The Welfare Implications of Patent Protection, Pricing, and Licensing in the Indian Oral Anti-Diabetic Drug Market

Chirantan Chatterjee[*], Kensuke Kubo[❖], Viswanath Pingali[⬩]

This version: March 15, 2013

(VERY PRELIMINARY: PLEASE DO NOT CITE)

Abstract

We evaluate the welfare effects of differential pricing, voluntary licensing, and compulsory licensing in the Indian market for oral anti-diabetic (OAD) drugs. This market includes a new class of molecules called DPP-4 inhibitors, all of which are under patent protection in India. The Indian prices of DPP-4 inhibitors are higher than those of other drugs in the same segment, but only a fraction of the price in the U.S. and other developed countries (i.e., the patent holders practice international differential pricing). The patent holders also license the products out voluntarily to local manufacturers who have wider geographical reach in the Indian market. Our methodology involves the application of a discrete choice demand model to market data from IMS India. The model allows us to calculate consumer welfare, under the status quo as well as under counterfactual policy scenarios such as compulsory licensing whereby the government forcibly assigns the right to sell the patented product to local manufacturers. It also allows for the simulation of market outcomes under different pricing and licensing strategies by the patent holders. Our results indicate that differential pricing and voluntary licensing together have a large positive impact on consumer welfare in the OAD market. We find that the assignment of compulsory licenses for DPP-4 inhibitors to local manufacturers generates an increase in consumer welfare, but the magnitude is small. We also simulate the welfare impact of freeing one of the molecules in the OAD segment from price control, and find it to be negative and large. These findings have significant implications for the policy choices faced by the Indian government.

Keywords: pharmaceuticals, India, patents, licensing, demand estimation, welfare

JEL Classification: L11, L24, L65, O12, O34

[*] Assistant Professor, Indian Institute of Management, Bangalore.
[❖] Associate Senior Research Fellow, Institute of Developing Economies, Japan External Trade Organization.
[⬩] Assistant Professor, Indian Institute of Management, Ahmedabad.

1. Introduction

Pharmaceutical markets in developing countries have seen drastic changes in recent years. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (henceforth, TRIPS Agreement), which came into force with the creation of the World Trade Organization (WTO) in 2005, member countries of the WTO have had to align their intellectual property regimes with international standards. In many developing countries, this involved providing previously unavailable protection to pharmaceutical product patents. Reduced competition due to patents meant that innovator firms who develop new drugs could price them higher than before.

But this comes about amid concerns on affordability of healthcare and the policy debate on access to medicines. Not surprisingly, the pricing of pharmaceuticals in developing countries has received greater attention from national governments and the international community, as they became more concerned about the health of citizens, particularly those at the lower end of the income distribution. These concerns have led to the improvement or introduction of institutions aimed at improving the access to drugs for the citizenry. Policy measures used in this regard include price controls along with the expansion of state-sponsored health insurance schemes. Some governments, notably those of Thailand, Brazil and India, have tried to undo the price-increasing effect of patents by issuing compulsory licenses which allow local companies to sell patented drugs without the patent holder's permission. Compulsory licenses are permitted within the ambit of WTO-TRIPS provided certain conditions are met. While some authors such as Tandon (1982) have theoretically analyzed the welfare consequences of compulsory licensing, no rigorous empirical analysis on this issue has been conducted till date.

Innovator firms from the OECD economies who engage in drug discovery have pursued their own strategies amid these developments. Their lobbying activities were influential during the negotiation phase of the TRIPS Agreement, which led to the adoption by signatory countries of a Western-style patent regime characterized by stronger protection (Yu, 2009). More recently, innovator firms have responded to concerns about the availability of drugs in developing countries by differentially pricing their products. Differential pricing, or tiered pricing, involves pricing the same drug differently across regions, with lower-income countries receiving significantly lower prices. While differential pricing, together with the licensing of patented drugs to local companies, has been widely recommended as a way to improve the

affordability of medicines in developing economies (see, for example, Danzon and Towse, 2003), no study till date has quantified the welfare effect of such strategies being adopted by innovator firms.

Our study addresses this gap in the literature by quantifying the welfare impact of differential pricing and voluntary local licensing in the Indian oral anti-diabetic drug market. We also evaluate the welfare effects of compulsory licensing and price controls. The oral anti-diabetic (OAD) segment contains a new class of drugs called dipeptidyl peptidase-4 (DPP-4) inhibitors which was introduced in the late 2000s. Three novel molecules belonging to this class were launched in the Indian market by their patent holders, all of whom have practiced differential pricing by setting lower prices for the Indian market. Two of the companies have also licensed the sale of their molecules voluntarily to local partners. Till date, the Indian patent rights pertaining to DPP-4 inhibitors have continued to be enforced, so that the innovators and their voluntary licensees remain the sole suppliers.

Our analysis consists of estimating a model of product-differentiated demand and supply for the Indian OAD market during 2004-2011. Using our estimates from the demand system, we are able to compute the welfare gains due to the introduction of DPP-4 inhibitors. We also investigate the welfare implications of differential pricing and voluntary licensing by comparing simulated consumer surplus levels under alternative scenarios. The welfare implications of compulsory licensing and price control policies are examined in a similar manner.

Our results indicate that differential pricing and voluntary licensing together have a large positive impact on consumer welfare in the OAD market. We find that the assignment of compulsory licenses for DPP-4 inhibitors to local manufacturers generates an increase in consumer welfare, but the magnitude is small. We also simulate the welfare impact of freeing one of the molecules in the OAD segment from price control, and find it to be negative and large.

Our study is closely related to Chaudhuri et al. (2006) and Dutta (2011) who examine the welfare impact of introducing patent protection into the Indian pharmaceutical market. They estimate demand in markets where there are no product patents, and simulate the welfare effect of newly introducing patent protection. In contrast, we estimate demand in markets where patents are currently protected, and simulate the impact of removing protection through compulsory licensing. Chaudhuri et al. (2006) and Dutta (2011) both find a large negative

impact on welfare due to patent protection. While the results are not directly comparable, our analysis suggests that this negative impact would be greatly ameliorated if patent holders engage in differential pricing and voluntary licensing.

The remainder of the paper is structured as follows: Section 2 presents relevant background information on the Indian pharmaceutical market, followed by a literature review in Section 3. Section 4 presents the econometric model which consists of a nested logit demand system and an oligopolistic price-setting industry. Section 5 describes the welfare analysis simulations. We describe the data in Section 6, followed by a discussion of our results in Section 7. Section 8 concludes.

2. Background

2.1 Pharmaceutical Patent Protection in India

India has been known for many years as the home of a vibrant generic pharmaceutical industry. The impetus came in 1972 when the Patents Act (1970) came into force and abolished pharmaceutical patents except those pertaining to manufacturing processes. Local firms, who could copy new drugs without worrying about infringement, rapidly gained market share within India and eventually began to export their products overseas (Lanjouw, 1998). Today, the Indian pharmaceutical market has revenues of around INR 1 trillion (around $18.4 billion), with roughly 60 percent being sold in the domestic market[1].

Another significant institutional change occurred in 2005 with the re-introduction of pharmaceutical patent protection under the TRIPS Agreement. India has been a signatory of TRIPS since 1994, but a transition provision allowed the implementation of pharmaceutical patent protection to be delayed until 2005. Pharmaceutical patent applications that were filed in the meantime were kept in a “mailbox”, to be examined after 2005.

