

International Trade Commission (ITC) Issues Its First Stay of a Cease and Desist Order (CDO)

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In the matter 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 Same

For the first time the **U.S. International Trade Commission (U.S. ITC)** issued a stay of a cease and desist order (CDO) issued at the conclusion of an investigation under § 337 of the **Tariff Act**. ***In the matter 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 Same***, Investigation No. 337-TA-833.

The investigation was instituted on April 5, 2012 based on a complaint by **Align Technology**. The complaint alleged that respondents' digital models, digital data and treatment plans for use in making incremental dental appliances infringed seven patents. The administrative law judge (ALJ) Rogers found a **violation of § 337** with respect to six of the patents and recommended a CDO. Over a rare dissent (by Commissioner Johanson) the Commission affirmed-in-part, modified-in-part and reversed-in-part, issued CDOs and terminated the investigation. In his dissent, Commissioner Johanson argued that data sets cannot be considered "articles" within the meaning of § 337.

Pursuant to § 10(d) of the **Administrative Procedure Act**, the respondents filed a motion to stay the CDO pending appeal. The respondents argued that whether electronic transmissions are "articles" within the meaning of § 337 was a "difficult question," that the CDOs would cause irreparable harm in the form of layoffs, disruption of operations and impaired relationships with vendors, as well as that the public interest supported a stay because doctors would not have an adequate substitute for the banned products. Align opposed the motion and argued that the Commission's decision concerning "articles" was entitled to deference and that no "difficult" question was presented.

The standard for a motion to stay under the APA is the same four part test as is used for adjudicating motions for preliminary injunction: likelihood of success on the merits; irreparable harm absent a stay; harm to other parties interested in the proceeding; and public interest. The Commission has explained that each element of the test does not have to be given equal weight and that the likelihood of success element is generally futile in this context. Accordingly, a stay of a Commission remedy may be appropriate when the Commission has ruled on "an admittedly difficult question and when

the equities of the case suggest that the status quo should be maintained.”

The Commission agreed with the respondents’ that the question of the meaning of the term “articles” § 337 was difficult one and that the extensive legal analysis already undertaken demonstrated the difficulty of the issue. The Commission agreed with Align “that the difficulty of the question presented counsels in favor of judicial deference to an agency’s interpretation of its organic statute,” however “the existence of that deference does not, in and of itself, obviate the fact that the question ruled upon by the Commission was a difficult one.” The Commission went on to find the respondents’ irreparable-harm arguments persuasive, in particular the fact that absent a stay Respondents would be forced to discontinue operations completely or drastically reduce its workforce.

The Commission stayed the CDOs, but noted that the decision “should not be viewed as a sharp departure from prior determinations denying stays” and that experience demonstrates that most investigations do not justify a stay of the remedies.

Practice Note: While the Commission stayed this CDO, such orders are unlikely to become a common practice at the ITC. An order staying a remedy remains extremely exceptional, but this decision provides a data point for a respondent confronted with a commission Decision that is truly one of first impression.

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