

Jury finds for Merck in hepatitis drug fight with Gilead

March 22 2016, by Linda A. Johnson

A federal jury in California has ruled in favor of drugmaker Merck & Co. in a high-stakes lawsuit against rival Gilead Sciences Inc. over patents for lucrative new drugs that rapidly cure hepatitis C.

Merck accused Gilead of infringing on <u>patents</u> it filed over a decade ago, claiming Gilead's sofosbuvir infringes on those patents. Merck, which is based in Kenilworth, New Jersey, is seeking billions in damages and royalties on sales of Gilead's two hepatitis drugs.

Sofosbuvir is the active ingredient in Gilead's Sovaldi and a component of its Harvoni. They were launched in 2013 and 2014, respectively, and became blockbusters overnight. Together, the two drugs brought in \$19.1 billion last year—nearly two-thirds of total revenue for Gilead, a biologic drugmaker based in Foster City, California.

On Tuesday, a jury in San Jose, California, ruled Merck's patents are valid. That came a month after a federal judge ruled that Harvoni and Sovaldi do infringe on Merck's patents. Now the jury's ruling sends the case to a new phase to decide damages.

"The jury's verdict accurately reflects the evidence in this case," Merck said in a statement.

Merck won U.S. approval on Jan. 28 for its own hepatitis C <u>drug</u>, Zepatier, and priced it well under Harvoni's list price of \$94,000 per treatment course. That set up a battle between the companies to win



favorable formulary positions, and thus more sales, from insurers and prescription benefit managers.

Meanwhile, the courtroom battle concerned whether Pharmasset, a company Gilead bought for \$11 billion in 2011 to get the rights to then-experimental drug Sovaldi, used Merck's 2002 patents to develop that drug.

Merck argued that Gilead infringed two patents for compounds and methods to develop treatments for the liver-destroying virus. Merck said it, a company called Ionis Pharmaceuticals of Carlsbad, California, and their partners spent years and significant money developing Zepatier.

Gilead denied any patent infringement, saying Pharmasset began working on sofosbuvir's development a year earlier.

In a statement Tuesday, Gilead said, "Although we are disappointed by the jury's verdict today, there are a number of remaining issues to be decided by the jury and the judge. Therefore, it is premature to comment any further."

According to Merck, Gilead initially filed the lawsuit, seeking a declaratory judgment that the Merck and Ionis Pharmaceuticals patents were invalid.

Merck had been a dominant maker of hepatitis C treatments until Gilead's drugs were approved. Those drugs, as well as Merck's and new ones from a couple other rivals, have revolutionized treatment for hepatitis C, which roughly 3 million Americans have.

Older drugs required a year of treatment, with awful side effects, yet barely cured half of the patients. The new drugs cure about 95 percent of patients in eight to 12 weeks.



In after-hours trading, Merck shares rose 1.8 percent to \$54, and Ionis Pharmaceuticals rose nearly 3 percent to \$42.95. Shares of Gilead dipped 2.5 percent to \$91.35.

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