

CHANGE IN PATENT REGIME AND THE ROLE OF BRANDED AND GENERIC DRUGS ON PRICE AND QUANTITY: EVIDENCE FROM THE INDIAN PHARMACEUTICAL INDUSTRY 1995-2009

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Policies that promote innovation i.e. patent rights are often controversial given their opposing effects on innovation and access to medicines at affordable prices. Our study suggests that stronger patent regimes increase the introduction of original drugs due to its effect on stimulating technology transfer and appropriability of R&D investments. We label this as the *appropriability effect*. It also stimulates imitation and increases the number of generics. We label this as the *imitation effect*. Due to preference for new drugs by physicians and/or customers, both these effects increase the prices and the quantity consumed in a market.

EMPIRICAL APPROACH TO ASSESS THE EFFECT OF RE-INTRODUCTION OF PRODUCT PATENTS

We use a unique data set that covers 429 four-digit Anatomical Therapeutic Classification codes (product markets, henceforth) covering 18 disease categories for which we could accurately match the market with Indian product patents. Our dataset covers the period 1995-2009. Our identification strategy is based on comparing changes in the number of original branded drug products and branded generic products and their prices and quantity within a disease category over time.¹ We also examined the differences between less sophisticated markets pre 2005 (i.e. *old* markets) to the more sophisticated markets those that came into being post 2005 (i.e., *new* markets).

KEY FINDINGS

Our results suggest that the introduction of products patents in a market increased the number of original branded products. This result is consistent with the view that stronger patent regimes increase appropriability of R&D investments and the number of innovative original products, confirming appropriability test. Our results also suggest that the introduction of products patents in a market also increased the number of branded generics. This is consistent with imitation effect i.e. stronger patents also stimulate inventing around an innovation, reverse engineering and imitation (Cohen et. al, 2000) and may stimulate the entry of generic brands in a market.

Whereas there was *no difference* in the increase in the number of original branded products between the *new* and *old* markets, the increases in branded generics were *higher* in *old* markets relative to *new* markets. These differences between the *old* and *new* markets indicate that *in newer markets, the imitation effect was far lower* whereas the

¹ A disease category also represents a two-digit ATC code. For instance, all drugs sold in the product markets with a prefix A10 represents medicines that are used to treat diabetes.

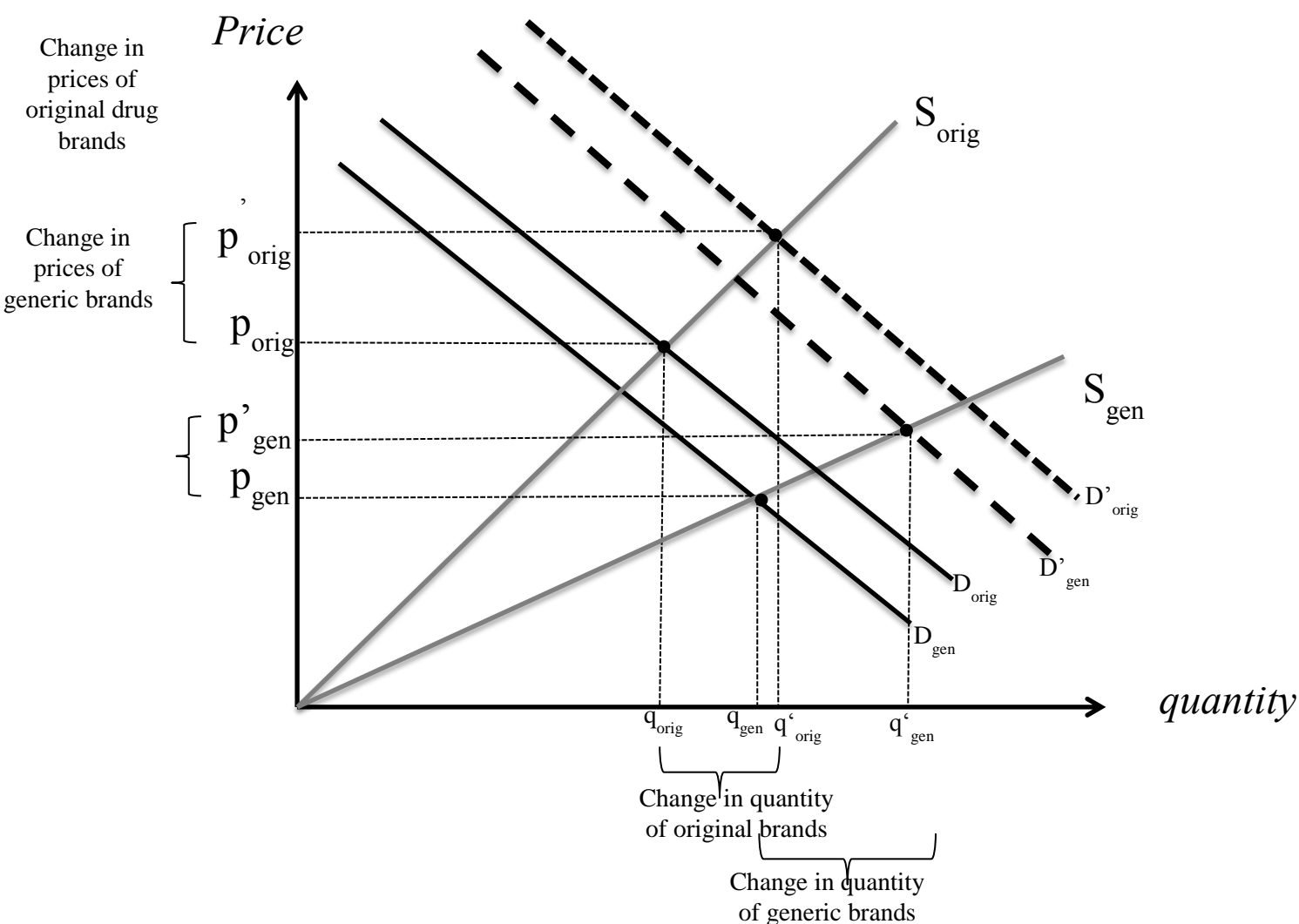
appropriability effect was more or less similar. As a result, we find that in the *new* markets, price increases were *higher*, whereas quantity increases were *lower* after the introduction of product patents.

