

**UNITED STATES INTERNATIONAL TRADE COMMISSION**  
**Washington, D.C. 20436**

**In the Matter of**

**CERTAIN INCREMENTAL DENTAL  
POSITIONING ADJUSTMENT  
APPLIANCES AND METHODS OF  
PRODUCING SAME**

**Investigation No. 337-TA-562**

**NOTICE OF COMMISSION DETERMINATION TO REVIEW-IN-PART  
AN INITIAL DETERMINATION GRANTING COMPLAINANT'S MOTION FOR  
SUMMARY DETERMINATION STRIKING AN AFFIRMATIVE DEFENSE OF  
INVALIDITY**

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

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review-in-part an initial determination ("ID") (Order No. 6) of the presiding administrative law judge ("ALJ") granting complainant's motion for summary determination striking an affirmative defense of invalidity.

**FOR FURTHER INFORMATION:** Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-3152. Copies of the ID and all other nonconfidential 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. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810. 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>.

**SUPPLEMENTARY INFORMATION:** On February 15, 2006, the Commission instituted an investigation under section 337 of the Tariff Act of 1930, 19 U.S.C. §1337, based on a complaint filed by Align Technology Inc. of Santa Clara, California ("Align"), alleging a violation of section 337 in the importation, sale for importation, and sale within the United States after importation of certain incremental dental positioning adjustment appliances by reason of

infringement of certain claims of U.S. Patent Nos. 6,685,469; 6,450,807; 6,394,801; 6,398,548; 6,722,880; 6,629,840; 6,699,037; 6,318,994; 6,729,876; 6,602,070; 6,471,511; and 6,227,850. The complaint also alleged a violation of section 337 by reason of misappropriation of trade secrets. 71 *Fed. Reg.* 7995 (February 15, 2006). The complainant named OrthoClear, Inc. of San Francisco, California; OrthoClear Holdings, Inc. of Tortola, British Virgin Islands; and OrthoClear Pakistan Pvt, Ltd. of Lahore, Pakistan (collectively, “OrthoClear”) as respondents.

On April 14, 2006, complainant Align filed a motion for summary determination striking affirmative defenses of invalidity. On May 16, 2006, the ALJ issued an ID (Order No. 6) granting Align’s motion.

On May 23, 2006, OrthoClear filed a petition for review of Order No. 6. On May 31, 2006, complainant Align filed its opposition to OrthoClear’s petition. On June 2, 2006, the Commission investigative attorney (“IA”) filed her response to OrthoClear’s petition in which the IA opposed OrthoClear’s petition.

The Commission has determined to review Order No. 6 to the extent that the ALJ determined that the Commission IA is not prohibited by the order from challenging the validity of the patents-in-suit. ID at 19, 20. The Commission has determined not to review Order No. 6 to the extent that the ALJ granted the motion for summary determination striking the respondents’ affirmative defense of invalidity. ID at 20.

On review, the parties are requested to submit briefing with respect to whether the Commission IA may challenge the validity of the patents-in-suit in the absence of such a challenge by any other party. In addressing that issue, the parties are requested to cite any relevant authorities, and in particular to comment on the relevance of the decision of the U.S. Court of Appeals for the Federal Circuit in *Lannom Manufacturing Co., Inc. v. U.S. International Trade Commission*, 799 F.2d 1572, 1580 (Fed. Cir. 1986) (“We conclude, therefore, that Congress did not authorize the Commission to redetermine patent validity when no defense of invalidity has been raised[;]” and “[t]he statute authorizes the Commission to consider ‘all legal and equitable defenses’, including that of patent invalidity, when, as the legislative history states, such issues are raised.”). In that respect, the parties may wish to comment on an investigation cited in *Lannom*, entitled *In re Certain Caulking Guns*, Inv. No. 337-TA-139, 223 USPQ 388 (USITC 1984). *Lannom Manufacturing*, 799 F.2d at 1578.

**WRITTEN SUBMISSIONS:** The written submissions should be concise and thoroughly referenced to the record in this investigation. The written submissions must be filed no later than the close of business on July 14, 2006. Reply submissions must be filed no later than the close of business on July 21, 2006. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request

confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R § 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

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 section 210.42 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.42).

By order of the Commission.

/s/  
Marilyn R. Abbott  
Secretary to the Commission

Issued: June 29, 2006