

Court Divide Could Spur More Hatch-Waxman Venue Fights

By **Matthew Bultman**

Law360, New York (January 5, 2018, 3:07 PM EST) -- A question that affects where drugmakers can sue their generic competitors has split district courts following the U.S. Supreme Court's landmark TC Heartland decision in May, likely giving rise to more fights over venue in cases involving abbreviated new drug applications under the Hatch-Waxman Act.

The TC Heartland v. Kraft Food Brands Group decision limited the filing of patent lawsuits to either where a defendant is incorporated or has committed an act of infringement and has a regular and established place of business. The split among district courts revolves around what is considered an "act of infringement" to support venue in ANDA cases.

One view is that a generics company's intent to sell the disputed product could be considered an act of infringement, meaning a suit could be filed in any state where the defendant intended to make a sale and has an established place of business. The other, more narrow view is that the act is limited to where the ANDA submission was prepared and submitted.

"The decisions and the fact that we don't have a consistent line of authority right now, at least from the district courts, is going to continue to cause significant uncertainty for all litigants in the ANDA space," Gary Hood of Polsinelli PC said.

The issue is especially important to drug companies that want to sue generics manufacturers in a state where the defendant is not incorporated. Hood noted that the consequences of filing suit in an improper district may be significant.

"The issue itself is very important, and we're starting to see some courts deal with it," he said. "I think we're going to continue to see this issue addressed, argued and litigated for quite a while."

The TC Heartland decision has forced lower courts to grapple with various issues, including questions about what constitutes a "regular and established" place of business and whether the high court ruling was a change in the law.

But the question about what is an "act of infringement" has become a unique issue in Hatch-Waxman litigation.

That's because in most patent cases, the alleged act involves products that have been or are being sold.

Hatch-Waxman litigation is different in that it involves a dispute over a generic drug product that will be sold in the future, after approval from the U.S. Food and Drug Administration.

Chief Judge Leonard Stark in the District of Delaware, who tackled the question in a case of first impression in September, said there appeared to be a near “impenetrable problem” with the language of the patent venue statute in the Hatch-Waxman context.

“[O]n the surface, there appears to be a complete mismatch between the backward-looking nature of the patent venue statute and the forward-looking nature of Hatch-Waxman litigation,” he wrote.

The judge, ruling in a case between Bristol-Myers Squibb Co. and Mylan Pharmaceuticals Inc., decided that “acts of infringement” include “all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is launched into the market.”

In other words, a generic maker can be sued in Delaware if it intends to sell the disputed product in the state, provided that it has a regular place of business there.

Two months later, a judge in the Northern District of Texas rejected that interpretation.

Chief Judge Barbara Lynn, who was overseeing a dispute between Galderma Laboratories LP and Teva Pharmaceuticals USA Inc., said the Delaware opinion, while “very thorough,” didn’t fit with the Federal Circuit’s intervening decision in *In re: Cray Inc.*, which set guidelines for where patent suits can be filed.

Judge Lynn limited the act of infringement to “where the ANDA submission itself was prepared and submitted.” In Teva’s case, the ANDA was prepared at its office in New Jersey and submitted electronically to the FDA in Maryland.

Companies are waiting to see how other courts — in particular the District of New Jersey, which, like Delaware, is a hotbed for Hatch-Waxman litigation — will come down on the issue. But it appears to be only a matter of time before the Federal Circuit weighs in.

“Ultimately, when you have the district courts fighting over the meaning of statutory language and its implication, the Federal Circuit will have to resolve the issue,” Michael Abernathy of Morgan Lewis & Bockius LLP said.

How the question is decided will go a long way in determining how restrictive venue rules are going to be in the Hatch-Waxman context in the wake of *TC Heartland*, according to Brian Burgess of Goodwin Procter LLP.

Before the Supreme Court’s ruling, the pharmaceutical industry expressed concern that more restrictive venue rules would make it increasingly difficult to sue multiple defendants in a single court. Some of these concerns may linger if a narrow view of “acts of infringement” sticks.

On the other hand, if courts were to look at future acts of infringement, like Judge Stark did, “it dramatically mitigates the practical obstacles it would have on Hatch-Waxman litigation going forward,” Burgess said.

Regardless of the eventual outcome, experts say there will still be plenty of ANDA cases in Delaware and New Jersey, in large part because many drug companies are either incorporated or have offices in one of

the two states.

“There is certainly a large footprint in Delaware and New Jersey, so it’s not going to be across the board that there are implications for these companies,” Stephen Hash of Baker Botts LLP said. “That said, there are companies that are incorporated in other states and/or have a substantial business presence in them.”

Given the current uncertainties, some believe drug companies may be inclined in certain situations to take precautions and file two lawsuits: one in their preferred district, and another in a court where they are confident that the venue will be proper, such as the state where the defendant is incorporated.

Under Hatch-Waxman, drug companies that sue generic makers for infringement get a 30-month stay of generic market entry. But in order to receive the stay, the lawsuit must be filed within 45 days of receiving the ANDA notification.

There is an argument that the stay could be extinguished if the lawsuit is dismissed after being filed in the wrong venue and is not refiled in the proper district within the 45-day window. While that doesn’t appear to have happened yet, Brian Nolan of Mayer Brown LLP said it was a legitimate concern.

“Until there’s more clarity on it, you probably will see increased protective suits filed by innovators who have patents because they don’t want to lose the 30-month stay,” Nolan said.

--Editing by Philip Shea and Jack Karp.