Our study suggests that the ultimate effect of patent rights on prices and the quantity consumed is contingent on two competing effects. While stronger patent rights stimulate innovation and the introduction of new products, they also aid in the diffusion of knowledge (Arrow, 1962). The mere fact that stronger patents increase price is often interpreted as loss to consumer welfare. The findings highlight gains for markets and suggest that policymakers may benefit by encouraging original branded entry along with the generic manufacturers.

IMPACT OF PATENT REGIME CHANGE

We first investigate the influence of product patent on the number of original branded products in Indian market. For instance, markets that have a greater demand may also have more original drugs (Aboulnasr et. al 2008). On the contrary, due its effects on appropriability of R&D investments, stronger patent rights may induce the introduction of more original drug brands. Also stronger patent rights may increase imitation leading to increases in the number of generic brands in a market. Given that the physicians and/or consumers may prefer newer products to older ones; both appropriability effect and imitation effect should cause an outward shift of the market demand curve which consequently should increase both the prices as well as the quantity consumed in a market (Refer Figure 1).

Figure 1: Effects of a stronger patent regime on prices & quantity consumed in a market (demand & supply)



We argue that in markets in which the increases in the number of original drugs brands are higher, the consequent increases in prices will be *higher* whereas the increases in the quantity consumed will be *smaller*. Conversely, in markets in which the increases in generic products are higher, the consequent increases in prices will be *smaller* whereas the increases in the quantity consumed will be *higher*. We use the two empirical facts alluded to above to construct the demand-supply framework in which the market prices and the quantity consumed are determined at equilibrium. The first is the fact that the original drugs despite their higher prices are also consumed in greater quantities relative to generics. All else equal, this plausibly reflects a greater preference on the part of physicians/customers for original drugs. The second, is the fact that the marginal cost of original drugs are higher than generics given that many of the original drugs are manufactured outside India.

ANALYSIS

We first examine how the reintroduction of product patents influences the number of original brands, branded and non-branded generics in new versus old markets. If the increases in (a) original branded drugs in new markets are higher than or equal to (lower) the increases in old markets and (b) increases in both generics are lower (higher) in new markets relative to old markets; then the increases in prices with the reintroduction of product patents should be higher (lower) in newer markets whereas the increases in the quantity consumed should be lower (higher) in new markets when compared to old markets.

The changes in the composition of brands on account of stronger patent rights can arise for two reasons – increased appropriability of R&D investments and effect of patenting on imitation (Arrow, 1962). Figure 2 shows that the number of original drug brands were higher in markets that atleast had *one product patent (dotted line)* compared to markets with *zero product patent (solid line)*. Figure 3 shows that the number of generic brands were higher in markets with atleast a single product patent relative to markets that did not even have a single product patent.

