and U.S. Patent No. 6,685,470 (“the ’470 patent”). The amended complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

**ADDRESSES:** The complaint, except for any confidential information contained therein, is 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, S.W., Room 112, Washington, D.C. 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (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>.

**FOR FURTHER INFORMATION CONTACT:** The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205-1802.

**SUPPLEMENTARY INFORMATION:**

**AUTHORITY:** The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10 (2017).

**SCOPE OF INVESTIGATION:** Having considered the complaint, the U.S. International Trade Commission, on December 13, 2017, **ORDERED THAT** –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain color intraoral scanners and related hardware and software by reason of infringement of one or more of claims 1, 2, 4, 5, 7, 18, 20, 21, and 26 of the '228 patent; claims 1-8 and 15-18 of the '456 patent; claims 1, 2, 4, and 15-21 of the '207 patent; claims 1, 4, 7, 10, 12, and 14 of the '433 patent; and claims 1-12 of the '931 patent; and claims 1-12 of the '470 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Align Technology, Inc.  
2820 Orchard Parkway  
San Jose, CA 95134

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

3Shape A/S  
Holmens Kanal 7,  
1060 Copenhagen K,  
Denmark

3Shape, Inc.  
10 Independence Boulevard  
Suite 150  
Warren, NJ 07059

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge, and the Chief Administrative Law Judge is authorized to consider whether to consolidate Inv. No. 337-TA-1091 with Inv. No. 337-TA-1090, and to consolidate them if he deems it appropriate.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.



Lisa R. Barton  
Secretary to the Commission

Issued: December 14, 2017

**PUBLIC CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **NOTICE OF INSTITUTION OF INVESTIGATION** has been served upon the following parties as indicated, on 12/14/2017



Lisa R. Barton, Secretary  
U.S. International Trade Commission  
500 E Street, SW, Room 112  
Washington, DC 20436

**Complainants:**

Align Technology, Inc.  
2820 Orchard Parkway  
San Jose, CA 95134

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

**On Behalf of Complainants:**

Blair M. Jacobs, Esq.  
**PAUL HASTINGS LLP**  
875 15<sup>th</sup> St. NW  
Washington, DC 20005

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

**Respondents:**

3Shape A/S  
Holmens Kanal 7, 4  
1060 Copenhagen K, Denmark

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

3Shape, Inc.  
10 Independence Boulevard, Suite 150  
Warren, NJ 07059

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

**CERTAIN INTRAORAL SCANNERS AND RELATED  
HARDWARE AND SOFTWARE**

**Inv. No. 337-TA-1091**

Certificate of Service – Page 2

**Embassy:**

Royal Danish Embassy  
3200 Whitehaven Street NW  
Washington, DC 20008

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

**Government Agencies:**

Edward T. Hand, Chief  
Foreign Commerce Section  
Antitrust Division  
U.S. Department of Justice  
450 5<sup>th</sup> Street NW, Room 11000  
Washington, DC 20530

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

U.S. Bureau of Customs and Border Protection  
Intellectual Property Rights Branch  
Mint Annex Building  
799 9<sup>th</sup> Street, NW, 7<sup>th</sup> floor  
Washington, DC 20229-1177

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

Elizabeth Kraus, Deputy Director  
International Antitrust, Office of  
International Affairs  
Federal Trade Commission  
600 Pennsylvania Avenue, Room 498  
Washington, DC 20580

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
National Institutes of Health  
31 Center Drive  
Bldg. 31, Rm. 47  
Bethesda, MD 20892

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

Align Technology Inc.  
2820 Orchard Parkway  
San Jose, CA 95134

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Sir/Madam:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

Blair M. Jacobs  
Paul Hastings LLP  
875 15th Street NW  
Washington, DC 20005

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Blair M. Jacobs:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

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Lisa R. Barton  
Secretary

Enclosures:

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2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

3Shape A/S  
Holmens Kanal 7 1060 Copenhagen K.  
Denmark

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). 3Shape A/S is a named respondent in this investigation.

We are hereby serving you with a copy of the Complaint and the Notice of Investigation issued in this matter. Enclosed is a copy of the Code of Federal Regulations. Also enclosed is a the Section 337 Mediation Program brochure. After reviewing this brochure, please sign and return the enclosed certification of receipt.

Please note that the Notice requires a response to the allegations in the Complaint and the response must be received not later than twenty (20) days after the date of service of the Complaint. Failure to file a response may result in inferences being drawn against your interests.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Complaint
2. Notice of Investigation
3. Code of Federal Regulation
4. Publication Regarding the Section 337 Mediation Program
5. Certification of Receipt of Mediation Materials





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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

3Shape Inc.  
10 Independence Blvd Suite 150  
Warren, NJ 71059

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). **3Shape Inc.** is a named respondent in this investigation.

We are hereby serving you with a copy of the Complaint and the Notice of Investigation issued in this matter. Enclosed is a copy of the Code of Federal Regulations. Also enclosed is a the Section 337 Mediation Program brochure. After reviewing this brochure, please sign and return the enclosed certification of receipt.

Please note that the Notice requires a response to the allegations in the Complaint and the response must be received not later than twenty (20) days after the date of service of the Complaint. Failure to file a response may result in inferences being drawn against your interests.

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Lisa R. Barton  
Secretary

Enclosures:

1. Complaint
2. Notice of Investigation
3. Code of Federal Regulation
4. Publication Regarding the Section 337 Mediation Program
5. Certification of Receipt of Mediation Materials



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

Embassy of Denmark  
3200 Whitehaven Street NW  
Washington, DC 20008

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). One or more of the parties named in the investigation is located in **Denmark**.

Pursuant to Commission Rule 210.11(a) (3), we are hereby serving you with a copy of the Complaint filed in this investigation together with a copy of the Commission's Notice of Investigation.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Complaint
2. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

Edward T. Hand, Chief  
Foreign Commerce Section  
Antitrust Division  
U.S. Dept of Justice  
450 5th Street NW, Room 11000  
Washington, DC 20530

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Mr. Hand:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

Intellectual Property Rights Branch  
Regulations and Rulings  
Office of International Trade  
U.S. Customs and Border Protection  
90 K Street, NE, 10th floor  
Washington, DC 20229-1177

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

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Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

Elizabeth Kraus, Deputy Director  
International Antitrust, Office of  
International Affairs  
Federal Trade Commission  
600 Pennsylvania Avenue, Room 498  
Washington, DC 20580

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Ms. Kraus:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

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Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

December 14, 2017

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
National Institutes of Health  
31 Center Drive  
Bldg. 31, Rm. 47  
Bethesda, MD 20892

**Re: Certain Color Intraoral Scanners and Related Hardware and Software  
Inv. No. 337-TA-1091**

Dear Mr. Berkley:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

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Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation