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Federal Circuit Clarifies That "Quantitatively Small" Investments Can Establish Significant and Substantial Investment in Domestic Industry

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February 11, 2025, 2:58 PM
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On Friday, Feb. 7, 2025, the Federal Circuit issued a precedential opinion in *Wuhan Healthgen Biotech. Corp. v. U.S. Int'l Trade Comm'n*, No. 23-1389, 2025 WL 420819 (Fed. Cir. 2025). The three-judge panel, consisting of Chief Judge Moore, Judge Chen, and District Judge John F. Murphy of the Eastern District of Pennsylvania sitting by designation, affirmed the Commission's opinion as to infringement and whether domestic industry had been satisfied. This opinion brings good news to small U.S. companies that might not yet have large absolute investments or revenues, as the Court clarified there is no threshold dollar value or rigid formula required to meet the economic prong of the domestic industry requirement.

One of the unique components of Section 337 investigations at the U.S. International Trade Commission (ITC) is the statutory domestic industry (DI) requirement under 19 U.S.C. § 1337(a)(2)-(3), which has no parallel in district court litigations. To meet the "economic prong" of the DI requirement, a complainant must show that it or its licensee has made a "significant investment in plant and equipment; significant employment of labor or capital; or substantial investment in its exploitation, including engineering, research and development, or licensing" in the U.S. with respect to the protected products.

In the present ITC proceeding, Complainant Ventria Bioscience Inc. cited evidence of its investments under all three subsections (plant/equipment, labor, and exploitation). The Commission held that Ventria had met the DI requirement with these "significant and

substantial" investments, noting the high ratio of its investments to its revenue and that 100% of Ventria's investments occurred in the United States. Respondent Wuhan Healthgen appealed and argued the Commission incorrectly relied on qualitative factors to overcome Ventria's "quantitatively small investments" (values redacted from public briefing).

On appeal, Federal Circuit rejected Wuhan Healthgen's argument, elaborating that "a finding of domestic industry cannot hinge on a threshold dollar value or require a rigid formula" and instead requires "a holistic review of all relevant considerations that is very context dependent." Here, the Court held that Ventria's investments being 100% in the U.S. and the high investment-to-revenue ratio signaled that "the company is investing heavily in the industry despite comparatively low revenue, highlighting the industry's importance and value to the company" and that this was "predictive of a significant market." In particular, the Court cited legislative history showing Congress's intent that "smaller businesses should not be denied the right to seek relief merely because they may have made smaller financial investments than large companies." *See id.*

Accordingly, small companies seeking relief at the ITC for violations of Section 337 may be able to meet the DI requirement without high investments, especially when they can show that their investments are predominantly in the U.S. and that the relevant market is a significant one.

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