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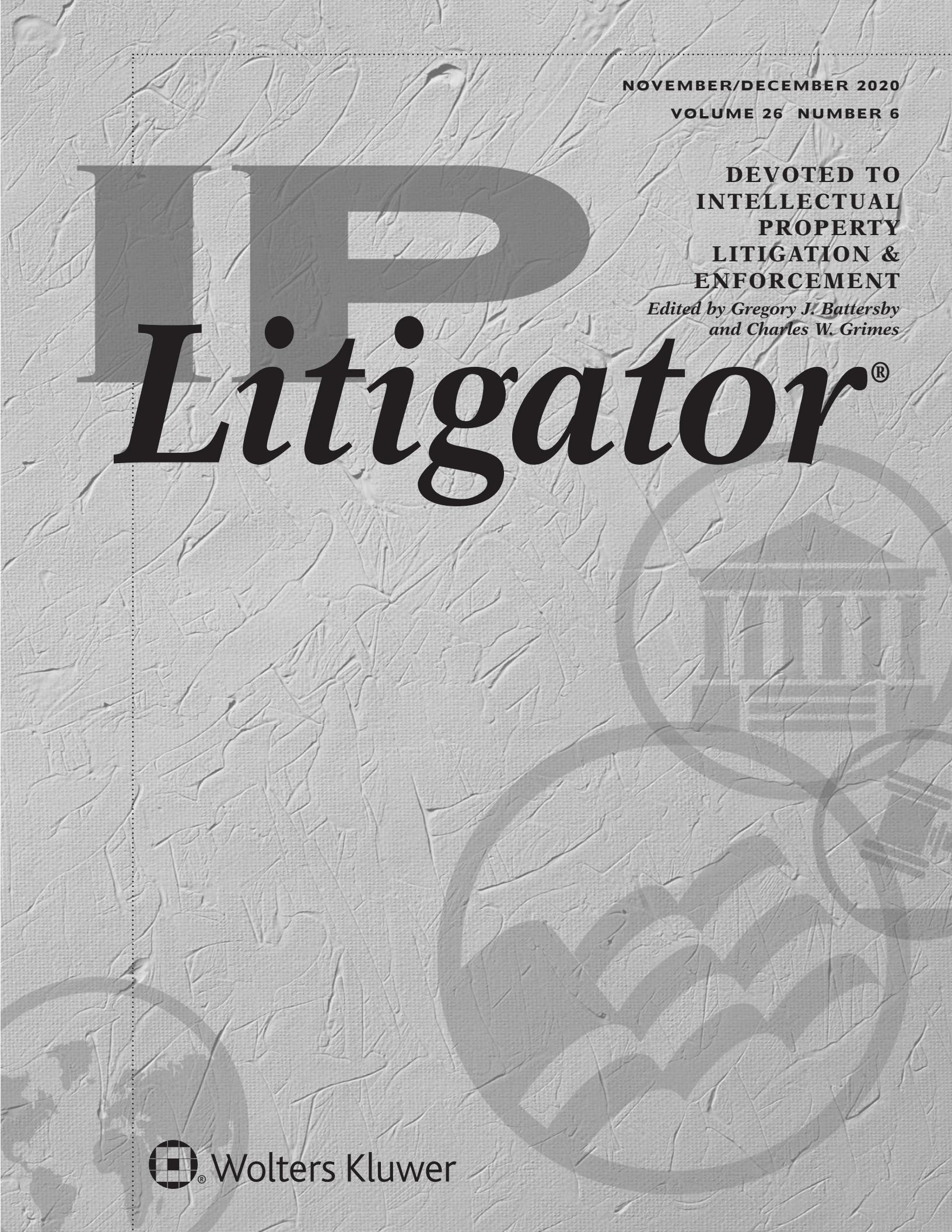

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ITC Proceedings

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ALJ's Initial Determination Implicates Scope of Territorial Jurisdiction and Trade Secret Protections against Unfair Imports

On August 6, 2020, the U.S. International Trade Commission (ITC) released a public version of the Final Initial Determination (ID) in the *Matter of Botulinum Toxin Products* (Inv. No. 337-TA-1145), that, if upheld by the full Commission, might signal an expansive view of the ITC's territorial jurisdiction and the scope of trade secret protection. The ITC's jurisdiction in trade secret investigations is limited to matters that destroy or substantially injure a "domestic industry in the United States." A key aspect of the ID is that it recommends banning importation of a Botox®-competitor product, Jeuveau® that was found to incorporate misappropriated trade secrets of a foreign Complainant whose domestic licensee and Co-Complainant have *yet to make any sales* of that product in the United States. The ID also found "domestic injury" based on the licensee's industry, not the licensed trade secret's industry. The Commission will issue its Final Determination in November, after press time for this article.

