



## F. Hoffmann-La Roche v. Gilead Sciences, Inc.

In 2012, Gilead Sciences, a leading biopharmaceutical company, placed a huge bet when it acquired Pharmasset Inc., a small pharmaceutical company that was developing an antiviral drug, sofosbuvir, to treat hepatitis C. Industry analysts considered the \$11 billion deal a risky move by Gilead given that sofosbuvir had not yet been approved by the FDA. Gilead's bet paid off and sofosbuvir (now marketed under the brand name Sovaldi®) was approved by the FDA as a breakthrough drug in December 2013.

When Hoffmann-La Roche sought to strip Gilead of its rights to this blockbuster drug, Gilead turned to Cooley.

### Groundbreaking Drug

Sofosbuvir is a revolutionary new therapy for individuals infected with the hepatitis C virus. The drug cures over 90 percent of patients with the most common form of hepatitis C and enables patients to avoid the need for more costly treatments, such as liver transplants.

Gilead launched the drug under the brand name Sovaldi®. Within the first six months of going to market, Sovaldi® earned nearly \$6 billion in sales, making it one of the most successful drug launches in history.

### Bet-the-Company Arbitration

In March 2013, Roche initiated an arbitration against Gilead, asserting rights over sofosbuvir under a 2004 collaboration agreement between Roche and Pharmasset. The collaboration agreement granted Roche an exclusive license to "PSI-6130," Pharmasset's then-lead drug candidate, and "its prodrugs." In its arbitration demand, Roche asserted that sofosbuvir was a "prodrug" of PSI-6130 and, accordingly, was subject to Roche's exclusive license. Roche further claimed that sales of Sovaldi® violated Roche's patent rights, which had been granted through the collaboration agreement. The case turned on the meaning of "prodrug," which was not defined in the agreement. In view of Roche's claim of exclusive rights and the enormous value of Sovaldi®, one analyst referred to a potential victory by Roche as the "Doomsday litigation scenario."

### CLIENT PERSPECTIVE

"This was a bet-the-company litigation and the Cooley team came through. The Cooley team's combination of deep trial experience and scientific expertise was critical to the success of this case. The cross examinations of Roche's witnesses were devastating to Roche's case. Thank you for helping us vindicate our strongly held belief that Roche's case was without merit."

– **Brett Pletcher, General Counsel,**  
Gilead Sciences

### KEY FACTS

- Gilead's new hepatitis C drug, Sovaldi®, is a breakthrough therapy and blockbuster product for the company, which analysts estimate will generate over \$10 billion in sales annually
- Competitor Roche challenged Gilead's exclusive rights to the drug in a three-member panel arbitration proceeding
- After a two-week arbitration hearing, Cooley secured a ruling in favor of Gilead, which found that Roche failed to establish any rights to the drug





## A Winning Defense Strategy

As one of Gilead's go-to law firms for over a decade, Cooley worked closely with a team of Gilead lawyers to develop a comprehensive strategy to defeat Roche.

The stakes were sky high and seeing the matter through to a ruling carried significantly more risk than agreeing to a settlement. However, Gilead had the fortitude to stay the course, trusting Cooley to present the case before a panel of three arbitrators during a two-week arbitration hearing in June 2014.

In August 2014, the arbitration panel issued its award, ruling in favor of Gilead and finding that Roche failed to establish any of its contract or patent-based claims to sofosbuvir. Although the panel's opinion remains confidential, the result of the ruling is that Roche has established no rights to sofosbuvir and will receive no damages.



## THE COOLEY TEAM



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