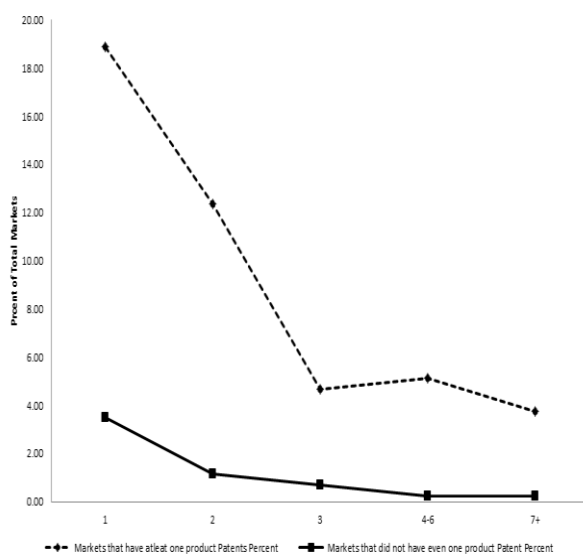


Fig 2: Distribution of Original Drugs by whether a market had a Patent (dotted line)

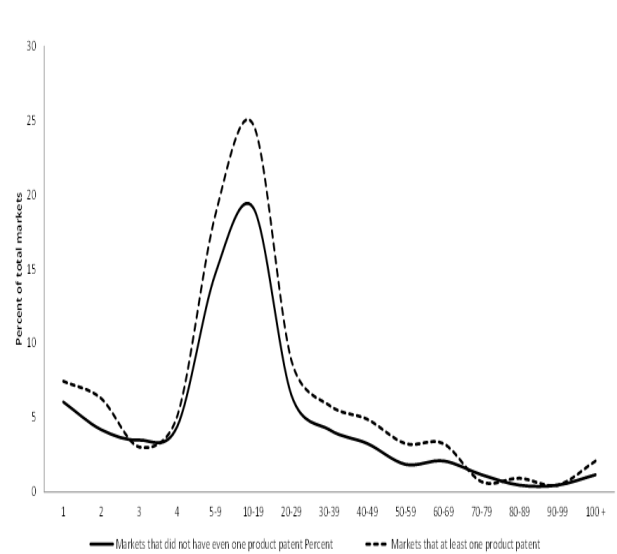


Fig 3: Distribution of Generics by whether a market had a Patent (dotted line)

Figure 4 below compares the (unconditional) percentage change in original drug brands from three years prior to introduction of a product patent in a market to three years after the product patent was introduced. Figure 5 compares the (unconditional) percentage change in generic drug brands three years before and three years after the introduction of product patent. Both the figures show that the number of original as well as generic drug brands increased after the introduction of product patents.

