

## WHY PHARMA SHOULD CONSIDER THE ITC

***The number of ITC cases involving pharmaceuticals, biotechnology, and medical devices is increasing. Given the ITC's expansive jurisdiction and powerful remedy to protect its U.S. market, we have seen recent publicly filed cases involving such companies as AbbVie, Genzyme, BASF, Ventria Bioscience, ARK Diagnostics, Celanese, Teva, Hanmi Pharmaceutical, Fosun Pharma, Sharda Cropchem, Thomas Scientific, and eEnzyme. Below are some considerations that we would be pleased to discuss.***

### The ITC's Attraction for Patentees

The ITC may be an attractive forum for disputes involving global trade, and competitors who manufacture abroad. Because the ITC's jurisdiction is not limited to the United States, a violation of Section 337 may be premised on unlawful activities occurring outside the United States. The ITC has the authority to **stop importation of articles** that have been sold abroad for importation to the United States. A foreign sale even without proof of a subsequent importation may be the basis for institution of an investigation into unlawful acts such as patent infringement, trade secret theft, false claims, and unfair competition. The ITC's discovery jurisdiction is unlimited for a named foreign respondent, giving tools for building a case of trade secret theft, patent infringement, and/or unfair competition outside the United States.

### Filing an ITC Complaint

A complainant must identify imported articles. Although importation must be an article, the asserted patent claims or trade secret may be a method. In the pharma space, the imported article may be a compound that is later incorporated into a U.S. patented composition. Or the compound may have been made by a patented process outside the United States. In this regard, the 271(g) exceptions may not apply in the ITC. The imported article may also be a pharmaceutical deliverable containing a U.S. patented pharmaceutical or kit with an infringing use.

A **domestic industry** is required, meaning the complainant or its licensee must have a product that is covered by the asserted IP or trade secret. There must also be U.S. investments related to the covered product(s). The U.S. investments may be in research and development, production, packaging, client educational and technical training, marketing, and sales of the covered product. It is not necessary that the covered product are manufactured in the United States.

### Excluding the Competitor

The ITC's **remedy** can be powerful. A successful ITC investigation removes the unlawful product from the U.S. market. The ITC's exclusion order directs U.S. Customs and Border Protection to stop the product at the border. The ITC may also prohibit all U.S. activities with respect to the unlawful product by stopping all distribution, sales, marketing, and advertising.

In IP cases, the **term of exclusion** is based on the validity and enforceability of the IP. In trade secret cases, the term may be for as long as it took to develop the trade secret or reasonable time to independently develop. Although the ITC must consider **the public interest impact** of its remedial orders, only once has the ITC withheld a permanent remedy to exclude a medical device or pharmaceutical, and that was because the complainant's could not supply the U.S. market.

For more information please contact:

**Kecia Reynolds** | Leader | ITC Litigation | [keciareynolds@paulhastings.com](mailto:keciareynolds@paulhastings.com) | +1.202.551.1740