The previous decade saw many multinational pharmaceutical manufacturers, who hitherto were reluctant to launch new drugs in the Indian market, showing renewed interest in the India market (Chaudhuri, 2011). Numerous pharmaceutical patents have been granted to them since 2005, and several patented products have already been launched. Events that began in 2008, however, raised doubts about the security of pharmaceutical patent protection in India. Several

[1] 1 Indian Rupee (INR) is equal to 0.018 US dollars as of February 2013.

Indian companies, notably Cipla and Natco Pharma, began to sell copies of patented drugs. The innovator firms have sought to exclude them through patent infringement suits, but failed to do so in many cases.

In March 2012, the Indian government took the drastic step of granting a compulsory license to Natco Pharma to sell sorafenib (a cancer treatment developed by Bayer Health Care) in the Indian market. Representatives of the innovator pharmaceutical industry have expressed their concern that this amounts to a drastic weakening of patent rights. Recent reports suggest that the Indian government may issue compulsory licenses for several additional drugs in the near future (Rajagopal, 2013).

2.2 Differential Pricing and Local Licensing in the Oral Anti-diabetic Market

While events such as the compulsory licensing of sorafenib have attracted the most media attention, several innovators have managed to maintain patent protection of their products in India. The most prominent of these belong to the DPP-4 inhibitor class of anti-diabetic drugs. DPP-4 inhibitors have a different mechanism of action from previous OAD drugs, and have been shown to be more effective or safer for certain types of patients. The first molecule in this class, sitagliptin, was first approved by the U.S. Food and Drug Administration in 2006. It was subsequently launched in India by MSD in May 2008. Two more DPP-4 inihibitors, vildagliptin and saxagliptin, were launched in September 2008 and April 2010, respectively. Vildagliptin was launched by Novartis and saxagliptin was launched by Bristol-Myers Squibb.

As Table 1 shows, the patent holders of DPP-4 inhibitors have engaged in differential pricing, setting an Indian price that is approximately one-fifth of the average price in the U.S., U.K., and Japan. These prices have been kept almost constant from the time of launch till date. In January 2009, Novartis began licensing the sale of vildagliptin to USV, an Indian manufacturer with strengths in the anti-diabetic segment. The objective was to utilize USV's wider reach in the domestic market. In response, MSD began licensing the sale of sitagliptin to Sun Pharma, another prominent Indian company. In both cases, the licensee has continued to charge the same price as the innovator.

It is not clear why the patent holders of DPP-4 inhibitor have thus far managed to maintain exclusivity over their products. One possibility is that the differential pricing and local licensing strategies of these firms have found favor with officials in the Indian government who

are in a position to influence the outcome of patent infringement suits and administrative procedures within the Patent Office. Incidentally, Bayer charged a high price for sorafenib (INR 280,000 for a months' supply) until it became the subject of a compulsory license in March 2012. This event was immediately followed by announcements by multiple innovator firms that they would lower the prices of their patented drugs in India. For example, Roche stated in the same month that it would license the Indian sale of its novel cancer drugs Hercpetin and Mabthera to a local company called Emcure. It also announced that the prices charged by Emcure would be lower than its own (Whalen, 2012). These actions were clearly aimed at preventing compulsory licensing of these products[2].

The innovators of DPP-4 inhibitors have thus far been able to keep compulsory licensing and at-risk entry at bay, perhaps as a result of differential pricing and voluntary licensing strategies. However, there is no assurance that this will continue It is in this context that this study aims to quantify the welfare effects of differential pricing, local licensing, as well as compulsory licensing.

3. Literature Review

The relevant literature for this study is that on estimation of demand for pharmaceuticals. A subset of this literature, to which this paper also belongs, estimates the welfare impact of changes in the regulatory environment. Demand estimation in the pharmaceutical market is of particular interest to economists because it is often the doctor and not the end user (patient) who determines the choice of the drug. Furthermore, any demand estimation in the Indian pharmaceutical industry has to consider not only the inter-molecular competition but also the intra-molecular competition as well. Given that the doctors in India write prescriptions based on the brand of the drug, and not its generic name itself, the decision making involves two steps: which molecule to choose from the available drugs, and within the chosen molecule which brand to choose. For example, in the context of oral anti-diabetics, a doctor has to decide first if metformin hydrochloride (a molecule) is appropriate for treating a patient, and second, within metformin hydrochloride, which brand to choose.

Several studies have estimated demand in the pharmaceutical industry using reduced

[2] Nevertheless, it was reported in January 2013 that the Indian government was considering compulsory licenses for Herceptin and other expensive biological drugs.

form regressions as well as, more recently, discrete choice modeling. In a pioneering study, Ellison et al. (1997) estimate the demand for cephalosporins (a class of anti-bacterial drugs) using a reduced-form regression equation. They model demand as a multi-stage budgeting problem highlighting various stages in decision making process. They compute own price and cross-price elasticity of demand and find high substitutability between the generic and branded versions of the same drug, as well between some molecule pairs. Cleanthous (2004) uses a random coefficients model to estimate the demand for anti-depressants in the US market. He uses the estimated model to compute welfare gains due to innovation in the therapeutic area, and finds substantial welfare gains to the patients resulting from such activity.

Given the vital importance of the pharmaceutical sector, it has been subjected to regulation. More importantly, the regulatory environment has been ever-changing. Several studies have estimated the welfare effect of such changes in regulatory framework, especially those pertaining to intellectual property. Grabowski et al. (1978) is one of the first studies to empirically capture the effect of regulation on innovation in the pharmaceutical industry. They show that the industry has experienced a decline in innovation following the tightening of regulation by the U.S. Food and Drug Administration.

In a highly influential study, Chaudhuri et al. (2006) estimate the impact of introducing product patents in the Indian market for fluoroquinolines, a class of anti-bacterials. While the study is aimed at examining the likely impact of patent protection after 2005, the data are from an earlier era and the products appearing in the dataset never came under patent protection in India. Chaudhuri et al. (2006) find that patent protection (i.e., exclusion of firms other than the innovator) leads to welfare losses of between $144 million and $450 million.

In a more recent study, Dutta (2011) estimates the welfare losses resulting from patent enforcement and price deregulation for 43 drugs in India. The drugs are spread across multiple segments including OADs. Using a discrete choice framework, she estimates the demand and supply parameters. Similar to Chaudhuri et al. (2006), she finds larges losses in consumer welfare due to patent protection and price deregulation ($378.5 million for the 43 drugs), and reasonable gains for the producers. As with the Chaudhuri et al. (2006) study, Dutta's (2011) dataset does not contain any drugs that are under actual patent protection in India; she estimates the impact of patent protection by simulating the market outcomes that would hold in the presence of patent protection.

Our study is differentiated from Chaudhuri et al. (2006) and Dutta (2011) in that we use data from an Indian drug market where the innovators actually enforce their patent rights, and examine the welfare impact of differential pricing and local licensing strategies taken by them. To our knowledge, ours is the first study to estimate the effects of differential pricing and local licensing within a rigorous structural econometric framework. We also examine the impact of compulsory licensing, i.e., the loss of patent protection for the innovator. While this quantity is comparable in absolute value to the simulated welfare loss caused by patent protection as computed by Chaudhuri et al. (2006) and Dutta (2011), there is an important difference between the two methods. Unlike these earlier studies, we observe the actual behavior of innovators when their patents are protected (including differential pricing and local licensing), and take it into account when calculating the welfare impact of patents.