Background of the Complaint

The Complainants here are Medytox Inc., a Korean-based pharmaceutical company, Allergan plc of Dublin, Ireland, and Allergan, Inc. of Irvine, California. Medytox developed Innotox, a drug similar to Botox® based on the living neurotoxic bacteria botulinum, and licensed to Allergan the right to distribute Innotox worldwide (except in Korea). Allergan is also responsible for domestic manufacturing and commercialization of the competing product Botox®. In the ITC complaint, Complainants allege that Respondent Daewoong Pharmaceutical Co. misappropriated Medytox's trade secrets in Korea by stealing a potent strain of the botulinum bacteria to develop, manufacture, and import Jeuveau®, sold in the United States by Respondent Evolus, to compete directly with Allergan's Botox®. The Complainants focused their domestic industry evidence on facts specific to Allergan, the licensee of the purported trade secret. In other words, the domestic industry analysis was based on harm to Allergan's market share in Botox®, rather than the licensed Innotox or the trade secrets at issue.

Medytox and Allergan brought this matter under Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), which authorizes the ITC to halt importation of goods into the United States if (1) their production is the result of unfair trade practices, including misappropriation of trade secrets, and (2) the importation would destroy or substantially injure a domestic industry.

The Ruling

The Administrative Law Judge (ALJ) in the case recommended a 10-year ban of Daewoong's importation of Jeuveau®, but if the Commission limited the misappropriation finding solely to the manufacturing process, the ALJ recommended a 21-month ban. The ALJ also recommended a cease-and-desist order against Respondent Evolus to enjoin sales of its domestic inventory of Jeuveau®. In making the recommendation, the ALJ found sufficient evidence of injury to the domestic industry of Medytox's licensee, Allergan. Allergan, however, has yet to sell the licensed Innotox in the United States and had no plans to do so until 2021 or 2022. The ALJ rejected the Respondents' argument that this case was a wholly foreign dispute between foreign companies with no relevant domestic injury. Instead, the ALJ found that Allergan has a license to sell imported products from Medytox, and Allergan was likely to lower its pricing for its Botox® products to compete with Daewoong's allegedly misappropriating products. In other words, the ALJ found that potential harm to Allergan's market share in *Botox*®, not the licensed *Innotox*, was sufficient connection to a domestic industry to ban Daewoong's product.

The ID relied on the Federal Circuit's 2011 decision in *TianRui* to find subject matter jurisdiction, quoting:

> [T]he foreign 'unfair' activity at issue in this case is relevant only to the extent that it results in the importation of goods into this country causing domestic injury. In light of the statute's [i.e., Section 337's] focus on the act of importation and the resulting domestic injury, the Commission's order does not purport to regulate purely foreign conduct. Because foreign conduct is used only to establish an element of a claim alleging a domestic injury and seeking a wholly domestic remedy, the presumption against extraterritorial application does not apply.

TianRui Group Co. v. U.S. International Trade Commission, 661 F.3d 1322, 1329 (Fed. Cir. 2011).

As required by Section 337, the Commission solicited comments on the effect the recommended remedy of banning the importation and sale of Jeuveau® would have on the "public interest" of the United States. In response, dozens of public interest statements were recently filed by interested companies, organizations, and scholars, suggesting that if affirmed, the ALJ's finding could lead to anticompetitive practices that make use of the ITC's exclusionary powers. One such statement warned that the ID "is not in the public interest because it creates perverse incentives for dominant U.S. firms to purchase protection from competition." For example, like Allergan, companies could strategically enter into license agreements for competing products that would afford sufficient standing as a domestic industry in the ITC and then leverage the ITC's power to ban importation of all other competing products. The public interest statements noted that in 2018, Allergan settled an antitrust class action challenging its partnership with Medytox and alleging that Allergan purchased the rights to keep Innotox *off* the market and maintain its dominance in U.S. markets. Now, under the ALJ's recommended remedy, Allergan could keep the only other Botox® competitor, Jeuveau®, off the market too.

In addition, several of the public interest statements expressed concern whether a living organism could be a protectable trade secret. Medytox asserted trade secret protection over a bacteria strain. In one public interest statement, Roger M. Milgrim, of the famed *Milgrim on Trade Secrets* treatise, argues that the particular bacteria strain's DNA is based on a bacterium that was first discovered in the 1940s and subject to widespread public research for decades. In other words, the public interest statements took the position that the material at issue had lost its "secret" status.

To further demonstrate concerns over Medytox's purported trade secret assertion, Respondent Daewoong subsequently identified a "new factual development," which it submitted in a confidential filing to the ITC on September 18, 2020. Much of the public version of that filing is redacted, but Daewoong claims it has new facts demonstrating the ALJ's ID was "clearly erroneous when it found that the strain (1) is a trade secret; (2) cannot be purchased on the open market and transferred to South Korea; and (3) would take at least 10 years to independently acquire." Those new facts relate to Daewoong's claim that it has "acquire[d] a copy of [REDACTED] Hall A-hyper strain in question through commercial purchase." Whether the Commission issues a Final Determination recognizing the bacteria as a trade secret or not, this issue will almost certainly be litigated at the Federal Circuit and possibly the Supreme Court of the United States.

The ITC's mandate under Section 337 is to protect industries in the United States from unfair import competition. Whether the ALJ's ID signals that ITC complainants may assert more indirect theories of injury to the domestic industry in matters involving theft of foreign trade secrets overseas to exclude foreign competitors from the U.S. is yet to be seen.

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