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26 February 2025 | Features | Patents | Cristen Corry, Paul Ainsworth And Uma Everett

Fed Circ ruling opens ITC door to small corporations

A decision in Wuhan Healthgen Biotech v ITC means smaller US companies can now choose to take on much larger, foreign opponents at the ITC, explain Cristen Corry, Paul Ainsworth and Uma Everett of Sterne Kessler.

According to a recent opinion [paywall] by the US Court of Appeals for the Federal Circuit, a domestic industry may never be too small as long as the commercial product is 100% American-made.

In ***Wuhan Healthgen Biotech v ITC,*** the Federal Circuit affirmed the US International Trade Commission's (ITC) conclusion that a patentee satisfied the economic prong of the domestic industry requirement by showing that 100% of the manufacturing occurred in the US even though the actual investments were small.

The commission is an executive branch agency charged with protecting domestic industries from acts of unfair importation.

In order to prove an act of unfair importation involving allegations of patent infringement, a patentee must demonstrate that it has a domestic industry within the meaning of the statute. 19 U.S.C. § 1337(a)(2)-(3).

The domestic industry requirement has two prongs. The first is the technical prong, which requires a showing that the patentee has a product (itself or via a licensee) that practices the asserted patent.

The second is the economic prong, which can be satisfied by showing at least one of three types of domestic investments: (1) significant investments in the US in plant and equipment relating to production of its domestic industry product; (2) significant investments in labour or capital relating its domestic industry product; or (3) substantial investments in exploitation of the patent, including engineering, research and development, or licensing that is tied to an article protected by the patent.

Although the domestic industry requirements are not contested in every case, when they are contested the issue often relates to whether the investments are significant or substantial enough to demonstrate a domestic industry.

Under the "economic prong," a complainant may satisfy the domestic industry requirement by showing at least one of three types of domestic investments: (1) significant investments in the US in plant and equipment relating to production of its domestic industry product; (2) significant investments in labour or capital relating its domestic industry product; or (3) substantial investments in exploitation of the patent, including engineering, research and development, or licensing that is tied to an article protected by the patent. ***See*** 19 U.S.C. § 1337(a)(2)-(3).

Ruling opens up ITC as a venue for smaller domestic industries

The ITC uses an approach that considers both quantitative and qualitative factors to determine whether a complainant has satisfied this requirement. The ITC will consider how much money a complainant has spent on a particular activity or asset, and other factors reflecting non-numerical measurements.

In ***Wuhan,*** the respondent argued that the patentee's investments in its plant-based recombinant cell culture media were too small to be significant or substantial under § 337(a)(3). It further argued that the patentee's domestic industry product's low revenue further undermined the conclusion that the patentee satisfied the domestic industry requirement.

The Federal Circuit rejected these arguments and concluded that the substantial evidence support the commission's findings. The court explained that small market segments can still be significant and substantial enough to satisfy the domestic industry requirement.

"[A] finding of domestic industry cannot hinge on a threshold dollar value or require a rigid formula; rather, the analysis requires a holistic review of all relevant considerations that is very context dependent." ***Wuhan Healthgen Biotech v ITC***, Case No. 23-1389, slip op. at 7 (Fed. Cir. Feb. 7, 2025).

The court also concluded that although the dollar amount of the patentee's investments were small, all of the investments were domestic, all market activities occurred within the US, and a high investment-to-revenue ratio indicated this is a valuable market.

Therefore, the Federal Circuit found that there was substantial evidence for the commission's finding that the domestic industry requirement was satisfied.

The ***Wuhan Healthgen Biotech*** holding underscores that an even lower dollar investments in domestic industry can be sufficient to establish domestic industry.

This is particularly true when all of the domestic industry product is manufactured in the US. Further, the holding confirms that the ITC is a forum open to domestic industries of any size.

Consider ITC relief early

The ramifications of this holding are significant. For complainants, companies with domestic industries in small market segments are no longer foreclosed from showing investments in domestic industry even though the domestic industry product market is much smaller compared to the non-domestic industry markets.

Further, an investment that may be deemed meagre is no longer categorically deemed as insignificant. ***See Wuhan Healthgen Biotech***, slip op. at 7.

This decision encourages companies facing infringers to consider seeking relief at the commission as early as possible and not wait until it makes additional domestic industry expenditures and potentially loses market share in the interim.

On the other hand, respondents must be wary and take steps to further contextualise the complainants' US expenditures. Respondents should investigate to confirm whether there are any foreign investments and ties in the domestic industry product.

There is a significant risk that this holding has allowed the commission's economic prong analysis to become a subjective test that amounts to "we know it when we see it" under this new interpretation of the "holistic" approach.

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