



INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1471]

Certain Clear Aligners and Components Thereof; Notice of a Commission Determination Not to Review an Initial Determination Granting In Part a Motion to Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding chief administrative law judge's ("CALJ") initial determination ("ID") (Order No. 11) granting a motion to amend the complaint and notice of investigation ("NOI") to (1) add allegations of infringement of claim 24 for U.S. Patent No. 11,766,313 ("the '313 patent"); (2) add allegations of infringement of claim 28 for U.S. Patent No. 11,766,314 ("the '314 patent"); (3) add allegations of infringement of claims 2 and 14 for U.S. Patent No. 8,866,977 ("the '977 patent"); and (4) add allegations of infringement of claim 9 for U.S. Patent No. 10,980,616 ("the '616 patent").

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3042. 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, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: On December 29, 2025, the Commission instituted this investigation based on a complaint filed by Align Technology, Inc. of Tempe, Arizona ("Align"). 90 FR 245 (Dec. 29, 2025). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, based on the importation into the United States, the sale for

importation, or the sale within the United States after importation of certain clear aligners and components thereof 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 U.S. Patent No. 12,059,321; claims 1, 12, and 20 of the '616 patent; and claims 1, 17, and 21 of U.S. Patent No. 11,490,996 (“the '996 patent”). *Id.* The Commission’s notice of investigation named the following respondents: Angelalign Technology Inc. of Shanghai, China; Wuxi EA Medical Instruments of Jiangsu, China; Wuxi EA Bio-Tech Co., Ltd. of Jiangsu, China; Shanghai EA Medical Instruments Co. of Shanghai, China; and USA Angelalign Technology Corp. of Newark, Delaware (collectively, “Respondents”). The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On April 14, 2026, Align moved under 19 CFR 210.14 to amend the complaint and NOI to (1) withdraw allegations of infringement of claim 16 and add allegations of infringement of claim 24 for the '313 patent; (2) withdraw allegations of infringement of claim 21 and add allegations of infringement of claim 28 for the '314 patent; (3) withdraw allegations of infringement of claims 1 and 9 and add allegations of infringement of claims 2 and 14 for the '977 patent; (4) withdraw allegations of infringement of claim 1 and add allegations of infringement of claim 9 for the '616 patent; and (5) withdraw allegations of infringement of all asserted claims, claims 1, 17, and 21, of the '996 patent. *Id.* at 1-2. Align argued that good cause exists for this amendment because it promptly moved to add the new claims after it received Respondents technical information and inspected Respondents’ treatment plans and determined it had sufficient information to assert the new claims in good faith. Align further argued that terminating claims would narrow the case and streamline the investigation. *Id.* at 3. Respondents opposed the motion, arguing that “Align had all the information it needed to assert the New Claims when it filed the Complaint in September 2025, and chose not to do so.” *Id.* at 4. Respondents further argued that “‘Align’s purported narrowing of its own case is illusory’ in that the new claims ‘depend directly or indirectly from the independent claims Align purports to

remove’ and thus ‘the limitations of the independent claims purportedly being removed are still part of this Investigation.’” *Id.* at 3.

On March 7, 2022, the CALJ issued the subject ID, granting the motion but only as to adding the new claims. The ID observed that Commission Rule 210.14(b) proves in part that

[a]fter an investigation has been instituted, the complaint and notice of investigation may be amended only by leave of the Commission for good cause shown and upon such conditions as are necessary to avoid prejudicing the public interest and the rights of the parties to the investigation.

Id. at 2 (citing 19 CFR 210.14(b)). The ID found that good cause exists to amend the complaint and NOI to add the new claims because “adjudicating the proposed claims here—rather than postponing them to subsequent litigation—will be a more efficient use of judicial and party resources.” *Id.* at 4. The ID also found that Respondents were “on notice that Align intended to assert the new claims at least as early as February 27, 2026, when it received Align’s initial responses to contention interrogatories” and “will have had time to explore defenses before the close of fact discovery on May 7, 2026, and the close of expert discovery on June 15, 2026.” *Id.* The ID denied Align’s motion to withdraw claims because Align did not comply with Commission Rules for terminating claims. *Id.* (citing 19 CFR 210.21(a)(1)).

On May 11, 2026, Respondents filed a petition for review challenging the ID’s finding that Align showed good cause to amend the complaint and NOI. On May 18, 2026, Align filed a response to Respondents’ petition.

Having reviewed the current record of the investigation, including the ID, the parties’ submissions to the CALJ, the petitions for review, and the responses thereto, the Commission has determined not to review the subject ID. The Commission notes that Align is adding allegations of infringement with respect to dependent claims found in patents that are already asserted in the investigation. Moreover, Align timely moved to add these claims after it received technical

information necessary to evaluate infringement of the new claims. *See* ID at 4. In addition, Align has stated that it is amenable to Respondents supplementing their contention interrogatory responses and other adjustments “to address the Dependent Claims” added by the amendment. *Id.* The Commission further notes that nothing prevents the Respondents from petitioning the CALJ to extend the time to accommodate the newly asserted dependent claims if necessary. The following claims have been added to the investigation: (1) claim 24 of the ’313 patent; (2) claim 28 of the ’314 patent; (3) claims 2 and 14 of the ’977 patent; and (4) claim 9 of the ’616 patent.

The Commission vote for this determination took place on June 3, 2026.

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: June 3, 2026.

Lisa Barton,

Secretary to the Commission.