

Idenix seen as unlikely to prevail against Gilead in HCV patent interference – attorneys **BioPharm Insight**

- Elapsed time to demonstrate diligence, reduction to practice a major hurdle
- Gilead's senior party status likely to trump all
- Idenix must submit brief on priority by 26 April, failure will lead to Gilead's win

Idenix Pharmaceuticals (NASDAQ:IDIX) faces an uphill battle to sufficiently demonstrate enablement in its ongoing patent interference against **Gilead Sciences** (NASDAQ:GILD) regarding their respective hepatitis C (HCV) intellectual property, attorneys said. Idenix is ultimately unlikely to prevail on the interference, they noted.

On 22 March 2013, Idenix announced the United States Patent and Trademark Office Patent Trial and Appeal Board (USPTO) issued a decision in the first phase of ongoing interference concerning Idenix's patent applications (U.S. Patent Application 12/131,868) and an issued Gilead patent (U.S. Patent 7,429,572) that covers certain 2'-methyl- 2'-fluoro nucleoside compounds useful in the treatment of HCV. Idenix was determined to have a later application filing than Gilead, thus designating the former as the "junior party" and the latter as the "senior party."

The second phase of the interference is expected to commence in 2Q13 and will determine which party was first to invent. The party who is deemed first to invent ultimately prevails in the interference.

"The decision from the Board of Patent Appeals and Interferences validates Gilead's perspective that we were the first to invent the compounds involved in the interference, as described in the '572 patent," a Gilead spokesperson commented. Idenix declined to comment.

Idenix's first claims to invention to be scrutinized

The primary outcome of the recent decision was to reallocate the junior and senior party, with Gilead now the senior party and Idenix the junior party. Idenix now has the burden of proof moving forward in this interference proceeding, said William Mulholland, counsel, Snell & Wilmer, Phoenix, Arizona. The senior party can sit back and wait to see what proofs of prior invention the junior party can provide, said Sandip Patel, partner, Marshall, Gerstein & Borun, Chicago, Illinois.

It is not uncommon for the junior and senior designations to change, as the interference may initially be set up without close investigation of the actual specification disclosures and priority dates of the inventions at issue, said Scott Chambers, partner, Patton Boggs LLP, Washington, DC.

Gilead's patent, US 7,429,572, was filed as U.S. Application No. 10/828,753, on April 24, 2004. The '572 application claimed priority to provisional application 60/474,368, filed on May 30, 2003. The Idenix patent application, U.S. Application No. 12/131,868, was filed June 2, 2008. The '868 application claimed earliest priority to provisional application 60/392,350, filed June 28, 2002

The USPTO granted Gilead's claim to the benefit of the '368 provisional application filing date, finding that Gilead had established "constructive reduction to practice" as the claimed subject matter was sufficiently described and enabled, Mulholland noted.

Idenix, on the other hand, was found not to have satisfied the requisite enablement threshold in its priority applications. The USPTO stated the Idenix teachings were incomplete, requiring "undue experimentation" for one skilled in the art to make and use the invention. The decision then denied Idenix's benefit claims to its prior applications, including the '350 application, and a prior divisional application 10/608,907, filed June 27, 2003, he said.

Given the change in the junior and senior party designations, it appears a case was made that Idenix's provisional applications do not fully support the subsequent utility applications, said Sandra Thompson, a shareholder in the Orange County office of law firm Buchalter Nemer. There could have been new things in

the utility filing that should not get the benefit of the earlier provisional application priority date, she said. It is not uncommon to file multiple provisional applications for each utility filing, as was done here, she added.

As part of the interference proceedings, both parties filed priority statements in June 2012, said Patel. In its priority statement, Gilead said the first conception of its HCV nucleoside was 6 December 2002, which predates its first patent application by about six months, he said. Idenix, in its statement, alleged a December 2001 conception date, he added. The USPTO would likely have ended the interference if Idenix alleged a conception date after the date on which Gilead filed its application, Patel noted.

Now Idenix must prove it conceived the nucleosides prior to Gilead and that Idenix was diligent in reducing the invention to practice from a period just before Gilead's December 2002 date up until the date Idenix actually made the nucleosides or up until 2 June 2008, the date the USPTO has now concluded that Idenix filed an application satisfactorily describing the nucleosides, Patel explained. Five years is an incredibly long period of time to show diligence for an invention like this, he said.

