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As ANDA Suit Venue Options Shrink, Del., NJ Rule For Now

By **Ryan Davis**

Law360 (November 24, 2021, 6:09 PM EST) -- One year after the Federal Circuit limited venue options for patent suits over generic drugs, a new ruling has clamped down further. But so far, most cases are still being filed in Delaware and New Jersey, the traditional hot spots for pharmaceutical litigation.

In November 2020, the appeals court ruled in Valeant v. Mylan that patent suits against generic drugmakers must be filed where the company is incorporated or where it performed actions related to its Abbreviated New Drug Application, departing from prior decisions that such suits could effectively be filed anywhere.

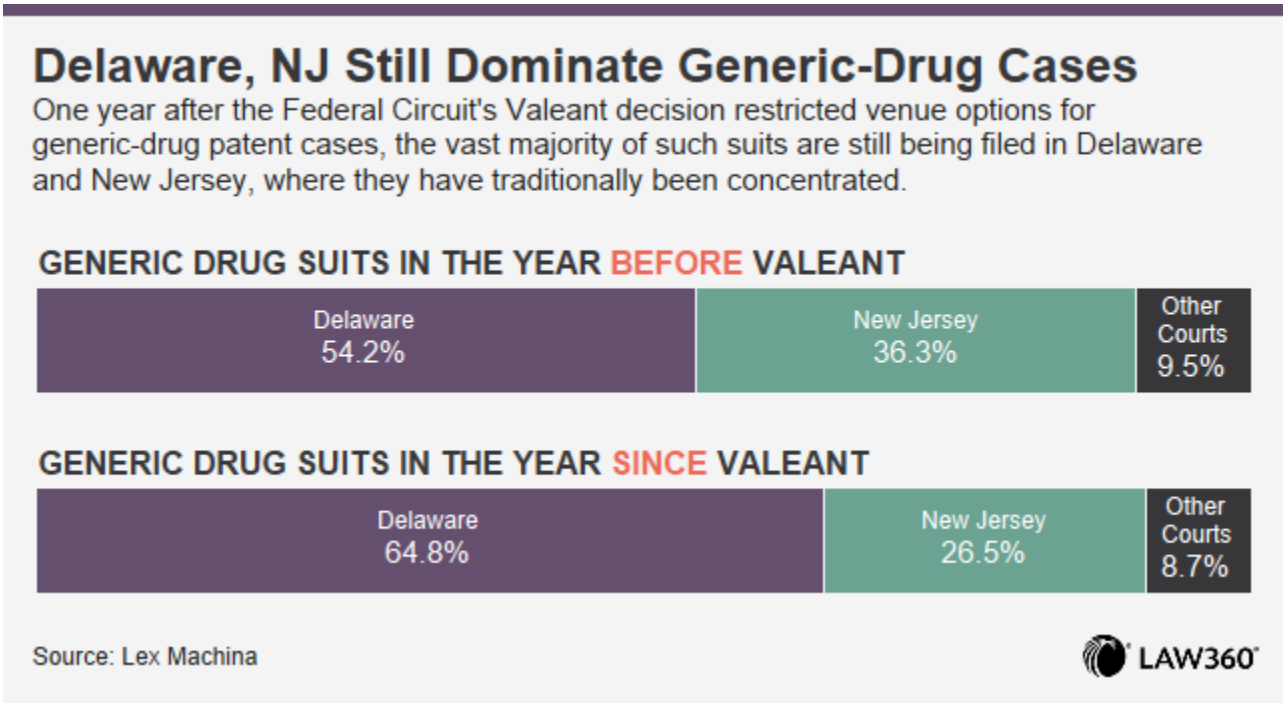
Earlier this month, on the one-year anniversary of that holding, the Federal Circuit cemented that holding by rejecting an argument from Celgene Corp. that a branded drug company should be able to file suit under the Hatch-Waxman Act where it receives notice from a generic that an ANDA has been filed.

When the courts held that ANDA suits could be filed in almost any court, branded drug companies filed the bulk of their patent cases 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's new restrictions suggest that might not always be possible.

"I think it's going to be much more difficult in many cases for branded companies to use those favored jurisdictions," said Michael Abernathy of Morgan Lewis & Bockius LLP. "It won't be across the board, but you could usually count on an ANDA case being filed in one of those two jurisdictions. I don't think you can necessarily count on that anymore."

To date, however, complaints in generic-drug patent cases have not started to spread to other courts. In the year after the Valeant decision, new Hatch-Waxman suits have remained as concentrated in Delaware and New Jersey as they were in the year prior to the ruling.

According to data from Lex Machina, 91% of ANDA suits in the year since Valeant were filed in either Delaware or New Jersey, compared to nearly 90% in the previous year. The percentage of cases filed in Delaware increased after the ruling, from 54% to 65%, while New Jersey's share declined from 36% to 27%.



Abernathy said it may be too soon to draw conclusions from that data, noting that the pandemic may have slowed ANDA filings and made some litigants more cautious about filing suits in places where COVID restrictions have slowed down litigation.

"So I'm not sure we have good, conclusive data yet that's really indicative of what we're going to see in the future," he said.