4. The Model

4.1 Discrete Choice Demand

Following the recent empirical literature on pharmaceutical demand (Stern, 1996; Cleanthous, 2004; Dutta, 2011), we employ a discrete choice model of demand which is based on utility expressions for individual consumers. Following Berry (1994), we employ the following linear specification for the utility of individual i from consuming one unit of product $j \in \{1,2,\dots,J\}$ at time t:

$$u_{ijt} = x_{jt}\beta - \alpha p_{jt} + \xi_{jt} + \upsilon_{ijt}$$
$$= \delta_{jt} + \upsilon_{ijt}.$$

x_{jt} is a vector containing product characteristics, p_{jt} is the price of product j, ξ_{jt} contains the effect of unobserved product characteristics on utility, and υ_{ijt} is an unobserved error term that varies over individuals. $\delta_{jt} \equiv x_{jt}\beta - \alpha p_{jt} + \xi_{jt}$ is called the mean utility of product j (Berry, 1994). We do not include observed individual characteristics in the utility expression as none are observed in our data. β and α are parameters to be estimated; α is usually interpreted as the marginal utility of income.

As our data consist of market-level observations on product-wise quantities and prices, we use the utility expression to derive market shares for each of the products. Let us assume that at a given time period, the J-dimensional vector $\boldsymbol{\upsilon}$ is distributed independently and identically

across individuals with distribution function $F(\boldsymbol{\upsilon})$ (we henceforth drop the time subscript for brevity). Then, the market share of product j is given as

$$s_j = \int \mathbf{1}\left(\delta_j + \upsilon_j \geq \delta_k + \upsilon_k, \forall k \in \Im\right) dF(\boldsymbol{\upsilon})$$

where $\mathbf{1}(\cdot)$ is the indicator function and $\Im$ is the set of all products.

When the elements of $\boldsymbol{\upsilon}$ are assumed to be independent with each having the standard extreme value distribution, the market share is written in the familiar logit form: $s_j = \frac{\exp(\delta_j)}{\sum_{k\in\Im}\exp(\delta_{k)}}$. As is well-known, the logit model can generate unrealistic substitution patterns (the so-called "independence of irrelevant alternatives" problem). We therefore employ the two-level nested logit model (McFadden, 1978) which allows for some correlation across products. Specifically, we assume that the set of products can be partitioned into groups denoted by $\Im_g, g = 1, \ldots, G$. We then specify the error term as

$$\upsilon_{ijt} = \zeta_{igt} + (1-\sigma)\varepsilon_{ijt}, \quad j \in \Im_g.$$

where ε_{ijt} is assumed to be distributed extreme value. We assume that ζ_{igt} is a group-specific error component whose distribution depends on the parameter σ (Cardell, 1997)[3]. $\sigma \in [0,1)$ describes the degree of correlation within groups: the utilities from different products become more correlated as σ increases; they become perfectly correlated as σ approaches 1. In our application, the products are defined as pharmaceutical brands. Following Dutta (2011), we let groups be defined by individual drug molecules.

With this specification of the error term, the market share of brand $j \in \Im_g$ among all brands in molecule g (called the "conditional market share") is given as follows (Berry, 1994):

$$s_{j|g} = \frac{\exp\left(\frac{\delta_j}{1-\sigma}\right)}{D_g}, \qquad (1)$$

$$D_g \equiv \sum\nolimits_{k\in\Im_g} \exp\left(\frac{\delta_k}{1-\sigma}\right).$$

As shown by McFadden (1978), the combined market share of all brands in molecule g is

$$s_g = \frac{D_g^{1-\sigma}}{1 + \sum_{h=1}^{H} D_h^{1-\sigma}}$$

[3] The distribution of ζ_{igt} is specified so that the marginal distribution of υ_{ijt} over consumers and time periods is extreme value. See Cardell (1997) for a detailed discussion.

where H is the number of molecules in the market and we have normalized the level of utility by setting it to zero for the outside good[4]. Using the definition of conditional probability, the share of brand j within the entire market (called the "unconditional market share") is derived as follows:

$$s_j = s_{j|g} s_g = \frac{\exp\left(\frac{\delta_j}{1-\sigma}\right)}{D_g^{\sigma}\left(1 + \sum_h D_h^{1-\sigma}\right)}. \qquad (2)$$

In order to estimate the demand system, we first take the log of s_j and s_0 to obtain

$$\ln(s_j) - \ln(s_0) = \frac{\delta_j}{1-\sigma} - \sigma \ln(D_g). \qquad (3)$$

Taking the log of s_g, we find that $\ln(D_g) = \frac{\ln(s_g) - \ln(s_0)}{1-\sigma}$. Plugging this into equation (3) and rearranging gives $\ln(s_j) - \ln(s_0) = \delta_j + \sigma \ln(s_{j|g})$. Applying the definition of mean utility yields our estimating equation:

$$\ln(s_j) - \ln(s_0) = x_j\beta - \alpha p_j + \sigma \ln(s_{j|g}) + \xi_j. \qquad (4)$$

Note that the product price p_j and log conditional market share $\ln(s_{j|g})$ are likely to be correlated with the unobserved product characteristic ξ_j. We therefore estimate equation (4) by linear instrumental variables regression. The choice of instruments is discussed in the data section.

We derive the own-price and cross-price elasticities of demand in terms of market shares as follows:

$$\eta_{jj} = \frac{\partial s_j}{\partial p_j}\frac{p_j}{s_j} = -\frac{\alpha p_j}{1-\sigma}\left[1 - s_j - \sigma(s_{j|g} - s_j)\right], \qquad (5)$$

$$\eta_{jk} = \frac{\partial s_j}{\partial p_k}\frac{p_k}{s_j} = \alpha p_k\left(s_k + \frac{\sigma}{1-\sigma} s_{k|g}\right), \qquad j,k \in \Im_g, j \neq k, \qquad (6)$$

$$\eta_{jk} = \frac{\partial s_j}{\partial p_k}\frac{p_k}{s_j} = \alpha p_k s_k, \qquad j \in \Im_g, k \notin \Im_g. \qquad (7)$$

Note that the own-price elasticity is always non-positive because $s_{j|g} \leq 1$ and $\sigma \leq 1$. The cross-price elasticities are always non-negative reflecting the fact that different brands and different molecules are all substitutes. When two brands are in the same molecule group, the cross-price elasticity between them is weakly greater than when they are in different molecule groups.

[4] The market share of the outside good is $s_0 = \frac{1}{1+\sum_{h=1}^{H} D_h^{1-\sigma}}$.

