

Gilead could move to bundle recent Idenix patent disputes, likely to hinge on issues of prior art, invalidity – attorneys **BioPharm Insight**
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- Same patents in play in Delaware lawsuit and USPTO interference proceedings
- Gilead or court could group lawsuits together
- Lab notebooks, novelty and nonobviousness to come under consideration

Gilead Sciences (NASDAQ:GILD) may move to consolidate the most recently filed patent infringement lawsuits filed by **Idenix Pharmaceuticals** (NASDAQ:IDIX), intellectual property (IP) attorneys said. The suits' ultimate fate will probably boil down to prior art or invalidity concerns, they added.

In December 2013, Idenix announced it filed two separate lawsuits against Gilead: a patent infringement suit in the US District Court in Boston, Massachusetts (Idenix US Patents 6,914,054 and 7,608,597) and a patent infringement and interference claim in the US District Court in Wilmington, Delaware (Idenix US Patent 7,608,600 and Gilead US Patent 8,415,322).

Concerning the recent Massachusetts filing, it is hard to give guidance on the next actions and timing, according to an Idenix spokesperson.

The '600 and '322 patents in the Delaware lawsuit are the same patents involved in a second patent interference. On 9 December, Idenix announced the United States Patent and Trademark Office (USPTO) declared a patent interference between Idenix's US Patent 7,608,600 and Gilead's US Patent Application 11/854,218, both related to the use of certain 2'-methyl, 2'-fluoro nucleoside compounds to treat HCV infections. The USPTO declared Idenix the senior party, per the 9 December press release.

The Delaware infringement and interference case that Idenix initiated in the beginning of December is separate from the USPTO interference case, she explained.

The Idenix spokesperson declined to comment further.

Gilead did not return request for comment.

Both companies are developing drugs in the "nuc" class. Gilead's Sovaldi (sofosbuvir) for the treatment of HCV was FDA-approved in December 2013. Idenix does not have an approved product, with its most late-stage asset in Phase II.

Actions could be consolidated to single jurisdiction

It is possible the two suits get lumped together, said Chad Landmon, partner, Axinn, Veltrop & Harkrider, Hartford, Connecticut, though Idenix could protest as it likely had reason for bringing actions in two different jurisdictions. The court will have to look at whether the two patents are infringed by Gilead and whether they are invalid, he added.

It is a bit unusual to have actions in two states, and Idenix may perhaps want to keep them separate to use information from one case against Gilead in the other case, suggested Michael Samardzij, partner, Bracewell & Giuliani, Houston, Texas. Still, Gilead may try to combine the actions, he agreed. All Idenix has to show is infringement of at least one claim to be eligible for damages, he added. Idenix could get a set of damages for one suit and another set of damages from the other suit, which is probably why Idenix wants two patent suits, Samardzij added.

It is possible for a complex litigation to get some consolidation, either at the hands of a district court judge or one of the parties could ask, said Imran Khaliq, partner, Arent Fox, San Francisco, California.

Gilead may try to consolidate the actions in one of the jurisdictions, said William Mulholland, partner, Snell &

Wilmer, Phoenix, Arizona, noting that Idenix may have identified some kind of advantage over Gilead in filing in two jurisdictions.

While the Delaware action cannot really be delayed, Gilead could ask the Massachusetts court to stay the action because there is a priority dispute over the IP, given the Delaware interference case, said Kevin Noonan, partner, McDonnell Boehnen Hulbert & Berghoff, Chicago, Illinois.

The multistate filing is somewhat unusual, said George Yu, counsel, Schiff Harden, San Francisco, California. While one litigation would be less expensive than two separate litigations, cost probably is not the main concern here, he added.

Infringement cases could evolve

The Massachusetts action seems like a more straightforward infringement action than the Delaware proceedings, noted Landmon. The Massachusetts suit will be more focused on the Idenix patents and the Gilead product, he said. The drug development process will be relevant, and the court may have to consider who made the compounds first and what the scope of the claims are, he said.

Sovaldi's label will be relevant for assessing the indirect infringement claims as the label relates to the method of treatment, said John Garretson, partner, Shook, Hardy & Bacon, Kansas City, Missouri. The product label is always important in assessing these types of infringement claims, he said.

Still, the ultimate suits' fates are not likely to hang on the matter of infringement, said one attorney. It seems the situation will play out as an invalidity or a priority case, where it comes down to which company can prove invention first, he said.

The Idenix '600 patent claims priority to provisional applications filed earlier than the Gilead '322 patent claims, Garretson noted. The Idenix patent is senior by about two weeks, but if the interference proceeds it will be a "trial by lab notebook," to look at inventor documents and records to examine who invented what, and when, said Yu.

"I strongly suspect that Gilead will bring prior art challenges, in terms of publication or perhaps internal work that Gilead had documentation of," said Yu. It is not unusual for a company to start off with a library of compounds until a lead compound is selected, so while the ultimate focus was on Sovaldi, experiments with other compounds in that collection could be prior art to the Idenix patents, Yu said.

The main debate will likely center around whether the patents include something new and not obvious, said Jeffrey Hovden, partner, Robins, Kaplan, Miller & Ciresi, New York. Given all the work being done by different parties in this area and the knowledge that nucs are important in viral treatment regimes, Gilead could try to invalidate Idenix's patents through obviousness, he added. Both company's compounds are nuc analogues, which essentially have the same structures and are tinkered with, he explained.

The designation of senior and junior parties in the interference proceedings could have some implications, at least in the Massachusetts case, said Marianne Timm-Schreiber, associate, Merchant & Gould, Denver, Colorado. In a previously filed interference proceeding, Idenix was not able to prove its provisional filing was a constructive reduction to practice, so it is curious if Idenix will be able to do so in the more recent actions, she said. Still, there are three provisional Idenix filings here, so Idenix may have a better chance of proving reduction to practice ahead of Gilead, she added.

In February 2012, the USPTO initiated a separate interference involving a pending Idenix patent application (US Patent 12/131,868) covering certain 2'-methyl, 2'-fluoro nucleoside compounds and a granted Gilead patent (US Patent 7,429,572) also related to certain 2'-methyl, 2'-fluoro nucleoside compounds. This patent interference is currently ongoing.

In the February patent interference, Idenix is the junior party in the second phase of the interference which is focused on "first-to-invent," said the spokesperson. Idenix is awaiting the decision of the second phase which is expected in 1H14, she said. Idenix is seen as unlikely to prevail in this patent interference, this



news service reported in April 2013.

Gilead has a market cap of USD 114.5bn. Idenix has a market cap of 944.7m.

by Christine Livoti in New York