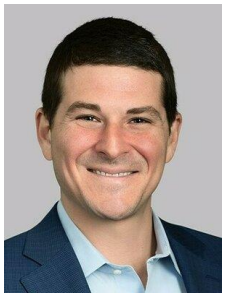
Venue Issues Drug Cos. Should Watch In Hatch-Waxman Suits

By **Benjamin Dach** (July 11, 2022)



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Known as the Hatch-Waxman Act, the Drug Price Competition and Patent Term Restoration Act of 1984 governs the regulatory approval and commercial marketing of pharmaceuticals, including generic drugs.

Hatch-Waxman litigation arises when branded pharmaceutical companies file suit asserting drug patents against companies attempting to market generic versions of branded drugs. This occurs after generic pharmaceutical companies file Paragraph IV notice letters through which generic applicants assert either the noninfringement or invalidity of patents held by brand manufacturers.[1]

The pharmaceutical industry's heavy dependence on patents and patent protection, and the potential market exclusivity Paragraph IV notice first-filers can secure, highlights the important and outsize impact Hatch-Waxman litigation has on the marketplace.

Current trends in Hatch-Waxman litigation include case filing trends, changes at the government and court levels, and recent court decisions.

This article discusses several notable cases that reveal key takeaways and unresolved issues of which drug companies should be wary.

Of particular note: One of the salient developments involves changes in venue for a Hatch-Waxman case — highlighting the need for concerned practitioners to stay close to the venue issue as it remains a major focus of the federal courts.

Though there are many factors pressing on Hatch-Waxman litigation, venue figures in significantly because it controls myriad aspects of a case. Each venue has its own specific rules and style for conducting a Hatch-Waxman case — including discovery and pleading protocols.

Further, some venues are favored by brand name companies, while other venues may be seen as more favorable to generic companies.

Venue rules in the Hatch-Waxman space have become stricter and more difficult for brand name companies. As a result of recent decisions in the U.S. Court of Appeals for the Federal Circuit, patent litigation over generic drugs — typically concentrated in Delaware and New Jersey — may spread to more states across the country, potentially making these Hatch-Waxman disputes more complicated.

In the 2020 Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceutical Inc. decision, the Federal Circuit held that under the U.S. Supreme Court's 2017 TC Heartland LLC v. Kraft Foods Group Brands LLC ruling on venue for patent cases, branded drug companies must file lawsuits under the Hatch-Waxman Act either where a generic company is incorporated or where it performed actions related to its abbreviated new drug application, or ANDA, to market a generic drug.

This decision is not only significant because it limits where brand companies can sue generics. It also allows generics to now manipulate where they will be sued.

It is speculated that courts may start offering speedier trials to appeal to generic pharmaceutical companies, in an effort to attract ANDA cases.

Another case that has given pause to brand companies attempting to bring generics to their venue of choice is the 2021 Celgene Corp. v. Mylan Pharmaceuticals Inc. decision. In Celgene, the Federal Circuit concluded that venue in New Jersey for the Mylan domestic companies was improper under Section 1400(b) because there was no act of infringement in New Jersey — the ANDA was filed in Mylan's headquarters in West Virginia.

The key questions there were: Where did the ANDA submission occur, and what acts did it include?

For Hatch-Waxman cases, according to the Valeant decision, this means venue is proper "where an ANDA-filer submits its ANDA to the [U.S. Food and Drug Administration]," not "wherever future distribution of the generic is contemplated."

In Celgene, the receipt of the notice letter in New Jersey was not enough to establish venue — it was not part of the ANDA submission. Mylan had no "regular and established place of business" in New Jersey. And homes in New Jersey belonging to Mylan employees were not enough to establish what the Federal Circuit in 2017 called "place of the defendant" in In re: Cray Inc.

There are a few key takeaways from Celgene.

First, a Paragraph IV letter is not considered part of an ANDA submission, so venue cannot be predicated upon where the letter is received. It is the ANDA — and only the act of its submission — that constitutes the act of patent infringement that determines venue.

Second, demonstrating that an in-district physical place is of the defendant requires a strong and particularized showing of the defendant's ratification of that place.

