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Hatch-Waxman Post-TC Heartland: What You Need To Know

By **Matthew Bultman**

Law360 (May 24, 2018, 4:37 PM EDT) -- The U.S. Supreme Court's TC Heartland decision, which limited where patent lawsuits can be filed, has led to a bump in cases over generic drugs in Delaware while raising some legal questions and strategic issues for pharmaceutical companies.

The high court in TC Heartland v. Kraft Food Brands Group did away with a rule that effectively allowed plaintiffs to sue companies anywhere they made sales, and imposed restrictions on where patent cases can be brought.

It's clear the ruling, which turns 1 year old Tuesday, has shifted overall litigation trends. While the impact on litigation involving abbreviated new drug applications under the Hatch-Waxman Act has been less pronounced, this space hasn't gone unaffected.

By the Numbers

Delaware and New Jersey have long been premier venues for Hatch-Waxman litigation. Historically, the two districts have come in first and second, respectively, in the number of cases handled. All other districts combined would be third.

These trends have continued in the wake of TC Heartland, although Delaware has been shouldering more of the load.

Prior to the Supreme Court's ruling, Delaware handled about 43 percent of all the Hatch-Waxman cases. Today, that number is close to 60 percent, according to an analysis from Filko Prugo of Ropes & Gray LLP.

New Jersey, meanwhile, has seen a slight dip in the number of Hatch-Waxman cases — down from 32 percent before TC Heartland to 27 percent. The remaining cases are scattered across districts courts around the country.

"I think TC Heartland focused the prominence of Delaware and New Jersey for Hatch-Waxman cases," Ralph Dengler of Venable LLP said.

Under TC Heartland, patent infringement lawsuits must be filed where the defendant is incorporated, or where it has a regular and established place of business and has committed an act of infringement.

For brand-name pharmaceutical companies, filing in Delaware can be a safe bet because many generics makers are incorporated in the state. A number of drug companies are also located in New Jersey.

"Because of a lot of companies have contacts with those two fora, you're likely to be able to sue them there," J.C. Rozendaal of Sterne Kessler Goldstein & Fox PLLC said.

There is also a sense, from both sides, branded and generic, that judges in those two districts are well-versed on the issues of Hatch-Waxman law and have experience with the technologies that are involved, attorneys said.

This perhaps helps explain why fights over venue are less common in drug cases, as compared to computer and other high-tech products cases. One outlier appears to be Mylan Inc., which has frequently looked to get cases moved to West Virginia, where it has operations.

"By and large, the generic companies are quite happy being in Delaware and New Jersey because of the expertise on the bench and they know these cases will be taken seriously," Chad Peterman of Paul Hastings LLP said.

Protective Lawsuits

For brand-name pharmaceutical companies, suing a generic-drug company in the wrong court can potentially have significant consequences.

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

The U.S. Food and Drug Administration has said the 30-month stay can be terminated if a court dismisses a lawsuit without prejudice, which is what one might expect to happen if a brand-name drug company were to file its case in the wrong venue.

Some companies looking to sue a generics maker where it has a place of business have taken precautions by filing two lawsuits: one in the preferred district and a second in the state of incorporation, where they are certain that venue will be proper.

While these types of "protective lawsuits" were filed before TC Heartland, companies now have all the more reason to file them, according to Prugo, who noted the FDA has said it will not terminate the stay when there is a protective lawsuit.

"It just makes sense legally to file a protective suit given the FDA's position on what would happen to the 30-month stay," he said. "It would be risky to file in a jurisdiction you're not 100 percent sure is the proper venue."

There could be one theoretical drawback to filing a protective suit, Peterman said. The generic-drug company could try to convince the court to keep the case in the venue that it wants to be in, rather than the brand-name company's preferred district. It's unclear if that has ever happened.

Act of Infringement

One unique legal issue that has sparked disputes and split district courts concerns the "act of infringement" to support venue in ANDA cases.

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.

In Delaware, one judge has taken the view that a generics company's intent to sell the product could be considered an act of infringement. This means a suit could be filed in any state where the defendant intended to make a sale and has an established place of business.

But a Texas federal judge has taken a more narrow view, deciding the act is limited to where the ANDA submission was prepared and submitted. In that case, which involved Teva Pharmaceuticals USA Inc., the paperwork was prepared at an office in New Jersey and submitted electronically to the FDA in Maryland.

Companies are waiting to see how other courts, including the District of New Jersey, will come down on the issue. But Christopher Loh of Fitzpatrick Cella Harper & Scinto said it's something the Federal Circuit will likely have to address.

"Certainly this disagreement between the [Texas court] and the District of Delaware is very apparent in the ANDA community," he said.

Multidistrict Litigation

In the aftermath of the TC Heartland ruling, there was speculation about a potential rise in multidistrict litigation, as more cases spread around courts. MDLs allow similar lawsuits to be transferred to a single court before trial, a special procedure not often seen in patent cases.

While brand-name companies in ANDA litigation will often sue multiple generics makers at once, to date, there has not been much use of the MDL procedures. No current ANDA MDLs are pending, according to federal judiciary data, and there are few instances of companies requesting them.

Sumitomo Dainippon Pharma Co. Ltd. is one example, seeking MDL treatment after suing various companies, including Amnea Pharmaceuticals Inc. and Accord Healthcare Inc., over patents for schizophrenia treatment Latuda. But the cases were dropped earlier this year.

The current lack of MDLs in the ANDA context can likely be attributed to the fact that the vast majority of Hatch-Waxman litigation is still taking place in either Delaware and New Jersey, attorneys said.

"It certainly has not been a recognizable phenomenon after TC Heartland," Peterman said.

But Prugo said it continues to be a point of concern for some drug companies who fear it could make litigation more expensive.

"There's a lot to an MDL proceeding and, ultimately, it does increase costs," he said.

--Editing by Katherine Rautenberg and Aaron Pelc.
