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TC Heartland & Hatch-Waxman: The Sky's Not Falling

By **John Kennedy**

Law360, New York (June 9, 2017, 1:24 PM EDT) -- The U.S. Supreme Court's recent TC Heartland decision is poised to shake up patent litigation across the country, but the process for suing over abbreviated new drug applications and biosimilars under the Hatch-Waxman Act will likely remain undisrupted and keep cases in the usual venues, experts say.

The May 22 ruling — issued in a dispute between TC Heartland and Kraft Food Brands Group over water-flavoring drops — restricted civil patent infringement suits to wherever defendants are incorporated, or where they have committed infringing acts and also have established places of business. In doing so, the court's eight justices — minus Justice Neil Gorsuch, who hadn't been confirmed when the case was argued — ended 27 years of patent holders essentially filing cases in jurisdictions with even the slightest connections to the alleged infringing acts, which many have long viewed as forum-shopping..

Commentary prior to the decision played up the possibility of a TC Heartland win being a significant game-changer, but experts say there's a good chance most Hatch-Waxman suits stay in Delaware and New Jersey, where they have long been filed and where many generics companies are incorporated or have offices.

"If you're a branded company, you had a pretty good run for the last 27 years or so," Baldassare Vinti, a partner at Proskauer Rose LLP, told Law360. "The visceral reaction was that 'the sky is falling' — I don't think that's going to play out in reality."

There will, of course, be generic-drug manufacturers that prefer to litigate in their home districts, as well as a possible increase in multidistrict litigation and perhaps an uptick in "protective suits" aimed at ensuring Hatch-Waxman cases are filed in the correct court, experts say.

"But I still have my doubts that [TC Heartland is] going to make a huge impact on Hatch-Waxman litigation," said Vinti, who focuses on patent litigation involving a variety of technologies, including medical devices and pharmaceutical capsules.

Business as Usual

While generics companies that are physically tied to Delaware and New Jersey will have a good reason to keep the cases there, those that aren't present in the two mid-Atlantic states may still decide to litigate Hatch-Waxman suits there, experts say, citing time constraints and the experience of the judges in those districts.

Some generic-pharmaceutical companies are comfortable in New Jersey, as they know the judges and the local rules, according to William F. Long, a partner at Dentons who has defended several generic-pharmaceutical companies in Hatch-Waxman suits.

“It’s not clear to me that they’re going to be all that anxious to go somewhere else,” Long said. “Why open a can of worms in front of a court that hasn’t handled that many Hatch-Waxman cases?”

Hatch-Waxman’s provision delaying the U.S. Food and Drug Administration’s approval of an abbreviated new drug application for 30 months after a lawsuit is filed could also play a role in keeping cases where they’ve historically been filed.

If a generics company fights the brand’s choice of venue, it could lose months and a decision might not be made by the end of that 30 months. In such a case, if the generic-maker wants to bring its product to market, it does so “at risk” and could potentially be liable for damages, says Ryan Blaney of Cozen O’Connor PC, explaining that generics typically want Hatch-Waxman cases to proceed efficiently and quickly.

Vinti agreed, saying the 30-month period means it may not be in a company’s interest to contest the location of the case.

“The more time you spend litigating venue, the more that cuts into your 30-month stay,” he said. “It may not be all that advantageous to be in your home court, if your home district is where there hasn’t been much ANDA litigation.”

More MDLs

Some, like Mayer Brown LLP partner Colleen Tracy James, expect to see a round of fights from generics arguing that they can only be sued where they’re incorporated or are otherwise established. This could lead to multiple cases in different jurisdictions, which is “difficult on a lot of fronts,” she said, naming inconsistent verdicts and tougher coordination as some such issues.

Many pharmaceutical companies, in that case, may turn to MDLs, James and others say.

“There are going to be situations that occur where the [new drug application] holder isn’t going to be able to sue all of the ANDA filers in the same jurisdiction,” says A. Antony Pfeffer, a partner at Orrick Herrington & Sutcliffe LLP.

While MDLs would streamline the process and consolidate multiple cases based in multiple courts, this route also has some potholes, including, again, maneuvering the 30-month stay. If an MDL doesn’t happen, the cases could go back to their original separate district, and if it does, it could take a while, burning up the 30 months, says Brian Burgess, a partner at Goodwin Procter LLP.

Another possibility is that the Judicial Panel on Multidistrict Litigation could send the cases to a court that’s inexperienced in handling ANDA disputes, since the JPML can ship cases anywhere they want. Given that Delaware judges are busy, the panel might not want to transfer an MDL there, Long says.

Protective Suits

The first part of the Supreme Court’s ruling is straightforward: sue companies where they’re incorporated.

But the second part, which deals with where alleged acts of infringement took place, is trickier. The filing of an ANDA is the act, which raises questions about where that's taking place — at the filer's office, at the FDA or elsewhere — Burgess says, adding that the law says "has committed" and ANDA suits are about planned acts.

James similarly said that ANDA infringement doesn't have a set location and differs from other cases likely to be affected by TC Heartland because it deals with an "artificial act."

"There's no actual event," she said. "In Hatch-Waxman, unlike other patent cases, you're creating an artificial scenario that hasn't happened yet."

Given the uncertainty surrounding the second part of law at issue in TC Heartland — 28 U.S.C. 1400(b) — branded plaintiffs choosing not to sue where a generics defendant is incorporated might also choose to file a second identical suit in a court where they know they're able do so, James says, noting that in order for the 30-month stay to take effect, a Hatch-Waxman suit has to be properly filed.

In such a situation, one case would likely be paused until the proper venue is sorted out, and then that case would proceed, she says.

Others don't think protective suits will be as necessary. If a company is fine with the state of incorporation, there's not really a reason to go elsewhere, Pfeffer said. He added that he doesn't think many branded companies will see such states as hostile territory, because there's often a difference between where companies are incorporated and where they actually call home.

Although Long understands why protective suits are filed, he also doesn't see their numbers increasing.

"If venue turns out to be incorrect in one state, then they've got a backup," he says. "The need for protective suits is now greatly diminished under TC Heartland. You can always sue someone where they're incorporated."

--Editing by Philip Shea and Kelly Duncan.