4.2 Supply-side considerations

We assume that in each period, single-brand firms engage in a static price-setting game. The profit maximization problem for firm j is given as

$$\max_{p_j} p_j \, M \, s_j(\mathbf{p}) - C_j\left[M \, s_j(\mathbf{p})\right]$$

where M is the market size, $\mathbf{p}$ is the vector of all prices in the market, and $C_j[\cdot]$ is the cost function for brand/firm j. We have explicitly written the market share of firm j to be a function of all prices. Let us assume that firm j's marginal cost is constant at c_j. Then, the first-order condition for profit maximization is given by

$$\left(p_j - c_j\right)\frac{\partial s_j(\mathbf{p})}{\partial p_j} + s_j(\mathbf{p}) = 0.$$

Rearranging gives the pricing equation for firm j:

$$p_j = c_j - \frac{s_j(\mathbf{p})}{\partial s_j(\mathbf{p})/\partial p_j}. \qquad (8)$$

For the nested logit model, $\frac{\partial s_j(\mathbf{p})}{\partial p_j} = -\frac{\alpha s_j}{1-\sigma}\left[1 - \sigma s_{j|g} - (1-\sigma)s_j\right]$, which is a function of market shares and demand parameters. Following Berry (1994), let us assume that the marginal cost is a linear function of firm and product characteristics as follows:

$$c_j = w_j\gamma + \omega_j.$$

where ω_j is a random error term. Suppose also that we know the demand parameter values so that the second term in (8) can be moved over to the left-hand side. We then have the following estimable form for the pricing equation:

$$p_j - \frac{1-\sigma}{\alpha\left[1 - \sigma s_{j|g} - (1-\sigma)s_j\right]} = w_j\gamma + \omega_j. \qquad (9)$$

Two of the molecules in our dataset (sitagliptin and vildagliptin) involve a voluntary license between the patent holder and local licensee. For these molecules, we assume that the licensor and licensee set a common price that maximizes joint profits. The estimating equation in this case can be written as follows:

$$p_j - \frac{1-\sigma}{\alpha(1-\sigma)(1-\sum_{j\in\Im_g} s_j)} = w_j\gamma + \omega_j, \qquad (10)$$

where $\sum_{j\in\Im_g} s_j$ is the combined market share of the licensor and licensee, and we have used the fact that the within-molecule market shares of the licensor and licensee add up to one.

Two molecules in our data have their prices regulated under the Drug Price Control Order (DPCO). For these drugs, we follow Dutta (2011) by assuming that the allowed margin is 10 percent so that the estimating equation becomes

$$0.91\mathrm{p} = \mathrm{w_j}\gamma + \omega_\mathrm{j} \qquad (11).$$

We follow a two-step procedure whereby we first estimate the demand equation (4) and obtain $\hat{\beta}$, $\hat{\alpha}$, and $\hat{\sigma}$. We then use these estimates to construct the left-hand side in (9). We estimate (9) by OLS[5].

5. Policy Simulations

5.1 Measuring Consumer Surplus

We estimate the welfare impact of various policy scenarios on the basis of consumer surplus. We choose to employ consumer surplus as the welfare measure as we do not have data (nor estimates) on firms' fixed costs which are required for calculating profits[6]. The basic methodology of our welfare analysis is to estimate the level of consumer surplus before and after a policy change. As described in detail below, the policy change may lead to new price levels and/or choice sets faced by consumers. The welfare impact of the policy change is defined as the before-and-after change in consumer surplus.

Following Small and Rosen (1981), Morey (1999), and Dutta (2011), expected per-period consumer surplus in the 2-level nested logit model can be expressed as

$$\mathrm{E(CS)} = \frac{1}{\alpha} M\, ln\left\{1 + \sum\nolimits_h \left[\sum\nolimits_{\mathrm{k}\in\Im_\mathrm{h}} \exp\left(\frac{\delta_\mathrm{k}}{1-\sigma}\right)\right]^{1-\sigma}\right\} + C. \qquad (13)$$

where C is an unknown constant. We need not know the value of this term as it drops out when taking before-and-after differences (Train, 2009).

---

[5] We can obtain greater efficiency by jointly estimating the demand and pricing equations while imposing cross-equation equality restrictions for α and σ. In this case, the pricing equation would be specified as

$$\mathrm{p_j} = \mathrm{w_j}\gamma + \frac{1-\sigma}{\alpha\left[1-\sigma \mathrm{s_{j|g}} - (1-\sigma)\mathrm{s_j}\right]} + \omega_\mathrm{j}. \qquad (12)$$

Estimation requires the use of generalized method of moments (GMM) as (12) is nonlinear in the parameters and both equations contain endogenous variables that need to be instrumented.

[6] Dutta (2011) estimates firms' fixed per-period entry costs by jointly estimating consumer demand, firms' pricing decision, and their entry decisions

5.2 Simulation of Policy Scenarios

The policy simulations are conducted using data from 2011, the final year in our dataset. There were 16 single-molecule oral anti-diabetics on the market in that year[7]. Three of the molecules are patent-protected DPP-4 inhibitors: saxagliptin, sitagliptin, and vildagliptin. Only one of the molecules is under price control: glipizide. 89 firms sold one or more of these single-molecule drugs in 2011. Using monthly observations from 2011, we generate, for each firm-molecule pair, representative values of the regressors contained in x_j and w_j[8]. These are stacked into matrices called $\bar{\mathbf{X}}$ and $\bar{\mathbf{W}}$. We also obtain a vector of within-year mean prices and call it $\bar{\mathbf{p}}^{(0)}$.

We consider the following five policy scenarios:

i. Baseline

This is the status quo where the Indian patents for the three DPP-4 inhibitors are protected. The patent holders for these products engage in differential pricing, which involves setting the profit-maximal price for the Indian market without taking into consideration how that might affect prices in overseas markets. They also license out these molecules to local partners. The prices of licensor and licensee products are set at the same joint profit-maximal level. Meanwhile, the DPCO molecule glipizide is under price control.

ii. No DPP-4 Inhibitors

This scenario involves removing all three DPP-4 inhibitors from the market. Glipizide stays under price control.

iii. No Differential Pricing

In this scenario, the DPP-4 inhibitors continue to be under patent protection. The patent holders continue to license their products to local partners. However, they no longer engage in differential pricing: prices are set at international levels without taking Indian market conditions into consideration. We obtain the international price for each molecule as the simple average of prices in the U.S., the U.K., and Japan. This is presented in Table 1. Glipizide remains under price control.

iv. No Local Licensing

[7] For reasons that are described Section 6, we only use observations for single-molecule products.
[8] Specifically, we take within-year means for the continuous regressors and within-year modes for the discrete regressors.

This scenario involves the patent holders of the DPP-4 inhibitors being the sole sellers of their respective products. They are allowed to engage in differential pricing. The price of glipizide is controlled.

v. Compulsory Licensing

The patents for DPP-4 inhibitors are no longer protected under this scenario. We allow two major Indian manufacturers – Cipla and Natco – to sell them alongside the patent holders and the original licensees. It is implicitly assumed that these two firms have applied for, and have been granted, compulsory licenses by the Indian Patent Office. The choice of Cipla and Natco is motivated by the fact that they have been the most aggressive at applying for compulsory licenses and entering at-risk into markets for patented products. The patent holders and original licensees no longer engage in joint profit-maximal pricing; differentiated-product Bertrand pricing takes place. Price controls continue for glipizide.

vi. No Price Control

The manufacturers of glipizide are no longer bound by price regulation under this scenario. They set their prices at the profit-maximal level - i.e., engage in Bertrand pricing. DPP-4 inhibitors are under patent protection. The patent holders engage in differential pricing and local licensing.

For each scenario, we obtain equilibrium prices and market shares as follows. We start with the vector of observed prices, $\bar{\mathbf{p}}^{(0)}$. Combining this with $\bar{\mathbf{X}}$ and the parameter estimates $\hat{\beta}$ and $\hat{\alpha}$, we can generate the conditional expectation of mean utility: $\bar{\delta}_j^{(1)} = \bar{x}_j\beta - \alpha\bar{p}_j^{(0)}$. These are plugged into the formulas (1) and (2) together with $\hat{\sigma}$ to generate market shares $\bar{s}_{j|g}^{(1)}$ and $\bar{s}_j^{(1)}$.

