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The Precedent: Federal Circuit Emphasizes that Dollar Amount Spent is Not Determinative of § 337's Domestic Industry Requirement in *Wuhan Healthgen Biotechnology Corp. v. Int'l Trade Comm'n*

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In this edition of *The Precedent*, we outline the decision in *Wuhan Healthgen Biotechnology Corp. v. Int'l Trade Comm'n*.

Overview

The United States Court of Appeals for the Federal Circuit recently emphasized that Section 337's domestic industry requirement does not focus on the dollar amount a patent holder spends on industry investments but rather the nature of such investments and their relation to the industry within the United States.

Issue

Was Ventria's relatively small investment in the ambulin industry sufficient to satisfy the domestic industry requirement of Section 337?

Holding

Although small, Ventria's investment in the ambulin industry satisfied Section 337's domestic industry requirement because the investment specifically related to Ventria's research, development and commercial production of its products within the United States.

Background and Reasoning

The decision in *Wuhan Healthgen* involved Ventria Bioscience, Inc. (Ventria), a company uniquely tied to the use of animal-friendly alternatives in cell culture media. Despite providing the necessary nutrients for cell growth in an artificial environment, the use of cell culture media has raised ethical concerns, given that it typically contains albumin, a protein derived from animal livers. Seeking to provide an animal-friendly alternative, the cell culture industry began relying on recombinant albumin, a technology that allows for the mass

production of proteins without the use of animal products. Ventria specifically has a patent for cell culture media based around recombinant human serum albumin (rHSA), which it produces in a genetically modified plant.

When Wuhan Healthgen Biotechnology Corp. (Healthgen) began importing rHSA products into the United States, Ventria filed a complaint with the International Trade Commission (ITC), alleging Healthgen violated 19 U.S.C. § 1337. Specifically, Ventria alleged Healthgen had violated Section 337, which encompasses unfair practices in import trade, by importing products that infringed on Ventria's patent. The sitting administrative law judge found both that (1) the products Healthgen imported infringed Ventria's patent; and (2) Ventria had satisfied the "domestic industry" requirement of Section 337. Both the ITC and the Federal Circuit affirmed the judge's findings. The Federal Circuit's analysis of Section 337's domestic industry requirement, however, creates lasting implications for the evaluation of patent holders' industry investments and should not be overlooked.

Section 337 addresses unfair practices in import trade. To show a patent infringement-based violation under the statute, Section 337(a)(2) requires a patent holder to demonstrate "an industry in the United States, relating to the articles protected by the patent[,] exists or is in the process of being established." Healthgen conceded that the products it imported practiced Ventria's patent but disputed that Ventria satisfied Section 337's domestic industry requirement because Ventria had only made relatively small investments into its industry. Thus, the crux of the Federal Circuit's analysis was whether Ventria had satisfied the domestic industry requirement.

Ultimately, the Federal Circuit disagreed with Healthgen, finding that Ventria's investments in its industry, while small, were sufficient to satisfy Section 337's domestic industry requirement. Specifically, the court found Ventria's investments in plant and equipment costs satisfied the domestic industry requirement because the entirety of the investments was made within the United States. Of particular importance was the court's emphasis that a finding of domestic industry does not hinge on dollar value but rather a review of all relevant considerations. Here, although the dollar amount of Ventria's investments were relatively small, the Court valued the fact that the investments were made exclusively within the United States and related specifically to the research, development and commercial production of Ventria products within the country. Accordingly, the court rejected Healthgen's contention that the dollar amount spent was determinative of the domestic industry requirement and found the nature of Ventria's small investments to satisfy Section 337.

Takeaways

Wuhan Healthgen serves as strong precedent for patent holders claiming unfair import trade practices under Section 337. The Federal Circuit's emphasis that Section 337's domestic industry requirement does not focus solely on dollar amount serves as a reminder to patent holders that the amount spent on domestic investment is less important than the actual ways in which the money is spent and where it is spent. According to the Federal Circuit, even small investments will satisfy Section 337's domestic industry requirement where specifically allocated toward the research, development and production of the patented products within the United States.