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HEALTHCARE

Patents and the Pharmaceutical Industry

by Elle Mahdavi

Patent protections were built to encourage research and development of life-saving medications. However, manipulations of the market exclusivity that comes with patents raise ethical concerns and incentive issues. Read more about patent-protected drugs.

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Patents are a way to prevent market failure and allow for greater investment in research. However, patent-protected drugs face no price caps nor competitors for about twenty years, giving patent holders market exclusivity. In an ideal world, medicine would be accessible to all. To continually create new and better medications, however, somebody has to invest in research for them, and unfortunately, the amount of financial capital

required is no small figure. In 2014, the Tufts Center for the Study of Drug Development estimated that it takes around $2.6 billion and a ten-year long time commitment to develop and license a new prescription drug. Without patents, certain pharmaceutical companies wouldn't invest in research themselves but would instead wait around for another group to discover and license the drug. Then, those companies could price the drug lower than their competition. This would result in a market failure, in terms of a positive externality, as other companies would benefit from the research of one group without having to pay for it.

Patents and Market Exclusivity

Corporations wouldn't want to invest their time and money in something they wouldn't be able to profit from due to competition. Thus, the amount of pharmaceutical innovations in society would be less than the socially optimal quantity. Patents are a way to combat this market failure. By giving pharmaceutical companies a twenty-year patent where prices can't be regulated by the government or altered by competition, companies are incentivized to make these huge financial and temporal investments.

Similarly, corporations wouldn't want to invest in research for drugs that treat only a small group of people such as people with "orphan diseases" like Lou Gehrig's or Tourette's. In the United States, an "orphan disease" afflicts only around 200,000 people, which in the eyes of companies, constitutes a small market when considering the amount of research required for developing prescription drugs. To stimulate production of these drugs, the U.S. government passed the Orphan Drug Act, giving companies seven years of market exclusivity for treating certain rare conditions. Much like a patent protected drug, an orphan drug could be set at any price during these seven years, as it doesn't face competition nor government restrictions.

The Issues

Too much regulation would stunt innovation, but too little regulation can restrict people's access to life-saving medications. Patent protections allowed Martin Shkreli to change the price of Daraprim, a medication used by AIDS patients, from $13.50 to $750 per pill in 2015. They would also allow Marathon Pharmaceuticals to price their muscular dystrophy medication at $89,000 a year.

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Some corporations who had been selling a specific drug on the mass market have filed for orphan drug status for that drug. Corporations usually attempt this once their patent has expired so that they can extend their market exclusivity for an additional seven years. AbbVie, one of these corporations, received orphan drug status for Humira, which alleviates rheumatoid arthritis symptoms. Although primarily advertised to treat rheumatoid arthritis, which afflicts 1.5 million Americans, AbbVie argued that Humira also treats uveitis, which afflicts only a few hundred thousand Americans. Although Humira does address an orphan disease, the research that went into Humira was towards alleviating arthritis rather than towards alleviating uveitis. AbbVie used the Orphan Drug Act to its advantage, receiving orphan drug status for Humira when the medication wasn't created with uveitis specifically in mind.

Besides ethical concerns, some claim that patent protections actually can cause incentive issues. Because patents can be sold, certain companies have adopted the strategy of purchasing licenses and hiking up drug prices instead of investing in research for new medicines themselves. Essentially, these patent laws have created a middleman between the inventors and the patients—a market for buying and selling patents. This new market, a byproduct of patent protections, is also left unregulated.

Necessary Changes

The goal of a business, at the end of the day, is to profit. There's a need for patents so companies are incentivized to make hefty investments for products that save lives. However, it's possible to regulate and incentivize at the same time. And, that's something Americans might prefer. According to a Kaiser Health News poll, seventy-eight percent of respondents supported a price ceiling on certain prescription drugs. During the 2016 presidential race, the controversy of drug prices came up frequently, as the topic was even related to a California ballot initiative. Hillary Clinton had proposed creating an agency to regulate drug prices and punish "unjustified" price hikes. Of course, the term "unjustified" is subjective and its definition would vary between administrations, but such an agency could determine which drugs are vital to a patient's health and calculate an equitable cap that allows companies to profit and most patients to have access. As for orphan drugs, the agency could determine what the marketed and primary use of a drug is in order to determine whether it warrants orphan status.

In general, businesses will try to maximize their profits, and these attempts typically result in an overall benefit to society in terms of cheaper prices and greater innovations. In the case of pharmaceutical companies with unregulated market exclusivity, however, these attempts to profit can end up hurting society, as unreasonable prices can restrict access to health care—an arguable human right.

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