The next step is to generate new prices. For those drugs that are under Bertrand pricing, joint profit-maximal pricing, or price regulation, the new prices are generated by the formulas implied by (9), (10), or (11). For example, Bertrand oligopoly prices are generated as

$$\bar{p}_j^{(1)} = \bar{w}_j\hat{\gamma} + \frac{1-\hat{\sigma}}{\hat{\alpha}\left[1-\hat{\sigma}\bar{s}_{j|g}^{(1)} - (1-\hat{\sigma})\bar{s}_j^{(1)}\right]}.$$

For those drugs that are priced at international levels under the "no differential pricing" scenario,

we fix prices at the values given in Table 1. The vector of prices thus generated, $\bar{\mathbf{p}}^{(1)}$, is now used to generate new market shares, which in turn are used to generate $\bar{\mathbf{p}}^{(2)}$. This iterative procedure is continued until the infinity norm of the difference between two consecutive price vectors falls below a specified tolerance level.

After obtaining the equilibrium price vector $\bar{\mathbf{p}}$ in this manner, we generate the conditional expectation of mean utility: $\bar{\delta}_j = \bar{x}_j\beta - \alpha\bar{p}_j$. These are plugged into the first term of the expected consumer surplus formula (13). By calculating this quantity under each policy scenario and taking differences, we can obtain estimates for the welfare impact of the policies in question.

6. Data

The main source of data for this study is the Secondary Stockist Audit conducted by IMS India, one of the primary market research firms pertaining to the Indian pharmaceutical sector. We obtained monthly data on brand-wise sales volumes and prices for the entire oral anti-diabetic (OAD) segment. The data contain observations on 18 single-molecule drugs belonging to 7 different classes of drugs that treat type II diabetes mellitus: biguanides, sulfonylureas, thiazolidinediones, DPP-4 inhibitors, alpha glucosidase inhibitors, aldose reductase inhibitors, and other blood glucose lowering drugs (excluding insulin). Table 2 presents details on these molecules, including therapeutic class, the number of firms producing each molecule, the standard daily dosage, and the year of introduction in India. 99 manufacturers, including 14 multinational innovator firms, appear in the data.

In order to estimate a demand system involving different drug products containing different molecules, we need to standardize the volumetric units. For this purpose, we convert quantities into daily dosages. Actual daily dosage depends on the characteristics of the patient. We therefore refer to various sources to obtain standard dosages during the initial treatment stage of each drug[9]. To illustrate, if the standard starting dosage of metformin hydrochloride is 750mg per day, then one tablet of 750mg strength of metformin hydrochloride is counted as one daily dose and 1000mg of metformin hydrochloride is counted as 1.33 daily doses.

Although there exist several combination drugs (formulations containing two or more active

[9] The sources of standard starting dosage data include drug label information filed with the US Food and Drug Administration and online documents of the Indian Monthly Index of Medical Specialities.

ingredients) in our dataset, we drop them from the analysis for the following reasons. First, there does not appear to be a reliable and objective method to convert the volumes of combination drugs into daily dosages. Second, the nested logit formulation presents technical problems for using data on combination drugs: allocating combination drugs to nests can become a subjective issue when one ingredient belongs to a particular nest and the other ingredient to another. Restricting attention to single-molecule products is not without precedent in the pharmaco-economics literature (see, for example, Dutta, 2011).

In order to measure market shares, we require data on market size. We assume that the market size for the oral anti-diabetic segment can be represented by the number of diabetic patients in India. Unfortunately, data on the prevalence of diabetes in India is not available for all years. Between 2000 and 2011, we are able to collect prevalence data from various sources for five years as shown in Table 3. We interpolate the values for the remaining years under the assumption of a constant growth rate. Specifically, we assume a constant growth rate during 2000-2006 and obtain interpolations for the intervening years (including 2005). Similarly, we assume a constant growth rate during 2006-2011, in the process replacing the figure for 2010 with an interpolated value.

The econometric specification of equations (4), (9), (10), and (11) involves the use of firm characteristics as exogenous regressors. We construct the following using the IMS data:

MNC : A dummy variable that equals one if the firm is a multinational innovator company and zero otherwise.

First Entrant : A dummy variable that equals one if the firm is the first to sell the molecule in question and zero otherwise.

Brand Age: The number of months since the firm began selling the molecule in question (scaled by 1/100).

Form Count : The number of different formulations of the molecule in question sold by the firm (scaled by 1/10).

Presence in OAD : The number of other OAD molecules in which the firm is present (scaled by 1/10)

The nested logit demand equation (4) contains two endogenous regressors: *Price Per Daily Dose* and the log of conditional market share, $\ln(s_{j|g})$. Following Cleanthous (2004) and Dutta

(2011), we employ the following instrumental variables to deal with this endogeneity problem:

- The number of molecules in the entire market
- The number of molecules in the same therapeutic class
- The number of firms in the same molecule
- Average value of *Form Count* among other firms in the same molecule
- Sum of squared *Form Count* for other firms in the same molecule
- Average value of *Presence in OAD* among other firms in the same molecule
- Sum of squared *Presence in OAD* for other firms in the same molecule

7. Results

7.1 Model Parameters

Table 4 presents the instrumental variable regression results for equation (4). The first set of columns present estimates for the specification without firm fixed effects, while the second set shows the results when those fixed effects are included.

The coefficient on *Price Per Daily Dose* is interpreted as the negative of the marginal utility of income, α. Its estimate is -0.9316, which implies that the mean utility of consumers decreases by that amount with a Rs. 1 increase in price (note that utility is *not* measured in money terms). The coefficient on $\mathbf{ln}(\mathbf{s_{j|g}})$ is our estimate for σ, which measures the extent to which the unobserved portion of utility is correlated across different brands of the same molecule, is fairly high at 0.6705. This is in line with previous studies such as Stern (1996) and Dutta (2011).

Moving on to the exogenous regressors, we find that products supplied by multinational innovator firms provide significantly higher utility to consumers. This can be explained by the fact that innovators tend to have superior product knowledge. In addition, there is a perception among consumers and prescribers that multinational drug companies tend to provide higher quality products. We find that the coefficient on *First Entrant* is also significantly positive. This shows that the company who first introduces a molecule into India (often, but not always the innovator) obtains a significant first-mover advantage in the market. This translates into a higher market share in general for the first entrant. Notice that the impact of *First Entrant* (0.9163) is more than five times that of *MNC* (0.1600) when firm dummy variables are included.

This shows how important it is, in terms of profit, for foreign innovator companies to be the first to enter with a new molecule. It also explains why innovator firms have become quicker at entering the Indian market in recent years.

