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Fed. Circ. Could Ease On-Sale Bar Threat To Pharma Patents

By **Ryan Davis**

Law360, New York (May 4, 2016, 1:23 PM ET) -- The full Federal Circuit will hear arguments Thursday in a patent case over the blood-thinning drug Angiomax that could narrow the reach of the on-sale bar and protect companies from invalidity findings if they outsource some parts of the manufacturing process for their inventions.

The on-sale bar holds that an invention cannot be patented if it has been on sale for a year prior to the patent filing. The court decided last year to reconsider when the bar applies after a panel used it to invalidate two of The Medicines Co.'s patents on Angiomax in a dispute with generics maker Hospira Inc.

The Medicines Co. did not sell Angiomax to the public before filing for a patent, but instead paid a supplier to make experimental batches while the drug was being developed. The panel said that was enough to trigger the on-sale bar and render the patents invalid, but the company told the full court the the decision expanded the rule "beyond any justifiable extension of precedent."

The court's decision to take the case en banc indicates it is interested in reconsidering the way the bar is applied, and a decision that relaxed the panel's strict interpretation would be welcome news in the life sciences industry, said Jeremy Cubert of VLP Law Group LLP.

"This is a very important case, especially in the biotech and pharmaceutical industry. Many companies rely heavily on third-party providers for manufacturing and testing because they're not vertically integrated to do all of those things," he said. "Having the on-sale bar triggered by going to a third party puts a serious burden on those companies and would gut patent protection for a whole range of things."

In recent years, companies have become less integrated and more have begun outsourcing aspects of the production process to third parties in order to save money and increase efficiency, so the outcome of the case will have widespread importance, said Jordan Sigale of Dunlap Codding PC.

The panel's holding that an outsourcing arrangement can render patents invalid under the on-sale bar "makes it really super tough for companies that can't make large quantities of things themselves, and there are a lot of companies like that," he said, adding that if the rulings stands, "it's going to stunt the further development of outsourcing culture."

The panel's decision took a literal approach to the on-sale bar and determined that since The Medicines Co. paid a third party to manufacture the drug, a sale took place and the bar applies. Sigale said that approach fails to take into account the policy behind the on-sale bar.

"It bothers me because the whole idea of the on-sale bar as I understood it was that we don't want companies to exploit their invention for a year of sales before they get a patent. But that's not what's going on here," he said.

Instead, The Medicines Co. made an arrangement with Ben Venue Laboratories to make the drug to ensure it met U.S. Food and Drug Administration requirements for impurity levels. That fact should have been given greater weight, Cubert said.

"There's a distinction in my mind between working with a third party to make sure the product meets FDA requirements and going out and selling to the public," he said.

Angiomax, which had U.S. sales of $599.5 million in 2014, is the brand name of a drug called bivalirudin used to treat blood clots. The Medicines Co. has two patents on methods of making the drug that reduce impurities and it alleged that Hospira's planned generic version infringes. The patents expire in 2028.

The case hinges on on The Medicines Co.'s arrangement with Ben Venue to prepare three batches of bivalirudin using the patented method more than a year before it filed applications for the patents at issue in 2008.

A lower court found that the deal did not trigger the on-sale bar, but the Federal Circuit reversed and invalidated the patents, finding that preparation agreement for the batches, which had a commercial value of more than $10 million, amounted to a sale.

When it agreed to hear the case en banc, the full Federal Circuit asked the parties to brief whether the arrangement at issue triggers the on-sale bar. It also asked whether the court should overrule a 2001 decision that there no "supplier exception" to the on-sale bar, which would have shielded The Medicines Co.

In its en banc brief, The Medicines Co. said that the panel's decision is unfair because a company that can develop its products in-house does not have to worry that its actions will trigger the on-sale bar, and the holding only impacts companies that outsource.

"These disparate results cannot be reconciled with this court's precedent or the policies underpinning [the on-sale bar]," it said. "The unequal application of the on-sale bar to confidential transactions between inventors and manufacturers who are working to develop a claimed product stifles innovation and hampers an inventor's ability to create his or her invention."

The company has the support of the U.S. Patent and Trademark Office, which filed an amicus brief saying that the on-sale bar should not apply in the case "because the patented drug product was never the subject of a commercial sale or offer for sale."

Hospira told the full court that the panel got it right and that The Medicines Co. and Ben Venue treated the outsourcing arrangement as "commercial in every respect," so "under settled legal principles, these circumstances triggered the on-sale bar."

The expansive questions the Federal Circuit asked when it agreed to hear the case en banc, including what constitutes a sale and whether there should be a supplier exception to the bar, show that the

court is considering an overhaul of the current standard, attorneys say.

"It's pretty wide open what the court can do with this," said Paul Calvo of Sterne Kessler Goldstein & Fox PLLC.

The court could retain its current practice of saying that arrangements with suppliers trigger the on-sale bar, create a new exception to the bar, or do something in between where whether or not there is an exception depends on the facts of the case.

"Once you introduce more of a sliding scale on what constitutes a supplier exception, things get gray really fast, so it might be be better to have more of a hard-and-fast rule," Calvo said.

The case is particularly important for smaller companies that often rely on outsourcing, but even large companies often don't do all of the manufacturing and research in-house, Sigale said.

Under the panel's interpretation, "if you need to manufacture anything outside the company that you ultimately decide is patentable, you're going to have a short leash and there's going to be a bar," he said.

It was perhaps more common for companies to do all their manufacturing under one roof years ago years ago when the on-sale bar was developed, but "the law needs to catch up with the reality of how the industry operates," Cubert said.

The patents-in-suit are U.S. Patent Numbers 7,582,727 and 7,598,343.

The Medicines Co. is represented by Edgar Haug, Porter Fleming, Angus Chen, Laura Krawczyk, Jason Kanter and Damon Lewis of Frommer Lawrence & Haug LLP.

Hospira is represented by Bradford Lyerla, Sara Horton and Aaron Barlow of Jenner & Block LLP.

The case is The Medicines Co. v. Hospira Inc., case number 2014-1469, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Katherine Rautenberg and Rebecca Flanagan.