Lawrence Green, a shareholder with Boston IP law firm Wolf, Greenfield & Sacks, agreed, indicating the demonstration of reduction to practice requires daily activity. Idenix does not sound like it has good evidence for this, Green said, adding he has never seen a party successfully provide sufficient evidence for such a long time duration.

Idenix also did not claim to make the product any earlier than 27 June 2003, which is after Gilead's presumptive invention date, so "that also does not bode well" for Idenix in view of the USPTO's decision, Patel said. It is not impossible, "but I would be shocked if [Idenix] was able to win on priority of invention if it also must establish it was diligent over a five year period" he said.

Thompson countered the time it took Idenix to reduce to practice is not unheard of. From a chemical arts standpoint, it could be hypothesized a molecule with various substituents could work to treat a disease. An application could be filed on the basis of having a reasonable belief the invention will succeed, though it will ultimately take a long time to reduce to practice in going through the various analogues which can be created and subsequently testing all of those analogues, she explained.

If Idenix can prove an earlier actual reduction to practice, or an earlier conception coupled with diligence over the critical period, it could prevail, said Deborah Sterling, a director in the Biotechnology/Chemical Group at Sterne Kessler Goldstein & Fox, Washington, DC. This will come down to things like meeting minutes, lab notebook documentation, and affidavits from employees, said Thompson. However, Green noted daily documentation is required and it is hard to have records that date back 10 years. Additionally, a witness, such as a lab technician is needed to corroborate the evidence, which is a "daunting" task, Green said.

While Gilead alleged some claims against Idenix on the grounds of lack of written description and enablement in the interference, the USPTO dismissed these claims, noted Mulholland. The rationale was that Gilead alleged these claims only in relation to some, but not all of the Idenix patent claims at issue in the interference, he said. The board dismissed these claims because, even if true, the interference would still continue because other, non-contested, Idenix claims would still remain, he added.

Senior party prevails majority of the time

Senior party status in interference proceedings is undeniably important due to the burden the junior party must meet in proving a prior date of invention, said Mulholland. It is commonly thought that the senior party wins the majority of the time, in part because of the difficulty meeting this burden, he said, citing estimates of a 67% advantage for the senior party (Holland C, et al., Intellectual Property: Patents, Trademarks, Copyrights and Trade Secrets 2007).

Patel estimated the senior party to win three out of four times. Chambers agreed, noting 75% is a reasonable metric on the frequency with which the senior party prevails. Given the time it took Idenix to reduce its invention to practice, and the fact Gilead is the senior party, Chambers predicted Gilead had a strong likelihood to ultimately prevail. Thompson wagered a 50% chance the senior party designation holds

for Gilead and that Idenix will not prevail.

Further recourse may be possible through appeals process

Idenix could concede the whole priority phase of the interference proceedings, and appeal the decision the USPTO made on 22 March to the Federal Circuit or file a district court action, said Patel. A district judge could essentially redo the interference, he noted. These district court actions are rare, but this is partly because there are not presently many interference cases, he explained.

However, it will be a long shot that Idenix would prevail on appeal, according to Robert Gould, partner, Husch Blackwell, Chicago, Illinois. He predicted Idenix would lose the interference considering the junior party almost never wins.

The district court actions are rare because often interferences have a sufficiently well-developed record of evidence and findings, with a resolution of a dispute of law being sought, which is easiest done with the Federal Circuit, said Patel.

It is almost always true that an interference will either go to district court followed by the Federal Circuit or straight to the Federal Circuit, said Chambers. Though the interference may only take a few years, the cases then get tied up in one of the courts for an additional period of time, he said. The cost of going to the Federal Circuit, and in some cases into district court, at that point is a minor addition compared to the cost that has already been sunk into the process. Chambers added there are not typically settlements involved in interferences in the pharmaceutical arts.

By 26 April this year, Idenix has to show diligence of reduction of practice, Green pointed out, as stipulated by the USPTO Interference Timeline to Priority Motions. While an extension is possible, if the junior party fails to submit a brief on priority by this time, the interference will end with Gilead as the winner, Green said.

Idenix has a market cap of USD 447.4m. Gilead has a market cap of USD 72.8bn.

by Christine Livoti and Anusha Kambhampaty in New York