

# Kluwer Patent Blog

## Is Work From Home a U.S. Venue Work-Around?

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As we begin year three of the COVID-19 pandemic, the rise of the Omicron variant has caused many workers, who had returned to the office during summer and fall 2021, to revert to working from home. This trend has further increased speculation that remote working arrangements will become more widespread, even after the pandemic ends, and may be here to stay.

In the United States, “[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.” The shift to working from home has raised new questions regarding a defendant’s “regular and established place of business” and thus, the proper venue for a patent infringement suit when a company’s remote employees work within many judicial districts in the United States. Recently, however, Hatch-Waxman plaintiffs in *Celgene Corporation v. Mylan Pharmaceuticals Inc.*, 17 F.4th 1111 (Fed. Cir. 2021), received the clearest guidance to date from the Federal Circuit regarding venue.

### Background

Celgene markets pomalidomide as a multiple myeloma drug under the brand name Pomalyst®. Mylan Pharmaceuticals Inc. (“MPI”) submitted an ANDA from West Virginia, seeking to market a generic version of pomalidomide. In accordance with the statute, MPI sent Celgene a paragraph IV notice letter stating the legal and factual basis for its position that MPI and its affiliates, including Mylan Inc., do not infringe any valid Celgene Orange Book-listed patent. MPI sent this notice from West Virginia to Celgene’s headquarters in New Jersey. MPI’s ANDA submission led to Celgene filing a series of patent infringement complaints against MPI and Mylan Inc., amongst other Mylan entities, in the District of New Jersey. Defendants moved to dismiss for improper venue and—after two years of jurisdictional discovery – the district court granted the motion <sup>[1]</sup>. Celgene timely appealed.

### Federal Circuit Decision

The Federal Circuit affirmed, in an opinion authored by Judge Prost joined by Judges Chen and Hughes.

**Firstly**, the Federal Circuit found that MPI and Mylan Inc. did not commit acts of infringement in New Jersey. In so finding, the Federal Circuit relied upon its previous Hatch-Waxman venue ruling in *Valeant Pharmaceuticals v. Mylan Pharmaceuticals*, 978 F.3d 1374 (Fed. Cir. 2020). The

Federal Circuit rejected Celgene’s argument that the “artificial act of infringement stemming from the ANDA submission extends nationwide” – which would include anywhere the generic drug will be marketed and sold, including New Jersey. According to the Court, this argument was “squarely foreclose[d]” by *Valeant*, which stands for the proposition that venue is proper in a Hatch-Waxman case “where an ANDA-filer submits its ANDA to the FDA,” not “wherever future distribution of the generic is contemplated.” *Valeant*, 978 F.3d at 1378-79, 1384. Celgene also argued that MPI’s act of sending the paragraph IV notice letter to Celgene’s New Jersey headquarters constituted an act of infringement in New Jersey. The Court rejected this argument because under *Valeant*, the act of submitting an ANDA to the FDA is the artificial act of infringement that creates the right to bring suit—not the sending of the paragraph IV letter.

**Secondly**, and perhaps more significantly, the Federal Circuit rejected Celgene’s argument that MPI and Mylan Inc. had regular and established places of business in New Jersey. Under Federal Circuit precedent, a plaintiff must fulfill three requirements to prove that a defendant has a regular and established place of business for the purpose of venue: “(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant.” *In re Cray Inc.*, 871 F.3d 1360 (Fed. Cir. 2017). Celgene did not dispute that MPI and Mylan Inc. did not have a physical presence in New Jersey – instead, they offered two theories to impute venue to MPI and Mylan Inc., both of which the Court rejected.

Specifically, Celgene argued that the homes of 17 of MPI’s and Mylan Inc.’s employees – amongst tens of thousands of employees – living in New Jersey and working from home offices were each a regular and established place of business of MPI or Mylan Inc. But the Federal Circuit rejected this argument because neither MPI nor Mylan Inc. (1) required the employees to live in New Jersey, (2) paid for their homes, (3) required the employees to store materials in their homes, or (4) paid secretarial or support staff to work at the homes. The Federal Circuit also rejected Celgene’s argument that the homes – as well as two small storage lockers – should *together* be deemed a regular and established place of business because (1) Celgene provided no precedent supporting its aggregate-place theory, and (2) even if that theory was viable, the homes and lockers would not be “of the defendant,” as required by statute<sup>[2]</sup>.

## Takeaways

This opinion helps clarify some important venue issues. First, the opinion confirms that an ANDA submission itself – not sending a paragraph IV notice – is an act of patent infringement. Second, because sending the paragraph IV notice is not an act of infringement, the notice may not give rise to venue in the district from where it was sent or in which it was received. Finally, the presence of remote workers in a district will not *by itself* be sufficient to show a regular and established place of business for purposes of venue. As acts of infringement are generally widespread in a typical patent litigation, the location of a defendant’s business is often the deciding factor for venue. Therefore, this Federal Circuit decision as it applies to remote workers may have a significant impact on venue in all types of patent litigation in a post-COVID world.

Celgene, however, still has time to appeal to the Supreme Court. So stay tuned.

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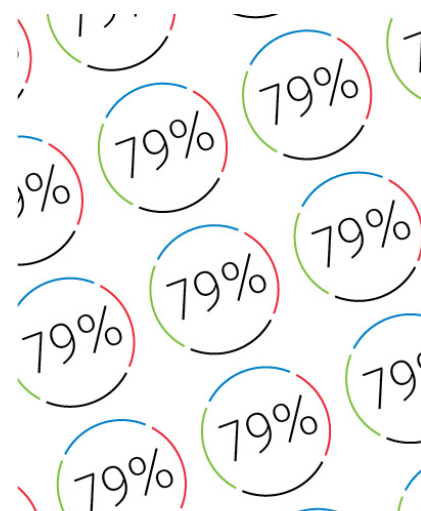
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