

# Client Alert

International Trade &amp; Litigation Practice Group

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## Trade Remedies Are Being Used to Combat Imports of Infringing Medical Devices

Medical device cases are being filed with increasing frequency at the U.S. International Trade Commission (ITC) to combat infringing imports. In particular, owners of intellectual property rights on medical devices regularly utilize the protections provided by Section 337 of the Tariff Act of 1930. Section 337 makes unlawful the importation into the United States of articles that infringe a valid U.S. patent, trademark or copyright. Section 337 also can be used to prevent imports of counterfeit, smuggled or gray-market medical devices.

A number of Section 337 investigations involving medical devices and pharmaceuticals have been instituted in recent years, including the following:

- *Certain Vaginal Ring Birth Control Devices*, Inv. No. 337-TA-768;
- *Certain Gemcitabine and Products Containing the Same*, Inv. No. 337-TA-766;
- *Adjustable-Height Beds and Components Thereof*, Inv. No. 337-TA-734;
- *Devices Having Elastomeric Gel and Components Thereof*, Inv. No. 337-TA-732;
- *Vein Harvesting Surgical Systems and Components Thereof*, Inv. No. 337-TA-645; and
- *Catheters, Consoles and Other Apparatus for Cryosurgery, and Components Thereof*, Inv. No. 337-TA-642.

Section 337 has many desirable features for complainants, including speed, well-informed judges, and effective remedies. The average Section 337 case proceeds from filing of the complaint to final judgment in approximately 16 months. Section 337 cases are adjudicated by administrative law judges (ALJs) who specialize in intellectual property infringement cases. And the ITC can exclude infringing articles from entering the United States and can

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issue a cease and desist order prohibiting infringing activities with respect to articles already in the U.S.

The ITC investigates Section 337 allegations, and it completes most investigations within 16 months of the filing of the complaint. The complainants' case initially is adjudicated by an ALJ. The ITC ALJs specialize in adjudicating intellectual property rights. During these proceedings, the ALJ makes an initial determination as to whether the patent or other intellectual property right is valid and infringed, and whether the other elements of a Section 337 violation have been met, including importation of infringing articles and the existence of a domestic industry. Activity that meets the domestic industry requirement includes U.S.-based manufacturing, research and development, engineering and licensing. The ALJ also makes a recommendation as to the appropriate remedy the ITC should issue.

If Section 337 has been violated, the ITC is required to issue a limited exclusion order barring infringing articles of the named respondents from entering the U.S. In certain circumstances, the ITC also may issue a general exclusion order against infringing articles irrespective of whether they are the articles of the named respondents. The ITC also may issue a cease and desist order prohibiting the respondents found to violate Section 337 from continuing their infringing activities with respect to articles already in the U.S. The ITC also evaluates whether an exclusion order or cease and desist order would be in the public interest, and Section 337 investigations are subject to mandatory review by the President.

Section 337 makes the ITC an important alternative to district courts as an effective forum for intellectual property litigation. Section 337 can be utilized by both U.S. and foreign holders of intellectual property rights, provided that there has been sufficient domestic activity to exploit the intellectual property at issue. Section 337 also may be preferable to district court litigation due to both the speed of the proceeding and the available relief, which is much faster than most district court actions. Section 337 also allows the complainant to obtain injunctive relief quickly, and without having to meet the test for injunctive relief required in the district courts. Although damages are not available at the ITC, there is no preclusion against settlements, including licensing agreements.

For additional information about the use of Section 337 to combat imports of medical devices that infringe U.S. intellectual property rights, please contact us.

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