9. Patent Right$

Hepatitis C is a stealthy blood-borne disease, displaying no visible symptoms for years, while insidiously destroying the liver over time. The Hepatitis C virus (HCV) causes inflammation of the liver, and can lead to serious liver damage such as scarring (cirrhosis), liver cancer, and liver failure. For about 80% of those infected, Hepatitis C becomes a chronic condition. According to the Centers for Disease Control and Prevention, approximately 3.2 million people in the United States have chronic Hepatitis C; the World Health Organization estimates that between 130 and 150 million people are currently infected with chronic Hepatitis C worldwide. Unlike Hepatitis A and Hepatitis B, there is no vaccine for Hepatitis C.

The traditional course of treatment for Hepatitis C lasts up to 48 weeks, with a drug cocktail that includes interferon or ribavirin. From 10-50% of those treated with the cocktail benefit. For some, the progression of the disease is slowed. For others, a cure is effected, with HCV no longer detectable in the blood, due either to the drugs or spontaneous viral clearance. Even those who benefit, however, almost universally suffer debilitating side effects from interferon or ribavirin. Additionally, any liver damage remains.

Created by Gilead Sciences, Inc., Sovaldi™ received a US Food and Drug Administration (FDA) Priority Review and Breakthrough Therapy designation. This designation is granted when a new drug demonstrates a significant improvement over other therapies in at least one aspect of treatment outcomes. In this way, a promising drug can move more quickly to market. Sovaldi™ evidenced several improvements over the standard treatment: reduction of treatment time to twelve weeks, reduction or elimination of interferon for most patients, and a cure rate of up to 90%. On December 6, 2013, the FDA approved Sovaldi™ for treatment of chronic Hepatitis C.

Despite its efficacy, access to Sovaldi™ is limited by its price. It is most expensive in the U.S. where drug companies determine the price for their products. At $1000.00 per pill, the twelve-week course of treatment costs $84,000. Many insurers are unwilling to add Sovaldi™ to their formularies because of the sheer number of those with Hepatitis C. Express Scripts, the country’s largest pharmacy benefit manager, tried for a year to negotiate with Gilead for discounts, but to no avail. Stating that Gilead’s price was too high. Express Scripts no longer includes Sovaldi™ in its formulary, including instead a less expensive drug from AbbVie that was recently approved by the FDA.

Gilead announced that it would allow pharmaceutical companies in 91 developing countries to make low-cost versions of Sovaldi™. Still, affordability remains an issue, even when Gilead offers deep discounts. For example, although Gilead offered India a 99% discount, the $840 cost of treatment exceeds India’s per capita annual income ($616 in 2012). In January 2015, India’s patent office denied patent protection to Sovaldi™, stating that the drug did not evidence an improvement over existing treatments. The decision allows local pharmacists to make cheaper generic versions of the drug.

Some accuse Gilead of making a cost-prohibitive drug that sick people desperately need. Dr. Andrew Hill of Liverpool University estimates that the cost of producing Sovaldi™ is somewhere in the range of $68–$136 per pill. Critics note that Sovaldi™ brought Gilead over $10 billion in its first year on the market.
Others defend Gilead’s actions. Pharmaceutical companies like Gilead create and bring new drugs to market. Research, development, and clinical trials are expensive, and drug companies need to be able to profit from their efforts. A 2013 study by Forbes places the cost at about $5 billion for each new drug that comes to market, a cost that reflects the failure of 95% of experimental drugs for reasons either of safety or effectiveness. Profits provide incentive for further research and development. Companies have an obligation to provide return on their investment to shareholders. Supporters of Gilead’s pricing policy point out that even at $84,000 for a course of treatment, the cost savings compared with a lifetime of traditional treatment are significant. Sovaldi™ costs significantly less than a liver transplant or treating complications of liver failure.

Critics express a further concern. They worry that a black market will develop for Sovaldi™, both within individual countries and internationally, with people from countries where Sovaldi™ costs more buying the drug from countries where the cost is less.

Case from the 2016 Intercollegiate Ethics Bowl National Competition
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