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The consumer welfare implications of governmental policies and firm strategy in markets for medicines

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ABSTRACT

This paper empirically examines the consumer welfare implications of changes in government policies related to patent protection and compulsory licensing in the Indian market for oral anti-diabetic (OAD) medicines. In contrast to previous studies on the impact of pharmaceutical patents in India, we observe, and estimate the welfare effects accruing from *differential pricing* and *voluntary licensing strategies* of patent-holding innovator firms. Three novel molecules belonging to the dipeptidyl peptidase-4 (DPP-4) inhibitor class of OADs have been launched in India by the patent holders, at lower prices than those prevailing in the developed countries. Using aggregate market transaction data, we structurally estimate demand and supply and use the parameter estimates in our model to simulate consumer welfare under various counterfactual scenarios. Our results suggest that the introduction of DPP-4 inhibitors generated a consumer surplus gain of around 7.6 cents per day for a typical DPP-4 inhibitor user under the existing differential pricing and voluntary licensing strategies. If the innovators decide to price at developed-country levels, this surplus is eliminated almost entirely. The issuance of *compulsory licensing* does not always improve consumer welfare because if innovators defer or delay the introduction of new drugs in response, the loss in consumer welfare could be substantial.

1. Introduction

Pharmaceutical markets in developing countries have seen drastic changes in recent years both from the policies adopted by the government, such as the introduction of patent protection under the Trade Related Intellectual Property (TRIPS) Agreement of the World Trade Organization (WTO), and the strategic responses by firms to such policy changes. In this paper we address two key questions related to these changes. First, what is the impact on consumer welfare in developing countries when innovator firms adopt a policy of differential pricing, perhaps as an *a priori* response to the potential threat of compulsory licensing?[1] While differential pricing is bound to lower prices and improve consumer welfare in developing economies, the magnitude of such an impact is an important empirical question and still remains under-investigated. Second, if a developing-country government were to impose compulsory licensing on pharmaceutical patents or fails to exclude unauthorized imitators of new patented molecules (thereby weakening the enforcement of patent rights), what could be the repercussions in terms of consumer welfare?[2] Therefore, while consumer welfare can improve in the short run due to lower prices, it may decrease in the long run if the innovators' response is to not enter (or delay entry) into markets with weak patent protection. The existence of these static and dynamic considerations necessitates a careful evaluation of how these policy and managerial decisions affect consumer welfare.

We answer the above questions in the context of the market for oral anti-diabetics (OAD) medicines in India. India has been

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[1] *Differential pricing* is a practice where the manufacturer charges different prices in different markets, equivalent to what economists commonly term as third degree price discrimination. A *compulsory license* is defined as a practice where a government allows an individual or firm other than the patent holder to produce the patented product or use the patented process without the consent of the patent owner in order to improve accessibility of the product. (See: WTO (2006)).

[2] Weakening of patent rights implies innovators have less incentive to launch new drugs in such markets (Kyle, 2007).

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labelled as the "diabetes capital of the world" with epidemiological estimates noting that one out of every six diabetics in the world resides in India (Chakrabarty, 2012; Verma, 2009). Needless to say, it is a vibrant market for OAD drugs sold by both domestic and multinational firms. In the late 2000s, a new class of OAD, dipeptidyl peptidase 4 (DPP-4) inhibitors, was introduced in India. Three molecules in this class—sitagliptin, vildagliptin, and saxagliptin—were some of the first molecules to be sold under patent protection in post-TRIPS India. The patent holders of these molecules launched these products at significantly lower prices than those in developed countries. Their marketing rights were also licensed out voluntarily to local companies. We exploit these changes in the market environment to obtain our results. First, following past work in the literature (e.g., Berry, 1994), we estimate a structural model of demand and supply for product-differentiated OAD drugs in the Indian market during 2004–2011. We then use the econometric estimates to simulate market outcomes under various counterfactual scenarios and calculate the change in consumer surplus relative to the baseline, wherein the DPP-4 inhibitors are patent-protected and the innovators engage in differential pricing and voluntary licensing.

To examine the impact of differential pricing on welfare, we construct a counterfactual where the prices of DPP-4 inhibitors are set at the levels prevailing in developed countries. The impact of compulsory licensing is evaluated by employing three different counterfactuals. In the first, we let all three DPP-4 inhibitors be supplied competitively by local firms. The resulting change in consumer surplus represents the maximum short-term gain that can be realized through a policy of compulsory licensing. In the second and third scenarios, we allow the older DPP-4 inhibitors to be supplied competitively under compulsory licensing, but assume that the remaining molecules are not launched in India. Such an outcome is likely if innovators expect their Indian sales to be unprofitable under a compulsory licensing regime or if they hope to influence the direction of future policy changes. The change in consumer surplus resulting from this sequence of actions represents, in a sense, the long-term impact of compulsory licensing.