The Federal Circuit's decisions applied the U.S. Supreme Court's 2017 TC Heartland ruling — which held that patent suits must be filed where a defendant is incorporated or has a regular and established place of business — to ANDA cases. While they discarded precedent that such suits could be filed wherever a generic drug may one day be sold, it's possible cases will still end in the same locations, said Adam Samansky of Mintz Levin Cohn Ferris Glovsky and Popeo PC.

Since many generic-drug companies are incorporated in Delaware or based in New Jersey, "my hypothesis is that we're not going to see a whole lot of change unless we see ANDA filers change where they're incorporated or where they're located," he said.

A Rise in Drug MDLs

After the Valeant decision held that the place where actions related to an ANDA filing are performed is key to determining the proper location for a suit, New Jersey-based Celgene argued that it should be able to file suit in that state, because that's where it received a notice letter that Mylan sent from West Virginia about an ANDA for a planned generic version of its multiple myeloma drug Pomalyst.

The Federal Circuit on Nov. 5 shot down that argument, saying the letter didn't count for venue because it was sent after the ANDA was submitted. That means branded companies may face the prospect of filing patent suits in districts they've avoided in the past.

If the generic is incorporated and principally located in another state, like West Virginia-based Mylan,

that company may have to be sued there, even if other suits over the same drug are pending in one of the traditional jurisdictions.

"Celgene reiterates that brands may not be able to sue some generics in New Jersey or Delaware," said Gregory Morris of Honigman LLP. "In those instances, brands can file suit where the generic resides and use multidistrict litigation to consolidate the case for discovery with cases pending against other generics in New Jersey or Delaware."

Morris noted that during debate in Congress over the Hatch-Waxman Act in the 1980s, the sponsors suggested that multiple ANDA suits over the same drug be coordinated through multidistrict litigation "to promote the just and efficient conduct of the patent infringement actions." That has been done in the past, and it may become more frequent going forward.

Rather than a dramatic shift in where ANDA suits are litigated, there may be more situations "where the branded drugmaker has already sued some ANDA filers in one jurisdiction, and venue might not be as appropriate to other generics in that same jurisdiction," said Joseph Rutkowski of Mintz.

When that occurs, there may be more MDLs, or just agreements among all the parties to proceed in one court in order to streamline the litigation, Mintz's Samansky said.

"Party and judicial efficiency is important to brands, it's important to generics and it's important to the judicial system," he said. "The practical realities of litigation also come into play."

For now, when branded companies receive a notice letter stating a particular unit of a generics maker submitted an ANDA, the infringement suit will likely have to be filed where the generics company is located. If other units of the generic based in other locations were involved in preparing the ANDA, possibly permitting venue elsewhere, that may not be apparent to the brand.

"A brand typically learns what generic entity filed a given ANDA by the statements made in the generic's required notice letter to the brand," Morris said. "Celgene highlights that in certain cases, it may be difficult for brands to sue generic entities other than the one that filed the ANDA, due to lack of information available at the time of filing of the complaint."

The Future of ANDA Cases

Even some generics makers that don't have ties to Delaware and New Jersey have consented to being sued there in the past. But others may now seek to face patent suits where they are based.

Mylan appears especially keen to have cases over its generics heard in West Virginia. In practice, it hasn't always benefited from home-field advantage. In March, a Northern District of West Virginia judge ruled against Mylan, rejecting its bid to invalidate patents on AstraZeneca's Symbicort that the generics maker stipulated that it infringed.

Branded companies say they prefer filing in Delaware and New Jersey because judges there are so familiar with Hatch-Waxman cases, which is especially notable since the cases are nearly always decided by bench trials. If more ANDA cases are filed in districts that have never had them before, the results may be less predictable.

"I would think that regardless of which side of the equation you're on, you'd want an experienced, smart

judge for those types of very technical, precise issues," Morgan Lewis' Abernathy said. "We'll see what the future holds for both sides if we go into other jurisdictions, which it seems clear we're going to."

It's possible that further litigation could lead to recalibrations of venue in ANDA cases. After the full Federal Circuit refused to review the Valeant ruling, it wasn't appealed to the U.S. Supreme Court, but the branded drug industry may decide to seek further review of the Celgene ruling.

The Federal Circuit also noted that Maryland, where the U.S. Food and Drug Administration is located and receives ANDAs, could possibly be a proper venue for a Hatch-Waxman suit, but it did not resolve that question, so that may come up in a future case.

And after the appeals court shot down Celgene's attempt to avoid suing Mylan in West Virginia, there may not be many ways left for branded companies to avoid the strict venue limits for ANDA cases.

"With this most recent case, I think the nail has been put in the coffin of the argument that wherever the drug may be marketed and sold at some point in the future represents infringing sales for the purposes of venue," said Peter Cuomo of Mintz.

Abernathy said, "I'm sure creative arguments can be made, but there's not a lot of room left, in my view, in the venue analysis."

The case is Celgene Corp. v. Mylan Pharmaceuticals Inc., case number 21-1154, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Kelly Duncan and Sarah Golin.

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