The *Brand Age* variable has a significantly positive coefficient, which suggests that a product's perceived value increases over time. This is probably due to learning effects on the part of consumers, as found by Ching (2010) for the U.S. pharmaceutical market. The number of formulations of the same molecule supplied by a firm (*Form Count*) also has a significantly positive impact on mean utility. This result has to be interpreted with some care, however. Recall that we defined products in terms of molecules when constructing our dataset, while actual products are presented in specific dosage forms and strengths of the molecule. When a firm increases the number of formulations for a given molecule, the utility derivable from each of the existing formulations is not likely to be affected. However, the maximum utility that can be obtained from the set of formulations may increase. Thus, the positive effect of *Form Count* should be interpreted as the impact of an expanded choice set. On the other hand, we can interpret the significantly positive coefficient on *Presence in OAD* in the first specification as an increase in the utility derivable from each product; when a firm increases its market presence by expanding its molecule portfolio, the perceived value of its existing products also increases. A larger molecule portfolio in a given therapeutic segment is likely to act as a signal of higher expertise by the firm in that segment. Also, there are likely to be significant intra-segment economies of scope in marketing and distribution. However, the coefficient on *Presence in OAD* becomes negative when we include firm fixed effects.

Turning to the molecule dummy variables, we find that the DPP-4 inhibitors (saxagliptin, sitagliptin, and vildagliptin) are the only molecules that have higher mean utility compared to the baseline molecule (voglibose). This has important implications for the welfare impact of this new class of molecules, as we shall see later in the section.

Table 5 presents our estimates for the own-price and cross-price elasticities of demand implied by the parameter values. They represent the percentage change in market share caused by a one percent increase in prices. The own-price elasticity is found to be greater than 10 in absolute value for the following molecules: acarbose, epalrestat, miglitol, nateglinide, repaglinide, rosiglitazone, saxagliptin, sitagliptin, vildagliptin, and voglibose. The same molecules tend to have high values for the within-group cross-price elasticities as well. As

seen from Table 2, these are all newer molecules with relatively high prices and small market shares. It is difficult to give an economic explanation for the exceptionally large own-price elasticities, which imply high substitutability across brands and molecules. Stern's (1996) study of the U.S. pharmaceutical market also finds large own-price elasticities, but only for a specific therapeutic segment: gout treatments. He attributes this finding to the lack of newly developed molecules in that segment. In contrast, the drugs shown to have large own-price elasticities in Table 5 are all relatively novel.

In the only comparable study on India, Dutta (2011) finds the average own-price elasticity of anti-diabetic drugs to be much lower at -0.610. She estimates within-molecule and across-molecule cross-price elasticities in this segment to be 0.010 and 0.003, respectively[10]. One explanation for the substantial difference between her results and ours is the difference in the definition of market size. Dutta (2011) defines the market size of the oral anti-diabetic drug market as the count of all prescriptions for oral anti-diabetic drugs. This is a very conservative measure of market size; it automatically excludes a large proportion of diabetic patients who choose the outside option. In contrast, our measure of market size – the entire diabetic population in India – may actually overstate the number of potential users of OADs, leading to smaller market shares. Since η_{jj} is negatively affected by both s_j and $s_{j|g}$, our estimates are naturally expected to be higher. Another possibility is that Indian consumers and prescribers have come to perceive the different molecules and brands as being more substitutable over time (our data cover a more recent period than that of Dutta, 2011). However, the magnitude involved is too large to be explained in terms of such behavioral change.

Table 6 contains estimates for the parameter vector γ in equations (9)-(11). We find that there is large variation in marginal costs across molecules. We also find that foreign firms have higher costs. This is likely due to the fact that foreign firms import some of their products rather than manufacture them in India.

Table 7 presents the average implied markup for each molecule along with the average observed prices. While the markups seem reasonable for many molecules, there are a few for which the implied markup is unreasonably large. Even if we exclude chlorpropamide and glipizide, whose prices are controlled under the DPCO, we have glibemclamide whose implied

[10] Dutta's (2011) dataset contains only 8 molecules in the anti-diabetic segment, which is less than half the 18 contained in ours.

markup surpasses its observed price. Also, the markups for the DPP-4 inhibitors (saxagliptin, sitagliptin, and vildagliptin) are unexpectedly small considering their high prices and patent-protected status.

There are two possible reasons why the implied markups exhibit these undesirable characteristics. First, the parameters that enter the markup terms in (9) and (10), α and σ, may be imprecisely estimated. In other words, there might exist values of α and σ for which the observed market shares and given formulas are consistent with reasonable values for the implied markups, but we have not obtained them (due perhaps to misspecification of the demand and supply equations). The more likely explanation, however, is that the problem lies with the markup formulas which impose strict restrictions on the relationship between markups and market shares. Resolving this problem will require us to use a more sophisticated demand model such as the 3-level nested logit or the random-coefficients mixed logit, as well as an alternative specification of the price-setting process. This is a topic of ongoing research by the authors.

7.2 Policy Simulation

We use the parameter estimates obtained above to run the policy simulations described in Section 5. For the demand parameters, we employ the specification containing firm fixed effects. The results are presented in Table 8. The last column shows the change in consumer surplus resulting from each of the policy changes considered. The second row presents the consumer impact of removing all DPP-4 inhibitors from the market. It can be considered as the negative of the welfare impact of introducing the DPP-4 inhibitor class into India. The estimate is INR 913 million (around $17 million) for the year 2011. This may appear to be small by international standards, but the total revenue from DPP-4 drugs in the same year was only INR 1,790 million. Combined with the large own-price elasticities estimated for DPP-4 inhibitors, this appears to be a reasonable figure.

The third row presents results for the counterfactual scenario of no differential pricing by the patent holders of DPP-4 inhibitors and their licensees. The loss in consumer surplus under this scenario is the same as when DPP-4 inhibitors are removed from the market. This is because at international price levels the market share of DPP-4 inhibitors in the Indian market falls to a negligible level. The following row shows the results from the scenario of “no local

licensing". We estimate that consumer surplus falls by INR 803 million in this case.

The impact of compulsory licensing is shown in the fifth row. We find that consumer surplus increases as a result, but the amount is modest at INR 58 million. Compulsory licensing of innovator patents increase the consumer welfare arising from DPP-4 inhibitors by a mere 6.2 percent. We must note, however, that this result is driven by the small markups estimated for DPP-4 inhibitors. The flipside of small markups is high marginal costs. Since our model assumes that the compulsory licensees have the same marginal cost as the innovator, equilibrium prices under compulsory licensing are high.

The last row looks at the impact of removing price controls for glipizide, the only oral anti-diabetic molecule that was regulated under DPCO in 2011. The result is a loss in consumer surplus of INR 677 million, which is large in comparison to the total revenue of INR 130 million for glipizide in 2011. There are two reasons for this apparent disconnect. First, the revenue from glipizide is kept artificially low by the price ceiling. Second, the relatively small demand elasticity estimated for glipizide implies that a price increase following deregulation leads to a large consumer welfare loss.

Comparing across scenarios, we find that differential pricing and voluntary licensing by the patent holders contributes greatly to consumer welfare. On the other hand, the issuance of compulsory licenses adds relatively little to welfare. As far as government policies are concerned, price controls appear to be more effective than compulsory licensing at raising consumer welfare. However, the following caveats must be kept in mind. First, as we noted earlier, further refinement of our econometric model may be necessary for obtaining better estimates of demand elasticities and markups. Such modifications may lead to changes in our welfare calculations, although we cannot say *a priori* what the direction would be. Second, while we have taken market structures to be exogenously determined, in reality they may change endogenously in response to policies. For instance, the removal of price controls may induce more firms to sell glipizide. Analyzing such possibilities require us to model the process of firm entry as in Dutta (2011).

