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Fed. Circ. Reins In Reach Of Double-Patenting Doctrine

By **Ryan Davis**

Law360 (December 14, 2018, 5:17 PM EST) -- Two recent Federal Circuit decisions have cleared up lingering questions about when patents can be invalidated under the double-patenting doctrine and identified situations where it does not apply, providing patent owners with ways to prevail against invalidity arguments.

The Dec. 7 decisions involved patents on different Novartis AG drugs. In each one, the court held that the patent at issue was not invalid for obviousness-type double-patenting, the doctrine aimed at preventing parties from extending the life of a patent by obtaining a second one that is not "patentably distinct" from it.

Both cases confronted questions that were left unanswered in the Federal Circuit's 2014 decision in Gilead Sciences Inc. v. Natco Pharma Ltd., which expanded the scenarios in which double-patenting can be found. As a result of the new decisions, the reach of that holding has been constrained in ways patent owners will welcome, attorneys say.

"The straightforward upshot of these decisions for the community and for sophisticated patent owners with large portfolios is that it really answers two outstanding questions that had put into doubt the validity of probably a reasonable number of patents," said Thomas Hedemann of Axinn Veltrop & Harkrider LLP.

The decisions the Federal Circuit reached in both cases "suggest the court is looking back and saying we need to limit the impact of Gilead," said N. Nicole Stakleff of Pepper Hamilton LLP.

The Gilead case reframed the way the doctrine of obviousness-type double-patenting is applied. Prior to the decision, courts would look at the order in which the two patents issued, and only the patent that was the last to issue could be could be found invalid for double-patenting.

However, the Federal Circuit held in Gilead that the key to the analysis is the order in which the patents expire, with the patent that is last to expire being the one subject to being found invalid. The holding left patentees, particularly in the pharmaceutical industry where companies have large and overlapping patent portfolios, with a "lot of angst," Stakleff said.

"You have to look at a lot more pieces right now, since Gilead it calls into question some of the terms for patents that ended up issuing earlier and expiring later," she said.

The change in the standard obviousness-type double-patent in Gilead "has created number of instances where defendants have been able to assert double-patenting as a defense," said Hedemann, who represented accused infringer Natco in the 2014 case.

This month's Federal Circuit decisions tackled some issues left unresolved in the Gilead case about how the new standard would be applied in practice, narrowing its application in each one.

"I would characterize the two decisions as further defining the contours of the obviousness-type double-patenting doctrine, particularly answering several questions that were raised by the Federal Circuit's decision in Gilead v. Natco," said Brianne Bharkhda of Covington & Burling LLP.

Interestingly, Federal Circuit Judge Raymond Chen authored the Gilead decision as well as both of the Novartis decisions.

"In some ways, it's almost Judge Chen circumscribing his own decision in Gilead from a few years ago," Hedemann said.

In one of the Novartis cases, Novartis AG v. Ezra Ventures LLC, the Federal Circuit addressed what happens when one patent expires later than another due to a patent term extension, a provision of the Hatch-Waxman Act allows patent owners to extend the life of a drug patent to compensate for delays in obtaining regulatory approval.

In the case, an earlier-filed Novartis patent on the multiple sclerosis drug Gilenya that was subject to a patent term extension ended up expiring later than a similar patent the company filed later. The Federal Circuit held that the later-expiring patent could not be invalidated for double-patenting based on the earlier-expiring patent, noting that the doctrine is a judge-made rule.

To hold otherwise, "would mean that a judge-made doctrine would cut off a statutorily authorized time extension," the court wrote. "We decline to do so."

The decision "affirmed the ability to obtain patent term extension without the threat that there might be an obviousness-type double-patenting problem raised based on the patent term extension itself," said Natalie Derzko of Covington & Burling. "That's an important determination that came out of the Federal Circuit."

The other new decision, Novartis AG v. Breckenridge Pharmaceutical Inc. dealt with a scenario where Novartis had two patents on the cancer drugs Zortress and Afinitor, and the one filed earlier expired later than the other due to a 1995 law that changed the length of patent terms.

The Federal Circuit held that because the earlier-filed patent expired later than the later-filed patent due to an act of Congress, not as a result of any gamesmanship by Novartis to obtain a longer patent term, it could not be invalidated for obviousness-type double-patenting based on the the earlier-expiring patent.

"A change in patent term law should not truncate the term statutorily assigned" to a patent, the court concluded.

"The court suggested in the Novartis v. Breckenridge case that they were focusing on when the challenged patent was actually filed and what obviousness-type double-patenting practice applied at the time," Derzko said.

The Federal Circuit's holding that a change in the law should not give rise to a double-patenting invalidation makes sense, but it seems to conflict in some ways with the Gilead decision, Hedemann said.

The court emphasized in Gilead that the rationale for the double-patenting doctrine is that once a patent expires, the public should have the right to use an access the claimed invention and any obvious variants, he noted. However, the Novartis v. Breckenridge ruling means that when patents have different terms due to the change in law, the public cannot access the invention after the earlier patent expires in some situations.

"The rationale was that this wasn't really the patent owner's fault because it was a just a change in the patent system," Hedemann said. "Of course that's a reasonable explanation, but it does run a little contrary to the big idea decision in the Gilead decision."

The two decisions did not clear up all the unanswered questions about double-patenting left by Gilead. For instance, it is not clear how the courts will treat patents with differing expiration dates as a result of patent term extension, which lengthens patents to account for delays at the patent office.

That practice is similar to patent term adjustment, which the court addressed in the Ezra decision, but is based on a different statute with different wording, so the court will have to address that in a future case.

"What we feel could be a positive light shining in the distance might not be there because there is a difference in the statutes," Stakleff said.

As a result of both decisions, the Federal Circuit has now identified exceptions to the Gilead holding that earlier-issuing but later-expiring patent can be invalidated for double-patenting based on later-issuing but earlier-expiring patents.

The court suggested that double-patenting applies when the patent owner engaged in gamesmanship, but not when the earlier patent has a longer term based on statutory provisions.

"These two cases provide helpful clarification about other factual scenarios to which arguments about the application of obviousness-type double-patenting based on Gilead were being made," Bharkhda said.

The cases are Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc. et. al., case number 17-2173, and Novartis AG et al., v. Ezra Ventures LLC, case number 17-2284, both in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Katherine Rautenberg.

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