

Align Technology is a publicly traded medical device company engaged in the design, manufacture and marketing of the Invisalign® system, the world's leading invisible orthodontic product, and the iTero® Intraoral scanning systems and services. Align Technology went public on the NASDAQ market under the trading symbol ALGN in January 2001.

## **Administrative Law Judge Determines 3Shape Infringes Three Align Patents; Initial Determination Declines to Find Section 337 Violation**

March 7, 2019

- **Align Will Seek Commission Review of ALJ's Initial Determination**
- **ALJ Declines to Address Two Other Align Patents because of Delay Resulting from U.S. Government Shutdown**

SAN JOSE, Calif., March 07, 2019 (GLOBE NEWSWIRE) -- Align Technology, Inc. (NASDAQ: ALGN) announced today that on March 1, 2019 an Administrative Law Judge (ALJ) with the United States International Trade Commission (ITC) issued an Initial Determination regarding his investigation of 3Shape's infringement of Align's patents. The ALJ determined that 3Shape infringes four claims from three Align patents, but declined to find a violation of Section 337 because, based on the ALJ's claim construction, he found that Align's own products do not practice the claims (a requirement unique to the ITC) and that certain claims are invalid. Notably, the ALJ also found that an order excluding the accused 3Shape products from import into the United States is appropriate should the Commission, upon its further review of the Initial Determination, find a violation occurred.

"We are pleased that the Initial Determination confirms our belief that 3Shape infringes Align's core patents regarding color intraoral scanning technology. As always, we remain committed to protecting our significant investment in innovation," said Roger George, senior vice president, chief legal and regulatory officer, general counsel and secretary. "Far from rejecting Align's claims, the ALJ found that 3Shape infringes Align's patents, but declined to find a Section 337 violation. To that end, we will seek review of the claim construction and related validity rulings that prevented the ALJ from recommending exclusion of 3Shape's infringing products from the United States, a remedy the Initial Determination found would be appropriate."

The ALJ declined to make any findings regarding two other patents raised by Align. These two patents in question are scheduled to expire after the original target date for conclusion of the investigation. Because of the government shutdown, the target date for conclusion of the investigation was extended and the two patents will expire prior to that date, thus greatly diminishing the likelihood of any remedy at the ITC.

The Initial Determination is now subject to review by the Commissioners at the ITC. Align intends to petition for review of the findings it believes are incorrect. Respondents may also petition for review of the Initial Determination. The Commission will then decide whether to review portions of or the entire Initial Determination. Once the issues under review have been briefed, the Commission may affirm, set aside, or modify the portions of the Initial Determination under review. These conclusions will be contained in a Final Determination which is currently scheduled to be issued by the Commission by July 1, 2019.

The parallel federal district court case filed by Align in Delaware, alleging infringement of the same patents, remains stayed pending the Final Determination and any related appeals. The Delaware federal district court cases alleging infringement of different patents not included in the ITC investigations are not stayed and are being actively litigated, with trials scheduled for the first half of next year.

### **About Align Technology, Inc.**

Align Technology designs and manufactures the Invisalign® system, the most advanced clear aligner system in the world, and iTero® intraoral scanners and services. Align's products help dental professionals achieve the clinical results they expect and deliver effective, cutting-edge dental options to their patients. Visit [www.aligntech.com](http://www.aligntech.com) for more information.

For additional information about the Invisalign system or to find an Invisalign doctor in your area, please visit [www.invisalign.com](http://www.invisalign.com). For additional information about the iTero digital scanning system, please visit [www.itero.com](http://www.itero.com).

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The logo for Align Technology, featuring the word "align" in a lowercase, sans-serif font. The letter "i" is stylized with a blue dot above it.

Source: Align Technology, Inc.