8. Conclusion

This paper estimates a 2-level nested logit model of demand for the Indian oral anti-diabetic

(OAD) drug market during 2004-2011. We also estimate a set of pricing equations for the oligopolistic firms in the market. The observation period covers the introduction of a new class of OADs called DPP-4 inhibitors. The patent holders of these molecules have maintained exclusivity over sales in India. They have engaged in differential pricing and voluntary licensing to local partner firms.

We use our model estimates to compute the welfare gains due to the introduction of DPP-4 inhibitors. We also estimate the welfare effect of differential pricing and local licensing, and find the combined impact to be around INR 913 million ($17 million) for the year 2011. Our simulation results for compulsory licensing show that welfare is increased by a mere INR 58 million. We also find that the removal of price controls in the OAD segment can lead to a INR 677 million reduction in consumer surplus. While these results may be affected by the quality of our parameter estimates, they suggest that the welfare gain from compulsory licensing may not be substantial when the innovator firm already engages in differential pricing and local licensing.

Some of our econometric results appear to suggest the need for further refinement in modeling demand as well as the price-setting process. More sophisticated demand models such as the 3-level nested logit and random coefficients mixed logit are natural candidates.

Reference

Berry, Steven (1994) "Estimating Discrete-Choice Models of Product Differentiation." *RAND Journal of Economics*, 25(2): 242-262.[

Cardell, N. Scott (1997) "Variance Component Structures for the Extreme-Value and Logistic Distributions with Application to Models of Heterogeneity." *Econometric Theory,* 13(2): 185-213.

Chaudhuri, Sudip (2011 "Multinationals and Monopolies: Pharmaceutical Industry in India After TRIPS." WHO Working Paper Series 685.

Chaudhuri, Shubham, Pinelopi Goldberg, and Panle Jia (2006) "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India." *American Economic Review,* 96: 1477-1514.

Ching, Henry (2010) "Consumer Learning and Heterogeneity: Dynamics of Demand for

Prescription Drugs After Patent Expiration." *International Journal of Industrial Organization*, 28(6): 619-638.

Cleanthous, Paris (2004) "Patient Welfare Implications of Innovation in the U.S. Antidepressant Market." Mimeograph.

Danzon, Patricia, and Adrian Towse (2003) "Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents." *International Journal of Health Care Finance and Economics*, 3(3): 183-205.

Dutta, Antara (2011) "From Free Entry to Patent Protection: Welfare Implications for the Indian Pharmaceutical Industry." *Review of Economics and Statistics*, 93: 160-178.

Ellison, Sara Fisher, Iain Cockburn, Zvi Grilliches, and Jerry Hausman (1997), "Characteristics of Demand for Pharmaceutical Products: An Examination of Four Cephalosporins," *RAND Journal of Economics*, 28(3): 426-446.

Grabowski, Henry, John Vernon and Lacy Glenn Thomas (1978), "Estimating the Effect of Regulation on Innovation: an International Comparative Analysis of Pharmaceutical Industry," *Journal of Law and Economics*, 21(1): 133-163.

Lanjouw, Jean O. (1998) "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering'?" NBER Working Paper 6366.

McFadden, Daniel (1978) "Modeling the Choice of Residential Location." In A. Karlqvist, L. Lundqvist, F. Snickars, and J. Weibull, eds. *Spatial Interaction Theory and Planning Models*, North-Holland: 75-96.

Morey, Edward R. (1999) "Two RUMSs Uncloaked: Nested-Logit Models of Site Choice and Nested-Logit Models of Participation and Site Choice." In J.A. Herriges and C.L. Kling, eds., *Valuing Recreation and the Environment: Revealed Preference Methods in Theory and Practice*, Edward Elgar.

Rajagopal, Divya (2013) "Compulsory License Likely for Three Cancer Drugs." *Economic Times*, January 14.

Small, Kenneth A. and Harvey S. Rosen (1981) "Applied Welfare Economics with Discrete Choice Models." *Econometrica*, 49(1): 105-130.

Stern, Scott (1996) "Market Definition and the Returns to Innovation: Substitution Patterns in Pharmaceutical Markets." Mimeograph.

Tandon, Pankaj (1982) "Optimal Patents with Compulsory Licensing." *Journal of Political*

Economy, 90(3): 470-486.

Train, Kenneth (2009) *Discrete Choice Methods with Simulation*, Second Edition, Cambridge University Press.

Whalen,Jeanne (2012) “Cancer Drugs Get Cheaper, in India.” *Wall Street Journal*, March 23.

Yu, Peter (2009) “The Objectives and Principles of the TRIPS Agreement.” *Houston Law Review*, 46(4): 979-1045.

Table 1: Global DPP-4 Inhibitor Prices in 2011 (INR per daily dose)			
Country	**saxagliptin**	**sitagliptin**	**vildagliptin**
India	22.94	36.70	22.60
United Kingdom	70.93	99.54	71.29
USA	198.04	262.64	179.12
Japan	Not approved	162.00	91.32
Simple Average of U.K., U.S.A. and Japan	134.49	174.73	113.91
Innovator companies: Bristol-Myers Squibb (saxagliptin), MSD (sitagliptin), Novartis (vildagliptin). Daily dose: 3.75mg for saxagliptin, 100mg for sitagliptin, 75mg for vildagliptin.			
Source: IMS India, UK National Health Service website, internationaldrugmart.com, corporate press releases			

Table 2: Molecules Considered in the Econometric Model				
Molecule Name	**Therapeutic Class**	**Number of Firms**	**Daily Dosage**	**Year of Introduction in India**
Acarbose	Alpha glocosidase inhibitor	15	75 mg	1997
Chlorpropamide	Sulfonylurea	1	250 mg	Before 1991
Epalrestat	Aldose reductase inhibitor	4	150 mg	2007
Glibenclamide	Sulfonylurea	19	3.75 mg	Before 1991
Gliclizide	Sulfonylurea	48	60 mg	Before 1991
Glimepiride	Sulfonylurea	64	1.5 mg	1999
Glipizide	Sulfonylurea	20	5 mg	Before 1991
Metformin	Biguanide	74	750 mg	Before 1991
Miglitol	Alpha glocosidase inhibitor	10	75 mg	2004
Nateglinide	Other blood glucose lowering drug	5	360 mg	2002
Phenformin	Biguanide	1	75 mg	Before 1991
Pioglitazone	Thiazolidinedione	50	22.5 mg	2000
Repaglinide	Other blood glucose lowering drug	6	1 mg	2000
Rosiglitazone	Thiazolidinedione	12	4 mg	2000
Saxagliptin	DPP-4 inhibitor	1	3.75 mg	2010
Sitagliptin	DPP-4 inhibitor	2	100 mg	2008
Vildagliptin	DPP-4 inhibitor	3	75 mg	2008
Voglibose	Alpha glocosidase inhibitor	37	0.75 mg	2006
Total firms		99		

Source: IMS Dataset; Label information from the U.S. Food and Drug Administration; Monthly Index of Medical Specialities.

