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Federal Circuit Clarifies Venue in Hatch-Waxman Case

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Addressing venue in the context of a Hatch-Waxman case, the US Court of Appeals for the Federal Circuit explained that sending a paragraph IV notice letter to a company in the district is insufficient to establish venue. *Celgene Corp. v. Mylan Pharmaceuticals Inc.*, Case No. 21-1154 (Fed. Cir. Nov. 5, 2021) (Prost, J.) The Court affirmed a district court finding that venue was improper since the defendant had not committed any acts of infringement and did not have a regular and established place of business in the district.

Celgene owns patents related to a multiple-myeloma drug that it markets and sells under the brand name Pomalyst. Mylan Pharmaceuticals Inc. (MPI) submitted abbreviated new drug applications (ANDAs) to the US Food & Drug Administration in order to bring a generic version of Pomalyst to market. Celgene filed suit in New Jersey against MPI and its related companies, Mylan Inc. and Mylan N.V. While Celgene is headquartered in New Jersey, MPI is based in West Virginia, Mylan, Inc. is based in Pennsylvania and Mylan N.V. is based in the Netherlands and Pennsylvania. The district court dismissed the case for improper venue (MPI and Mylan, Inc.) and for failure to state a claim (Mylan N.V.). Celgene appealed.

Citing *Valeant v. Mylan*, the Federal Circuit reiterated that venue for Hatch-Waxman cases must be predicated on past acts of infringement, and "it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context." Celgene argued that because MPI sent a paragraph IV notice letter from West Virginia to Celgene's headquarters in New Jersey, acts of infringement occurred in New Jersey. Celgene also argued that since the notice letter was mandatory and the ANDA had to be amended to include proof of delivery, the delivery of the letter was "sufficiently related to the ANDA submission." The Court disagreed, explaining that venue in Hatch-Waxman cases is focused on the submission of the ANDA itself, including acts involved in the preparation of an ANDA submission. The Court noted these acts must be part of the ANDA submission and that Celgene's "related to" standard was impermissibly broad. The Court found that since the submission of the ANDA did not take place in New Jersey, venue there was improper.

The Federal Circuit also found that neither MPI nor Mylan, Inc. had a regular and established place of business in New Jersey. Celgene argued both had a regular and established place of business based on places associated with Mylan employees as well as Mylan affiliates. In rejecting these arguments, the Court noted that the employees Celgene pointed to were working remotely from home, and that the employee's home numbers were contained in business communications. However, the Court noted that there was no indication that the defendants owned, leased or rented the employees'

homes; participated in the selection of the homes; stored inventory there or took any other actions to suggest that they had an intention to maintain a place of business in New Jersey should the employees move their homes. Absent such facts to show defendants' control over the employees' home, there was no place of business and, therefore, no venue in New Jersey.

Celgene also advanced a veil-piercing theory by arguing that because a now-defunct entity, Mylan Laboratories Inc. (MLI), had a physical office in New Jersey, that office should be imputed to MPI and Mylan Inc. Celgene pointed to shared marketing and branding, and to the fact that MLI's sole officer was also an officer of Mylan Inc. The Federal Circuit found that Celgene failed to make sufficient factual findings to show that the two entities acted as one. The Court explained that simply sharing trade names or an officer was insufficient to pierce the veil. Instead, Celgene would have needed to show that MPI or Mylan Inc. asserted domain over MLI's finances, policy or business practices.

The Federal Circuit also affirmed the district court's dismissal on the basis that Celgene failed to state a claim as to Mylan N.V. While it was undisputed that MPI—not Mylan N.V. —signed and submitted the ANDA, the question was whether the complaint pled sufficient facts that showed Mylan was actively involved in and benefited from the ANDA filing, and that MPI acted as Mylan N.V.'s alter ego. The Court found that the complaint did not allege sufficient facts, explaining that nothing in the complaint suggested how Mylan N.V. was involved in the ANDA process nor how it bypassed corporate form to make MPI its alter ego. The Court also rejected Celgene's request for leave to amend the complaint to add additional allegations because the deadline for such amendments had long since passed under the district court's rules. The Court found that Celgene offered no good cause for modification of that deadline, particularly since Celgene knew about the pleading deficiency for many years but made no attempt to amend in a timely manner.

This article was written by Mike Baldwin.

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