Patent challenges reduce pharmaceutical innovation and productivity, researchers say

October 15 2009

A Georgia Tech study suggests that successful Paragraph IV patent challenges are decreasing the incentives for pharmaceutical innovation and contributing to productivity and revenue declines in the pharmaceutical industry. Credit: Georgia Tech Photo: Gary Meek

The development of new and innovative pharmaceuticals is being stifled by a U.S. law and successful patent challenges that embolden generic competition, according to an article published in this week's issue of the journal *Science*.

Matthew Higgins and Stuart Graham, assistant professors in the College of Management at the Georgia Institute of Technology, argue in their article that the recent surge in Paragraph IV patent challenges -- a provision of the Hatch-Waxman Act of 1984 -- is decreasing the incentives for pharmaceutical innovation and contributing to

productivity and revenue declines in the pharmaceutical industry.

"With the current healthcare debate, consumers and policy-makers need to understand that while we are getting cheap drugs now, it may be at the cost of novel future innovations and long-term access to new treatments because in our current system, industry revenues support continued research and development, and patents support revenues," explained Higgins, the Imlay assistant professor of strategic management at Georgia Tech.

While Congress passed the Hatch-Waxman Act to ensure timely, affordable access to innovative drugs, 25 years later its balance between pharmaceutical innovation and access is tipping away from the incentives needed to support innovation, the researchers said.

A contributor to this shift is the recent surge in Paragraph IV challenges, which allow manufacturers of generic drugs to challenge a brand company's patents by claiming that either the patent is invalid or the generic drug does not infringe the patent. If the generic company wins the challenge, the brand company loses its remaining market exclusivity for that product.

Federal Trade Commission statistics show that generic firms won 42 percent of the Paragraph IV challenges filed from 1992 to 2000. Since 2001, pharmaceutical companies have filed 749 lawsuits responding to Paragraph IV challenges on 243 unique brand-name products. These suits nearly tripled from 2002-2003 and doubled from 2006-2007.

"A Paragraph IV lawsuit will likely cost a generic manufacturer $5 to $10 million, compared to at least $800 million required for a brand company to develop a drug and bring it to market," said Graham, who is also a licensed attorney. "And the reward for being the first successful Paragraph IV challenger is substantial -- 180 days during which no other

generic-producing company may enter the market and an average potential payoff during those 180 days alone of $60 million. The law is creating incentives to bring challenges on more and different types of drugs."

As the number of patent challenges has increased, the number of new compounds approved annually by the U.S. Food and Drug Administration (FDA) has fallen from an average of 35 in 1996-2001 to 20 in 2002-2007. Without policy intervention, the effective life of key patents will continue to decline, which will further compress the payback period during which brand-name firms can recoup research and development investments, according to the researchers.

"Lawmakers should consider increasing the length of time brand-name drugs are on the market before generic drugs can enter, because the current five-year period is typically insufficient to recoup research and development costs," added Higgins.

Graham and Higgins suggest that exclusivity be extended for first-in-class and high-risk, high-necessity drugs, such as a preventive medicine for Alzheimer's disease or osteoarthritis. In addition, they propose that policy-makers use incentives to encourage private investments in research to complement public research or offer increased exclusivity to curative and preventive drugs. Auctions could allow companies to bid on specific research projects in return for extended data or market exclusivity.

A 2007 report from The National Academies recommended that the United States should at least double the duration of data exclusivity to bring it closer to allowances awarded in the European Union, Japan and Canada. Congress is currently debating a rule allowing 12-year data exclusivity for biologic drugs. These drugs include a wide range of products such as vaccines, blood and blood components, allergenics,

somatic cells, gene therapy, tissues and recombinant therapeutic proteins.

Currently, the researchers are continuing their investigations into the causes of pharmaceutical productivity decline through a recently formalized relationship that allows them access to IMS Health's databases. The relationship came through Georgia Tech's connection with former IMS board member and Georgia Tech alum John Imlay. The company's databases -- widely considered the gold standard in pharmaceutical and healthcare market intelligence -- cover the entire life cycle of drugs from how doctors and patients used them to how they fared in the marketplace.

In other research, Higgins and Graham are investigating the causes and responses of internal productivity declines experienced by the pharmaceutical industry and Graham is examining the importance of patenting to startup biotechnology firms.

Source: Georgia Institute of Technology