Our results indicate that a combination of differential pricing and voluntary licensing by innovators significantly improves consumer welfare. Specifically, a typical DPP-4 inhibitor user gains an incremental surplus of 3.58 Indian rupees (INR) per day (around 7.6 cents) because of the introduction of DPP-4 inhibitors, but that surplus is eliminated almost entirely if the innovators price the drugs at developed-country levels.[3] We also find that the consumer surplus gain due to DPP-4 inhibitors increases by around 23% if all three molecules belonging to that class are supplied under compulsory licensing. However, if compulsory licensing is imposed only on sitagliptin, and the patent holders of the other two DPP-4 inhibitors respond with a strategy of not entering the market, there is a loss in consumer welfare of around INR 2.5 (around 5.3 cents) per DPP-4 inhibitor user, relative to the baseline. We also show that should compulsory licensing be imposed not just on sitagliptin but also on vildagliptin, and if that is accompanied with saxagliptin not being launched in the Indian market, there is a loss in consumer welfare of around INR 0.15 (less than a cent) per DPP-4 inhibitor user, relative to the baseline.

These results provide novel evidence on how governmental policies and accompanying firm responses can have significant welfare implications, along the lines of Erfle and McMillan (1990), Glazer and McMillan (1992), and Ellison and Wolfram (2006). This is also one of the few papers that documents the welfare consequences of international price discrimination, especially in the context of pharmaceutical markets in the developing world (Danzon, 1997). While Verboven (1996) and Goldberg and Verboven (2005) have shown the presence of price discrimination in the European car market, they do not calculate welfare effects resulting from this practice. This has been now discussed in the context of pharmaceutical patent policy in developing economies (Lanjouw, 1998; Fink, 2001). In addition, we also extend prior work that estimates the welfare implications of shifts in pharmaceutical patent policy in developing economies such as India (Chaudhuri et al., 2006; Dutta, 2011). The results also contribute to a better understanding of the diffusion of new drugs in developing economies in the post-TRIPS era (Cockburn et al., 2014; Berndt and Cockburn, 2014; Kyle and McGahan, 2012; Berndt et al., 2011; Scherer and Watal, 2002) and adds to the debates around evergreening, patent challenges, and effective market life in medicine markets (Hemphill and Sampat, 2012).

The rest of the paper is organized as follows: Section 2 reviews the relevant literature and provides some institutional and industry background. In Section 3, we present our research design and methodology, discussing the alternative policy scenarios, outlining our structural model of a discrete choice demand system and an oligopolistic price-setting industry. Sections 4 and 5, respectively, describe the data and the results. Section 6 concludes.

2. Literature review and industry background

2.1. Literature review

Our work builds on the literature that examines the welfare consequences and firm responses to changes in the policy framework for pharmaceuticals. Grabowski et al. (1978), in one of the first studies, capture the effect of regulation of product approval on innovation in the pharmaceutical industry. They show that the industry experienced a decline in innovation following the tightening of regulation by the US Food and Drug Administration. In a recent study pertaining to the debate on innovation versus affordability in the pharmaceutical market, Filson (2012) shows that price controls result in welfare decreases not only in the US, but also in the rest of the world. He finds that while consumers benefit from lower branded drug prices under price controls, they also lose from the decreased flow of new drugs. In another related study, Branstetter et al. (2011) explore the impact of accelerated generic entry on innovation and welfare in the US hypertension drug market.

The welfare impact of pharmaceutical patent protection has also attracted some theoretical attention. For example, Hughes et al. (2002) simulate the emergence of new drugs in a world without pharmaceutical patents and find that long-run welfare is decreased as a result of slower innovation. Several other papers have examined the welfare implications of compulsory licensing, in which a government (usually, but not necessarily, of a developing country) allows generic drug manufacturers to sell a patented pharmaceutical product without the innovator company's permission. Bond and Saggi (2014) show that when the technological gap between two countries is large, the mere threat of compulsory licensing leads to significant gains for the importing (i.e., technologically backward) country.

In terms of geographical setting, our study is closely related to Chaudhuri et al. (2006) who examine the welfare impact of introducing patent protection in the Indian pharmaceutical market using demand data on fluoroquinolones, a class of antibacterials. In a more recent study which is also methodologically similar to this paper, Dutta (2011) estimates the welfare losses resulting from patent enforcement and price deregulation for 43 drugs in India.

[3] Between 2004 and 2011, the period covered by our dataset, the exchange rate between the Indian rupee and the US dollar (USD) ranged from 45.2 to 48.8 INR per USD. Throughout the paper we use the exchange rate of INR 47 per USD.