Third, venue may be imputed to a parent based on a subsidiary's place of business under an alter ego theory, but only when corporate formalities are disregarded and corporate separateness is not maintained.

Finally, bare allegations of cooperation and control are insufficient to state a claim against a potential defendant who did not sign or submit the ANDA. Finally, these venue cases could now provoke multidistrict litigation if multiple generic drug companies file ANDAs on the same drug.

Subsequent cases continue to cite Valeant and Celgene as limiting venues for ANDA litigation.

For example, in the March 8 Bausch Health Ireland Ltd. v. Mylan Laboratories Ltd. decision, the U.S. District Court for the District of New Jersey clarified the purpose of TC Heartland, Valeant, and Celgene, saying:

> [T]he clear import of the TC Heartland, Valeant, and Celgene decisions is to insert a level of certainty in the determination of venue without turning it into extraordinary game of collateral litigation to select the forum or judge that litigants want.

There have also been a number of cases transferred to other venues. For example, in the

November 2021 Melinta Therapeutics LLC v. Nexus Pharmaceutical Inc. decision in the District of New Jersey, venue was transferred to the Northern District of Illinois because venue inquiries related to ANDAs must focus on the submission of the ANDA itself in Illinois, and not post-submission conduct.

Further, in the January 2021 Fresenius Kabi U.S. LLC v. Custopharm Inc. decision, in the U.S. District Court for the District of Colorado, the case was transferred to the Western District of Texas because the dispositive issue was whether the defendant resided in Colorado and, for Section 1400(b) purposes, a corporate defendant resides only in the state where it is incorporated — in this case Texas.

We may expect more ANDA cases to be transferred for venue purposes in the future.

Other courts have dismissed cases outright without transferring venue. Take, for example, the U.S. District Court for the District of Delaware's 2019 Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc. holding that venue was not proper in Delaware over Mylan Pharmaceuticals Inc. in connection with Novartis' Hatch-Waxman patent infringement claim arising from Mylan's submission of an ANDA seeking approval to market a generic version of the multiple sclerosis drug Gilenya.

The court there dismissed the case and did not transfer venue. The court recognized that its ruling was prejudicial to Novartis, but noted that Novartis would be free to file a new declaratory judgment claim against Mylan in any district where Novartis believes venue is proper and could potentially initiate multidistrict litigation.

In general, branded pharmaceutical companies may refile cases that are dismissed for lack of proper venue in other districts.

Some courts have denied venue discovery when defendants have tenuous ties to a particular state.

For example, courts have denied venue discovery in patent infringement actions despite allegations that a defendant's employee lived and conducted business in the district, absent further "fact-specific allegations or evidence that could support a finding that venue is proper" — as the U.S. District Court for the Eastern District of New York cited in a May UI Technologies Inc. v. Ricoma International Corp. order denying UI Technologies' request for venue discovery.

We may expect courts in ANDA cases to continue to deny venue discovery, dismiss cases for lack of proper venue, and transfer cases to other venues with these stricter venue requirements. Branded pharmaceutical companies may, however, present sufficient factual evidence to obtain venue-related discovery.

Ultimately, both branded and generic pharmaceutical companies should be aware of venue issues in Hatch-Waxman litigation. As courts become stricter with respect to choice of proper venue, brand name companies must pivot to be able to litigate cases in courts that may not have historically heard Hatch-Waxman cases.

Further, generic companies may choose to be incorporated in and have headquarters in different states with courts that may be viewed as unfavorable to brand name pharmaceutical companies. These new venue rules will create new litigation strategies that will change the Hatch-Waxman landscape for years to come.

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[1] PIV notice letters are filed pursuant to PIV of the Hatch-Waxman Act. Under PIV, a generic applicant asserts non-infringement or invalidity of one or more Orange Book patents held by brand manufacturers and covering pharmaceutical compounds, polymorphs, formulations, and methods of treatment. A brand manufacturer can file suit for infringement upon receiving a PIV notice letter. If filed, a Hatch-Waxman suit will delay marketing approval of the generic drug application for 30 months. If more than one generic company files a PIV notice letter, the first generic company to file its PIV letter may be eligible for 180 days of market exclusivity.