

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

In the Matter of

**CERTAIN CLEAR ALIGNERS AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1471

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 September 23, 2025, under section 337 of the Tariff Act of 1930, as amended, on behalf of Align Technology, Inc. of Tempe, Arizona. A letter supplementing the complaint was filed on November 20, 2025. The complaint, as supplemented, 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 clear aligners and components thereof by reason of the infringement of certain claims of U.S. Patent No. 11,766,313 (“the ’313 patent”); U.S. Patent No. 11,766,314 (“the ’314 patent”); U.S. Patent No. 8,899,977 (“the ’977 patent”); U.S. Patent No. 12,059,321 (“the ’321 patent”); U.S. Patent No. 10,980,616 (“the ’616 patent”); and U.S. Patent No. 11,490,996 (“the ’996 patent”). The 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, may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. 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>.

FOR FURTHER INFORMATION CONTACT: Susan Orndoff, 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 (2025).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on December 19, 2025, 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 products identified in paragraph (2) by reason of infringement of one or more of claims 1 and 16 of the '313 patent; claims 1,11, and 21 of the '314 patent; claims 1 and 9 of the '977 patent; claim 1 of the '321 patent; claims 1, 12, and 20 of the '616 patent; and claims 1, 17, and 21 of the '996 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “clear plastic aligners used to treat misaligned teeth and bites, and components of those aligners including the tri-layer material used to construct the aligner”;

(3) 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.
410 North Scottsdale Road
Suite 1300
Tempe, Arizona 85288

(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:

Angelalign Technology Inc.
6/F-7/F, Building No. 7, KIC Business Center
No. 500 Zhengli Road
Yangpu District
Shanghai
China

Wuxi EA Medical Instruments
Technologies Co., Ltd.

No.1619, Huishan Avenue
Huishan Economic Development Zone
Wuxi, Jiangsu 214174
China

Wuxi EA Bio-Tech Co., Ltd.
No. 36 Guanshan Road
Xinwu District
Wuxi, Jiangsu 214000
China

Shanghai EA Medical Instruments Co., Ltd.
Room 601-603
No. 500 Zhengli Road
Yangpu District
Shanghai 200433
China

USA Angelalign Technology Corp.
300 Creek View Rd Ste 209
Newark, DE 19711-8548

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

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.

A handwritten signature in black ink, appearing to read "Lisa Barton", enclosed within a thin black rectangular border.

Lisa Barton
Secretary to the Commission

Issued: December 19, 2025