Evidence suggests that introducing product patents on drugs in India led to a limited overall increase in drug prices with no effect on use.

Governments policy toward the pharmaceutical sector can potentially affect incentives for innovation as well as the use of available treatments. While there has been much work on policies affecting the pharmaceutical sector in the United States and other industrial countries, relatively little empirical work has been done on developing countries. This is surprising given the profound changes affecting the pharmaceutical market in developing countries in recent years.

One type of policy recently implemented in India, China, and Brazil and now being considered in many African countries is an increase in patent enforcement. From the 1970s through the 1990s in India, for example, patents were issued on the process of manufacturing a product rather than on the product itself. This meant that a slight modification in the synthesis of a molecule yielded a new patent and thus allowed several firms to produce essentially the same drug. Indeed, copies of global brands such as Lipitor and Prozac were manufactured and sold in India by generic firms within two years of being introduced in the United States.

The policy controversy over the impact of stronger intellectual property rights (IPRs) in developing countries is stark. A weak IPR regime might benefit developing countries by allowing domestic firms to imitate foreign technologies to enhance access to pharmaceuticals. But it might also reduce incentives for R&D investments in drugs that could especially benefit developing countries. Perhaps in part because of this second point, the World Trade Organization recently started to require member countries to change their enforcement of patents. The implementation of the Uruguay Round agreement in 1995 entailed putting in place a system of product patents and legal protection for all Trade-Related Intellectual Property Rights (TRIPs), including pharmaceuticals. As a result, beginning in January 2005 firms in India (and in 2002 for China and 1997 for Brazil) could no longer reverse-engineer patented products.

The debate about the merits of implementing TRIPs has also been contentious in the economics literature. Patent enforcement is likely to lead to higher prices for drugs, which might lower their use and adversely affect health. Several recent academic papers have echoed these concerns, using theory and empirics to forecast the potential welfare losses for current and future consumers through higher drug prices. But prices may not rise if most drugs affected by the patent reform have therapeutic substitutes and thus face substantial competition from other products. In addition, the innovator patent holder might be somewhat more efficient at production than generic imitators, and its lower costs might to some extent offset the market power effect.

A new paper by Duggan and Goyal explores the effects of introducing product patents for one segment of the Indian pharmaceutical market—central nervous system drugs. In terms of retail sales, this is the second largest therapeutic category in the world and one of the fastest-growing segments in India. The authors use proprietary data on pharmaceutical sales in India during 2003–08 and link these data to when product patents were granted. They differentiate between two types of product patents. A product patent claiming the active ingredient is generally the strongest and is likely to prevent any use of the same drug. In contrast, ancillary patents on chemical variants, alternative formulations, delivery systems, and relatively minor aspects of the drug may not exclude generic entry. The reason is that a local manufacturer may be able to use a different, noninfringing mechanism to accomplish a similar incremental drug innovation.

The identification strategy exploits the differential timing of product patents across drugs during the 2003–08 period. The key identifying assumption is that the timing of the patents is not correlated with other, unobserved factors that might affect the price and use of the drug. The findings suggest that the introduction of product patents was associated with a significant increase in the share of total quantity sold by the innovator, especially for patents granted to the drug compound. The share did not increase to 100 percent in most cases because innovator firms could still grant voluntary licenses to generic firms to manufacture and sell their products. The authors also find an increase in average prices after the introduction of stronger product patents, but no detectable significant effect on use.

The findings contribute to the growing theoretical and empirical work on the effect of patent policies on the pharmaceutical industry. Access to data on actual pharmaceutical product patents granted by the government of India provides a unique opportunity to empirically examine the impact of product patents on pharmaceutical prices and use. The preliminary analysis undertaken by Duggan and Goyal underscores the importance of heterogeneous effects on prices by the type of product patent granted on drugs, implying the need for a careful examination of the product patent portfolio.