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Fed. Circ. Ruling May Reshape Hatch-Waxman Litigation Map

By **Ryan Davis**

Law360 (November 17, 2020, 8:40 PM EST) -- Patent litigation over generic drugs, which has long been concentrated in Delaware and New Jersey, may spread out to more states across the country as a result of a recent Federal Circuit ruling, potentially making disputes more complicated, attorneys say.

In a decision earlier this month, the appeals court held that under the U.S. Supreme Court's 2017 TC Heartland ruling on venue for patent cases, branded drug companies must file suits under the Hatch-Waxman Act either where a generics maker is incorporated or where it performed actions related to its application to market a generic drug.

The holding, which rejected an alternative argument that would have effectively allowed suits over Abbreviated New Drug Applications to continue to be filed anywhere, will mean that multiple suits against different generics companies over the same drug may often have to be litigated in separate courts.

"That is a big, big change," said Michael Abernathy of Morgan Lewis & Bockius LLP. "It certainly portends a variety of jurisdictions across the United States will be potentially handling ANDA litigation. In the past, it was really confined to a handful of jurisdictions, including New Jersey and Delaware."

Having numerous patent suits over the same drug in different courts is "going to create all sorts of problems for everybody," said Zachary Silbersher of Markman Advisors. That could include a risk of inconsistent rulings, longer and more burdensome litigation, and the possibility that generics makers can manipulate where they are sued, he said.

The Federal Circuit said in its decision that it was "sympathetic" to those concerns, which were raised by Valeant Pharmaceuticals, the branded company in the case. However, the court wrote that "while intuitively persuasive, these policy arguments cannot trump the plain language" of the patent venue statute and the Hatch-Waxman Act.

"Congress can revise the two statutes to the extent it finds these, or other, policy concerns compelling; all we can do is give the statutes their current plain meaning," it said.

As a result, attorneys said they expect the decision to be appealed further, and that there is a possibility that Congress could get involved to pass a new law.

"I'm certain this isn't the end of the road for this case, whether it's an en banc petition or a cert position

directly to the Supreme Court," said Matthew Rizzolo of Ropes & Gray LLP.

Venue Shakeup

Branded drug companies have long chosen to file ANDA suits primarily in either New Jersey, which is close to their home base for many of them, or Delaware, where most companies are incorporated. The Federal Circuit cemented that practice in a 2016 ruling that generic drugmakers could be sued for patent infringement any place they plan to sell their product, which for a generic drug is everywhere.

However, that holding was based on an interpretation of venue law in patent cases that was tied to personal jurisdiction, and was discarded by the Supreme Court the following year in TC Heartland. In that case, the justices said patent defendants must be sued either where they are incorporated or whether they have a regular and established place of business and have committed an act of infringement.

Over the past three years, judges in generic drug cases have debated what constitutes an "act of infringement" under the Hatch-Waxman Act, the law that allows branded drugmakers to file patent suits before a generic product enters the market.

Some judges have held that the act of infringement is the theoretical future sale of a generic drug, which would allow branded companies to keep suing in their preferred venues of Delaware and New Jersey. However, in the Valeant case, the Federal Circuit said that is incorrect.

"We hold that venue in Hatch-Waxman cases must be predicated on past acts of infringement — i.e., acts that occurred before the action alleging infringement was filed," it said. "And we hold those acts occur only in districts where actions related to the ANDA submission occur."

For generics makers that are incorporated in Delaware, the ruling will have little practical impact, since they can still be sued there. But any companies that are incorporated and based elsewhere will now have to be sued in that location.

"I do think it's likely going to alter the landscape," said Taras Gracey of Polsinelli PC.

In the Valeant case, defendant Mylan will have to be sued in West Virginia, where it is incorporated and based, the court ruled. That is despite the fact that Valeant has sued 18 other generics makers over the patent on the same anti-fungal drug in New Jersey, and none of them challenged venue.

More courts, more complications

Attorneys said they could envision scenarios in future Hatch-Waxman cases where multiple generics makers based in different parts of the country all plan versions of the same drug and will have to be sued separately.

"At the end of the day, it's going to be a lot harder for the brand to basically sue all the generics in the same place and have a streamlined litigation," Silbersher said.

It could therefore take longer to completely resolve infringement litigation over a given drug, which may end up benefiting branded drug companies, and hurting consumers by delaying the entry of lower-cost generic drugs, he said.

"The longer the case takes, the less likely it is that the generic is going to enter the market. And that delay is money in the pocket of the branded company," Silbersher said.

While ANDA litigation against different companies over the same drug could be coordinated as multidistrict litigation for proceedings leading up to a trial, that would not solve all the problems.

"There are a lot of judicial inefficiencies with that because you very well should be expecting multiple trials to take place, and of course trials are the most expensive part of the process," said Filko Prugo of Ropes & Gray.

In addition to potentially requiring Hatch-Waxman litigation to spread across the country, the decision also leaves unanswered questions about what constitutes "actions related to the ANDA submission." The Federal Circuit expressly left that issue to be determined in a future case "where the precise contours are presented and briefed."

If the actions include something other than putting the application in the mail at a generics company's headquarters, branded companies may not know who is performing them or where, and discovery could be needed to determine if a suit has been filed in the right district, Prugo said.

He suggested that branded drug companies could ultimately ask the FDA to create rules requiring ANDA filers to answer those questions in their application, since "patent owners rightfully should have the ability to understand the venue analysis at the beginning of the case."

Some generics makers might feel comfortable with Delaware and New Jersey and could consent to keep being sued there, attorneys said. But under the Federal Circuit's ruling, any generic company that would prefer to be sued elsewhere can now arrange that by only working on their ANDA submissions in locations where they feel the courts may give them a favorable ruling.

"This decision is important not just because [it] limits where the brands can sue the generics, it allows the generic to now manipulate where they will be sued," Silbersher said. He speculated that some courts could start offering quick trials to appeal to generics companies, in an effort to attract ANDA cases.

If the appeals court's interpretation survives on appeal, Congress will likely face calls to revisit the statute. If lawmakers feel that it's too inefficient for ANDA cases to be litigated in multiple courts, that the ruling is hindering access to generic drugs, or that generics makers shouldn't have the power to choose where they are sued, they could step in.

"Congress might actually go and change the statute, which they can do," Gracey said. "They created the rules, so they can alter them."

The case is Valeant Pharmaceuticals North America LLC et al. v. Mylan Pharmaceuticals Inc. et al., case number 19-2402, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Emily Kokoll.