Table 3: Number of Diabetes Patients in India		
Year	**Number of Patients**	**Source**
2000	31,700,000	http://www.who.int/diabetes/facts/en/diabcare0504.pdf
2005	35,000,000	http://www.rediff.com/news/2005/sep/23dia.htm
2006	40,900,000	http://www.hindu.com/2006/12/25/stories/2006122502601800.htm
2010	50,800,000	http://www.nature.com/nature/journal/v485/n7398_supp/full/485S14a.html
2011	61,300,000	http://www.idf.org/diabetesatlas/5e/south-east-asia

Table 4: Estimate of 2-level Nested Logit Demand Model for Indian OAD Market, 2004-2011						
	Linear 2SLS-IV regression					
	Model 1 (no firm-fixed effects)			**Model 2 (with firm fixed effects)**		
	coef	**s.e.**	**t-value**	**coef**	**s.e.**	**t-value**
Price Per Daily Dose	-0.863	0.044	-19.670	-0.932	0.042	-22.180
$\ln(s_{j\|g})$	0.823	0.020	41.830	0.670	0.024	27.960
MNC	1.066	0.058	18.360	0.160	0.077	2.080
First Entrant	1.157	0.078	14.810	0.916	0.074	12.460
Brand Age	0.057	0.024	2.380	0.153	0.027	5.680
Form Count	1.994	0.157	12.690	2.309	0.150	15.410
Presence in OAD	0.919	0.064	14.290	-0.533	0.110	-4.850
Acarbose	-6.012	0.297	-20.240	-6.156	0.273	-22.550
Chlorpropamide	-17.316	0.694	-24.960	-16.804	0.619	-27.130
Epalrestat	-5.859	0.194	-30.130	-5.377	0.178	-30.230
Glibenclamide	-10.717	0.677	-15.830	-11.886	0.655	-18.140
Gliclazide	-10.184	0.582	-17.500	-10.894	0.555	-19.620
Glimepiride	-9.397	0.578	-16.260	-10.067	0.546	-18.450
Glipizide	-11.218	0.660	-17.000	-11.918	0.622	-19.170
Metformin	-9.895	0.627	-15.770	-10.854	0.603	-18.000
Miglitol	-3.772	0.137	-27.560	-3.909	0.131	-29.760
Nateglinide	-2.318	0.117	-19.810	-1.529	0.131	-11.630
Phenformin	-18.991	0.635	-29.910	-19.564	0.593	-32.970
Pioglitazone	-9.546	0.558	-17.110	-10.109	0.524	-19.310
Repaglinide	-10.660	0.489	-21.820	-11.627	0.475	-24.470
Rosiglitazone	-9.646	0.457	-21.110	-10.280	0.438	-23.500
Saxagliptin	3.014	0.349	8.630	4.859	0.405	12.010
Sitagliptin	14.489	0.826	17.540	18.937	0.996	19.020
Vildagliptin	4.753	0.287	16.550	6.080	0.312	19.500
Constant	5.947	0.677	8.780	6.877	0.616	11.160
No of Observations	23,671			23,671		
R-Squared	0.809			0.8271		
The instrumental variables used for the 2SLS-IV regression are described in Section 6.						

Table 5: Elasticity Estimates Within and Across OAD Molecules in India, 2004-2011			
Molecule	**η_{jj}**	**η_{jk} (j,k in same molecule)**	**η_{jk} (j,k in different molecules)**
Acarbose	-23.9446	1.8550	0.0013
Chlorpropamide	-0.2294	0.4667	0.0013
Epalrestat	-23.4889	11.8618	0.0013
Glibenclamide	-0.9501	0.0902	0.0013
Gliclazide	-6.5844	0.1822	0.0013
Glimepiride	-6.9054	0.1330	0.0012
Glipizide	-1.6301	0.0852	0.0013
Metformin	-3.9295	0.0554	0.0013
Miglitol	-33.5928	3.2074	0.0013
Nateglinide	-34.4714	16.5858	0.0013
Phenformin	-2.6944	5.4822	0.0013
Pioglitazone	-8.1226	0.1598	0.0014
Repaglinide	-11.6097	2.7902	0.0013
Rosiglitazone	-14.1160	1.4644	0.0013
Saxagliptin	-21.2550	43.2722	0.0013
Sitagliptin	-42.9404	57.5714	0.0013
Vildagliptin	-46.0640	17.4084	0.0013
Voglibose	-42.9123	1.7399	0.0013

Table 6: OLS Estimates of the Pricing Equation in Indian OAD Market, 2004-2011			
	coef	**s.e.**	**t-value**
Acarbose	-6.03622	0.046247	-130.52
Chlorpropamide	-15.0601	0.163619	-92.04
Epalrestat	-2.94091	0.102102	-28.8
Glibenclamide	-14.0152	0.04528	-309.52
Gliclazide	-12.1245	0.035822	-338.47
Glimepiride	-12.0265	0.034167	-351.99
Glipizide	-14.0139	0.0429	-326.66
Metformin	-13.047	0.033947	-384.33
Miglitol	-2.45836	0.051044	-48.16
Nateglinide	2.202424	0.082699	26.63
Phenformin	-11.6008	0.189457	-61.23
Pioglitazone	-11.6183	0.035141	-330.62
Repaglinide	-9.85586	0.062036	-158.87
Rosiglitazone	-9.33405	0.049968	-186.8
Saxagliptin	5.44597	0.241054	22.59
Sitagliptin	17.17934	0.156954	109.45
Vildagliptin	5.568158	0.11542	48.24
MNC	1.092418	0.027588	39.6
Constant	14.23285	0.030393	468.3
Number of Observations	23,671		
R-Squared	0.9362		

Table 7: Estimates of Markup in Indian OAD Market, 2004-2011			
Molecule	**Average Price**	**Average Markup**	**Markup as % of price**
Acarbose	9.13	0.39	4.3
Chlorpropamide	0.25	1.07	436.0
Epalrestat	12.50	0.56	4.4
Glibenclamide	0.37	0.40	109.7
Gliclazide	2.39	0.36	15.1
Glimepiride	2.49	0.36	14.4
Glipizide	0.61	0.39	63.9
Metformin	1.41	0.36	25.5
Miglitol	13.02	0.40	3.0
Nateglinide	18.06	0.66	3.7
Phenformin	2.89	1.07	37.1
Pioglitazone	2.93	0.36	12.3
Repaglinide	5.09	0.44	8.6
Rosiglitazone	5.51	0.39	7.1
Saxagliptin	22.83	1.07	4.7
Sitagliptin	35.55	1.07	3.0
Vildagliptin	22.45	1.07	4.8
Voglibose	15.80	0.37	2.4

Table 8: Policy Scenarios & Welfare Implications in Indian OAD Market, 2011						
Scenario Name	**Molecules Directly Affected**	**Differential Pricing for DPP-4 inhibitors**	**Local licensing for DPP-4 inhibitors**	**Sellers of directly affected molecule**	**Price control for DPCO molecules**	**Change in consumer surplus (INR million per year)**
Baseline	All DPP-4 inhibitors	Yes	Yes	Patentee + local licensee(s)	Yes	
No DPP-4 inhibitors	All DPP-4 inhibitors	Not Applicable	Not Applicable	None	Yes	-912.5
No differential pricing*	All DPP-4 inhibitors	No	Yes	Patentee + local licensee(s)	Yes	-912.5
No local licensing	All DPP-4 inhibitors	Yes	No	Patentee	Yes	-802.5
Compulsory licensing	All DPP-4 inhibitors	Yes	Yes	Patentee + local licensee(s) + compulsory licensees	Yes	57.8
Removal of price control	Glipizide	Yes	Yes	Existing sellers	No	-677.4
* "No differential pricing" involves setting the price-per-daily-dose at the following international levels: Rs.134.49 for saxagliptin, Rs.174.73 for sitagliptin, Rs.113.91 for vildagliptin						