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Par Pharma Suit Tests FDA's Drug Pricing Pushback

By **Jeff Overley**

Law360, New York (October 30, 2017, 8:30 PM EDT) -- Efforts by the U.S. Food and Drug Administration to combat dramatic price spikes for prescription drugs are being tested by a new Par Pharmaceutical lawsuit accusing regulators of improperly letting compounding pharmacies sell cheaper copycats, attorneys say.

Par, a unit of Endo Pharmaceuticals Inc., filed its complaint last week in D.C. federal court. It accuses the FDA of creating an "unlawful regime" that will allow compounders to churn out huge quantities of blood-pressure drug vasopressin, despite Par holding the only FDA-approved application for a vasopressin product.

Par's product, Vasostrict, won clearance in 2014 as part of the FDA's Unapproved Drugs Initiative. The initiative encourages drugmakers to invest in proving the safety and effectiveness of medicines that have been sold without formal approval for decades. But doing so results in all unapproved versions being temporarily kicked off the market, opening the door to price increases.

The increases have often been substantial and even eye-popping. Vasopressin sold for $5 per vial prior to Vasostrict. Now, Vasostrict's list price is more than $150 per vial, a Par spokeswoman said Monday.

In July, the FDA announced that compounding pharmacies could manufacture vasopressin in bulk quantities. Attorneys told Law360 that the FDA was almost certainly motivated by Vasostrict's soaring cost, even if the agency — which declined to comment — hasn't publicly said so.

"Clearly the level of price increase obviously has a lot to do with the public focus, and government officials are part of the public," Morgan Lewis & Bockius LLP partner Stephen Paul Mahinka said. "They see the issue. It's not like they don't know what's going on."

Par's complaint appears to be one of the first of its kind following Congress' passage in 2013 of the Drug Quality and Security Act. The law's 503B section created a special class of "outsourcing facility" compounders that can mass-produce drugs that are in short supply or satisfy a clinical need.

In its complaint, Par argues that compounded versions of vasopressin don't meet the DQSA's criteria. The FDA hasn't responded publicly, but compounders have said that a clinical need exists because Vasostrict — unlike compounded vasopressin — requires refrigeration and dilution that could delay emergency treatment.

Par wants to nullify much of the FDA's approach toward bulk compounding, arguing that it improperly allows unapproved copies of FDA-approved drugs. Lee Rosebush, a BakerHostetler partner who represents a vasopressin compounder, told Law360 that the case's outcome will likely have far-reaching implications.

"For a 503B facility, this has the potential to be a seminal case," Rosebush said. "And I think it's a matter of first impression on what is allowed or what is not allowed underneath 503B."

The fight is similar to litigation involving the FDA and K-V Pharmaceutical Co., which in 2011 won formal approval for Makena, a drug to prevent premature births, and then jacked up the price to $1,500 per dose from $20. The FDA responded by telling compounders that it wouldn't object if they produced Makena copycats, which subsequently nabbed much of Makena's market share.

"K-V made the terrible mistake of making the price of the drug super, super high," Hyman Phelps & McNamara PC director Karla Palmer said.

A court battle ensued, with a D.C. district judge finding that the FDA's "enforcement discretion" was immune from court review and the D.C. Circuit vacating that ruling in light of new legal precedent and passage of the DQSA. The parties ultimately settled prior to a final ruling on the merits.

That case made clear the financial stakes of allowing compounded competition, with K-V blaming its bankruptcy on the FDA. For Par, the FDA's endorsement of compounded vasopressin could seriously damage the market for Vasostrict, which has patent protection until 2035 and last year earned almost $345 million, accounting for two-thirds of Endo's revenue from sterile injectables.

A key issue in Par's case is the degree of similarity between compounded vasopressin and Vasostrict. The DQSA restricts bulk compounding involving a product that is "essentially a copy of one or more approved drugs."

According to Par, the FDA "has chosen to avoid rigor in examining what does and does not constitute a copy, leaving it to self-serving representations and misrepresentations of compounders."

But Rosebush pushed back, asserting that the FDA has wide latitude to make scientific determinations about whether two drugs are the same.

"The simple argument is that they're not substantially equivalent," Rosebush said. "The FDA's released their ... guidance, and I would argue that the discretion should given to the agency on this issue."

The guidance, which came out in January, describes an "interim policy" on products that can be compounded in vast quantities. But Par notes that the Trump administration has officially said it isn't developing further regulations on bulk compounding at this time. That's important because it lets Par argue that the purported interim policy is actually a final policy subject to court review.

However, FDA Commissioner Scott Gottlieb last month outlined new steps to encourage compounders to register with the FDA. In doing so, Gottlieb described "ongoing efforts to implement the DQSA" and said that the agency is "committed to realizing DQSA's framework" for 503B compounders.

Experts told Law360 that the FDA will likely argue that Par is acting prematurely and that the agency is

working in good faith to flesh out DQSA policies.

"It would presumably say it has set up procedures under the [DQSA] that are interim procedures ... and maybe it's not being done as quickly or precisely as the plaintiff would like, but we aren't doing nothing," Mahinka said, adding that the FDA routinely takes many years to draft and finalize regulations.

Par's lawsuit adds to a wealth of drama surrounding Vasostrict. For one, Par is facing an antitrust suit from Fresenius Kabi USA LLC, which says it has been unlawfully prevented from accessing vasopressin samples that are needed to develop a generic version.

In addition, Par is suing former employees for allegedly stealing information about Vasostrict and then starting QuVa Pharma Inc., which is now hoping to launch a compounded version of vasopressin.

Importantly, Par's complaint underscores the FDA's increasing willingness to intervene when consumers are facing major increases in drug costs. The agency has traditionally focused narrowly on ensuring that drugs are safe and effective. But more and more, it is signaling that public health also requires drugs to be affordable.

"This is a different economic and political context than you would have had 10 years ago," Mahinka said. "You would have said, 'Oh, by the way, this is going to have the following economic consequences. The agency would say, 'We don't deal with that. We're not interested in that. We won't even listen to that.' Now, it's different."

Par is represented by Philip J. Perry, John R. Manthei, J. Ben Haas and Andrew D. Prins of Latham & Watkins LLP.

Counsel information for the FDA was not immediately available.

The case is Par Sterile Products LLC et al. v. Hargan et al., case number 1:17-cv-02221, in the U.S. District Court for the District of Columbia.

--Additional reporting by Emma Cueto and Kat Greene. Editing by Pamela Wilkinson and Catherine Sum.