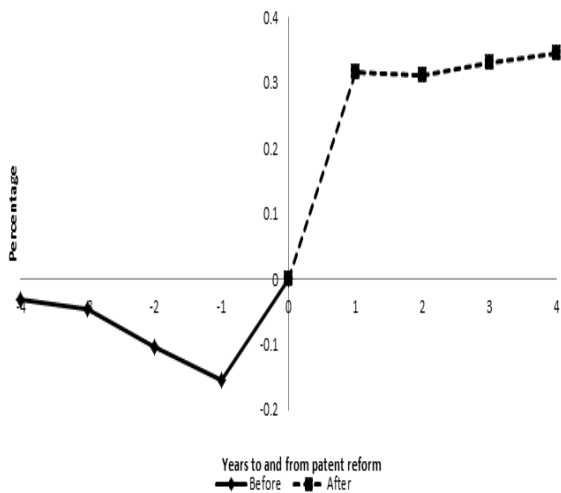


Figure 4: Change in Original Drugs before and after product patent

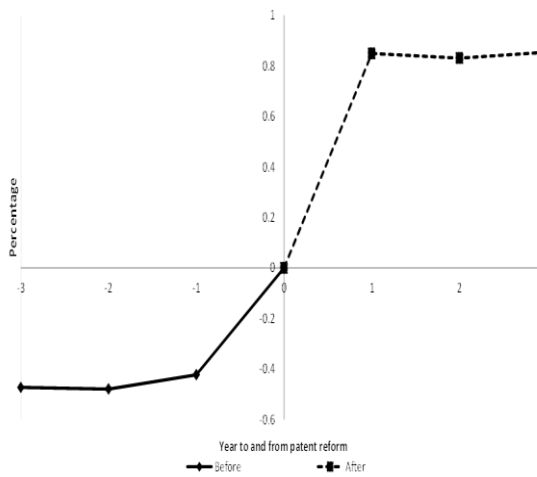


Figure 5: Change in Generics before and after product patent introduction

Our data suggests that introduction of product patent increased the number of original drug brands by 14 percent (approx.) and generic brands by 28 percent (approx.). Using sample averages, this translates to around 0.12 more original brands per market and around 5.12 additional generic brands in markets with atleast one product patent.² Our results also suggest that in markets in which the reintroduction of product patents increased original drug brands by more, the quantity increases in markets that had at least one product patent were lower whereas the prices increases in markets in such reform markets were higher.

Figure 6 depicts the percentage change in prices three years before and after introduction of patents in India. We also analysed the percentage change in total quantity consumed three years before and after patent introduction (refer Figure 7) and came to the conclusion that the reintroduction of patent not only boosts the prices but also the consumption.

² Calculated as follows: The sample mean of branded generics in a market is 18.29. An increase of 28 percent implies $18.29 \times 0.28 = 5.12$

Figure 6: Change in prices before and after product patent introduction

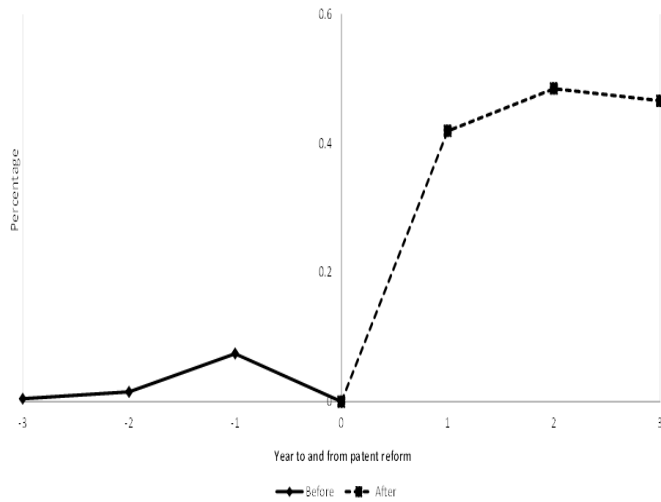
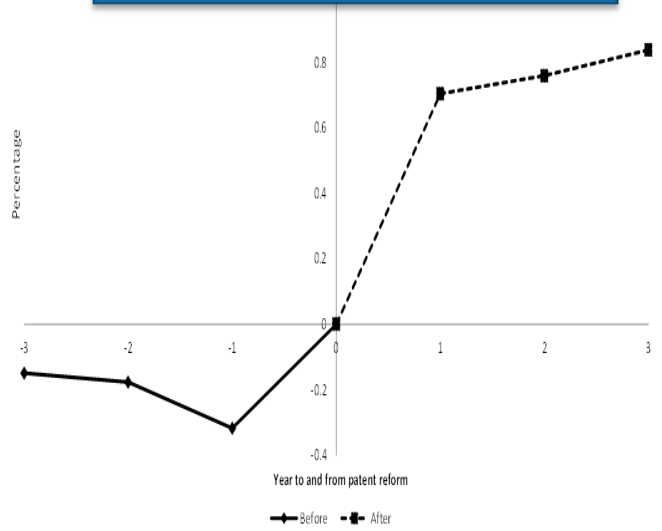


Figure 7: Change in quantity consumed before and after product patent



INSIGHT

The dynamic gains that arise from stronger patents may take two forms – the introduction of original products as well as generic products. Consistent with the view that stronger patent regimes increase appropriability of R&D investments and should increase the number of innovative original products (Lanjouw, 1998; Cockburn, Lanjouw and Schankerman, 2016), our results suggest that, the introduction of products patents increased the number of original branded products .

Consistent with an alternate view, that stronger patent regimes can also stimulate reverse engineering and imitation (Cohen et. al, 2000), they also appear to increase imitated products . To the extent that consumers or physicians prefer new products, both increases in original and generic products should shift out the market demand curve and increase both the market prices and the quantity consumed. However, our results also suggest that the extent of the increases in price and quantity depends on how the composition of products changes in a market.

Our study has implications for policy. Policy makers often concentrate on the static loss aspect of stronger patents and the effect of patent rights on prices. They also highlight the gains to the market from increased imitation by generics. In addition, our results suggest that the extent of dynamic gains in a market may be contingent upon how the composition of product is altered by changes in the patent regime.

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