

Insights: Publications

Using the ITC to Litigate Biopharma Cases: An Introduction

Corporate Disputes Magazine

March 23, 2026

The US International Trade Commission (ITC) is a federal agency with a powerful but often overlooked role in the enforcement of intellectual property (IP) rights, especially patents.

Unlike district courts, the ITC does not award damages. Instead, it provides some of the strongest remedies available in US law: the limited exclusion order, an order barring the defendant's infringing products from entering the US market, and the general exclusion order, which stops any and all infringing products from entering the US, regardless of the party making or selling them.

For biopharma companies facing global competition and complex infringement scenarios, the ITC offers a unique and often underutilised forum for protecting proprietary innovations.

The ITC's authority to investigate and adjudicate allegations of unfair trade practices, including IP infringement, arises under section 337 of the Tariff Act of 1930. Section 337 investigations have become a critical part of the US patent enforcement landscape, especially in industries characterised by high research and development (R&D) costs, short product lifecycles or substantial international competition.

In 2025 alone, the ITC presided over 25 percent of all patent trials in the US, reflecting the ITC's importance as a forum for resolving patent disputes across a variety of industries, including biopharma, chemicals and medical devices.

Types of products involved:

Biopharma and chemical ITC investigations have covered a wide array of products, such as: (i) medical equipment, including X-ray devices, surgical staplers, electrocardiograms, bone cements, hydrodermabrasion devices and lasers; (ii) chemicals such as pyraclostrobin, potassium chloride and ultraviolet coatings; (iii) pharmaceuticals including Botox, tirzepatide, albumins, recombinant factors VIII and IX, taurine, and adalimumab; and (iv) laboratory and diagnostic devices such as glucose monitoring strips, blood separating systems, digital polymerase chain reaction systems and immunoassays.

Related People



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