



INTERNATIONAL TRADE COMMISSION

Investigation No. 337-TA-833

Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making the Same: Commission Determination to Affirm-In-Part, Modify-In-Part, and Reverse-In-Part the Final Initial Determination and to Find a Violation of Section 337;

Issuance of Cease and Desist Orders; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final initial determination (“final ID” or “ID”), and to find a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (“Section 337”) in the above-captioned investigation. The Commission has issued cease and desist orders.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. 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, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The

public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://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: This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc., of San Jose, California (“Align”), on March 1, 2012, as corrected on March 22, 2012. 77 FR 20648 (April 5, 2012). The complaint alleged violations of Section 337 in the sale for importation, importation, or sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 6,217,325 (“the ‘325 patent”); U.S. Patent No. 6,471,511 (“the ‘511 patent”); U.S. Patent No. 6,626,666 (“the ‘666 patent”); U.S. Patent No. 6,705,863 (“the ‘863 patent”); U.S. Patent No. 6,722,880 (“the ‘880 patent”); U.S. Patent No. 7,134,874 (“the ‘874 patent”); and U.S. Patent No. 8,070,487 (the ‘487 patent”). The notice of institution named as respondents ClearCorrect Pakistan (Private), Ltd. of Lahore, Pakistan (“CCPK”) and ClearCorrect Operating, LLC of Houston, Texas (“CCUS”) (collectively, “the Respondents”).

On May 6, 2013, the presiding administrative law judge (“ALJ”) issued the final ID, finding a violation of Section 337 with respect to the ‘325 patent, the ‘880 patent, the ‘487 patent, the ‘511 patent, ‘863 patent, and the ‘874 patent. He found no violation as to the ‘666 patent. The ALJ recommended the issuance of cease and desist orders directed to the Respondents.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto.

On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

On June 16, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013.

On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. 78 FR 46611 (August 1, 2013). On August 8, 2013, each of the parties filed written submissions. On August 15, 2013, each filed reply submissions.

On September 24, 2013, the Commission issued notice of its determination to extend the target date to November 1, 2013.

On November 18, 2013, the Commission issued notice of its determination to extend the target date to January 17, 2014.

On January 17, 2014, the Commission determined to extend the target date for completion of the above-captioned investigation to March 21, 2014, and to solicit additional briefing from the parties and the public.

On March 21, 2014, the Commission issued notice of its determination to extend the target date for completion of the investigation to April 3, 2014.

After considering the ID and the relevant portions of the record, and the submissions of the parties and the public, the Commission has determined to affirm-in-part, modify-in-part, and

reverse-in-part the final ID and to find a violation of Section 337. The Commission has issued its opinion setting forth the reasons for its determination. Commissioner Johanson dissents and has filed a dissenting opinion.

Specifically, the Commission affirms the ALJ's conclusion that the accused products are "articles" within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B). The Commission has determined to find a violation with respect to (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. The Commission has issued cease and desist orders directed to CCUS and CCPK, with an exemption for activities related to treatment of existing patients in the United States. The investigation is hereby terminated.

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.

Lisa R. Barton

Acting Secretary to the Commission

Issued: April 3, 2014